Embedded Research in an Integrated Health Care Delivery System

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Preview

- Describe the KPSC Care Improvement Research Team
- Provide overview of portfolio of internally focused and externally funded research projects
- Share results of ongoing projects
  - Hospital-associated venous thromboembolism
  - Surveillance of small pulmonary nodules
- Discuss opportunities and challenges for research embedded in health systems

KPSC

- Pre-paid, capitated health plan (KFH/HP)
- Independent medical group (SCPMG)
- Integrated delivery system
- Comprehensive electronic health records
- Values:
  - Quality
  - Affordability
  - Physician autonomy
  - Small “m” managed care

KP Southern California

>4.2 Million Members

209 Medical Offices

14 Hospitals

6,035 Physicians

20,393 Nurses

61,897 Employees

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Department of Research and Evaluation

- >30 full-time research scientists
- About 300 support staff
- Located in Pasadena, CA
- Employed by SCPMG
  - Report to Medical Director for Quality and Clinical Analysis
- Data resources: RDW, VDW, PCORnet CDM
- Researchers embedded in health system

Care Improvement Research Team

- Created by KPSC leadership in 2013
- Help improve care and increase affordability for members
- Weave research into existing fabric of clinical care and quality improvement
- Create and share generalizable knowledge about improvement
- Foster a culture of inquiry and evaluation
- Help to realize the potential of the learning health care system

CIRT Vision and Mission

Vision

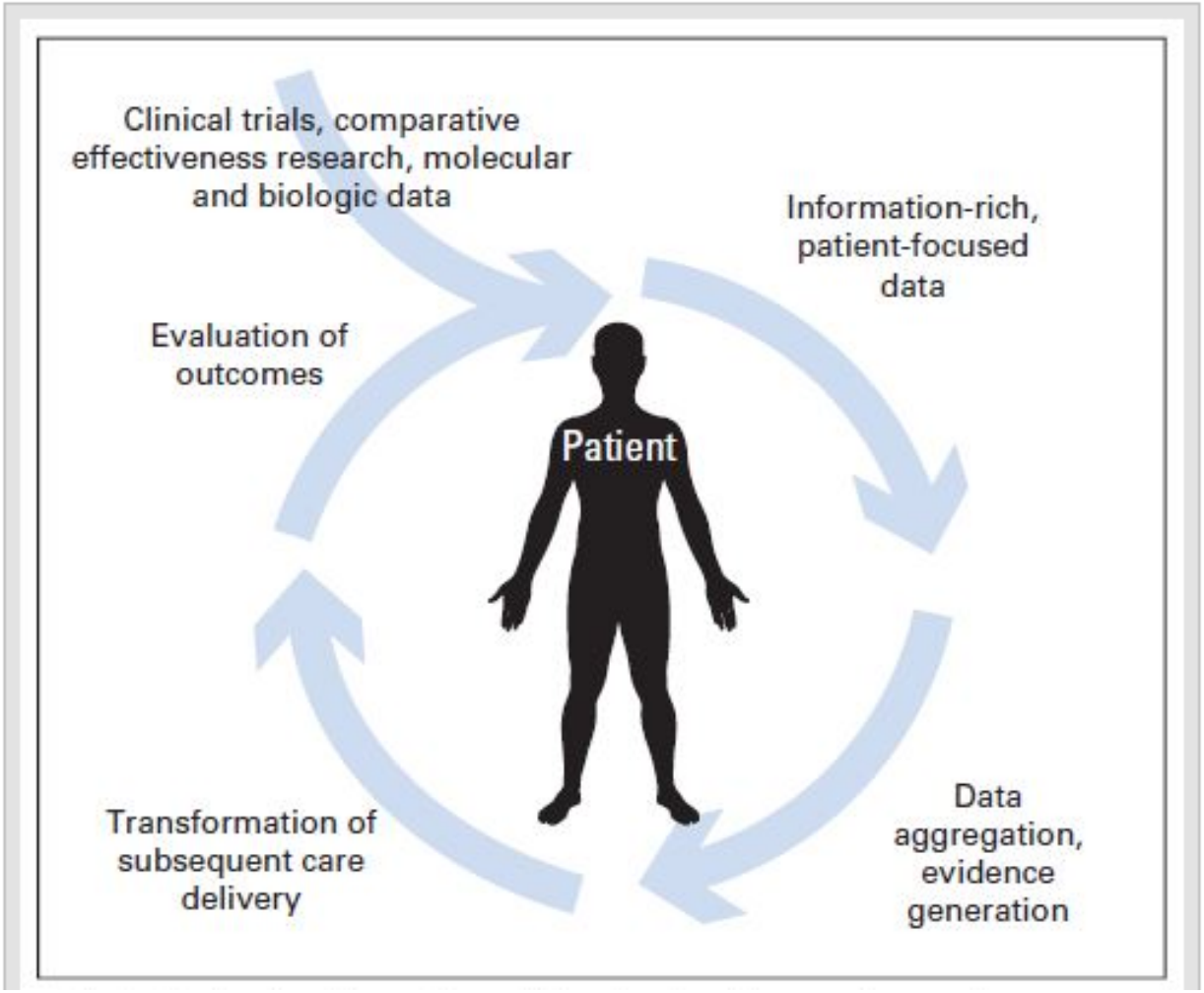
- To be the model for embedded research within a learning health care system.

Mission

- To enhance the health of individuals and populations through systematic study of ways to improve health care delivery.

We collaborate with clinicians, patients, operational leaders, and other stakeholders to identify gaps in care delivery and apply rigorous research methods to understand and close these gaps within the KPSC system.

The Learning Health Care System



Abernethy et al. J Clin Oncol 2010;28;4268-74.

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CIRT Sponsors

Kaiser Foundation Hospitals & Health Plan

- Benjamin K. Chu, MD, MPH, MACP
- Nirav R. Shah, MD, MPH
- Angela Coron, MPH

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Southern California Permanente Medical Group

- Michael H. Kanter, MD
- Steven J. Jacobsen, MD, PhD

Key Contributions of Leadership

- Made hard-money investment in program development
- Provide researchers with unprecedented access to operational decision-makers
- Facilitate relationships with operational work groups
  - VTE Regional Steering Committee
  - Regional Readmissions Group
  - LAMC Cancer Care Redesign
- Help to translate findings back into practice

CIRT Members

Scientists

Michael Gould, MD, MS

Erin Hahn, PhD, MPH

Brian Mittman, PhD

Huong Nguyen, PhD, RN

Adam Sharp, MD, MS

Shayna Henry, PhD (post-doc)

Anna Davis (UCLA doctoral student)

Project Managers

Danielle Altman, MA

Angel Alem, MS, MPH

Tania Tang, PhD, MPH

Research Support

Fernando Barreda

Erika Estrada, MS

Mayra Macias, MS

Leah Maddock, MPH

Corrine Munoz-Plaza, MPH

Ellen Rippberger, MPH

Su Wu, MS

Biostatistics

Brian Huang, MPH (UCLA doctoral student)

Alice Kwan, MPH

Janet Lee, MS

Amy Liu, MS

Ernest Shen, PhD

David Yi, MPH

Jianjin Wang, MS

Yi-Lin Wu, MS

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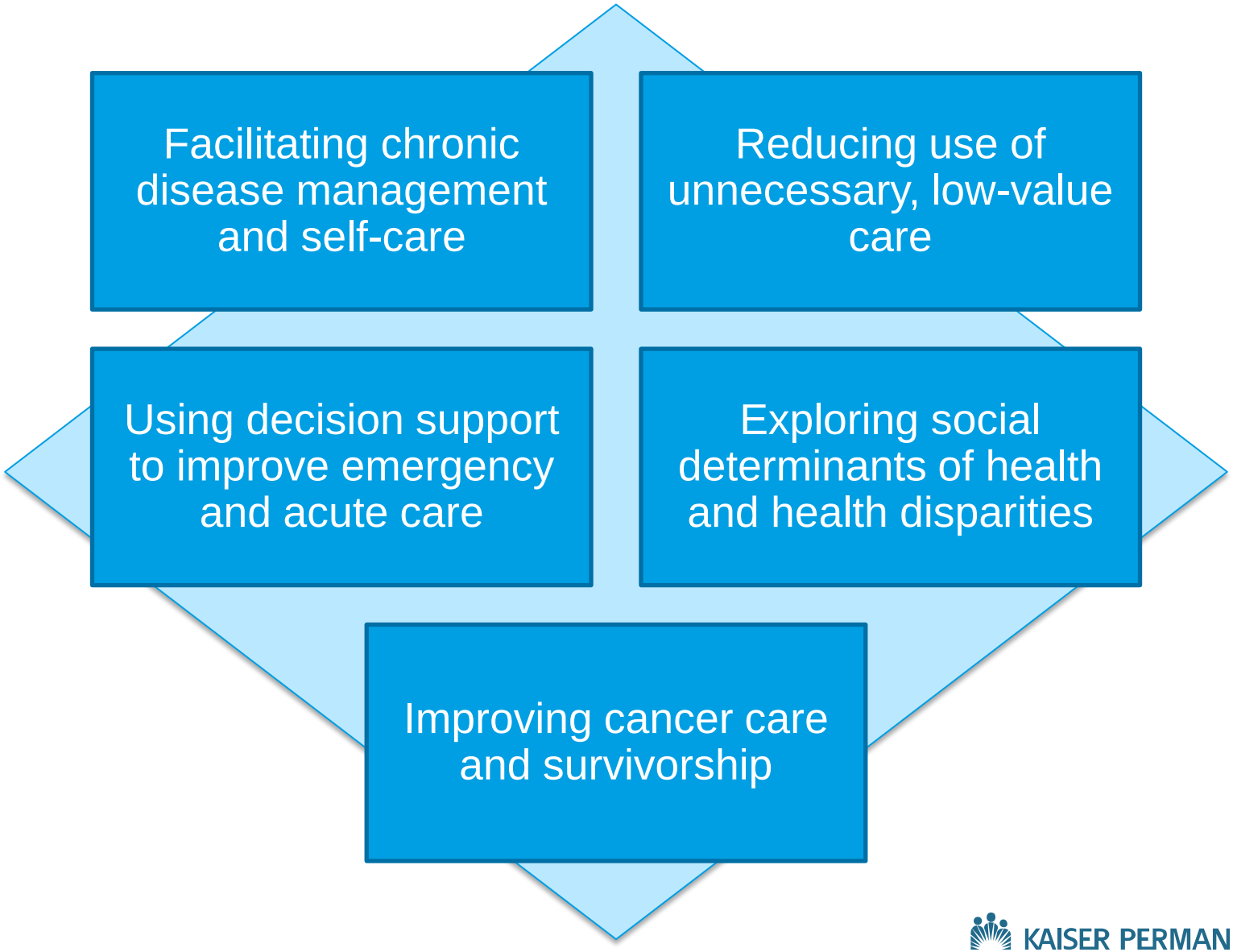
CIRT Research Themes: The Health System as a Laboratory for Improvement



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CIRT Strategy and Tactics

- Develop sustainable partnerships between researchers, clinicians and operational leaders
  - Embed researchers within existing work groups
- Create virtuous cycle of internally focused and externally funded research
  - Goal: ~50-50 distribution
- Use variety of research methods and select efficient designs to improve feasibility of practice-based research
  - Observational studies to identify gaps in care
  - Qualitative approaches to understand barriers and facilitators to change
  - Quasi-experimental studies to evaluate new interventions
  - Pragmatic trials to use health system as laboratory

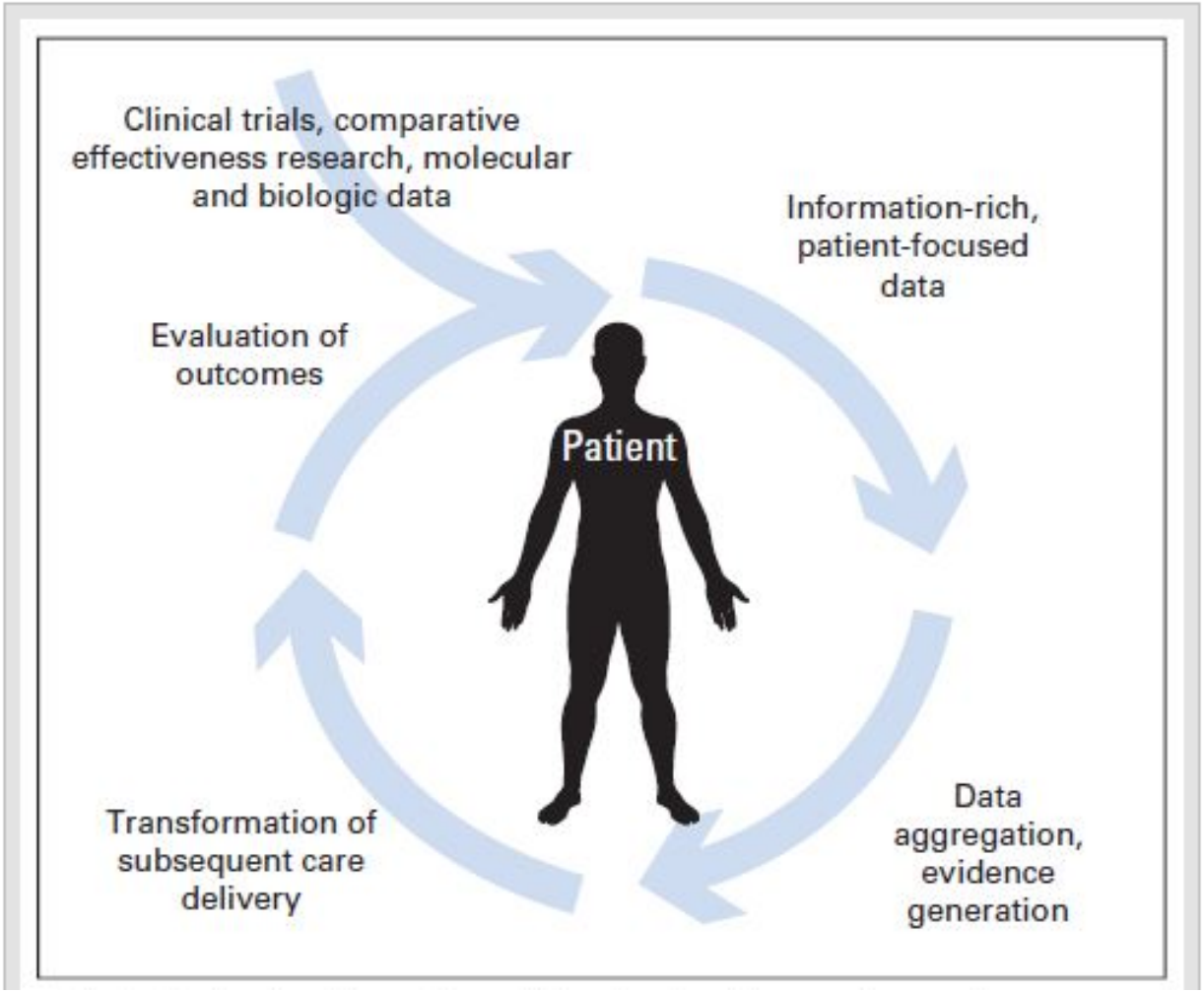
Internally-Focused Projects

- Understanding high-need, high-cost patients
- Addressing members' unmet social needs
- Evaluation of the online personal action plan
- Evaluation of Open Notes
- Reducing readmissions for COPD
- Improving prophylaxis for VTE
- Reducing use of biomarker testing in breast cancer survivors
- Implementation of lung cancer screening
  - Evaluation of pulmonary nodules
- Decision support for triage of pneumonia and use of head CT in ED
- Reducing antibiotic prescribing for acute sinusitis
- Embedded PCP to improve care for cancer survivors
- Improving adherence with CPAP in sleep apnea
- Improving outcomes for patients with CKD and ESRD

Externally Funded Projects

- Home-based physical activity coaching for COPD (PCORI)
- Care transitions for chronic disease (PCORI)
- Early palliative care for lung cancer (NINR)
- Distress screening for breast cancer (CBCF)
- Sleep apnea, PAP and kidney disease (NIDDK)
- Improving palliative care for chronic disease (PORTAL)
- Kidney transplant education and living donation (HRSA)
- Watch the Spot Trial (PCORI)
- Lung cancer comorbidities, treatments and outcomes (NCI)
- Research Networks: PCORnet (PORTAL), NCOPR CCDR, HCSRN/CRN

The Learning Health Care System



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Improving VTE Prophylaxis: Methods

- Retrospective, observational study of VTE prophylaxis and outcomes
- Assembled cohort of ~250,000 adult members of KPSC with hospital admission for medical illness
  - July 2010 through June 2014
- Collected data from electronic health records
  - VTE risk factors, e.g. age, cancer, prior VTE
  - VTE prophylaxis, including chemical and mechanical methods
  - VTE events (in hospital or within 90 days of discharge)
  - Validated VTE outcome definitions
- Compared accuracy of 4 VTE risk prediction models

Validation of VTE Outcomes

Validation of VTE Outcome Definitions	Sens	Spec	PPV	NPV
≥ 1 VTE diagnosis code	100	47	68	100
≥ 1 diagnosis code AND (≥1 procedure code OR ≥1 pharmacy code)*	94	72	79	92
≥ 1 diagnosis code AND ≥1 pharmacy code	82	81	83	80
≥ 1 diagnosis code AND ≥1 procedure code	76	84	84	76
≥ 1 diagnosis code AND (≥1 procedure code AND ≥1 pharmacy code)	64	93	92	70

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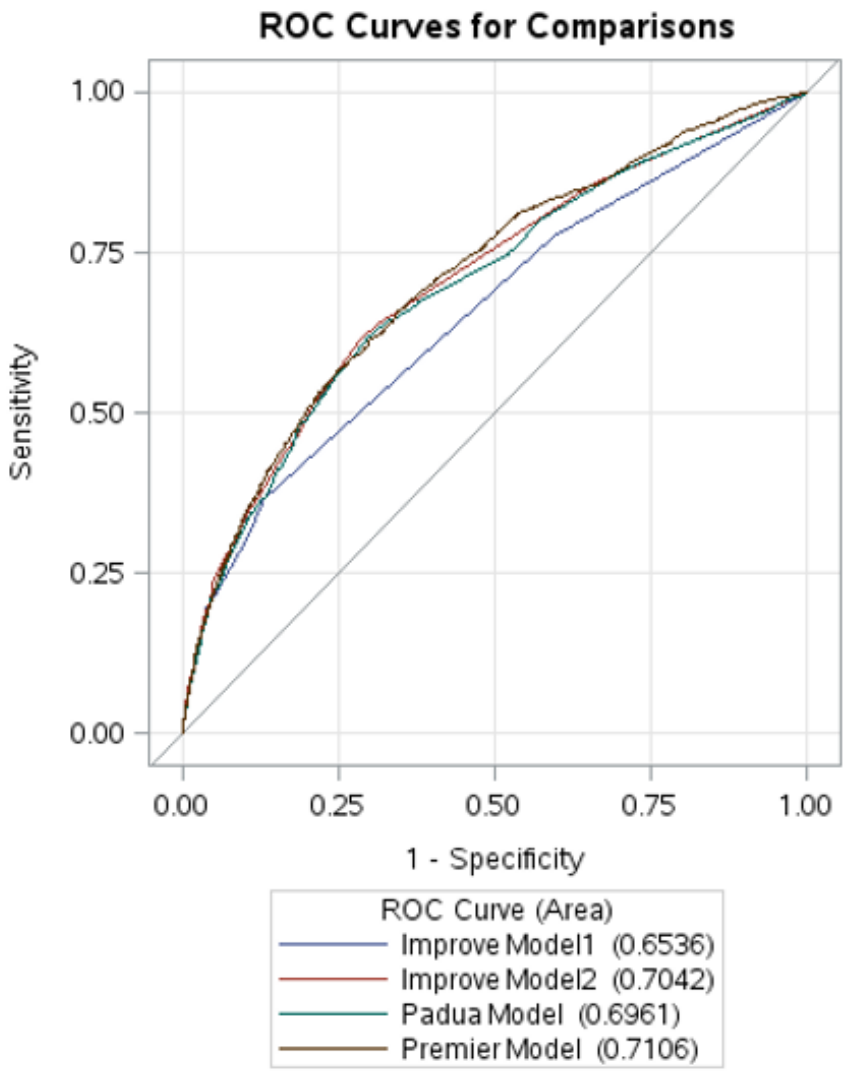
Accuracy of Existing Risk Models



- Existing risk assessment models perform similarly in our patient population at KPSC, but have only fair accuracy for predicting VTE
- 7-variable IMPROVE-2 model may represent best tradeoff between accuracy and simplicity

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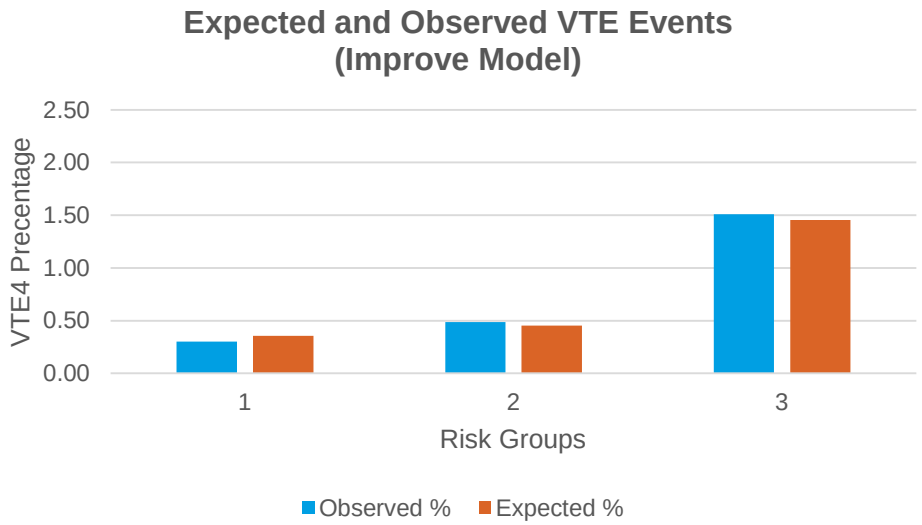
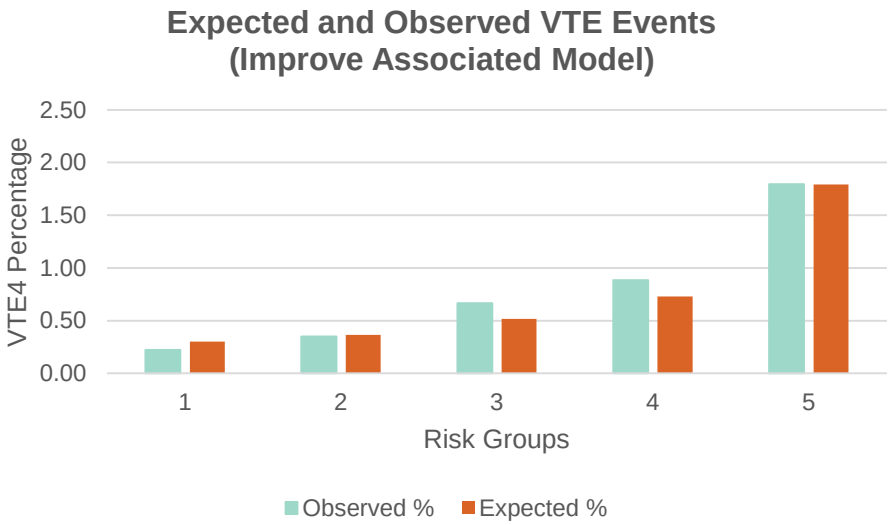
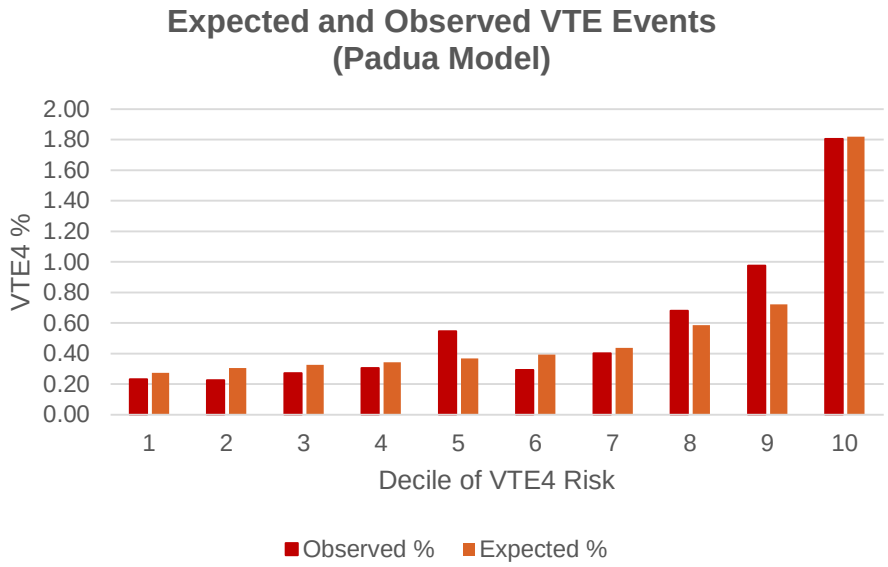
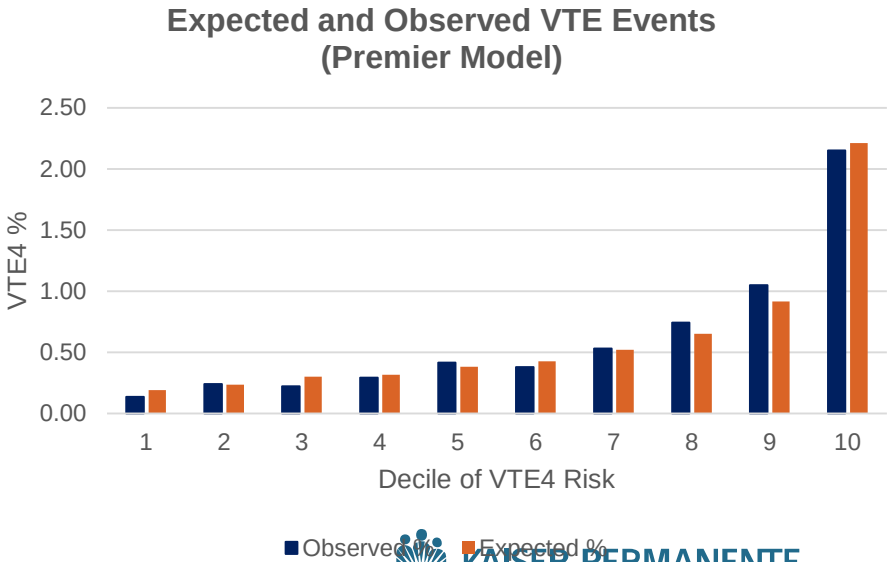
All Risk Models Well-Calibrated









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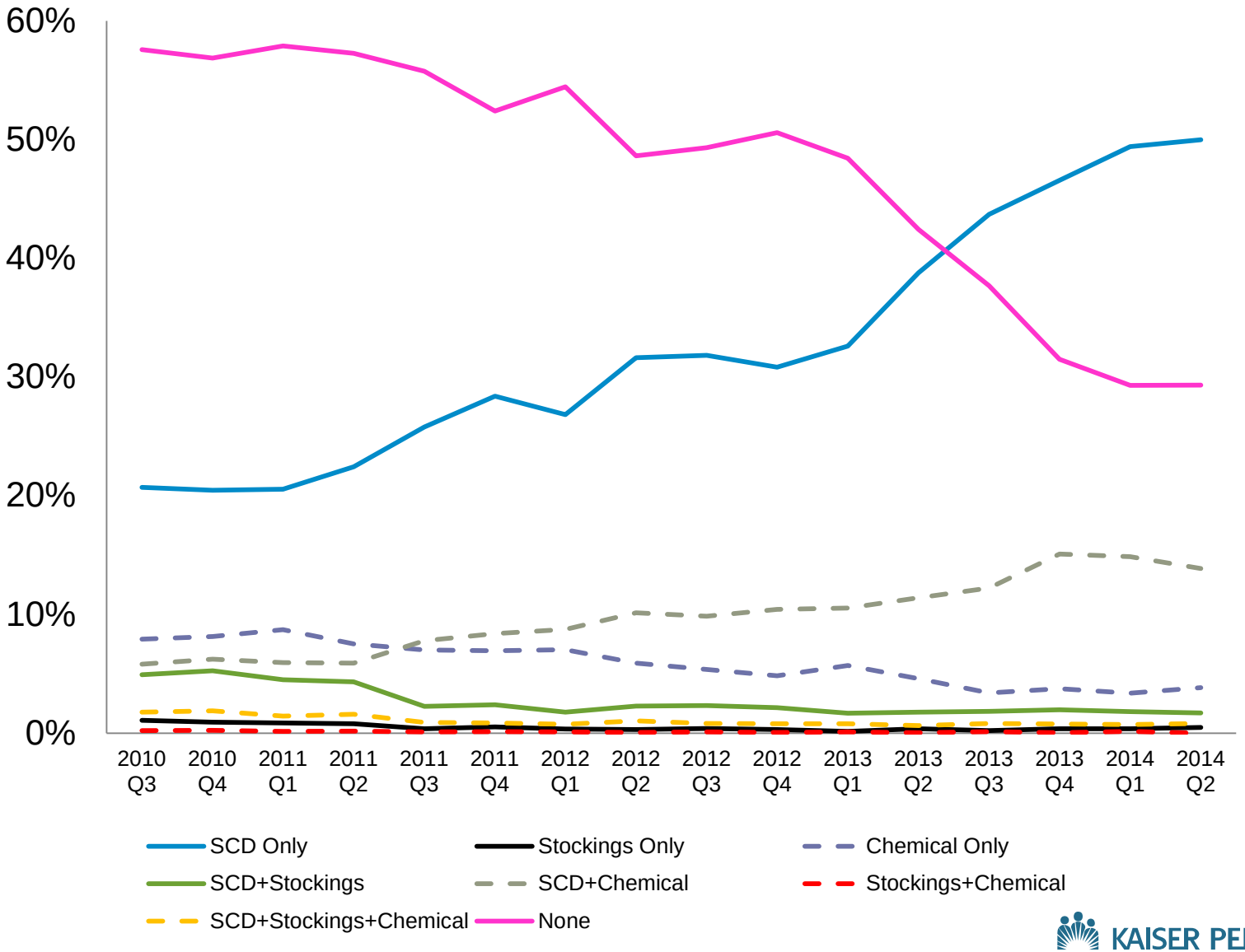
VTE Incidence by IMPROVE Risk Score

VTE Risk Score	% of Sample (n=246,822)	VTE Risk (%)	% of All VTE
Low (0-1)	73	0.3	40
Moderate (2-3)	21	1.0	37
High (4-5)	5	1.9	16
Very High (6+)	1	3.5	6

Timing of VTE Outcomes

Time Period	LOS ≤48h Absolute risk per 1,000	LOS ≤48h % of total	LOS >48h Absolute risk per 1,000	LOS >48h % of total
In-hospital	0.1	2	2.3	27
≤30 days	1.9	59	4.2	50
31 to 90 days	1.2	39	2.0	24
Total	3.2	100	8.4	100
	33% of all VTE		67% of all VTE	

Trends in Use of Prophylaxis



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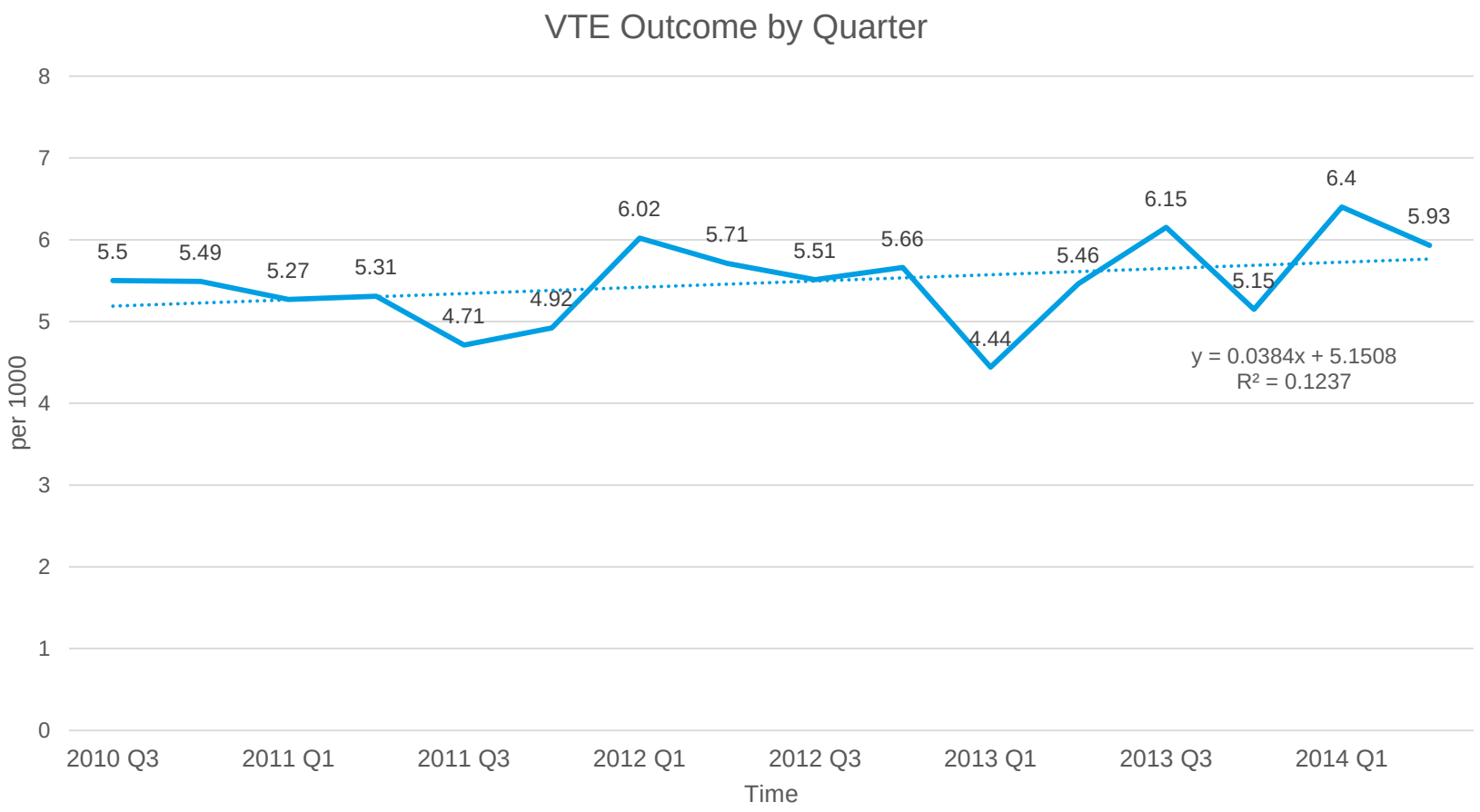
Trends in VTE



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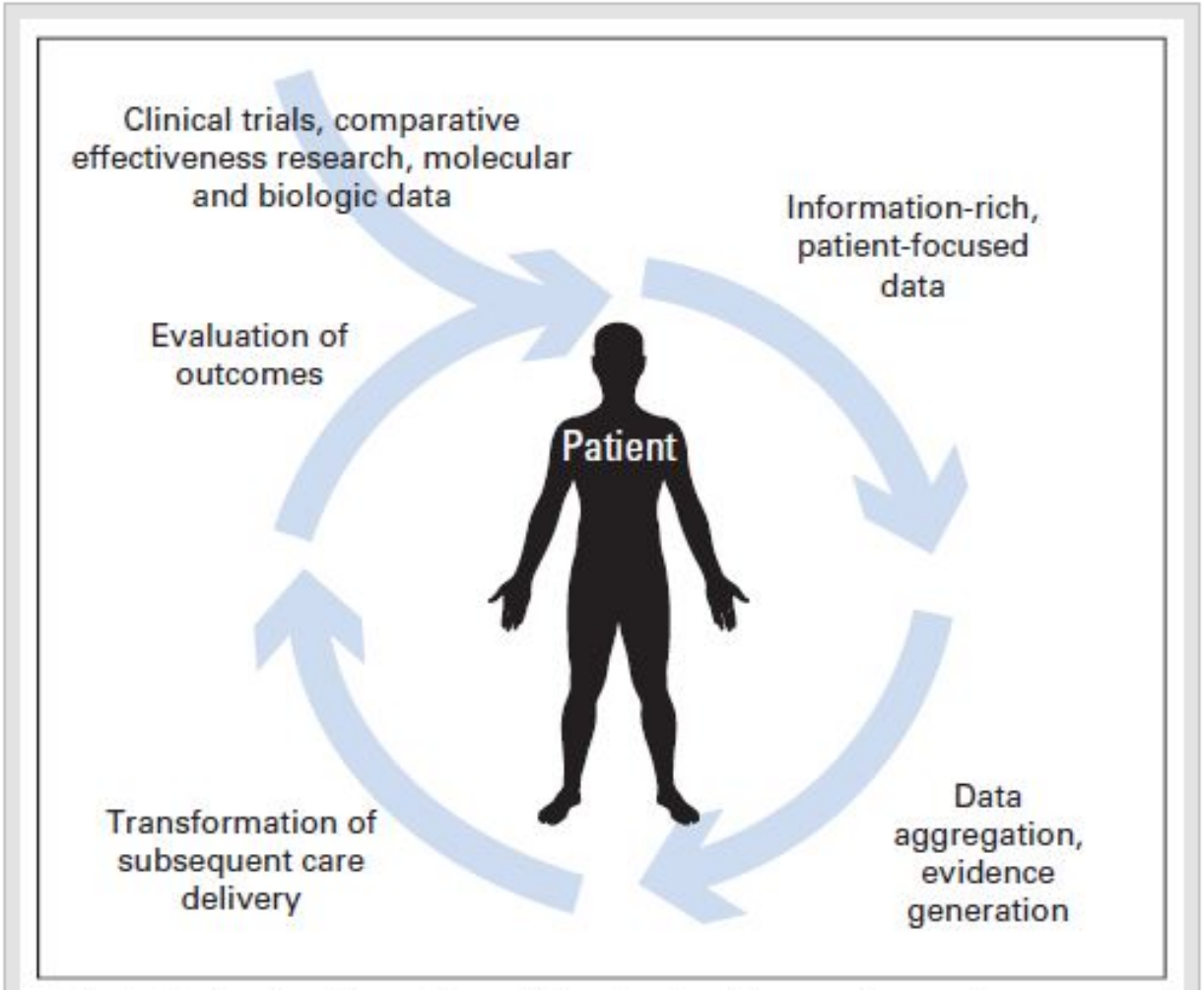
VTE: Ongoing Activities and Next Steps

- Presented results to health system leaders at Regional VTE Summit
- Working with local and national leaders (CDC) to implement computerized decision support
- Encourage adherence with mechanical prophylaxis
- Act on modifiable risk factors
  - Early ambulation, in-hospital and at home
  - Remove (or do not place) central lines and urinary catheters
  - Consider extended duration prophylaxis in high-risk patients

The Learning Health Care System



Abernethy et al. J Clin Oncol 2010;28;4268-74.

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How Common are Pulmonary Nodules?

- Pulmonary nodules are commonly seen in primary care and specialty practice
  - 150,000 cases per year in the 1980s, but recent estimates of incidence not available
- Slow uptake of lung cancer screening with LDCT will further exacerbate the problem
- Most small nodules are benign and harmless, but ~3% represent a potentially curable form of lung cancer

Rate of Chest CT Scanning

Year	Members (millions)	Unique Members with ≥1 CT scan (thousands)	Rate per 1,000 Person-Years
2006	2.62	34.9	15.4
2007	2.67	37.3	16.1
2008	2.67	41.1	17.5
2009	2.66	45.4	19.3
2010	2.70	47.8	20.0
2011	2.82	51.5	20.5
2012	2.92	53.9	20.7
All years	4.61	218.1 (4.7%)	18.6 (18.5 to 18.6)
Increase	11%	55%	

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Rate of Positive Chest CT Scans

Year	Members (millions)	Unique Members with ≥1 Positive CT Scan (thousands)	Rate per 1,000 Person-Years
2006	2.62	9.0	3.9
2007	2.67	10.9	4.6
2008	2.67	12.1	5.1
2009	2.66	13.8	5.8
2010	2.70	15.6	6.5
2011	2.82	16.3	6.4
2012	2.92	17.4	6.6
All years	4.61	69.0 (1.5%)	5.6 (5.6 to 5.7)
Increase	11%	94%	

Gould et al. Am J Respir Crit Care Med 2015;192:1208-1214.

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Standardized Rates and Estimates, 2010

	Rate (per 1,000)	Standardized Rate (per 1,000)	Extrapolated Total
Chest CT scans	20.0	20.7	4.8 M
Positive scans	6.5	6.7	1.6 M
New positive scans	5.7	4.7	1.1 M
Lung cancer cases	0.34	0.26	62,000

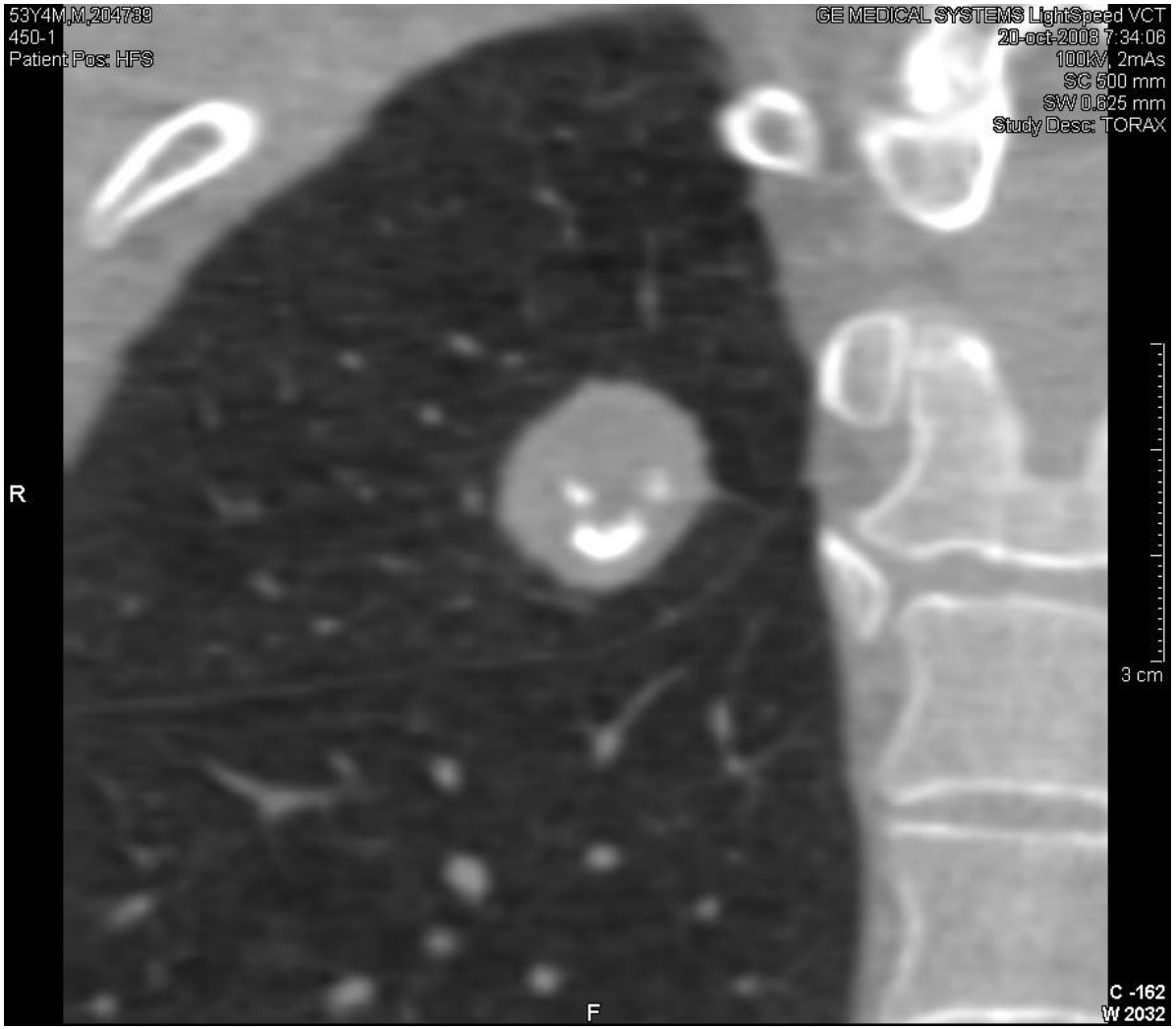
*Adult population of U.S. in 2010: ~234 million

Guidelines for Evaluation of Small Pulmonary Nodules

- For incidental nodules, frequency and duration guided by recommendations from the Fleischner Society (2005, 2013) and ACCP (2007, 2013)
- For nodules detected by screening, recommendations have been developed by ACR (Lung-RADS) and NCCN
- New guidelines recently published by BTS
- Optimal frequency and duration have not been determined
- Revised Fleischner guidelines expected in next few months

MacMahon et al. Radiology 2005;237:395-400.
Naidich et al. Radiology 2012;266:304-317.
Gould et al. Chest 2013;143(suppl):e93S-e120S.
http://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf
http://www.acr.org/Quality-Safety/Resources/LungRADS

Does This Nodule Require Follow-Up?



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WATCH the Spot

- Design: Large, simple, pragmatic trial with cluster randomization by hospital or health system
- Funding: Patient-Centered Outcomes Research Institute
- Patients: ~40,000 individuals with small (≤15 mm) lung nodules on chest CT, detected incidentally or by screening
- Intervention/comparator: recommendations for more versus less frequent CT surveillance embedded in radiology report
- Outcomes
  - Primary: Percent of cancer patients with stage >T1a N0 M0
  - Survival, time to diagnosis/treatment
  - Impact of Event scale, State Anxiety Scale, Short Form Health Survey (SF-36)
  - Resource use, procedure-related complications, radiation exposure
  - Adherence with recommended surveillance

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Description of Study Sites and Enrollment Targets

Health Care Organization	Type of Setting	Unique patients with chest CT during 20 months of enrollment	Estimated patients with nodules ≤15 mm	Estimated patients with lung cancer
Boston Medical Center	Safety Net	7,840	1,250	37
Cleveland Clinic	Referral	26,670	5,330	160
Health Partners, MN	Integrated	4,920	780	23
Kaiser Colorado	Integrated	23,320	3,720	111
Kaiser Northwest	Integrated	12,680	2,020	61
Kaiser Southern California	Integrated	90,000	14,330	430
Marshfield Clinic	Integrated	6,160	980	29
Med. Univ. South Carolina	University	12,500	1,460	29
National Jewish Health	Referral	10,540	1,680	50
Portland VAMC	Veterans	8,790	1,120	34
UC Davis	University	11,640	780	16
UCLA	University	20,000	2,100	63
UC San Francisco	University	13,990	960	29
University of Pennsylvania	University	30,520	3,470	104
Total		279,550	39,980	1,177

Study Procedures: Pragmatic Design

- Goals of pragmatic design:
  - Integrate study procedures into existing clinical workflow
  - Few special assessments or visits outside of routine clinical care
  - Study data collected from readily available information in electronic health records
- Intervention targeted at the level of the radiology department
- Assigned protocol for CT surveillance applies to ALL patients with newly identified nodules at each site
  - Exclusions age <35, patients with known cancer, pregnant women
  - Radiologist's discretion: multiple nodules; nodules with benign calcification or other reliable features of a benign etiology; accompanying findings that raise concern for cancer

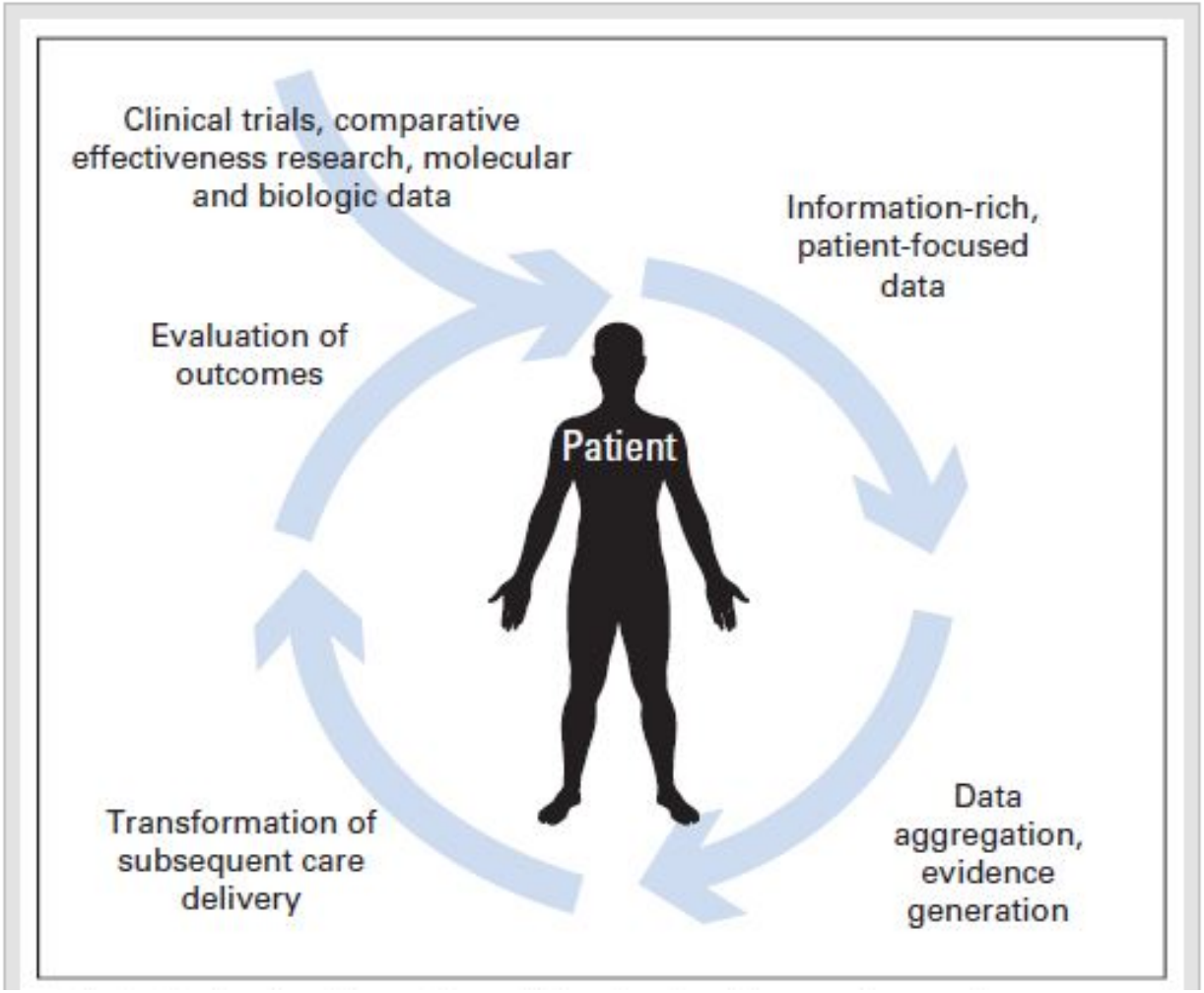
Study Procedures: Human Subjects

- Waiver of individual consent
  - Risk of participating in study no greater (and no different) than risks commonly encountered in usual clinical care
  - Intervention delivered at the system level
  - Patients and providers permitted to deviate from recommended follow-up when indicated
  - Study not feasible or logistically possible without waiver
- Respect for persons: all enrolled patients to be notified of study
  - Patients permitted to opt out for data collection purposes
  - Consent to be obtained for participation in patient surveys

Novel Aspects of Methodology

- Pragmatic design
  - Integration into routine clinical practice
- Automated enrollment and data collection
- Cluster randomization
- Comparison of competing guidelines
- Waiver of consent
- Ambitious target for enrollment

The Learning Health Care System



Abernethy et al. J Clin Oncol 2010;28;4268-74.

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Implementation Science

- Conceptual models
  - Over 100 models from which to choose!
  - Extensions of simple Diffusion of Innovations Theory

    Tabak et al. J Prev Med 2012;43:337-350.
- Implementation strategies
  - Systematic intervention process to adopt and integrate innovations into routine care
  - At least 68 different approaches in 6 categories
  - Often take the form of complex, multi-component, multi-level social interventions

    Powell et al. Med Care Res Rev 2012;69:123-157.

Implementation Strategies

- Planning: understanding needs, resources, local context
- Educational: lectures, conferences, KP Clinical Library
- Quality management: reminders, audit & feedback, PDSA cycles, improvement advisors, Collaboratives
- Restructuring: create teams, revise roles
- Financial: incentives (P4P) and penalties (readmissions)
- Policy: accreditation, credentialing, liability, public reporting

Powell et al. Med Care Res Rev 2012;69:123-157.

Embedded Research: Lessons Learned

- Health care is increasingly complex
  - Likely to become more so with move to precision medicine
  - Need for data-driven explanations and solutions
- Limited tolerance for disruption
  - “Don’t mess with my workflow”
- Operational imperative is to do something/anything and do it quickly
  - “Paralysis by Analysis” versus “Extinction by Instinct”

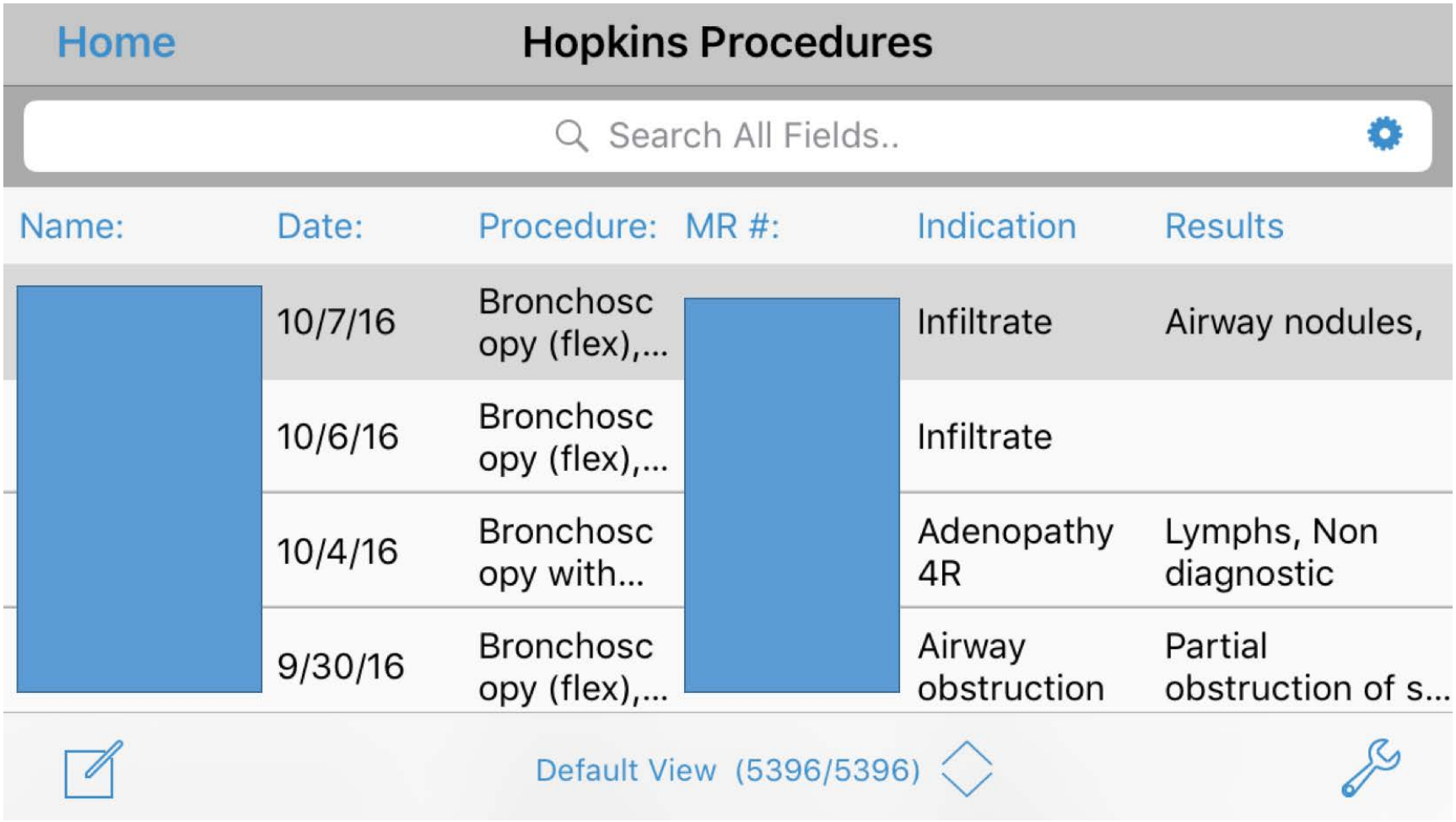
Embedded Research: Lessons Learned

- Stakeholder engagement is crucial
  - Never underestimate the value of a motivated clinical champion
- Hard money investment is helpful
  - Embedded research should be the R&D of health care systems
- Squeaky wheel gets the grease
  - Do we have the right measures?
  - What do we learn from measurement?
  - What are we not measuring?
- Physician behavior profoundly shaped by training and professional norms

Conclusions

- CIRT is a model for embedded research within a learning health care system
- Embedded research is the R&D of the health care industry
- Health systems must find ways to serve as laboratories for improvement without compromising work-flow or patient care
- “If we want more evidence-based practice, we need to create more practice-based evidence!”

Relational Database for Mobile Devices



David Feller-Kopman, MD, personal communication

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Thank You!

michael.k.gould@kp.org

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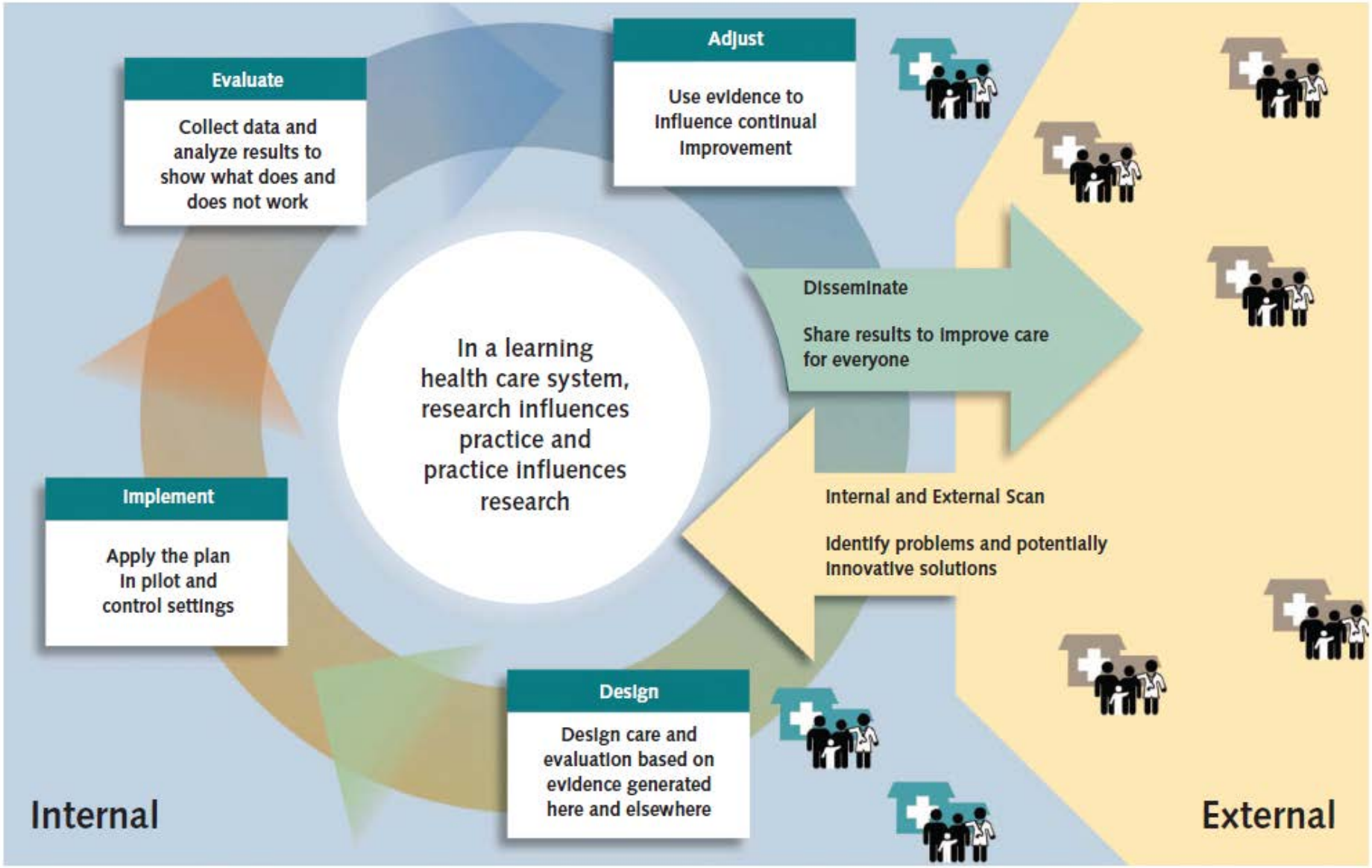

Greene et al. Ann Intern Med 2012;157:207-210.

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CIRT Sponsors

Michael H. Kanter, MD

CIRT has really advanced the way KP approaches learning and innovation in an evidence based fashion. This team has become mainstream operations in many areas of Kaiser Permanente.

CIRT represents the very best of the next generation of research. Fully integrated into operations, CIRT is helping create the "learning healthcare system" so many have spoken about for years, but no-one has seen until now. With our new KP medical school, CIRT will play an important role in helping train the next generation of physicians -- exposing students from their first day in what is the "new normal" in practice-research partnership.

Nirav Shah, MD, MPH

CIRT Partners:
The Implementation Ecosystem

- Unmet Social Needs Initiative
- Home Health Care
- Vital Few: High Needs, High Utilizers

KFH/HP

CIRT

Research Networks

SCPMG

- Clinical Analysis
- Complete Care
- Readmission Reduction Team
- EBM Services
- Regional Chiefs (Emergency, Pulmonary, and Oncology Departments)
- Systems Solutions & Deployment
- VTE Improvement Collaborative
- Health Education
- LAMC Residents
- Renal Business Group

- HCSRN, CRN
- PORTAL, PCORnet
- NCORP Cancer Care Delivery
- KP CESR

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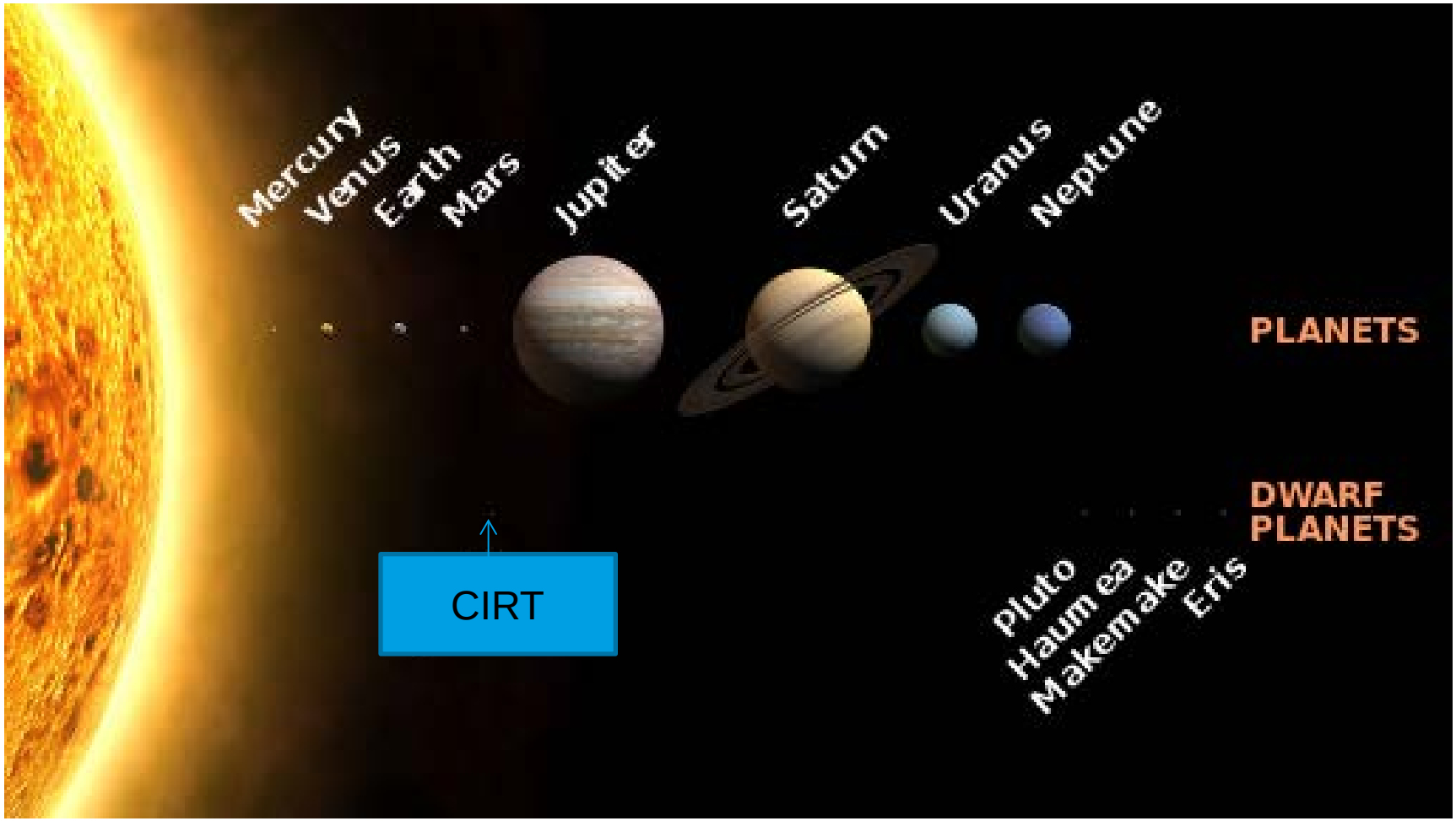
KPSC Implementation Ecosystem: How to Weave Research into the Fabric?



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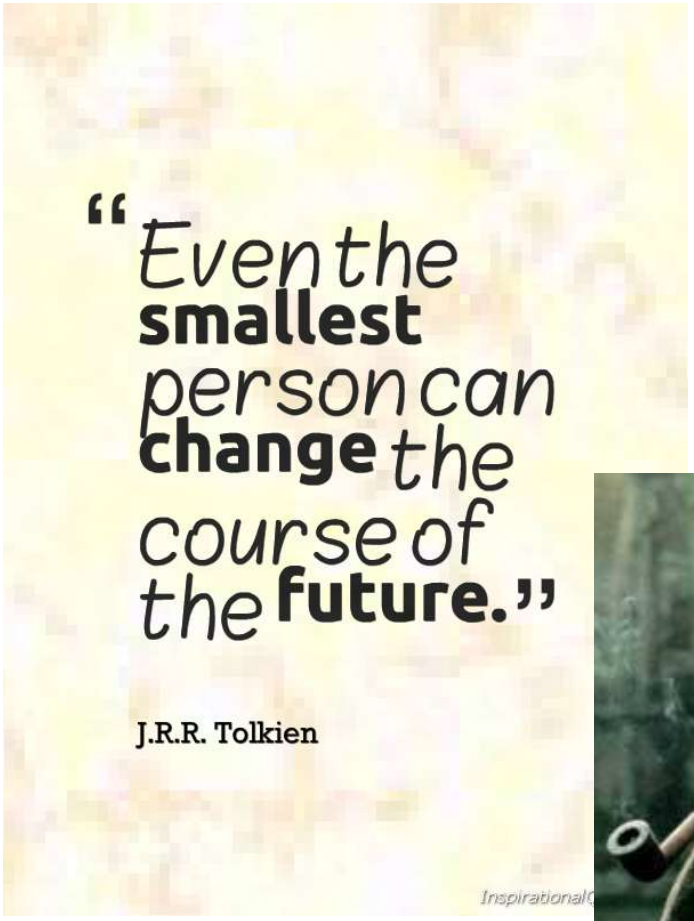

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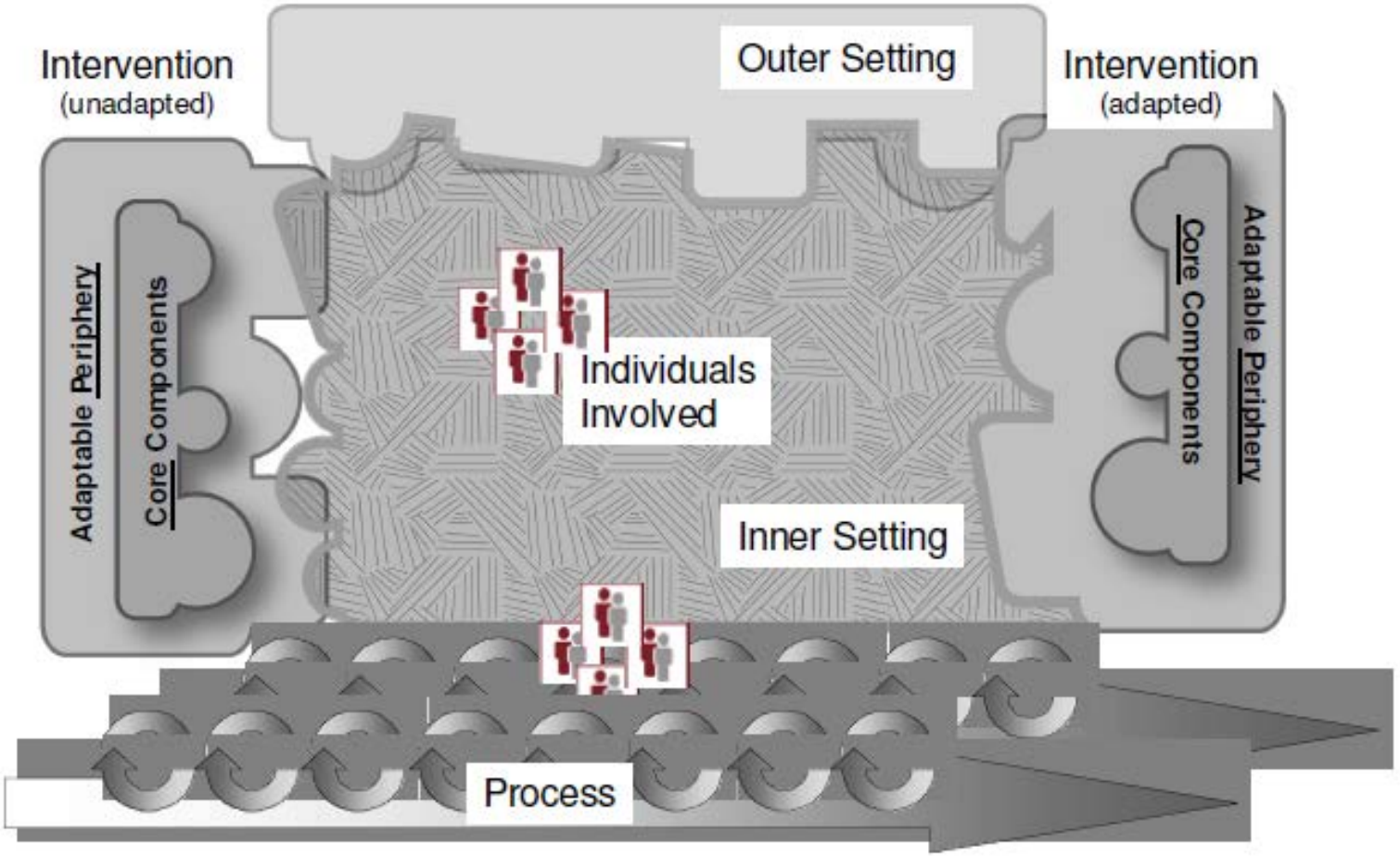
Consolidated Framework for Implementation Research (CFIR)



Damschroeder et al. Implementation Science 2009;4:50.

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Technical vs. Adaptive Challenges

- Technical
  - Easy to identify
  - Quick and easy solutions
  - Often solved by an authority or expert
  - Require change in a few (contained) places
  - People generally receptive
  - Solutions can be implemented quickly
- Adaptive
  - Easy to deny
  - Require changes in values, beliefs, roles, approaches to work
  - Require change in numerous places that cross boundaries
  - People often resist
  - Solutions require experiments and new discoveries

Heifetz RA and Laurie DL. Harvard Business Rev 1997

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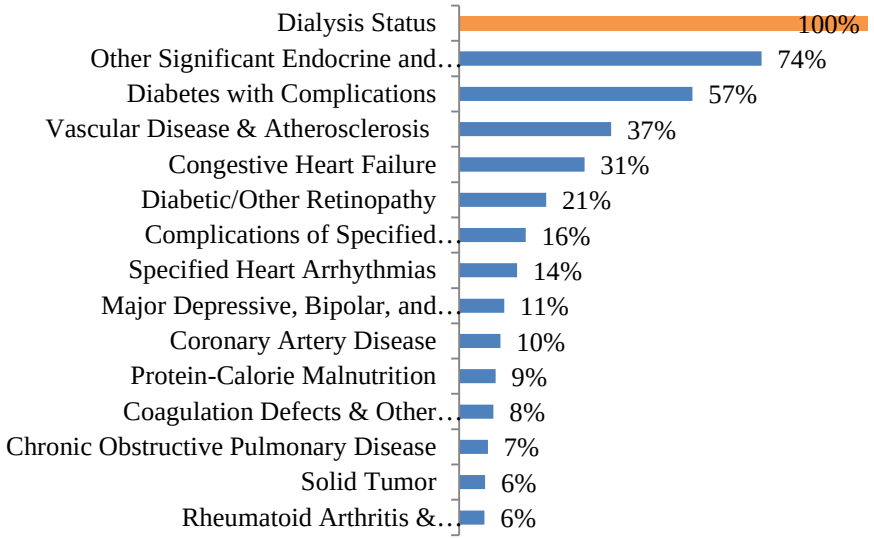
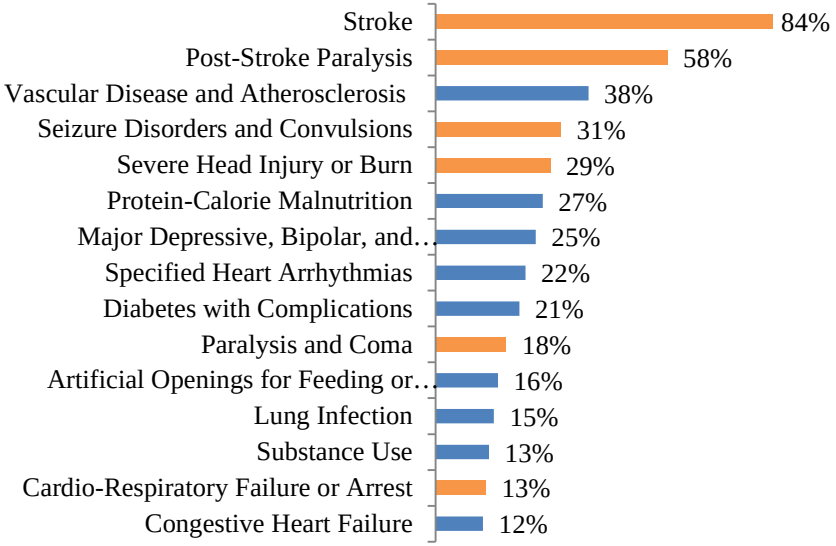
Segmenting High-Needs High-Cost Patients

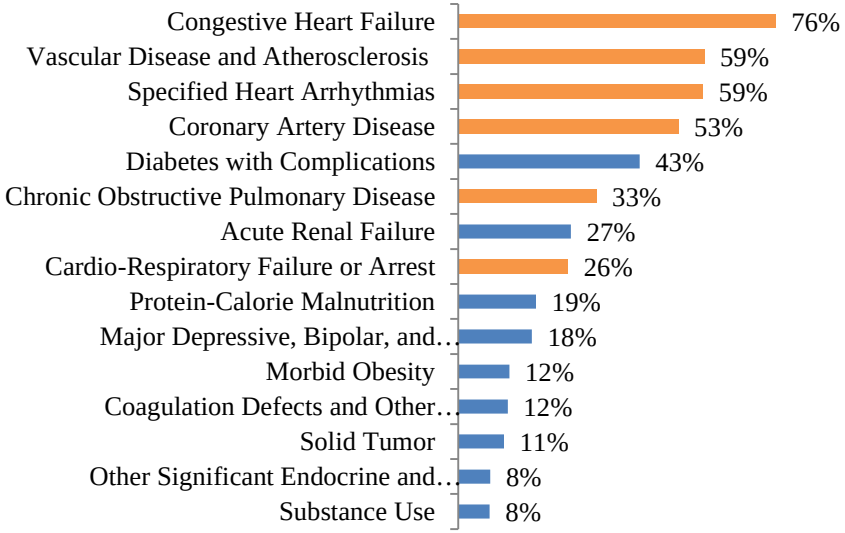
Class 1: "End-Stage Renal Disease"



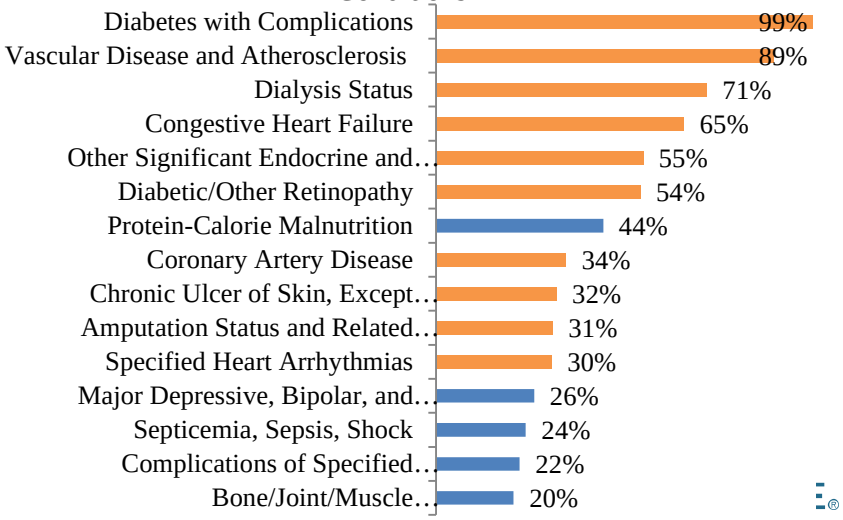
Class 2: "Neurologic and Catastrophic"



Class 3: "Cardio-Vascular and Pulmonary"

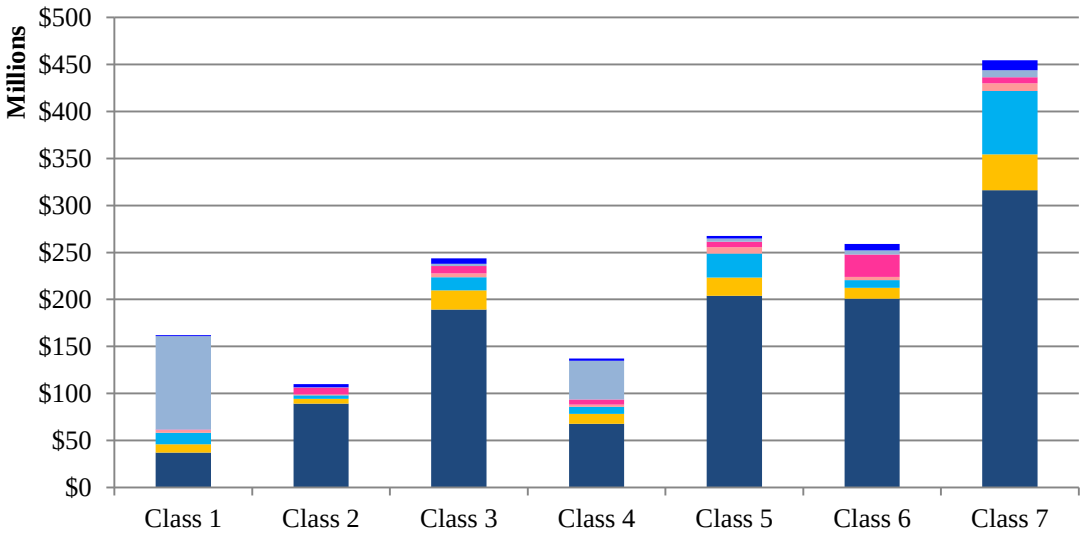


Class 4: "Diabetes with Multiple Comorbid Conditions"

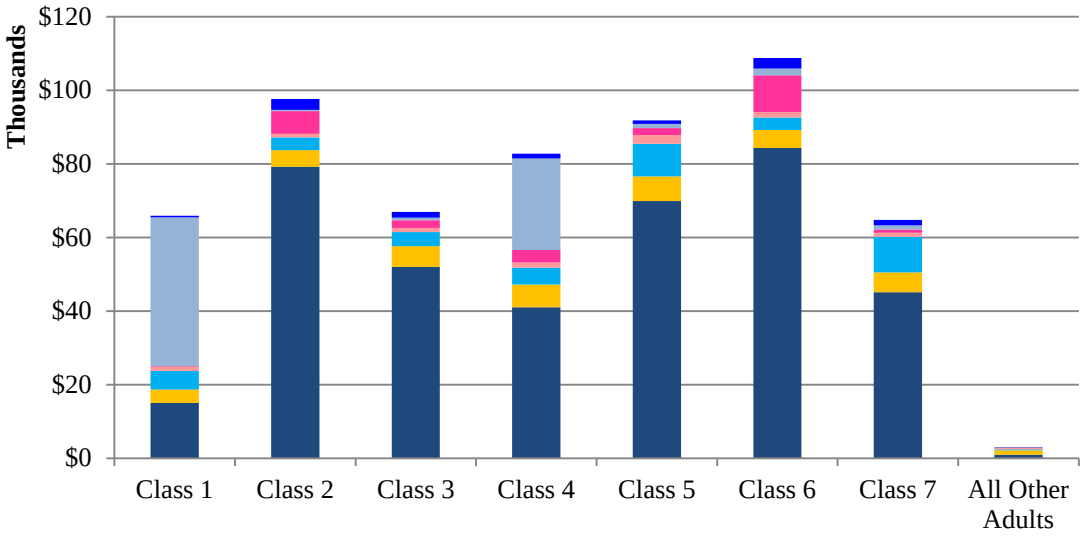


Spending Patterns by Class

Total Aggregate Spending



Average Per Patient Spending



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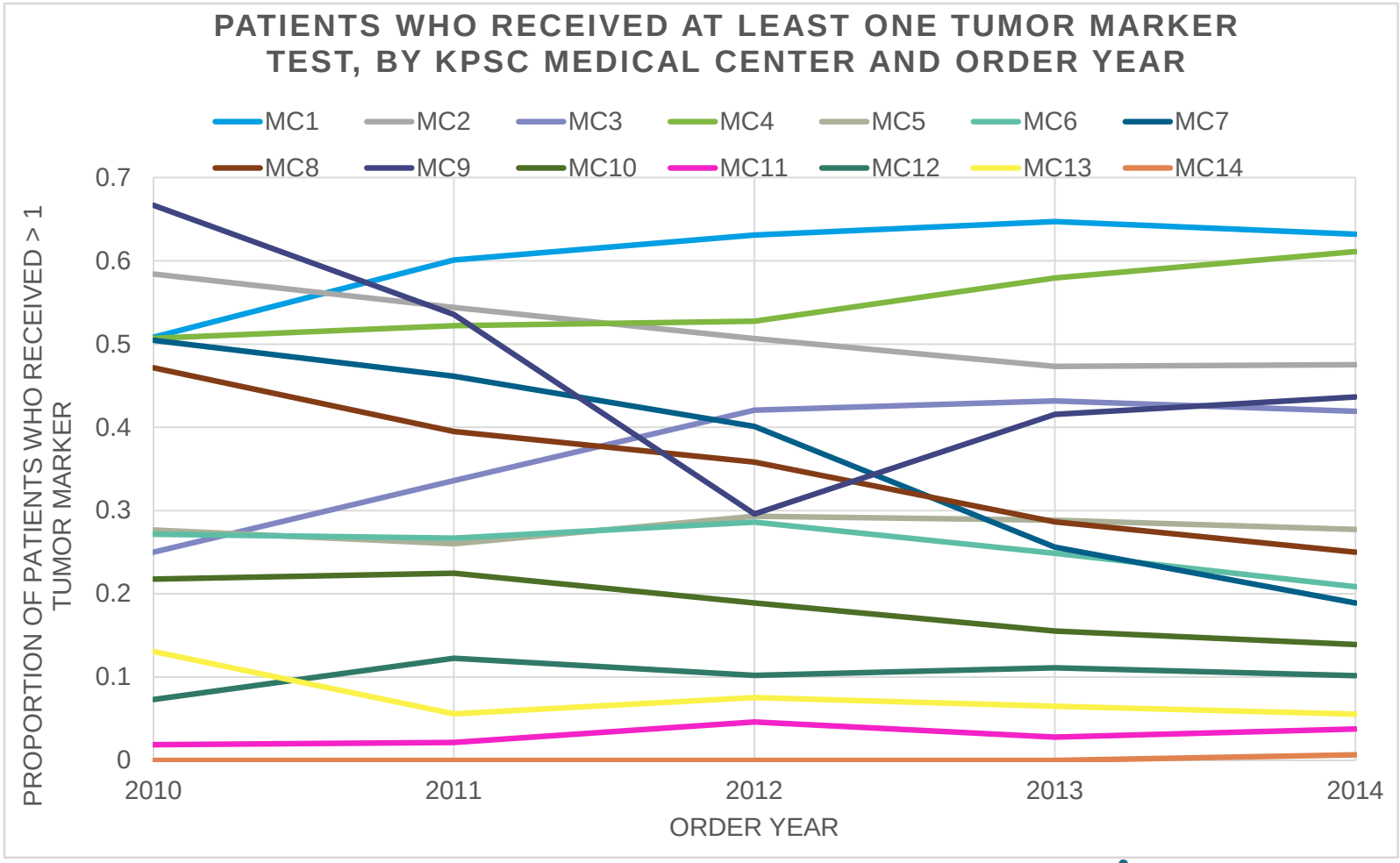
Within-KPSC Variation in Serum Biomarker Testing in Breast Cancer



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Qualitative interviews with high and low using oncologists

- Factors associated with high use:
  - Perceived patient anxiety
  - Oncologist anxiety
  - Concern about patient satisfaction
  - Peer use
- Factors associated with low use:
  - Beliefs about consequences (e.g., causes harms)
  - Medical center culture (e.g., collective decision to follow guidelines).

Theoretical Domains Framework

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