Clinical Registries in a Rapidly Evolving Healthcare System

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Massachusetts General Hospital

CMSS Summit, May 10, 2018

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)
  - Readily available, cheap
  - Structured data, increasingly granular with ICD-10
  - Longer-term and non-clinical (e.g., cost) data
  - Many providers distrust claims data for accountability applications
- EHR
  - Initial expense
  - Data are collected routinely as part of patient care (increased structure = increased burden)
  - Much of the data unstructured, lacks standardized definitions
- Clinical Registries (Local/Regional/National)
  - Highly structured data, standardized definitions, designed by clinicians
  - Trained data managers, but data collection burden and cost
  - Often limited to specific populations (disease, procedure), short-term

Registry functions

- Performance measurement & improvement
  - Clinical outcomes, PROMs, costs
  - 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

EXHIBIT 1

Hospitals' Adherence To Swedish National Guidelines For Treating Acute Myocardical Infarction, 1998–2009

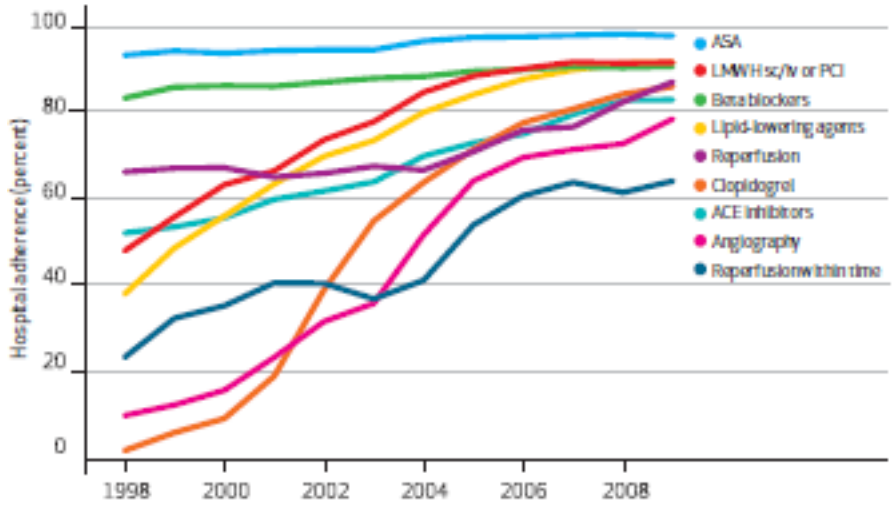


EXHIBIT 3

Hospital Scores On The Swedish Coronary Care Registry Quality Index, 2005–09

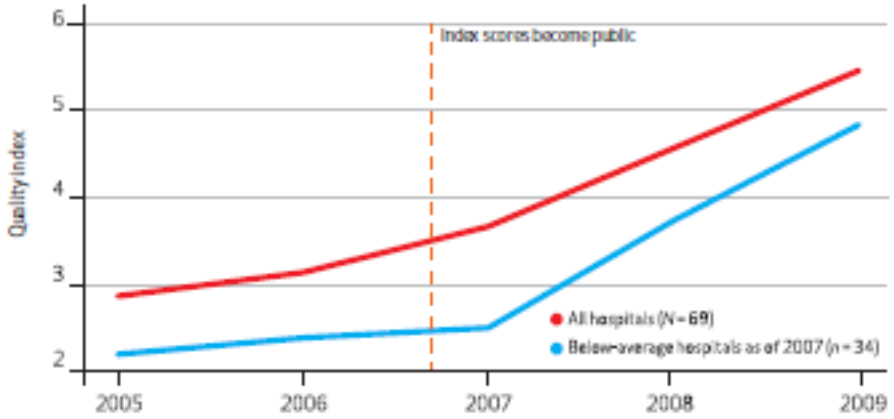
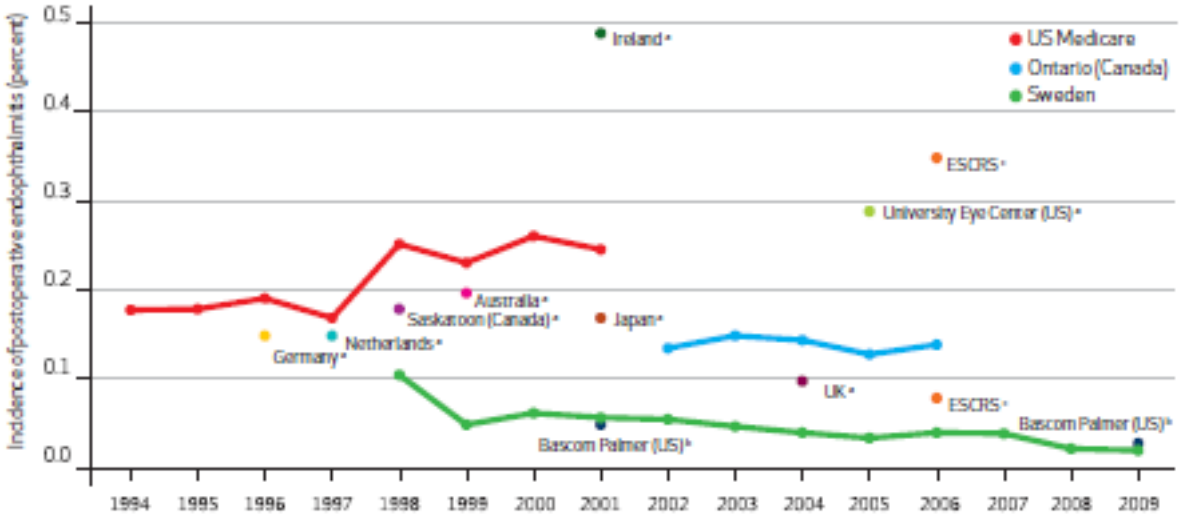


EXHIBIT 4

Incidence Of Postoperative Endophthalmitis In Cataract Patients, 1994–2009



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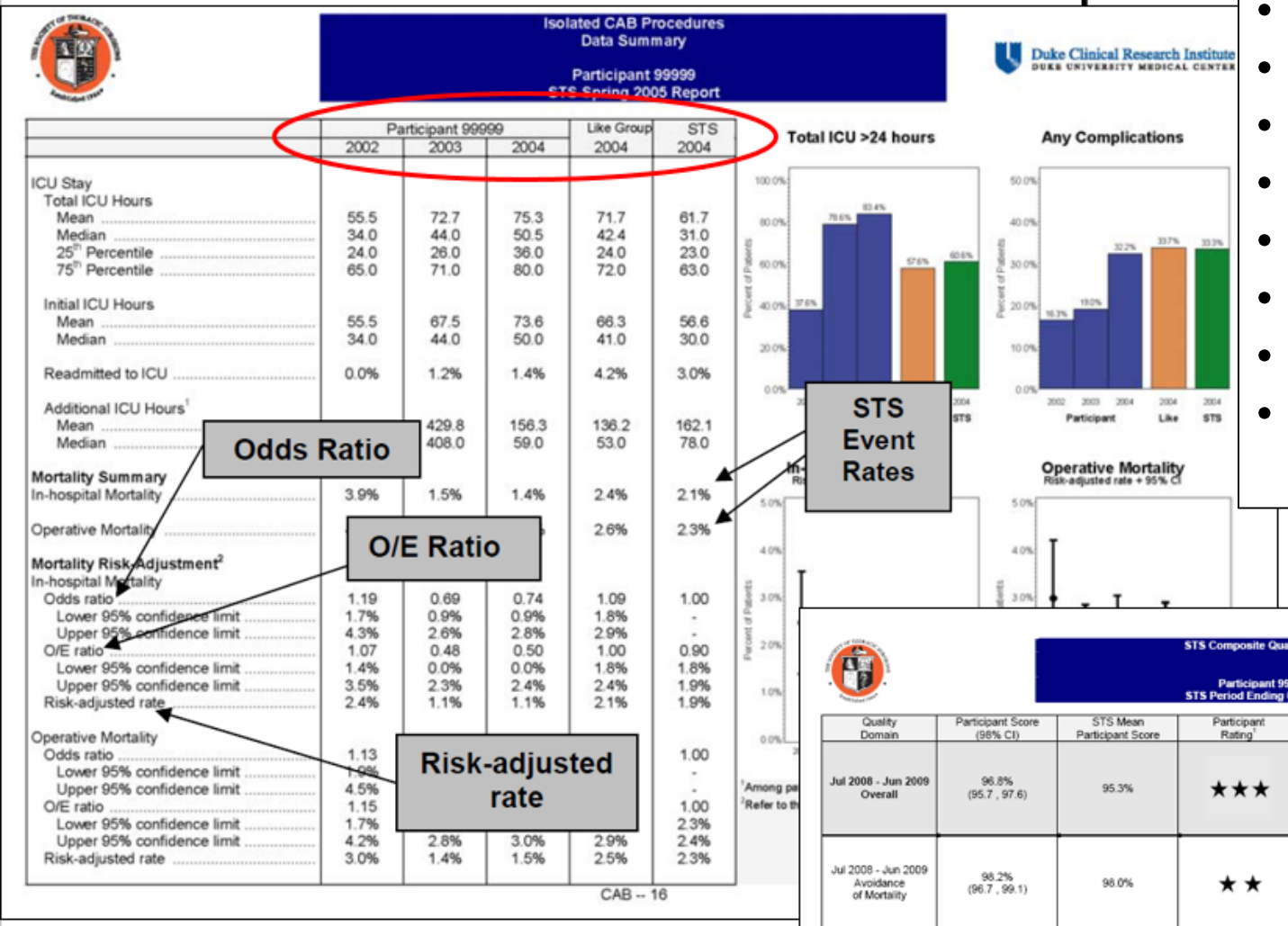
GENERAL ANIZATION

Source: Larsson S, et al. Health Aff 2012.

Routine feedback reports



Isolated CAB Procedures
Data Summary

Participant 99999
STS Spring 2005 Report

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

	Participant 99999			Like Group	STS
	2002	2003	2004	2004	2004
ICU Stay					
Total ICU Hours					
Mean	55.5	72.7	75.3	71.7	61.7
Median	34.0	44.0	50.5	42.4	31.0
25th Percentile	24.0	26.0	36.0	24.0	23.0
75th Percentile	65.0	71.0	80.0	72.0	63.0
Initial ICU Hours					
Mean	55.5	67.5	73.6	66.3	56.6
Median	34.0	44.0	50.0	41.0	30.0
Readmitted to ICU	0.0%	1.2%	1.4%	4.2%	3.0%
Additional ICU Hours[1]					
Mean		429.8	156.3	136.2	162.1
Median		408.0	59.0	53.0	78.0
Mortality Summary					
In-hospital Mortality	3.9%	1.5%	1.4%	2.4%	2.1%
Operative Mortality				2.6%	2.3%
Mortality Risk-Adjustment[2]					
In-hospital Mortality					
Odds ratio	1.19	0.69	0.74	1.09	1.00
Lower 95% confidence limit	1.7%	0.9%	0.9%	1.8%	-
Upper 95% confidence limit	4.3%	2.6%	2.8%	2.9%	-
O/E ratio	1.07	0.48	0.50	1.00	0.90
Lower 95% confidence limit	1.4%	0.0%	0.0%	1.8%	1.8%
Upper 95% confidence limit	3.5%	2.3%	2.4%	2.4%	1.9%
Risk-adjusted rate	2.4%	1.1%	1.1%	2.1%	1.9%
Operative Mortality					
Odds ratio	1.13				1.00
Lower 95% confidence limit	1.9%				-
Upper 95% confidence limit	4.5%				-
O/E ratio	1.15				1.00
Lower 95% confidence limit	1.7%				2.3%
Upper 95% confidence limit	4.2%	2.8%	3.0%	2.9%	2.4%
Risk-adjusted rate	3.0%	1.4%	1.5%	2.5%	2.3%

CAB -- 16

Total ICU >24 hours

Any Complications

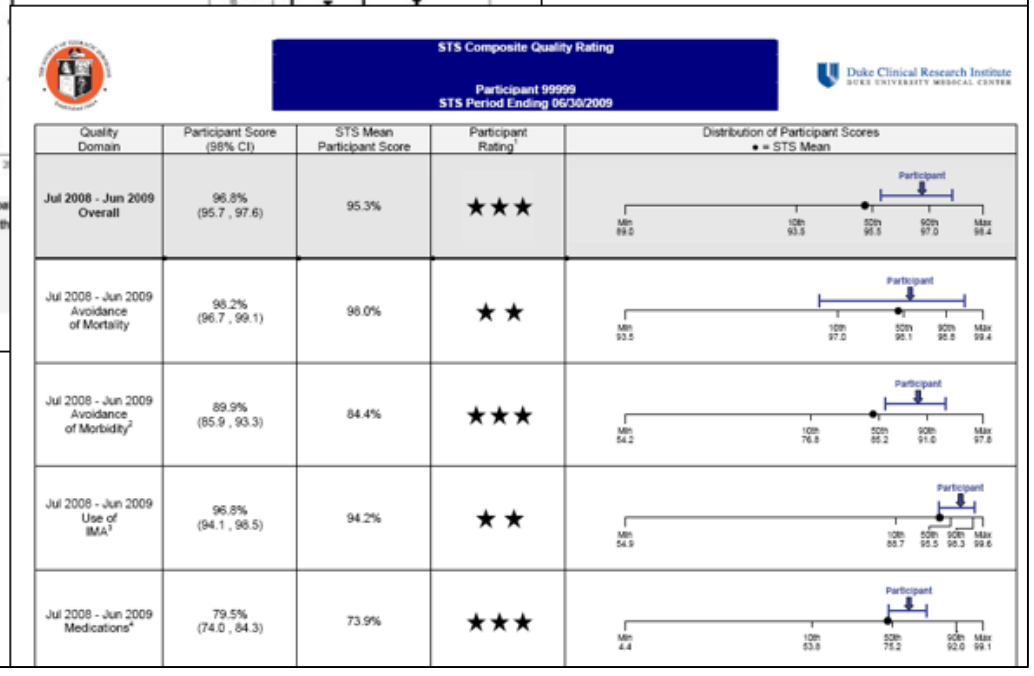
Operative Mortality
Risk-adjusted rate + 95% CI

Odds Ratio

O/E Ratio

Risk-adjusted rate

STS Event Rates



STS Composite Quality Rating

Participant 99999
STS Period Ending 06/30/2009

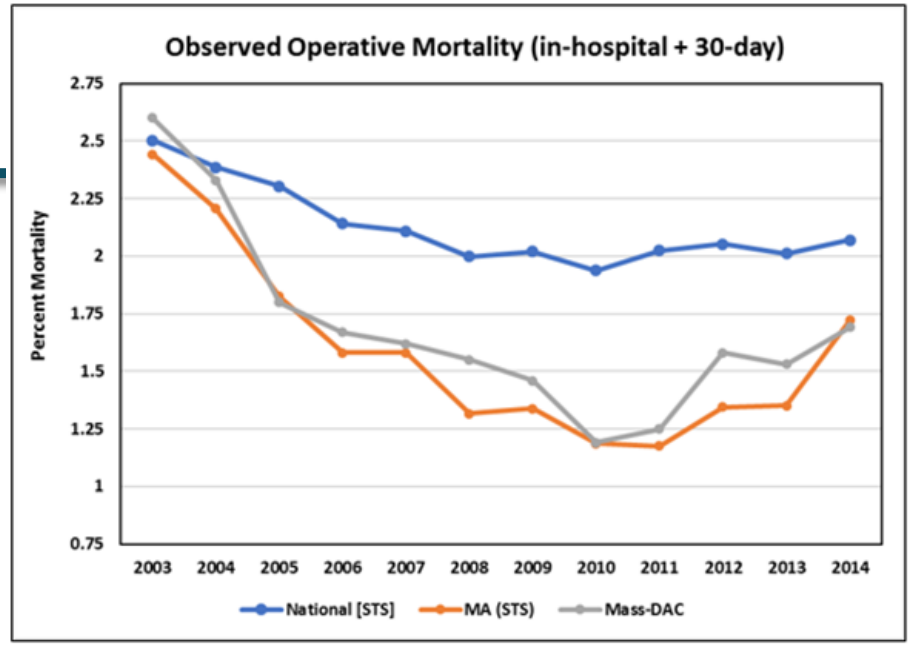
Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

Quality Domain	Participant Score (98% CI)	STS Mean Participant Score	Participant Rating[1]	Distribution of Participant Scores • = STS Mean
Jul 2008 - Jun 2009 Overall	96.8% (95.7 , 97.6)	95.3%	★★★	
Jul 2008 - Jun 2009 Avoidance of Mortality	98.2% (96.7 , 99.1)	98.0%	★★	
Jul 2008 - Jun 2009 Avoidance of Morbidity[2]	89.9% (85.9 , 93.3)	84.4%	★★★	
Jul 2008 - Jun 2009 Use of IMA[3]	96.8% (94.1 , 98.5)	94.2%	★★	
Jul 2008 - Jun 2009 Medications[4]	79.5% (74.0 , 84.3)	73.9%	★★★	

- 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"

Society of Thoracic Surgeons
National Database

NQF-endorsed
composite scores



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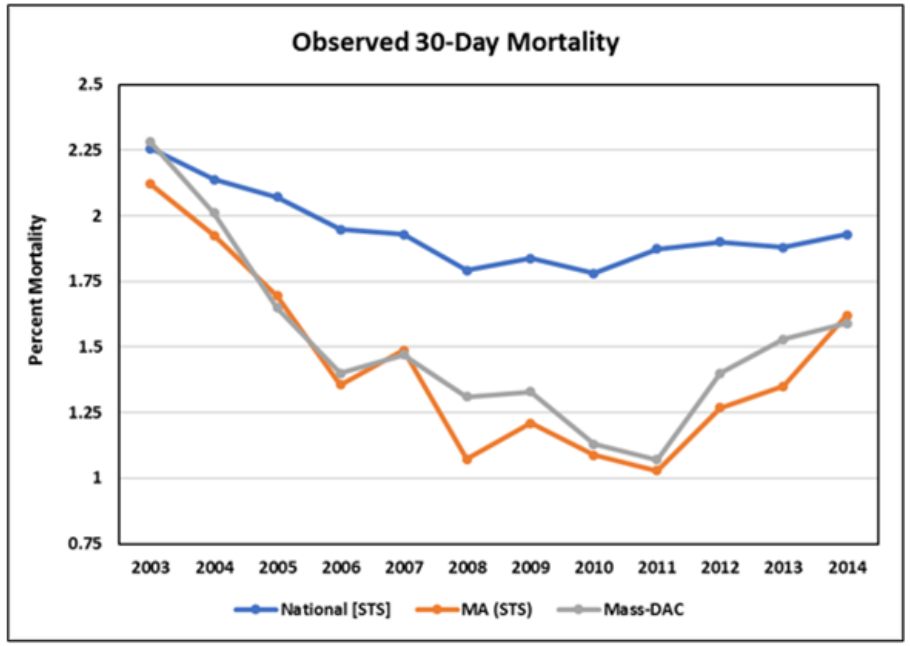

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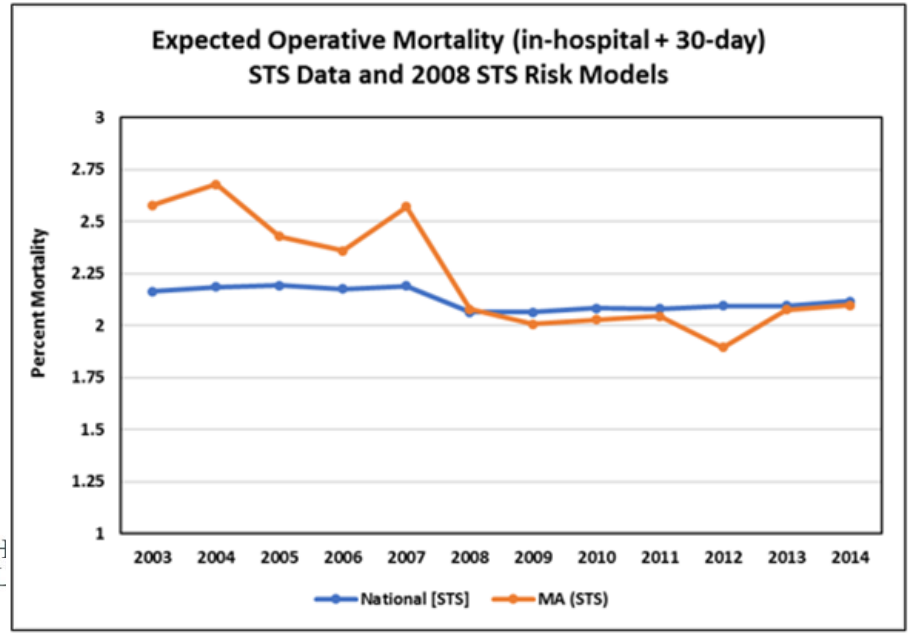

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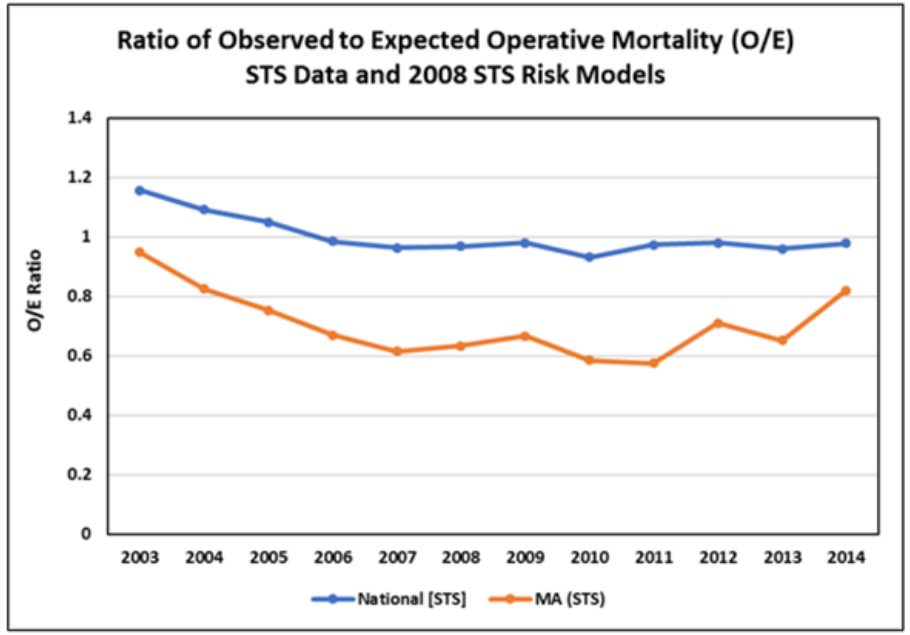

D

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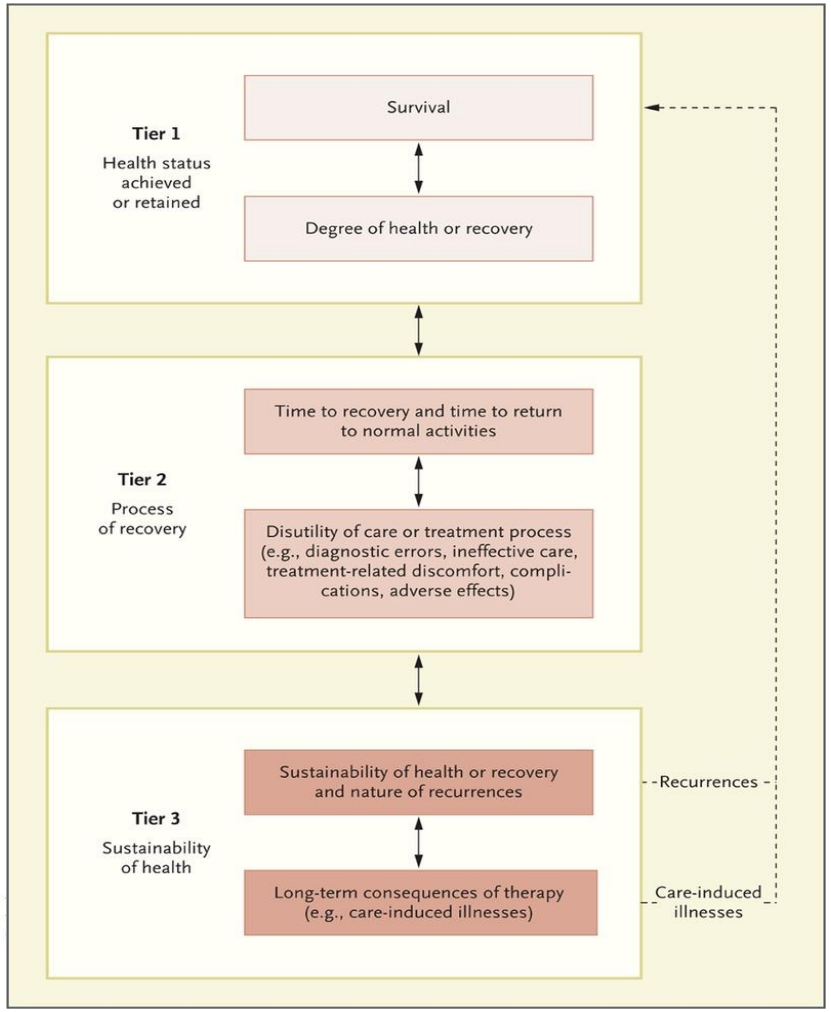
Shahian et al, 2018

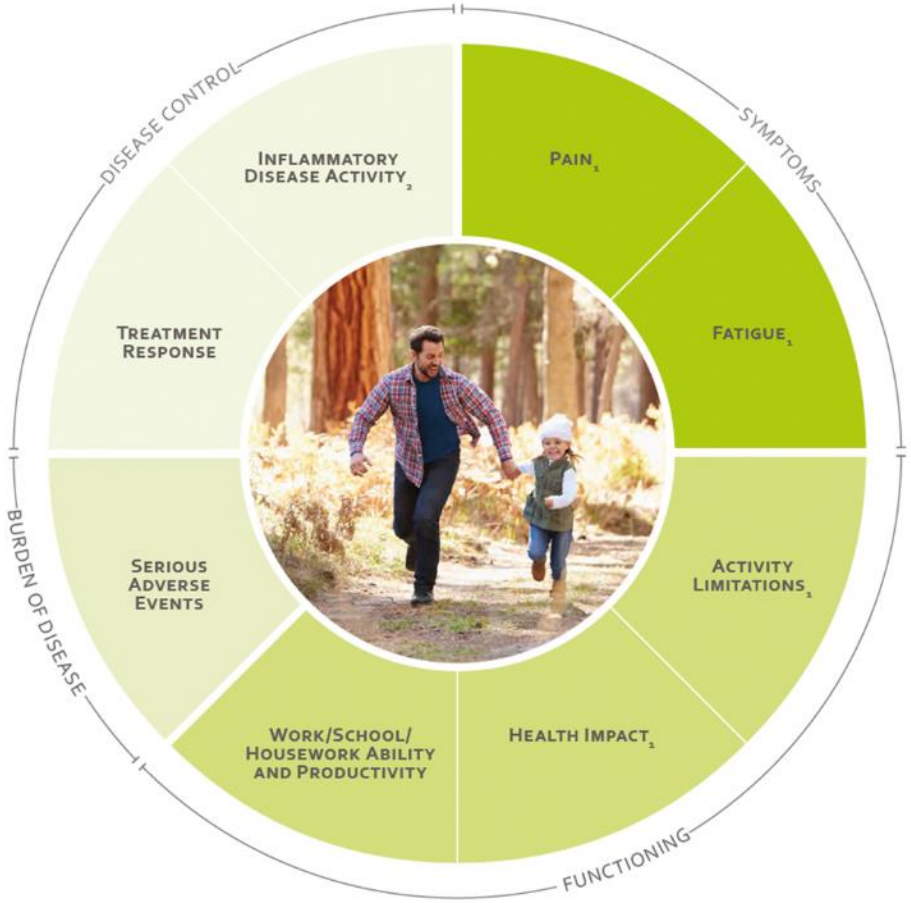
Rise of consumerism in healthcare

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



ICHOM

INFLAMMATORY ARTHRITIS



Source: ichom.org

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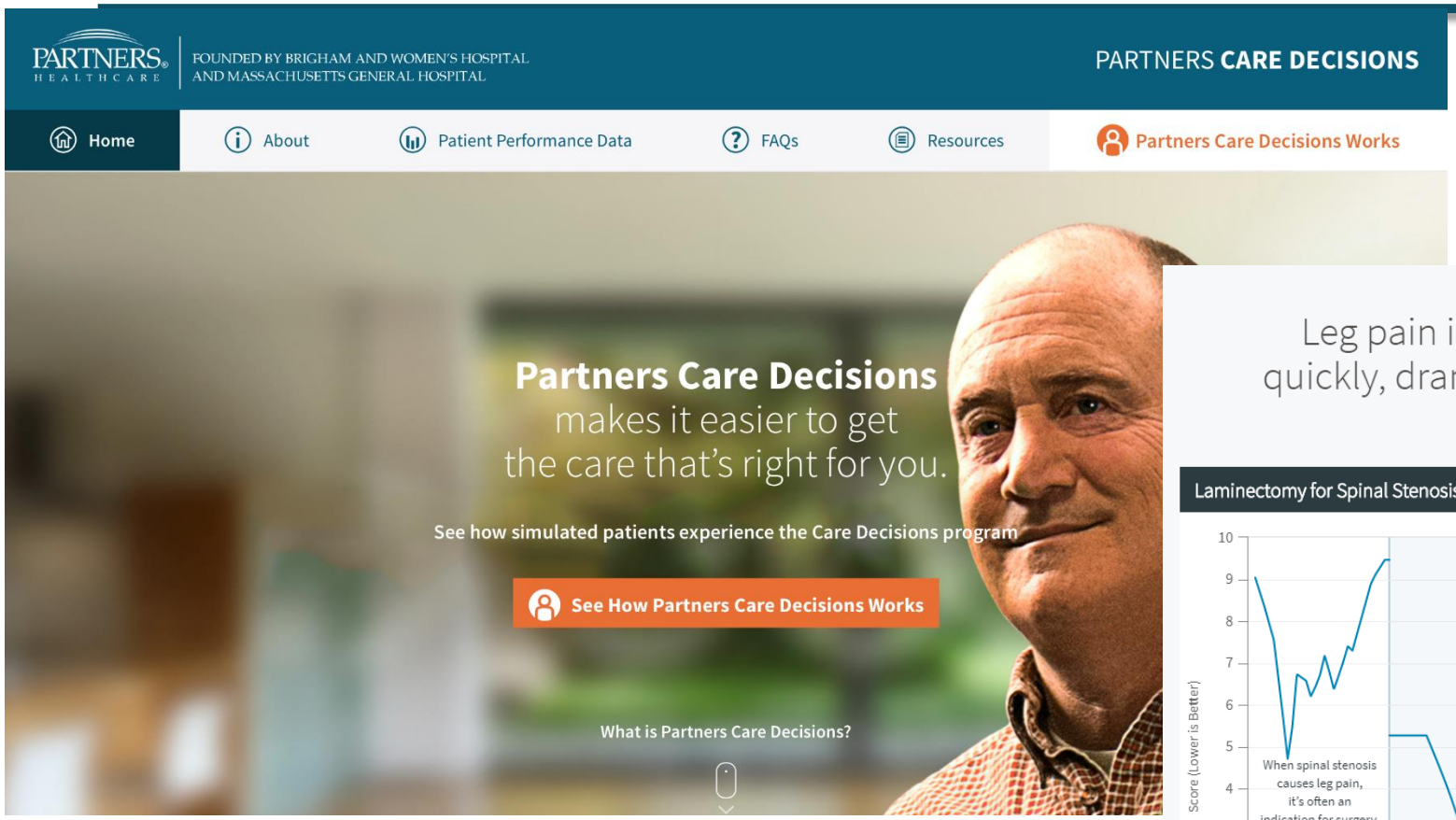
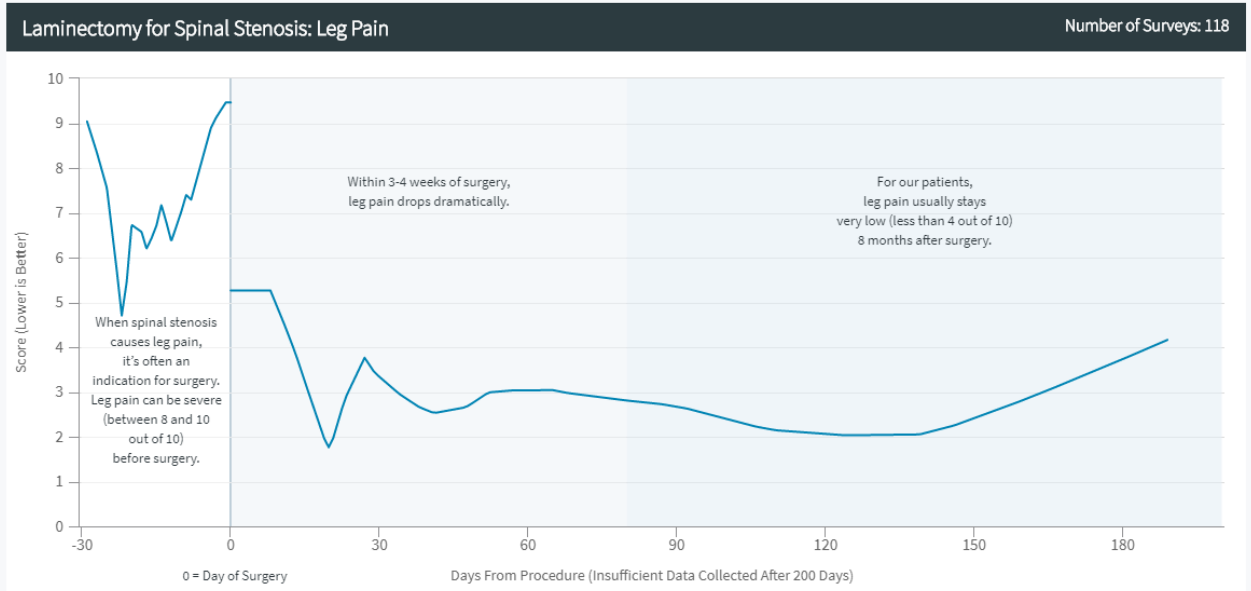
Consumers: PROMS - CareDecisions.Partners.org



Leg pain is a symptom caused by spinal stenosis and it is quickly, dramatically, and sustainably relieved for most of our patients.



Summary: A higher score means more leg pain. This is a standard pain scale from 0-10 where 0 is no pain and 10 is the most pain. Most patients see a dramatic decrease in leg pain very quickly after surgery, often because the nerves from their spine are no longer being compressed. Once it is gone, this pain stays away, even improving a bit more by 8 months after surgery. The vertical line represents the time of surgery.

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If I was a payer, and I wanted to actually improve quality, what would I pay for?

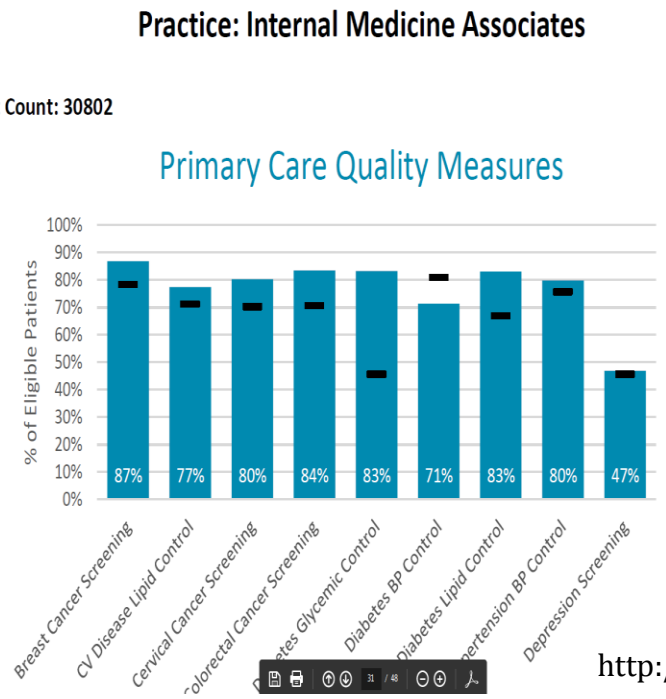
- HEDIS served a purpose, but time to move on . . .
- Limitations:
  - Focused on primary care (only 8% of care by cost, 20% by volume)
  - Sorts patients by payer, but improvement occurs at the practice
    - If performance on every patient is measured, performance improves for all, independent of payer or plan (HMO, PPO, etc.)
  - At upper levels of performance, most variation is measure error
  - Hard to use the data for improvement
- **Evolution from HEDIS to ECQM**
  - Use of EHR based clinical registries; denominator = everyone
  - Practice performance comparisons on all patients using national standard metrics

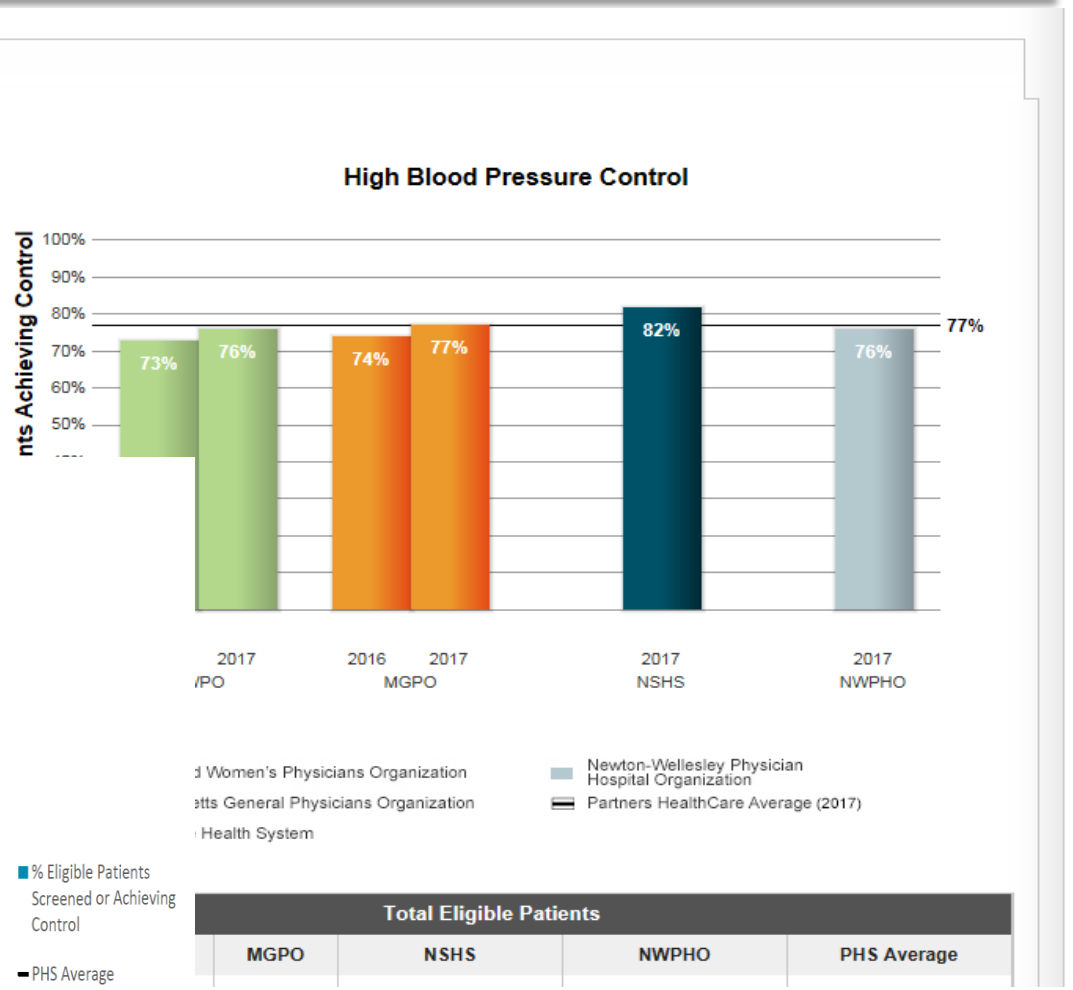
Partners Publicly Reports performance on all primary care practice metrics

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





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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* or

DBP ≤70 or

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

Improving Hypertension Quality Measurement Using Electronic Health Records; Persell, Stephen D. MD, MPH*†; Kho, Abel N. MD, MS*; Thompson, Jason A. BA*; Baker, David W. MD, MPH*† Medical Care: April 2009 - Volume 47 - Issue 4 - pp 388-394

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

MEDICAL PROFESSIONALISM

2005 ❧ ABIM FOUNDATION ❧ ACP FOUNDATION ❧ EUROPEAN FEDERATION OF INTERNAL MEDICINE

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 maximize 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.
    - 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
    - If (Adoption Burden < Cost of Injury × Probability of occurrence), then accused has not met the standard of care.

CMS Condition of Participation
Quality Assessment and Performance Improvement Program*

- Each hospital must develop, implement, and maintain an effective, on-going, 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
  - It is the right thing to do for our patients
- Does your registry output conform to the Porter framework?
  - It should, otherwise it is not including all the measures that matter
- Does your hospital participate in every applicable registry?
  - It is a abdication of professional obligation not to
  - It should be required by all payers (and satisfy MIPS/MACRA)
  - It may be negligent not to
- Does your hospital have a registry of all your registries?
  - It is a violation of Joint Commission QAPI rules not to
  - Your senior executives and board need to know

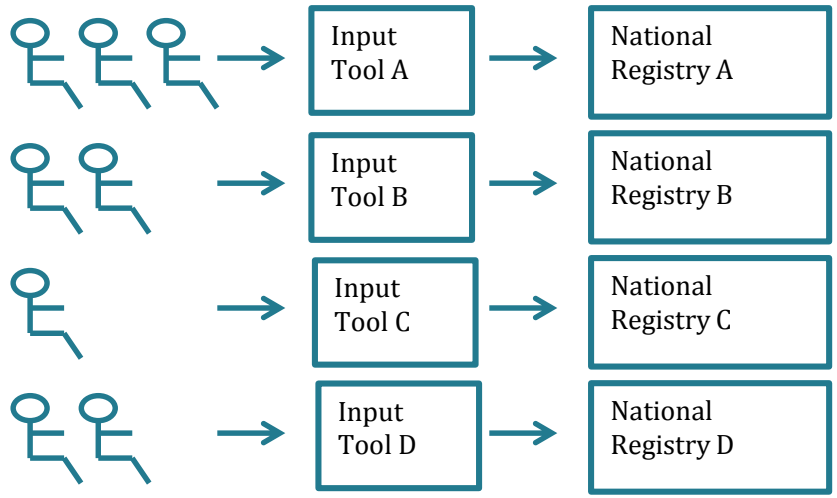
- Now the bad news

Challenge as a provider: variation, complexity, expense

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

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

- Multiple input clinical FTEs
- Multiple input tools, registry vendors, & contracts
- Minimal automation of data extraction
- Multiple database administrators



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We need a better way

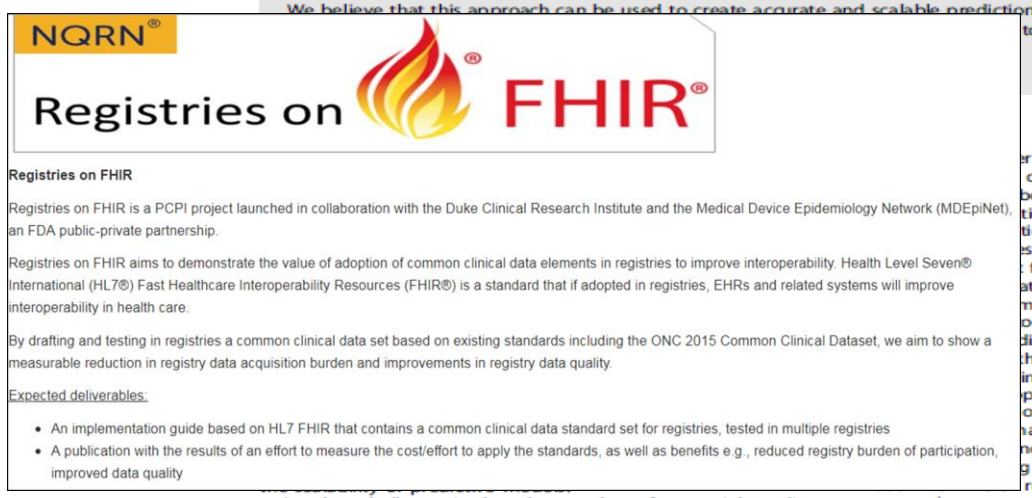
Registry	FTEs	Patients / year
ACS-NSQIP	1.5 FTE registered nurse, 0.125 data analyst, 0.05 manager	1,800
ACS-NSQIP Peds	0.5 FTE data collector, 0.125 data analyst, 0.05 manager	900
MBSA-QIP	0.5 FTE registered nurse, 0.125 data analyst, 0.05 manager	460
ACS-NTDB and ACS-TQIP	3.5 FTE staff responsible for data abstraction, data entry, data validation, research support and performance improvement, 0.3 manager	2,500
Burn Registry	0 .5 FTE data abstractor, 0.15 manager	400
Emergency Surgery Registry	0 .5 FTE data abstractor	2,000
SRTR	7.0 – 10.0 FTE registered nurses, 1.5 manager and general auditing support.	750
STS-Cardiac	3 FTEs registered nurses, 0.5 PSC	1,300
STS-Thoracic	1 FTE registered nurse and manager	1,000
CeSQIP	0.5 FTE, 0.125 data analyst, 0.05 manager	700
Intermacs	3 part time research coordinators, 1 part time research nurse	30

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



NQRN®

Registries on FHIR®

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

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www.nature.com/npjdigitalmed

ARTICLE OPEN

Scalable and accurate deep learning with electronic health records

Alvin Rajkomar[1,2], Eyal Oren[1], Kai Chen[1], Andrew M. Dai[1], Nissan Hajaj[1], Michaela Hardt[1], Peter J. Liu[1], Xiaobing Liu[1], Jake Marcus[1], Mimi Sun[1], Patrik Sundberg[1], Hector Yee[1], Kun Zhang[1], Yi Zhang[1], Gerardo Flores[1], Gavin E. Duggan[1], Jamie Irvine[1], Quoc Le[1], Kurt Litsch[1], Alexander Mossin[1], Justin Tansuwan[1], De Wang[1], James Wexler[1], Jimbo Wilson[1], Dana Ludwig[2], Samuel L. Volchenboum[3], Katherine Chou[1], Michael Pearson[1], Srinivasan Madabushi[1], Nigam H. Shah[4], Atul J. Butte[2], Michael D. Howell[1], Claire Cui[1], Greg S. Corrado[1] and Jeffrey Dean[1]

Predictive modeling with electronic health record (EHR) data is anticipated to drive personalized medicine and improve healthcare quality. Constructing predictive statistical models typically requires extraction of curated predictor variables from normalized EHR data, a labor-intensive process that discards the vast majority of information in each patient's record. We propose a representation of patients' entire raw EHR records based on the Fast Healthcare Interoperability Resources (FHIR) format. We demonstrate that deep learning methods using this representation are capable of accurately predicting multiple medical events from multiple centers without site-specific data harmonization. We validated our approach using de-identified EHR data from two US academic medical centers with 216,221 adult patients hospitalized for at least 24 h. In the sequential format we propose, this volume of EHR data unrolled into a total of 46,864,534,945 data points, including clinical notes. Deep learning models achieved high accuracy for tasks such as predicting: in-hospital mortality (area under the receiver operator curve [AUROC] across sites 0.93–0.94), 30-day unplanned readmission (AUROC 0.75–0.76), prolonged length of stay (AUROC 0.85–0.86), and all of a patient's final discharge diagnoses (frequency-weighted AUROC 0.90). These models outperformed traditional, clinically-used predictive models in all cases. We believe that this approach can be used to create accurate and scalable predictions for a variety of clinical scenarios. In a case ... to identify relevant information from the

... providers are included. Traditional modeling ... dealt with this complexity simply by choosing a ... ber of commonly collected variables to consider.[7] ... tic because the resulting models may produce ... tions: false-positive predictions can overwhelm ... s, and other providers with false alarms and ... fatigue,[10] which the Joint Commission identified ... atient safety priority in 2014.[11] False-negative ... miss significant numbers of clinically important ... o poor clinical outcomes.[11,12] Incorporating the ... ding clinicians' free-text notes, offers some hope ... these shortcomings but is unwieldy for most ... ing techniques.

... pments in deep learning and artificial neural ... ow us to address many of these challenges and ... nation in the EHR. Deep learning emerged as the ... ne learning approach in machine perception ... g from computer vision to speech recognition, ... recently proven useful in natural language processing, sequence prediction, and mixed modality data settings.[13–17] These systems are known for their ability to handle large volumes of relatively messy data, including errors in labels

Another challenge is that the number of potential predictor variables in the electronic health record (EHR) may easily number in the thousands, particularly if free-text notes from doctors,

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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

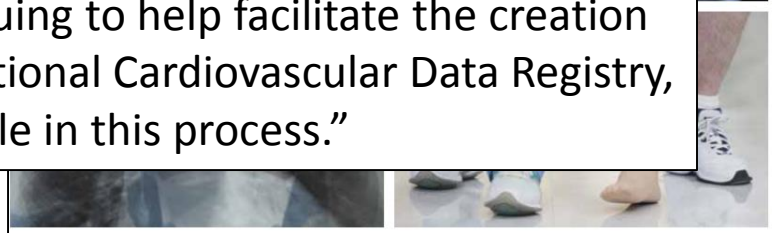
Shahian et al, *Heart*, 2013

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 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."



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Medical Device Registries

Recommendations for Advancing Safety and Public Health

Click here to redirect to www.nestcc.org

NEST
National Evaluation System for health Technology
Coordinating Center

The current fragmented health care system lacks adequate infrastructure to enable high-quality, near real-time, and low-cost Real-World Evidence (RWE) generation for medical devices. The inability to access and integrate longitudinal datasets has slowed medical device innovation, delayed the detection of safety signals, and created regulatory inefficiencies, impacting stakeholders across the medical device ecosystem, including industry, regulators, payers, patients, clinicians, and health systems. Solving these challenges could improve patients' timely access to safe medical devices and their quality of life.

To change the current ecosystem, the **National Evaluation System for health Technology (NEST)** was designed to serve as a catalyst in establishing functional and efficient pathways for key stakeholders to generate lower-cost, nearer real-time RWE of sufficient quality for regulatory, coverage, patient, and clinical decision-making.

In September 2016, FDA awarded a grant to the Medical Device Innovation Consortium (MDIC) to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). The selection of a third-party entity was important given the need for NESTcc to establish relationships and agreements between partners in a neutral, objective manner, and to solicit a balanced representation from stakeholders.

ORIGINAL ARTICLE

Registry-Based Prospective, Active Surveillance of Medical-Device Safety

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ABSTRACT

BACKGROUND
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 CathPCI 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 end points 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

VIEWPOINT

Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks

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In June 2014, the Medical Device Epidemiology Network (MDEpiNet) Public Private Partnership,[1] on behalf of the US Food and Drug Administration Center for Devices and Radiologic Health (CDRH), convened the Medical Device Registries Task Force (MDRTF) (see eAppendix in the Supplement). The task force was launched to address the CDRH's commitments[2,3] to strengthen the medical device postmarket surveillance system using existing resources and under current authorities and to develop an integrated system that efficiently and effectively achieves its basic functions, from timely identification of postmarket signals to facilitating premarket device clearance and approval.

The MDRTF included broad stakeholder representation and was mandated to examine the objectives and logistics of leveraging existing electronic registries and information repositories in support of a national system. This work was done in parallel with efforts at the Engelberg Center at the Brookings Institution, which in 2015 reported recommendations from their planning board for a "national medical device surveillance system." These recommendations depicted a system that "supports optimal patient care by leveraging the experiences of patients to inform decisions about medical device safety,

The MDRTF recognized that most existing registries, electronic health records (EHRs), and data sources do not contain all the elements necessary for device evaluations, including device and procedural details, patient descriptors, or long-term outcomes. However, the MDRTF recognized that such limitations could be mitigated through interoperability solutions that strategically link complementary registries and data sources to produce networks for which the data composite could support robust device evaluation. The MDRTF termed this structure the strategically *coordinated registries network*, or CRN—with the recognition that many key elements in such networks (such as EHRs, administrative claims data, or mobile device outputs) are not registries per se. The MDRTF recommends strategic CRNs as the foundational architectural construct for the national system that will augment national registry development and unique device identifier implementation rather than replace them.

The proposed CRN structure could provide novel, important attributes to the national system. Creation of CRNs could encourage efficient "dual-purpose" leveraging of existing registries, EHRs, administrative data resources, and lessons learned from existing linked-registry models such as the Transcatheter Valve Therapy[6] registry administra-

Interoperability

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.

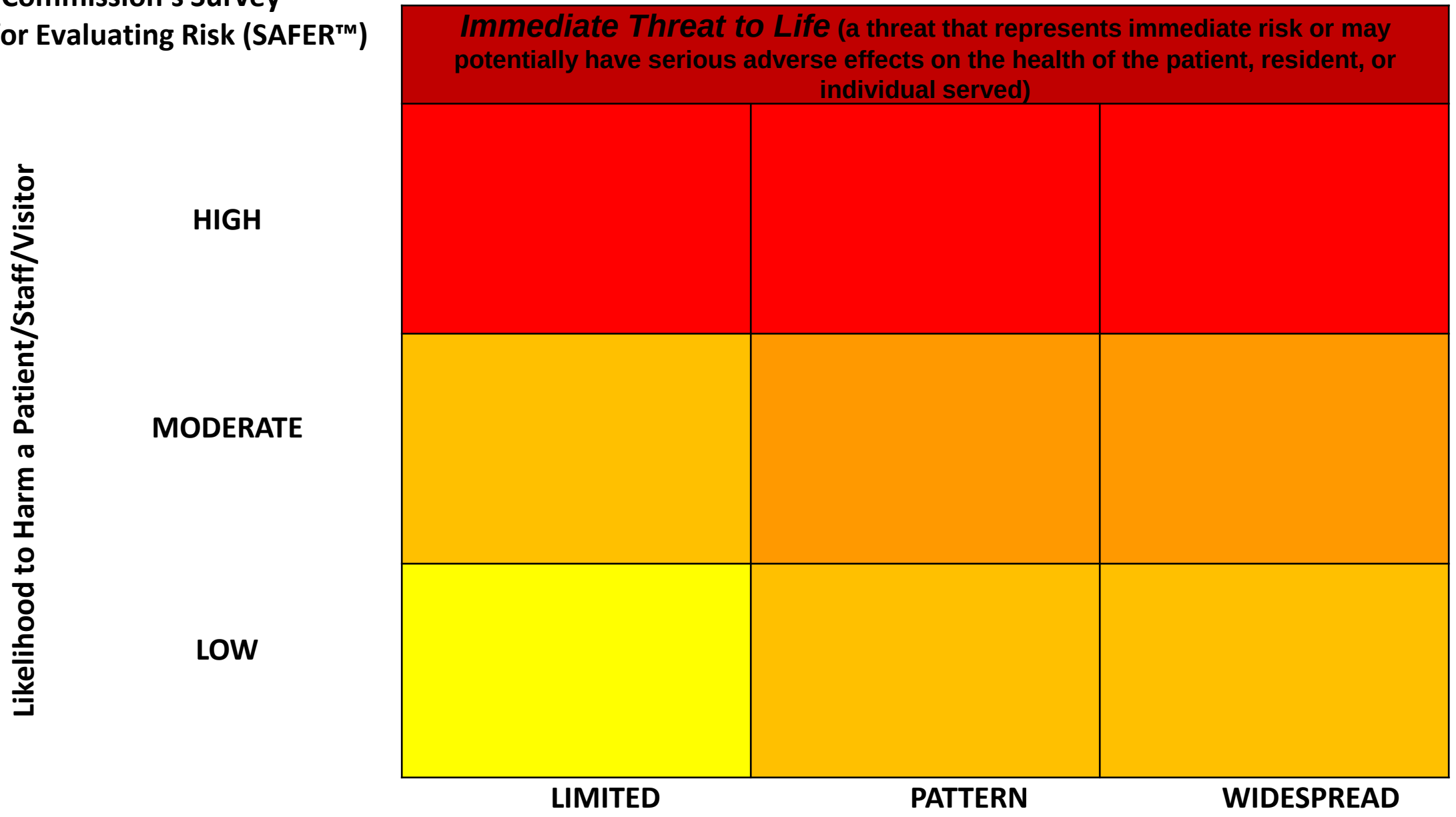
Registries on FHIR aims to demonstrate the value of adoption of common clinical data elements in registries to improve interoperability. Health Level Seven® International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) is a standard that if adopted in registries, EHRs and related systems will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



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Abbott Northwestern Hospital Minneapolis, Minnesota	★★	★★	★★	★★	★★★
Abington Memorial Hospital Abington, Pennsylvania	★★	★★	★★	★★	★
Adena Health System Chillicothe, Ohio	★★	★★	★★	★★	★★
Adventist Health Gelndale Glendale, California	★★	★★	★★	★★	★★

Registries to support providers

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