Research-Operations Partnerships to Improve Care

Michael H. Kanter, MD
Marguerite A. Koster, MA, MFT
Michael E. Gould, MD, MS
Huong Q. Nguyen, RN, PhD

The presenters of this session have nothing to disclose.

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Session Overview/Objectives

- About Kaiser Permanente
- Improving Care through Research-Operations Partnerships
- Evaluating the Evidence for New Medical Technologies
- Improving COPD Outcomes by Promoting Physical Activity
- Care Improvement Research Team (CIRT): Improving Care One Study at a Time
Research-Operations Partnerships

Michael H. Kanter, MD
Medical Director, Quality & Clinical Analysis
Regional Quality & Risk Management
Kaiser Permanente Southern California

Kaiser Permanente
Eight Regions
<table>
<thead>
<tr>
<th>Kaiser Permanente</th>
<th>Southern California</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.762 Million</strong> Members</td>
<td></td>
</tr>
<tr>
<td><strong>209</strong> Medical Offices</td>
<td></td>
</tr>
<tr>
<td><strong>14</strong> Hospitals</td>
<td></td>
</tr>
<tr>
<td><strong>6,035</strong> Physicians</td>
<td></td>
</tr>
<tr>
<td><strong>20,393</strong> Nurses</td>
<td></td>
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<tr>
<td><strong>61,897</strong> Employees</td>
<td></td>
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</tbody>
</table>

- Integrated delivery system
- Includes
  - Lab
  - Pharmacy
  - Radiology
Operations - how to decide if a proposed change will work

- “suggestion” from senior management
  - Often wrong
- Internal “expert” opinion
  - Not infrequently wrong
- Idea provided at conference (e.g. IHI meeting)
  - No comment
- Recently published article
  - Accuracy depends on study
- Comprehensive evidence review
  - Often not available, of poor quality, not generalizable

Need to change a practice - try a “pilot”

- What is a “pilot”
  - A practice that is normally prohibited but someone wants to do anyways? These often last a long time.
  - A practice that the creator is certain will improve care such that data collection and testing is not necessary.
  - A innovative practice that uses lots of new technology and gadgets created by innovative start companies in the Silicon Valley so they must be good. Data collection and testing will merely slow the innovative process
What happens when operational leaders want a change

- Urgency to try a “pilot”
- Once the pilot is running, urgency to spread the best practice
  - Lots of hand wringing about why it is so hard to spread best practices

Can traditional research help decide if a practice should be changed?

- Find a qualified researcher interested in the subject
- Apply for external grants
- Get external grants after some rejections
- Get approval of IRB
- Get clinical sites to change practice and observe results
- Analyze results and submit to journal
- Manage initial manuscript rejections and revisions
- Convince clinicians to change practice
Research and Operations

<table>
<thead>
<tr>
<th></th>
<th>Research</th>
<th>Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed</td>
<td>slow</td>
<td>fast</td>
</tr>
<tr>
<td>Generalizability</td>
<td>important</td>
<td>Not important</td>
</tr>
<tr>
<td>Hypothesis testing</td>
<td>important</td>
<td>Not important</td>
</tr>
<tr>
<td>Outcome</td>
<td>Publication</td>
<td>Change in clinical practice</td>
</tr>
</tbody>
</table>

Care Improvement Research Team (CIRT)

- Newly created subunit of the Department of Research and Evaluation
- Potential answer to the problem of needing to make operational changes when the evidence is unclear and there is a need to know if the change is beneficial
- Faster than traditional research
CIRT Mission and Vision

**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 close them within the KPSC system.

**Vision:**
To be the model for embedded research within a learning health care system.

CIRT Goals

- Build sustainable partnerships with SCPMG clinicians and KPSC operational leaders
- Identify and prioritize opportunities for care improvement
- Execute studies to describe, diagnose and explain gaps in clinical practices
- Understand current strategies to implement clinical practices supported by evidence
- Evaluate new models of care delivery
- Help to foster a culture of inquiry and continuous improvement
CIRT

- Dept. of Research, population health care, quality, clinical analytics, physician education, evidence-based medicine/guidelines unit all report to the Regional Medical Director for Quality and Clinical Analysis.
  - Coordination of activities is critical
  - Funding comes from the hospital/health plan working collaboratively with the medical group with some ability to get external grants
  - Monthly meetings between the research scientists and regional medical director for quality and clinical analysis
  - Researchers meet regularly with regional chiefs groups and other implementation and operational groups.
  - Blurred distinction between research and operational activities

CIRT Projects

<table>
<thead>
<tr>
<th>Documenting Overuse, Underuse, &amp; Misuse</th>
<th>Evaluating Current Practice</th>
<th>Changing Practice</th>
<th>Evaluating Care Innovations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Use of antibiotics and head CT for acute sinusitis</td>
<td>• Use of lung fx tests to monitor Amiodarone use</td>
<td>• Develop VTE risk models</td>
<td>• Hem-Avert to reduce c-sections</td>
</tr>
<tr>
<td>• Pulmonary rehabilitation in COPD</td>
<td>• Advanced medical home for complex patients</td>
<td>• Physical activity coaching for COPD</td>
<td>• Lung CA screening; nodule eval safety net</td>
</tr>
<tr>
<td>• Use of intravesicular adjuvant chemo for bladder CA</td>
<td>• Care transitions</td>
<td>• Reduce ATB use for acute sinusitis</td>
<td>• Bronchial thermoplasty for severe asthma</td>
</tr>
<tr>
<td>• Knee arthroscopy for meniscal damage in OA</td>
<td>• Optimizing colon and lung CA care</td>
<td>• De-implementation of biomarker tests for surveillance in early stage breast CA</td>
<td>• Activity sensors to promote ambulation in hospital</td>
</tr>
<tr>
<td>• Use of biomarkers for surveillance in early stage breast CA</td>
<td>• Timeliness of care for lung CA</td>
<td>• Cancer survivorship care</td>
<td>• Palliative care for advanced lung CA</td>
</tr>
<tr>
<td>• CT use in eval of traumatic head injury</td>
<td>• A Fib; pneumonia care in the ED</td>
<td>• Changing d-dimer threshold for PE eval</td>
<td>• Online action plan to close care gaps</td>
</tr>
<tr>
<td>• Post treatment screening in Hodgkin lymphoma survivors</td>
<td>• Observation medicine</td>
<td>• Remote monitoring and visits for members with gestational diabetes</td>
<td>• Telestroke</td>
</tr>
<tr>
<td></td>
<td>• Co-management: physician communications</td>
<td></td>
<td>• On call nurse video visits</td>
</tr>
</tbody>
</table>

Completed Projects: 6  
Active Projects: 24
What is Evidence-Based Medicine?

- “The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients...integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

Sacket DL. Evidence based medicine: what it is and what it isn’t. BMJ. 1996;312.
Health (Medical) Technology Assessment

- The **systematic evaluation** of properties, effects, or other impacts of health care technology
- The main purpose is to **inform policy making** for the use of various technologies in health care
- “Technologies” can include:
  - Devices, equipment, supplies (e.g., cardiac pacemaker, MRI scanner, etc.)
  - Medical and surgical procedures: (e.g., acupuncture, bariatric surgery, cesarean section, etc.)
  - Population health programs (e.g., vaccinations, care of chronic conditions, smoking prevention programs, etc.)
  - Organizational, delivery, or other systems that impact clinical care (e.g., implementation of clinical interventions)

KP Southern California Region
Medical Technology Management Process (MTMP)

- **Ongoing structure for evaluation and management of new and existing** medical technologies that impact the Southern California Region
- Primarily on **high cost** and/or **high volume** technologies
- Ensures that evidence-based decision making is behind evaluation and adoption of new medical technologies
- Considers all aspects of quality of care, service and cost during the planning and implementation of technologies
Medical Technology Assessment Team (MTAT)

- Evaluates the evidence for new and existing technologies
  - Safety and effectiveness data, benefits and harms
  - Impact on short and long term health outcomes
  - Reviews governmental status (FDA and CMS)
  - Considers relative cost and burden of suffering

- Solicits clinical expert opinion on clinical relevance and medical appropriateness of new and existing technologies
The Evidence Review Process (MTAT)

Systematically search for, critically appraise & summarize the evidence from key sources:

- Medical literature databases (e.g., PubMed, EMBASE, etc.)
- Subscription evidence review databases
- Cochrane Collaboration, ECRI Institute, Hayes Inc., etc.
- Technology Assessment Organizations
  - Agency for Healthcare Research & Quality (AHRQ)
  - Blue Cross Blue Shield, Technology Evaluation Center
  - California Technology Assessment Foundation (CTAF)
- FDA, CMS/Medicare, clinical trials registries
- Professional society guidelines and statements
- Medical policies of other health plans
Rating the Quality of Evidence

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are very confident that the true effect lies close to that of the estimate of the effect.</td>
<td>++++</td>
</tr>
<tr>
<td>Moderate</td>
<td>We are moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of effect, but possibility to be substantially different.</td>
<td>++++ ○</td>
</tr>
<tr>
<td>Low</td>
<td>Our confidence in the effect is limited: The true effect may be substantially different from the estimate of the effect.</td>
<td>+++ ○ ○</td>
</tr>
<tr>
<td>Very low</td>
<td>We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.</td>
<td>++ ○ ○ ○</td>
</tr>
</tbody>
</table>

Source: Adapted from GRADE Working Group

Medical Technology Deployment Strategy Team (MTDST)

- Plans the deployment and operations for new and existing technologies
  - Monitors existing equipment inventory, approves equipment forecasts and budgets for certain high cost medical technologies, and reviews Medical Center budget submissions
  - Forecasts potential utilization
  - Obtains input from clinical experts
  - Identifies and assesses options and their feasibility (e.g. business cases)
  - Recommends deployment strategy to relevant stakeholders
  - Recommends process for quality monitoring
  - Involves and informs appropriate stakeholders in deliberations and decisions
Deployment Decision (MTAT → MTDST)

**DECISION/RECOMMENDATION**

- **Takes into consideration:**
  - Quality of evidence
  - Balance benefits/harms of intervention
  - Values and preferences
  - Resource use (cost)

- **Potential decisions:**
  - Deployment
  - No deployment/monitor literature
  - Further study

Source: Adapted from GRADE Working Group

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**Do it / Don’t do it**

1. Clear balance
   - benefits clearly outweigh risks/hassle/cost
   - risk/hassle/cost clearly outweighs benefits

2. Sufficient confidence in estimates (high or moderate)

3. Patients values & preferences:
   - almost all **same** choice

Source: Adapted from GRADE Working Group/MAGIC

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**Research / Study?**

1. Close balance
   - Close call between benefits and risks/hassle/cost
   - More sensitive to preferences/values

2. Low confidence in estimates

3. Patients values & preferences:
   - choice **varies** appreciably
     - (or is very uncertain)

Source: Adapted from GRADE Working Group/MAGIC
From Evidence to Research/Operations: Putting It All Together

MTAT
- Discuss technology & indication(s)
- Review evidence
- Agree on evidence quality/grade
- Assess benefits vs. harms

"Joint Chairs"
Recommend Deployment Discussion?
No
Yes

MTDST
- Assess burden of suffering
- Discuss resource & operational issues
- Consider deployment options

Research/Operations
IRB Study
Pilot Study
Region-wide deployment
Limited deployment

Periodic deployment updates to MTDST and/or the Procedural Outcome Strategy Team (POST)

START
Conduct evidence review (EBM Services staff)

Archive assessment, update as necessary

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Improving COPD Outcomes by Promoting Physical Activity

Huong Q. Nguyen, RN, PhD
Research Scientist, Department of Research & Evaluation
Care Improvement Research Team (CIRT)
Kaiser Permanente Southern California
Why COPD, why now?

It’s about deconditioning
Pulmonary Rehabilitation: Guideline Recommended Care

- Multi-disciplinary
- Supervised exercise training
- Self-care education & skills training
- 2-3 times/week for 6-8 weeks
- Lifetime Medicare benefit of 36-72 sessions
- Average cost: $2,500

Pulmonary Rehabilitation: ↓ Hospitalizations

<table>
<thead>
<tr>
<th>Years: 2008-2012</th>
<th>Pulmonary Rehab in KPSC (n=557)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12-mos Pre</td>
<td>12-mos Post</td>
</tr>
<tr>
<td>% patients hospitalized</td>
<td>253 (45%)</td>
<td>205 (37%)</td>
</tr>
<tr>
<td>% patients hospitalized for COPD</td>
<td>153 (27%)</td>
<td>100 (18%)</td>
</tr>
<tr>
<td>% patients w/ED visits</td>
<td>302 (54%)</td>
<td>287 (51%)</td>
</tr>
<tr>
<td>% patients w/ED visits for COPD</td>
<td>166 (30%)</td>
<td>122 (22%)</td>
</tr>
</tbody>
</table>

Rehabilitation ↓ all cause hospitalizations by 8%

Nguyen et al. (accepted) J Cardiopulmonary Rehab
Pulmonary Rehabilitation: Adjusted Analyses

<table>
<thead>
<tr>
<th></th>
<th>12-Mo Hospitalization Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RR</td>
</tr>
<tr>
<td>Pulmonary rehab (PR) participant (n=557)</td>
<td>1.0</td>
</tr>
<tr>
<td>Referred but declined PR controls (n=90)</td>
<td>1.40</td>
</tr>
<tr>
<td>Matched non-PR controls (n=1,114)</td>
<td>1.14</td>
</tr>
</tbody>
</table>

*Adjusted for age, gender, marital status, race/ethnicity, smoking status, use of oxygen supplementation or systemic steroids, Charlson co-morbidity index, depression, and hospital-based and outpatient utilization

Compared to COPD patients who participated in PR, those who were referred but declined had a trend for ↑hospitalizations

Nguyen et al. (accepted) J Cardiopulmonary Rehab

COPD struck me down when I didn’t expect it. My doctor referred me to rehab but I kept putting it off but then finally, I was tired of not feeling well and knew I needed to do something about it.

I HAD NO IDEA WHAT REHAB WAS BUT THOUGHT IT WAS LIKE THE TRADITIONAL GYM WHERE THEY PUSH AND PUSH AND I DON’T LIKE THAT AT ALL. NOW I KNOW WHAT REHAB IS AND THAT IT CAN TOTALLY CHANGE YOUR LIFE. IT DID FOR ME.
"REHAB INCREASED MY QUALITY OF LIFE BY 80%! I would have never thought I could travel again before rehab and guess what, I went on a two week vacation with my daughter and I did very well.

I can do some of my housework now although I still get help; I DON'T NEED TO STOP AS MUCH OR USE MY WHEELCHAIR OR THE SCOOTERS in the store. I’ve learned how to breathe so much better, control my anxiety, take my inhalers correctly"

Improvement Opportunity: Under-utilization

Uptake of pulmonary rehab is DISMAL at 2-5%
National & Global Issue

System
- Space
- Staffing
- Capacity

Provider
- Knowledge
- Attitude
- Referrals

Patient
- Transportation
- Distance
- Scheduling
- Motivation

**Patient-Level Barriers to Rehab**

- Physical or mental health limitations: 29%
- Transportation/Scheduling conflicts: 2%
- No interest/perceive no benefit from participation: 13%
- Missing: 7%
- Other (current smoker, weight limitation already active, unable to contact, etc.): 13%

n=365 patients

**Physical Activity Associated with Lower Risk of 30-Day Readmission**

<table>
<thead>
<tr>
<th>EVS</th>
<th>RR, 95%CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 mins/wk</td>
<td>1.0</td>
<td>-</td>
</tr>
<tr>
<td>1-149 mins/wk</td>
<td>0.67 (0.55, 0.81)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>&gt;150 mins/wk</td>
<td>0.66 (0.51, 0.87)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

n=4,596 patients admitted for a COPD exacerbation with 5,862 index admissions from Jan 1, 2011 – Dec 31, 2012

Adjusted for age, gender, marital status, race/ethnicity, insurance status, BMI, smoking status, flu & pneumonia vaccination, use of inhaler medications, comorbidities, previous hospitalizations, length of stay, discharge disposition, ED/Obs. Stay, and receipt of inpatient palliative care consultation.

Any PA → ↓ 34% readmission risk

Cumulative Incidence of Death or Rehospitalization

n=2,370 hospitalized COPD patients

Inactive vs. Insufficiently active
RR: 0.83 (95% CI: 0.70, 0.97), p=.02

Inactive vs. Active
RR: 0.73 (95% CI: 0.59, 0.90), p<.01

Days to Hospitalization, Death or End of Follow-up
Implementation Structure

Regional Leadership & Champions

Medical Center Leadership “Sponsors”

Research Consulting & Implementation

Local Co-leads/Champions Pulmonary Chiefs, Dept Administrators, & Pulm Rehab Directors & Coordinators

Regional Structures

- Pulmonary Rehab Workgroup
  - Standardize rehab; ↑ efficiency
  - COPD Task Force
  - Readmissions Reduction Workgroup

Chiefs Goals 2014

- ↑ referrals to pulmonary rehab for patients hospitalized for COPD
- ↓ 30-day readmission

Research

- Pilot test physical activity coaching (Walk On!) as alternative to rehab at 5 medical centers
- External funding for pragmatic RCT to test Walk On! vs. standard care

Kaiser Permanente
Physical Activity Coaching for COPD (Walk On!)

Funding from PCORI 2014-2018
CIRT:
Improving Care One Study at a Time

Michael K. Gould, MD, MS
Senior Scientist and Leader, Care Improvement Research Team (CIRT)
Director for Health Services Research and Evaluation
Department of Research and Evaluation
Kaiser Permanente Southern California

Importance of Study Design

- Use the design that will answer the question most efficiently
- Examples:
  - Choosing Wisely: Retrospective cohort study
  - Bronchial Thermoplasty: Prospective registry
  - Hem-Avert: Quasi-experimental, pragmatic trial
Choosing Wisely

- “Don’t perform surveillance testing (biomarkers) for asymptomatic individuals who have been treated for breast cancer with curative intent.”
  - American Society of Clinical Oncology, 2012
- Research question: How are we doing with adherence?
- Design: retrospective cohort study using structured data from EHR plus chart review

Biomarkers for Surveillance: Stage 0-IIB Breast Cancer

<table>
<thead>
<tr>
<th>Region</th>
<th>Southern California (N=3,796)</th>
<th>Mid-Atlantic (N=321)</th>
<th>Northwest (N=435)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one biomarker test</td>
<td>1,453 (38%)</td>
<td>144 (45%)</td>
<td>21 (5%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Percent clinically indicated</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Medicare/SEER: 30% biomarker
Academic center: 77% biomarker

Hahn et al. Cancer 2013;119
Biomarkers, Medical Center Level Data

Biomarkers, Physician Level Data
Choosing Wisely: Next Steps for Care Improvement

- Engage stakeholders
  - AMD for Quality
  - Oncology Regional Chiefs
  - Individual physicians
- Activate change
  - Provider education
  - Audit and feedback
  - Decision support
- Repeat PDSA cycles
  - Use statistical process control to track improvement over time

Bronchial Thermoplasty (BT)

- New treatment for patients with moderate to severe asthma who do not respond to conventional therapy
- MTAT Technology Assessment: Fair quality evidence
  - Increases adverse respiratory events following initial treatment
  - Reduces severe exacerbations 4-12 months following treatment
  - Caveat: studies performed at centers of excellence by highly experienced operators
- ATS: “Perform only in IRB-approved trial”
- Research question: Can BT be performed safely in our hospital settings?
BT Outcomes from RCT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>BT (%)</th>
<th>Sham (%)</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe AEs (treatment period)</td>
<td>3.1</td>
<td>1.5</td>
<td>2754</td>
</tr>
<tr>
<td>Severe exacerbations (post-treatment)</td>
<td>26</td>
<td>40</td>
<td>352</td>
</tr>
<tr>
<td>Entire study period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe exacerbations</td>
<td>54</td>
<td>46</td>
<td>1226</td>
</tr>
<tr>
<td>ED visits</td>
<td>8</td>
<td>15</td>
<td>650</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>11</td>
<td>5</td>
<td>640</td>
</tr>
</tbody>
</table>

BT Study Design

- Develop prospective registry of all cases
- Outcomes
  - Volume of procedures
  - Appropriateness
  - Clinic visits, ED visits, hospitalizations
  - Exacerbations, use of oral steroids
  - Patient-reported outcomes?
- Use statistical process control to track outcomes over time
Hem-Avert

- Perianal stabilizer
- Found to reduce external hemorrhoids occurring during labor and delivery
- Research question: Will it also decrease the risk of Cesarean-Section?

Hem-Avert Study Design

- Pragmatic, quasi-experimental, step-wedge design
  - Variation on standard pre-post comparison to better control for threats to validity such as secular trends and influential champions
- Staggered implementation at 4 hospitals
  - Each hospital assigned to ≥1 month of usual care, followed by ≥1 month of intervention
  - Random assignment at the level of the hospital
  - During intervention months, all patients receive the device
- Outcomes ascertained retrospectively via EHR
- Set to launch in January 2015, pending IRB approval
Conclusions

- There’s more than one way to peel an orange…
- Choose the right tool for the task
  - Study design should fit the research question
- RCTs are the gold standard but are not always feasible or even desirable
- Quasi-experimental and non-experimental studies often yield the desired information most efficiently

CIRT: The Hobbits of KPSC

“Even the smallest person can change the course of the future.”
J.R.R. Tolkien
Questions/Discussion