Embedded Research in the Learning Healthcare System: Ongoing Challenges and Recommendations for Researchers, Clinicians, and Health System Leaders

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Embedded research is an innovative means to improve performance in the learning healthcare system (LHS). However, few descriptions of successful embedded research programs have been published. In this perspective, we describe the Care Improvement Research Team, a mature partnership between researchers and clinicians at Kaiser Permanente Southern California. The program supports a core team of researchers and staff with dedicated resources to partner with health system leaders and practicing clinicians, using diverse methods to identify and rectify gaps in clinical practice. For example, recent projects helped clinicians to provide better care by reducing prescribing of unnecessary antibiotics for acute sinusitis and by preventing readmissions among the elderly. Embedded in operational workgroups, the team helps formulate research questions and enhances the rigor and relevance of data collection and analysis. A recent business-case analysis cited savings to the organization of over $10 million. We conclude that embedded research programs can play a key role in fulfilling the promise of the LHS. Program success depends on dedicated funding, robust data systems, and strong relationships between researchers and clinical stakeholders. Embedded researchers must be responsive to health system priorities and timelines, while clinicians should embrace researchers as partners in problem solving.

E mbedded research is rapidly gaining traction as an innovative means to improve care delivery in the learning healthcare system (LHS).[1] Many researchers are eager to see their work lead to improvements in clinical practice, while some visionary health system leaders recognize that embedded research adds value to daily operations. A recent national conference brought together health system leaders, researchers, and other clinical stakeholders to discuss the "state of the art" of embedded research. One important gap identified during pre-conference planning is that very few descriptions of successful embedded research programs have been published.[2, 3] In this paper, we describe the Care Improvement Research Team (CIRT), a mature research-operations partnership that has been in place at KPSC since 2012. We also provide recommendations for both embedded researchers and clinical stakeholders based on our experience.

SETTING

KPSC is a fully integrated healthcare system that serves a socio-demographically diverse population of over 4.6 million members. The system currently includes over 7600 physicians and 26,000 nurses, who provide care at 15 hospitals and 231 medical office buildings. Clinical care is administered and delivered under a federated model, in which practicing physicians serve as leaders at both the local and regional levels. Most day-to-day operational decisions are made by leaders of local "medical service areas," while regional leadership provides strategic direction, sets clinical policy, and supervises programs for quality improvement and population health management.

Within the regional offices, the Department of Research and Evaluation employs approximately 30 research scientists and over 300 support staff, including five core scientists and 6–8 full-time equivalents of support staff who constitute the CIRT program. While the department primarily functions as a traditional soft-money academic research unit, the CIRT program was founded by executive leadership with hard-money support to build capacity for embedded research that simultaneously aims to improve health system performance and create valid scientific knowledge. CIRT scientists have training and experience in clinical medicine, nursing, health services research, sociology,

implementation science, clinical epidemiology, and biostatistics.

PROGRAM DESCRIPTION

Like many other organizations, KPSC has developed a number of mechanisms to execute the core functions of the LHS.[4] Practicing physicians play key roles in this ecosystem. By serving on local or regional improvement teams, they identify important clinical questions, help to set goals and priorities, provide feedback about intervention fit and feasibility, and work to implement changes in practice. To integrate research into the fabric of the LHS at KPSC, the CIRT program adopted a strategy of embedding research scientists with relevant expertise into existing operational teams, reasoning that such groups were already empowered to lead improvement efforts (Table 1). Once embedded, they provide expert consultation to help formulate operational research questions and enhance the rigor and relevance of subsequent data collection and analyses. For example, a CIRT project performed in partnership with the Readmissions Steering Committee found that to reduce the frequency of 30-day readmissions for older adults, the optimal timing of a post-hospital outpatient follow-up visit was within 7 days of discharge, resulting in a system-wide change in policy that affected over 70,000 patients each year.[5]

CIRT research scientists meet monthly with executive sponsors to identify and prioritize opportunities for health system–based research. In partnership with clinical stakeholders, they design and execute studies to describe, diagnose, and reduce undesirable variation in clinical practices, develop strategies to implement evidence-supported interventions and de-implement ones that are ineffective, and participate in the evaluation of new and existing programs and practices, when more rigorous research methods are deemed valuable. Ultimately, decisions that affect practice are made by health system leaders, with input from CIRT scientists and clinical stakeholders. As one example, team members evaluated the effect of a novel online Personal Action Plan (oPAP) that used the kp.org patient portal to remind eligible patients when they were due for routine preventive services such as annual pneumonia vaccination, hemoglobin A1c testing, and screening for breast, cervical, and colorectal cancer. In this evaluation, the adjusted odds of timely cancer screening and HbA1c testing were 6% to 12% higher among oPAP users than non-users.[6]

CIRT investigators are expected to support approximately 50% of their effort with external grant funding, while the remainder of their time is devoted to operational projects and supported by internal funds. This enables each investigator to maintain a professional identity as a researcher, while fostering synergies between internally and externally funded projects. Increasingly, questions of importance to clinical stakeholders are becoming well aligned with the interests of funding agencies. For example, an ongoing organizational effort to reduce unnecessary hospitalizations for low-risk patients with chest pain led to a successful grant proposal to study the implementation of a validated risk assessment model using a computerized decision support tool in the electronic health record (EHR).[7]

Thematic areas of emphasis reflect the clinical interests and methodological expertise of team members. These include (1) enabling chronic disease self-management through the adoption of health communication technologies;[8] (2) finding ways to support patients with complex needs[9] or serious illness and their caregivers;[10] (3) improving care for cancer patients and survivors;[11] (4) using computerized decision support to improve emergency and acute care;[12] (5) reducing unnecessary, low-value care;[13] and (6) addressing the social determinants of health.[14]

CIRT projects leverage a diverse set of research methods. Consistent with the VA QUERI model,[15] most CIRT projects follow a process that begins with an analysis of EHR data to identify undesirable practice variation and gaps in care delivery. For example, one such analysis found that antibiotics were prescribed in 89% of all cases of acute sinusitis, representing substantial overuse and providing an opportunity to de-implement a low-value practice.[16] As a next step, a qualitative study identified multiple determinants of over-prescribing, including patient expectations, limited time for discussion, and provider concerns about patient satisfaction scores.[17] Subsequently, a stepped-wedge, pragmatic clinical trial demonstrated that a multi-pronged intervention including provider education and computerized decision support reduced unnecessary antibiotic prescribing by approximately 20%.[18] Of note, the best practice alert developed for this study remains in use throughout the health system and continues to influence care.

PROGRAM EVALUATION

The traditional research metrics of publications and external grants do not fully capture the contributions of research that is embedded in health systems. Accordingly, we conceptualize the CIRT program as a collection of specific projects, each one evaluated using a rubric that includes five domains: innovation, actionable findings, efforts to disseminate the findings internally, planned or ongoing implementation activities, and improvements in quality (processes and outcomes) and affordability (Fig. 1). CIRT scientists review these metrics quarterly with executive sponsors and assemble a slate of new and ongoing projects twice yearly for sponsors to prioritize.

To date, demonstrated improvements in quality include increased uptake of screening for depression and anxiety among breast cancer survivors, decreased prescribing of opioids for patients with non-cancer pain, and greater use of tools

Table 1 Examples of CIRT Projects with Clinical/Operational Partners and Impact

Topic	Idea generation	Organizational partner	Funding	Impact
Observational studies to encourage best practices				
Readmissions in older adults	Health system	Readmissions Steering Committee	Internal (CIRT)	Identified optimal timing of post-discharge follow-up visit to reduce the 30-day readmission rate
Prevention of venous thromboembolism	Health system	Regional VTE Steering Committee	Internal (CIRT)	Identified missed opportunities for chemical prophylaxis; validated existing risk assessment models; and implemented decision support in EHR
Studies to identify variation in practices and reduce low-value care				
Biomarker testing for breast cancer survivors	Investigator	Chiefs of Oncology	Internal (CIRT)	Identified substantial variability in testing at both the medical center and provider levels; attempted to reduce inappropriate prescribing with limited success
Lung cancer screening	Health system	Enhanced Implementation of Lung Cancer Screening Steering Committee	Internal (CIRT)➔ Lung Cancer Research Foundation	Identified substantial underuse as well as inappropriate use of screening; implemented new standardized order sets to reduce use among low-risk patients who do not meet standard eligibility criteria
Qualitative studies				
Models of cancer survivorship care	Investigator	Chiefs of Oncology	Internal (CIRT)➔NCI	Identified a novel model of survivorship care that is feasible and acceptable to implement
Overuse of antibiotics for acute sinusitis	Health system	Chiefs of Primary Care	Internal (CIRT)	Improved stewardship by identifying root causes of overuse and implementing education and decision support
Pragmatic trials				
Physical activity coaching for COPD	Investigator	Pulmonary Rehabilitation Work Group	Internal (CIRT)➔ PCORI-funded pragmatic trial ($4M)	Completed externally funded trial of home-based physical activity coaching that improved activity but did not reduce acute care utilization or death
Step-wedge trial of a device to reduce the frequency of unplanned Cesarean section	Health system	Medical Technology Assessment/Deployment Committees	Internal (CIRT)	Prevented deployment of poorly tolerated device, leading to substantial cost avoidance
Guideline-recommended distress screening for breast cancer survivors	Investigator	Chiefs of Oncology	Internal (CIRT)➔ California Breast Cancer Research Program	Markedly increased screening and referral for anxiety and depression, with minimal impact on oncology workflow
Individualized risk assessment and technology-enabled care				
Evaluation of patients with suspected acute coronary syndrome	Investigator	Chiefs of Emergency Medicine	Internal (CIRT)➔ NHLBI	Validated and implemented risk assessment model in EHR and reduced unnecessary admissions and non-invasive testing for low-risk patients with chest pain
Self-activated online reminders for CRC screening	Health system	Online Personal Action Plan Team	Internal (CIRT)	Improved uptake and timeliness of screening for colorectal cancer
Evaluation of patients with pulmonary nodules	Health system	Regional "SureNet" Program	Internal (CIRT)➔ PCORI-funded pragmatic trial ($14.5M)	Extended reach of existing program to identify patients with nodules who require follow-up

CIRT, Care Improvement Research Team; COPD, chronic obstructive pulmonary disease; CRC, colorectal cancer; EHR, electronic health record; NCI, National Cancer Institute; NHLBI, National Heart, Lung and Blood Institute; NIH, National Institutes of Health; PCORI, Patient-Centered Outcomes Research Institute

for individualized risk assessment for conditions such as hospital-associated venous thromboembolism. In addition, a recent internal analysis cited savings to the organization of over $10 million for several CIRT projects that helped to reduce low-value care, such as advanced imaging for patients with minor head trauma.

ONGOING CHALLENGES AND RECOMMENDATIONS

To date, the program has made substantial contributions to improvements in health system performance and helped to create new scientific knowledge by sharing findings in the public domain.

Multiple factors contribute to program success, including access to data from the EHR and being embedded in a healthcare system with an organizational culture that values performance improvement. The ability to access rich, longitudinal data from the EHR provides opportunities to identify gaps in care, monitor trends in utilization, and measure clinical outcomes. The hard-money commitment provides stable funding and allows researchers to devote a substantial fraction of their effort to operationally focused projects instead of relying exclusively on external grant support. Lastly, the

Physical Activity Coaching for Patients with COPD

PROJECT DESCRIPTION

- PI: Huong Nguyen, PhD
- Organizational sponsor: Michael Kanter, MD
- Operational partners: Regional Chiefs of Pulmonary Medicine, Regional Pulmonary Rehabilitation Work Group
- External partners: Research collaborators at Harvard Medical School and the University of Washington
- Team members: Practicing pulmonologists, respiratory therapy coaches at 6 medical centers, health services researchers, statistician, programmer/analyst
- Funding: CIRT/iFund→ PCORI ($4.5mil)
- Aims
    - Describe uptake of a home-based physical activity coaching intervention (Walk On!)
    - Determine the effects Walk On! on acute care utilization and survival, as well as physical activity, symptom burden, and quality of life

IMPACT

- Innovation
    - Integrated data from two activity sensors and systems and developed population management dashboard
- Actionable findings
    - Walk On! increased physical activity but did not reduce acute care use
- Dissemination
    - Study protocol (*Contemp Clin Trials*. 2016;46:18-29), description of lessons learned (*Nursing Outlook*. 2018 66(5):455-463) and primary findings (*JAMA Network Open* 2019 2(8):e199657)
    - Delivered multiple presentations to internal KP audience and externally at national scientific meetings
- Implementation
    - Respiratory therapists acquired motivational interviewing and population management skills
    - Lessons learned from Walk On! is informing current collaborations to design "virtual" pulmonary rehabilitation
- Improved affordability
    - Reduced outside referrals for pulmonary rehabilitation for sites without a PR program

Figure 1 Rubric used to describe CIRT projects and their impact.

program has worked diligently to cultivate strong relationships with its executive sponsors and relies on them to "make things happen" when leadership support is necessary. Equally important are the relationships with practicing physicians, who make critical contributions as leaders and members of multidisciplinary improvement teams.

A number of similar programs have been described in other healthcare systems, including Kaiser Permanente Northern California (KPNC),[2] the University of California, San Francisco (UCSF),[3] the Department of Veterans Affairs (VA),[18] and NYU Langone Health.[19] What distinguishes the CIRT program is its core team of researchers and staff with dedicated time and resources to work in an ongoing partnership with executive sponsors and practicing clinicians, using diverse research methods to identify, understand, and address care gaps in real-world clinical practice.

To sustain and spread programs for embedded research in the LHS, several challenges need to be addressed (Table 2). These challenges include uncertain funding, misaligned timelines, understandably low tolerance for experimental disruption in busy clinical settings, and a limited supply of individuals trained in embedded research methods.

In our view, embedded research should be funded by health systems, and it is highly preferable to have a dedicated stream of funding over several years to avoid interruptions in ongoing projects and sustain programs administratively. The internal funding is justified not only by the anticipated return on investment but also by the recognition that embedded research is an engine of health system innovation.

The clinical and operational imperative for rapid-cycle learning can be negotiated by developing a research pipeline that includes both short-term and long-term projects, each with specific deliverables. A staggered timeline would ideally

Table 2 Challenges of Embedded Research and Recommendations for Researchers, Practicing Clinicians, and Health System Leaders

Challenge	Recommendations
Uncertain funding	Health system leaders: provide internal funding to support researchers and staff, justified by return on investment and recognition that research is an engine of health system innovation Researchers: respond to grant opportunities from external funding agencies that target problems that align with health system priorities and capabilities
Misaligned timelines	Leaders, clinicians, and researchers: negotiate timelines that are both responsive to health system needs and realistic to accomplish; develop a portfolio of projects with staggered timelines to allow for learning at regular intervals
Low organizational tolerance for disruption	Health system leaders: recognize important limitations of conventional before vs. after comparisons, i.e., regression to the mean, secular trends; be open to randomization at patient level or cluster randomization when feasible Researchers: embrace less disruptive and quasi-experimental designs, e.g., stepped-wedge trials, interrupted time series analyses, regression discontinuity approaches Clinicians: be willing to embrace designs such as cluster randomization; consider potential benefits to research and quality improvement of entering structured data into patient registries
Limited supply of embedded researchers	Health system leaders: provide real-world training opportunities; participate in sponsored training programs Researchers: develop proficiency in the 33 core competencies of learning health system research
Silos between research and operations	Health system leaders: provide access to operational workgroups, practicing clinicians, and decision-makers; codify roles and responsibilities of researchers and other team members; clarify boundaries between QI and research Researchers: cultivate "soft" skills of listening and collaborating; do not be afraid to challenge conventional wisdom Clinicians: be open to working with embedded researchers to evaluate novel practices and programs as part of routine clinical care Leaders, clinicians, and researchers: build authentic relationships based on mutual trust

provide a stream of research findings that could be reviewed and acted upon by clinical leaders at regular intervals. Similarly, while health system leaders may have limited tolerance for experimental or quasi-experimental trials of care delivery interventions, it can be argued that such experiments are not fundamentally different than the typical before vs. after comparisons that characterize most operational evaluations, but allow for much stronger inferences and presumably better decisions.

To address the limited supply of embedded researchers, AcademyHealth has administered a training program in Delivery System Science since 2013. More recently, the Agency for Healthcare Research and Quality and the Patient-Centered Outcomes Research Institute have jointly sponsored a K12 training program to support mentored, patient-centered outcomes research within the LHS. In tandem, thought leaders have defined 33 core competencies for embedded researchers.[20] These training programs and core competencies should help build capacity gradually over time, but more rapid dissemination will necessarily occur at the health system level.

Above all, embedded researchers need to be responsive to health system priorities and timelines. It is therefore essential to be flexible with regard to topic and nimble in moving from project to project as organizational priorities shift over time. While not mandatory, it helps to be a generalist with multiple areas of interest and training in diverse research methods. Ultimately, the most important tools of the embedded researcher are the "soft" skills of listening, asking questions, (politely) challenging the conventional wisdom, and working with others as equal members of the team.

Health system leaders and practicing physicians who wish to leverage the rigor of research to improve organizational performance should embrace embedded researchers as genuine partners in problem solving. They should facilitate interactions with influential clinical stakeholders, provide access to existing operational workgroups, and empower researchers by giving them a seat at the table where decisions are made. The roles and responsibilities of researchers as members of the organizational team should be codified in the system's governance structure, in particular to clarify any boundaries between QI and research.

CONCLUSIONS

The promise of the LHS is to enhance population health by improving the quality and affordability of care. Embedded research programs like CIRT can play a key role in fulfilling this promise, by working collaboratively with practicing clinicians and other stakeholders to generate, disseminate, and translate new evidence into practice. The role of embedded researchers is to help clinicians improve care by bringing research skills and rigor to the existing quality improvement enterprise. Program success depends on a number of factors, including dedicated funding, robust data systems, and strong relationships between members of the embedded research team and clinical stakeholders.

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Compliance with Ethical Standards:

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