Original research

Methods to identify and prioritize research projects and perform embedded research in learning healthcare systems

Thearis A. Osuji a, Julie Frantsve-Hawley b, Monica Perez Jolles c, Heather Kitzman d, Carly Parry e, Michael K. Gould f, For the Embedded Research Conference Priorities and Methods Workgroup

a Department of Research and Evaluation, Kaiser Permanente Southern California, United States
b Analytics and Evaluation, DenosQuest Partnership for Oral Health Advancement, United States
c University of Southern California (USC) Suzanne Dworak-Peck School of Social Work and USC Gebr Family Center for Health Systems Science, United States
d Baylor Scott and White Health and Wellness Center, Clinical Associate Professor, Robbins Institute for Health Policy and Leadership, Hankamer School of Business, Baylor University, United States
e Patient-Centered Outcomes Research Institute, United States
f Division of Health Services Research and Implementation Science, Department of Research and Evaluation, Kaiser Permanente Southern California, Professor Kaiser Permanente School of Medicine, United States

ABSTRACT

Background: The Embedded Healthcare Research Conference aimed to promote and enhance research-operations partnerships in diverse health care settings. Within this conference, the Priorities and Methods Workgroup set out to define a vision of embedded research that leverages diverse methods to address clearly articulated research questions of importance to health systems.

Methods: The Workgroup session involved a combination of small and large group discussions around three broadly focused topics: the integration of embedded research within the existing quality improvement (QI) ecosystem; the identification, prioritization and formulation of embedded research questions; the creation of an embedded research “tool kit.”

Results: Workgroup participants envisioned a future for embedded research that is characterized by authentic engagement between researchers and health system leaders; seamless integration between research, QI and clinical operations; clear and explicit articulation of research questions; an appropriate balance between rigor and relevance in applied methodology; alignment between study design, available resources and the importance of the knowledge to be gained; efficient processes; and bi-directional communication. Important barriers to achieving this vision include limited access to executive leaders, silos that discourage integration of research and QI, generally low tolerance for disruption in high-risk clinical settings, limited access to data, and limited availability of researchers with requisite skills and training.

Conclusions: Embedded research holds potential to enhance the relevance, value and use of research, while also creating generalizable knowledge. Key recommendations include building authentic relationships, discouraging silos, encouraging innovation and experimentation, and expanding opportunities for funding research in delivery systems.

1. Background

Embedded research is a term used to describe activities conducted by research teams working within healthcare delivery systems in close partnership with health system leaders. By definition, it is health system-based and inwardly focused, although it can be funded either internally and/or externally. Proponents believe that embedded research holds potential to enhance the relevance, value and use of research in health system decision-making, while also creating generalizable knowledge to be shared in the public domain.

With the Embedded Research Conference, the host organizations (Kaiser Permanente Southern California, AcademyHealth, and the Veterans Health Administration) and funders (the Agency for Healthcare Research and Quality and the Patient-Centered Outcomes Research Institute) sought to apply a formal, structured process, to share knowledge and develop recommendations for enhancing embedded research in diverse health system settings. The conference included workgroups organized around several key topics. This paper provides a summary of
discussions held by the Priorities and Methods Workgroup, along with a synthesis of their recommendations for researchers, funding agencies, and delivery system leaders.

2. The embedded research Priorities and Methods Workgroup

The workgroup included 20 professionals (see supplemental material) representing health system leaders, research center directors, embedded researchers and representatives from the government and funding agencies. The group set out to define a specific vision for embedded research that leverages authentic engagement between researchers and health system leaders to: (1) integrate research and quality improvement (QI) seamlessly in the context of usual clinical care; (2) formulate research questions that clearly and explicitly address health system priorities; (3) balance rigor and relevance while employing a diverse set of methods to accomplish research goals; (4) ensure alignment between research goals and available resources; and (5) communicate effectively to develop efficient processes for prioritization and execution of studies (Fig. 1).

One of the authors (MKG) organized and facilitated the workgroup session, which involved a combination of small and large group discussions around three broadly focused topics, including: (1) the integration of embedded research within the existing QI ecosystem; (2) the identification, prioritization and formulation of embedded research questions; and (3) the creation of an embedded research “tool kit” that includes both existing and enhanced methods to address questions of clinical or operational importance (Fig. 2).

3. Relationship between embedded research and quality improvement

Much has been written to distinguish QI from research; however, there is much overlap between the two fields. Often an institution’s Institutional Review Board (IRB) will determine whether a project is designated QI or research, with the latter requiring IRB approval and oversight to protect human subjects. In general, QI is focused on making improvements in local clinical settings rather than creating generalizable knowledge, and results are disseminated internally rather than published for a wide target audience. In contrast, research is seen as using more scientific-focused methodology to allow for stronger inferences and to create generalizable knowledge that is disseminated through publication and subsequently applied across diverse settings.

While acknowledging the school of thought that suggests that researchers should “let QI be QI,” workgroup members posited that the distinction between QI and research is increasingly blurry, with multiple professional journals dedicated to the publication of broadly generalizable findings from innovative local QI projects, while other journals such as Implementation Science exist to facilitate the local adoption of findings from rigorous research studies.

Accordingly, QI and research can be thought of as spanning a continuous spectrum of activities, two distinctive intellectual traditions working towards the shared goal of improving care. QI helps bridge the gap between evidence and practice at the micro level, using locally available resources and operating over shorter time horizons by using iterative “Plan-Do-Study-Act” (PDSA) cycles, including embedded researchers on QI teams has the potential to increase the rigor and expand the scope of QI projects in simple ways without necessarily increasing project time or costs. As one workgroup participant stated, “research can put QI on steroids,” by applying core research skills such as formulating...
questions, designing interventions, making accurate measurements, applying rigorous methods for analysis and appreciating nuance when interpreting study findings.

4. Identification, prioritization and formulation of research questions

Within the concept of a learning healthcare system, embedded research must be aligned with the healthcare system’s needs to improve local practice. This process requires engagement between researchers and health system leaders to identify and prioritize operational research questions of importance.

Workgroup members noted that many types of operational questions are suitable for embedded research, especially formative research questions, outcomes assessment and evaluation of implementation fidelity. In many existing programs, operational research questions often come from the leadership in a top-down manner. Bottom-up questions from front-line clinicians and investigator-initiated projects can also be addressed by embedded researchers. To facilitate the identification, prioritization and specification of viable research questions, workgroup members emphasized that the process should involve intensive engagement with all clinical and operational stakeholders.

To help set priorities among potential research projects, important considerations include comparative advantage, alignment with organizational strategy, the presence of a strong champion or existing operational workgroup, and the availability of staff and expertise to engage in the research. The ultimate goals of the prioritization process are to ensure that the project is both feasible and relevant to operational decision-making.

Increasingly, health systems seek to leverage real-world data from electronic health records to learn and improve. These efforts are sometimes hampered when the research project has a loosely defined target or objective. Researchers can bring clarity to an otherwise ill-defined process by applying skills in formulation of a fully specified “PICO” question that includes details about the target population (P), the intervention or exposure of interest (I), the comparison group (C), and important outcomes of interest (O).

Successful execution of embedded research requires alignment between the research question, the methodological approach and available resources. For example, a randomized, controlled trial that requires prospective enrollment of large numbers of participants is typically not feasible without the additional resources provided by external funding. Feasible projects account for the pragmatic aspects of conducting research in busy clinical environments and may require methodological pluralism: the ability to leverage diverse methods to answer any given question. This is important because real-world factors, such as clinical workflow, data availability and clinician buy-in may require flexibility in study design. Workgroup members noted that there are often unavoidable trade-offs between feasibility and rigor that must be navigated.

4.1. Challenges to achieving the vision

Potential barriers to effective identification, prioritization and formulation of research questions include:

1. limited contact between researchers, operational leaders and stakeholders;
2. nascent environments where the concept of embedded research is exclusively “pushed” by investigators rather than “pulled” by leadership;
3. lack of knowledge about alternative research methods amendable to embedded research; and
4. unrealistic expectations for success.

4.2. Case example

Within a mature embedded research program described by one workgroup participant, the process for identification and prioritization of projects has evolved over time. At this health system, the embedded research program supports approximately 25 projects at any given time. Initially, researchers with relevant training and experience were assigned to existing organizational working groups. For example, a researcher with a nursing background and expertise in care transitions was embedded in the health system’s Readmissions Reduction Team. Once embedded, the researcher shared her content expertise, facilitated access to necessary data elements, provided assistance with data analysis, participated in intervention planning and program evaluation and (importantly) was ultimately able to identify an opportunity for a successful external grant application. In contrast, other research opportunities may be suggested by clinical leaders, such as an evaluation of a novel device to reduce the incidence of Cesarean sections that was motivated by the need for a cost-benefit analysis to guide operational decision making about device adoption. Over time, researchers built a strong relationship with executive sponsors that resulted in regular monthly team meetings to exchange ideas about embedded research opportunities and priorities. More recently, the embedded research program’s leadership team is working to develop a more formal process for intake and tracking of embedded research topics. Many scholarly articles have resulted from this particular research-operations partnership.
5. Embedded research methods and approaches

Workgroup members discussed the current state of study designs and methods applicable to embedded research, challenges to achieving the workgroup vision and recommendations for future efforts. The group emphasized the need to achieve alignment between the research question and methodological approach. For example, a study to understand why clinicians order a non-recommended, low-value lab test would probably require a mixed-methods design that comprised both quantitative research to examine the frequency of testing at the hospital and provider levels and qualitative research to understand the factors driving inappropriate utilization.

Embedded research projects typically apply traditional research methods (Table 1). These approaches most commonly include observational studies to describe variation in existing practices, but also controlled before and after comparisons, development and validation of risk models to predict adverse outcomes, and both quasi-experimental and experimental approaches to make causal inferences. For example, quasi-experimental methods such as stepped-wedge trials, interrupted time series, and regression discontinuity approaches allow for stronger inferences than the typical pre-versus post-intervention comparison or a simple description of post-intervention outcomes, weak designs that are often the default in most practice settings. These quasi-experimental approaches may be more feasible and cost-efficient for health systems to implement. In the experience of some workgroup members, stepped-wedge trials are often preferred by clinicians and health system leaders, because all patients eventually receive the intervention being studied. While experimental study designs (including cluster and patient-level randomized controlled trials) are preferred for the ability to make stronger scientific inferences, most experimental studies require substantial resources. In contrast, pragmatic trials are used to determine the effectiveness of a given intervention in real-world settings, while comparative effectiveness trials help to clarify for whom, in what settings and under what circumstances the intervention will be most effective. As mentioned previously, qualitative and mixed methods studies enable researchers to capture nuances in practice dynamics and come to a deeper understanding of research results in the local context. Common qualitative approaches include interviews, focus groups, direct observations and usability testing.

5.1. Challenges to achieving the vision

Group participants identified several challenges to applying rigorous methods in busy clinical practice settings. First, there is limited tolerance among health system leaders, clinicians and patients for the disruption that characterizes many experiments, which is understandable in high-stakes clinical environments. Second, there will always be tradeoffs between methodological rigor and the need to adapt to organizational timelines when performing embedded research within complex and dynamic health care settings. Third, hospitals and clinics have limited capacity and resources to support rigorous research and health system staff usually have competing demands for their time that take priority. Last, the boundaries between embedded research and QI are often blurred, as discussed previously. To date, there are relatively few examples of model programs that seamlessly weave the rigor of research into the existing fabric of QI activities.

5.2. Case example

A workgroup participant shared a recent example of how research brings greater rigor to existing health system evaluations. This system partners with local churches to train volunteers to become Faith Community Caregivers (FCCs), who spend 1 h per week with complex needs patients to serve as an advocate/health translator, help pick up prescriptions, and encourage adherence to plan of care, medication regimen and follow up appointments. Pre-post assessments showed this program was reducing emergency department visits, inpatient hospitalizations, and associated costs. However, this could be due to regression to the mean, lack of a control group, or other confounding variables not considered in the pre-post evaluation.

Researchers used data from electronic health records to identify a comparable control group and used multivariable statistical modeling to adjust for residual differences and to examine program effects in relevant subgroups. Compared to controls, patients in the FCC program were 22% less likely to experience an additional ED visit during the one-year follow-up (hazard ratio = 0.78, p-value = 0.04). However, African American patients were 2.2 times more likely to experience an additional ED visit (p-value < 0.0001) in comparison to Whites, and there was no significant difference in inpatient hospitalizations between the FCC group and controls (hazard ratio = 1.11, p-value = 0.60).

The findings were shared with health system leaders and new components have been added to strengthen the intervention, guided by ongoing data collection. Integrating researchers into the evaluation allowed for stronger inferences about effectiveness and alerted decision makers that the program was not effective in an important segment of the target population, leading to program redesign. While these results were not published, we support the dissemination of generalizable knowledge through publication of findings from embedded research activities. In response to the observation that dissemination of generalizable knowledge is a defining characteristic of research, several workgroup members noted a distinction between “embedded research” and “embedded science”, which does not necessarily involve publication.

6. Recommendations

Workgroup participants developed a list of recommendations for researchers, funding agencies, and healthcare system leaders.

6.1. Recommendations for researchers

6.1.1. Build authentic relationships

Embedded research cannot be impactful without successful engagement and collaboration. Alignment between research and organizational goals requires researchers to invest in “pre-work,” which should include active engagement with clinicians and health system leaders. Clinical champions are indispensable partners that can make or break efforts to improve care.
6.1.2. Build consulting and “soft” skills

Effective communication and collaboration skills are essential for embedded researchers. Participatory research, professional services consulting, and program evaluation offer theoretical foundations, frameworks, approaches and some solutions. Proposed competencies for learning health system researchers include a domain for engagement, leadership and research management, which emphasizes effective communication and alignment with health system needs, timelines and values.15

6.1.3. Do not let the perfect be the enemy of the good

Researchers are academically inclined people who are trained to use the most rigorous methods and typically rewarded for perfection. Healthcare data is often messy and health system needs for timely solutions may challenge the feasibility of implementing some rigorous research methods.

6.1.4. Bring the outsider perspective to challenge the conventional wisdom and “appreciate the mundane”

Additional training and immersion into the healthcare context may help researchers think outside of the box and question the status quo. Problems that are invisible to clinical insiders may be more obvious to a researcher who is not part of the care team.

6.1.5. Advance methods by building an enhanced tool kit

Workgroup members suggested that investigators leverage existing tools for causal inference that better align with embedded research approaches such as the use of interrupted time series and regression discontinuity designs, when feasible (Table 1). Methods that allow researchers to immerse themselves into local contexts are well suited to embedded research, such as direct observations, time-motion studies and shadowing. Moreover, the group emphasized the need to embrace innovation by developing and adapting flexible methods and approaches that better capture the dynamic and evolving nature of healthcare systems. These recommendations will likely require a workforce with specific training in embedded research as well as the provision of mentoring by more experienced researchers.

6.2. Recommendations for Healthcare System Leaders

6.2.1. Discourage silos between research and operations

Healthcare leaders should develop shared governance structures for embedded research and QI to discourage silos and promote complementary and synergistic efforts between the two disciplines. Leaders should define explicit roles and responsibilities for research and QI. This may help clarify distinctions and highlight the unique contributions of embedded research to the healthcare system.

6.2.2. Facilitate bi-directional exchanges

Leaders can facilitate bi-directional flow of information and ideas by providing embedded researchers with access to executive sponsors, organizational work groups and clinical stakeholders. This will help researchers stay informed and up to date about institutional priorities.

6.2.3. Encourage innovation

Embedded researchers must experiment and innovate to best meet organizational needs and fill critical gaps in care practices. Leaders can sponsor “skunk works” or innovation labs to facilitate dialogue and novel idea generation.

6.3. Recommendations for Funding Agencies

While specific mechanisms targeted to embedded research are still rare, funding opportunities are increasing, particularly with respect to training opportunities for learning health system researchers, such as those supported by AHRQ, PCORI, and AcademyHealth. The development of embedded research requires funders to shift the way they envision, review, fund, and manage research to become more rapid, responsive, and agile.

6.3.1. Re-envision funding mechanisms

Rapid response mechanisms are needed to fund projects that align with systems’ operational timelines. Targeted mechanisms encouraging pragmatic research and novel design/methodological approaches are needed, as well as pilot and stepped mechanisms, and opportunities to simultaneously evaluate the effects of embedded research on the impact of funded projects and stakeholder engagement.

6.3.2. Align scientific review processes

Scientific review processes should be reimagined for rapid review and funding; include health system representatives as stakeholder reviewers; and ensure reviewer expertise encompasses methodological and design advances (i.e. pragmatic trials, SMART designs) and an astute understanding of the balance needed between rigor and relevance, and between QI and generalizable research.

6.3.3. Expand funding areas

Funding is needed to expand methodological development and train investigators in core competencies, such as methods, designs, ethical considerations, and the interpersonal and strategic skills needed to build effective relationships with systems partners.

6.3.4. Be flexible in research oversight

Finally, funders need to be prepared to accommodate the uncertainty that accompanies such real-world research, being flexible and agile in their approach to project oversight.

7. Summary

In this paper, we provide a summary of discussions and recommendations from the Priorities and Methods Workgroup of the Embedded Research Conference. This group aimed to describe approaches used to identify and prioritize targets for embedded research, describe opportunities for embedded researchers to work productively within the existing QI ecosystem, and help clinical and organizational partners formulate questions that are both feasible and relevant to operational decision-making. In addition, the group aimed to create an inventory of existing and enhanced methods that can be applied to answer a range of important questions in busy clinical environments. The group envisioned a future for embedded research that is characterized by authentic engagement between researchers and health system leaders; seamless integration between research, QI and clinical operations; clear and explicit articulation of research questions; an appropriate balance between rigor and relevance in applied methodology; alignment between study design, available resources and the importance of the knowledge to be gained; efficient processes; and effective bi-directional communication. Important barriers to achieving this vision include limited access to executive leaders, silos that discourage integration of research and QI, generally low tolerance for disruption that understandably characterizes many high-risk clinical settings, limited access to data, and limited availability of researchers with appropriate skills and training. Key recommendations for researchers include building authentic relationships with executive leaders, developing “soft skills” in communication and consultation, bringing the outsider perspective, and selecting from among a variety of methodological approaches to fit the question and available resources. For health system leaders, key recommendations include discouraging silos, providing access and encouraging innovation. Funding agencies are encouraged to expand opportunities for funding research in delivery systems (including partnering with health systems to provide joint funding), develop time-sensitive review processes to meet health system expectations for shorter timelines, and be more flexible and agile in research oversight.
Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix. Priorities and Methods Workgroup Members

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<th>Name</th>
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<tr>
<td>John Adams, PhD</td>
<td>Kaiser Permanente Center for Safety &amp; Effectiveness Research</td>
</tr>
<tr>
<td>Terry Adirim, M.D., M.P.H., FAAP</td>
<td>US Department of Defense</td>
</tr>
<tr>
<td>Heather Black, PhD</td>
<td>Merck</td>
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<tr>
<td>Deborah Cohen, PhD</td>
<td>Oregon Health &amp; Science University</td>
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<tr>
<td>David Glass, PhD</td>
<td>Kaiser Permanente Southern California</td>
</tr>
<tr>
<td>Michael Gould, MD, MS</td>
<td>Kaiser Permanente Southern California</td>
</tr>
<tr>
<td>Reshma Gupta, MD, MSHPM</td>
<td>University of California, Davis</td>
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<tr>
<td>Julie Frantsve-Hawley, PhD, CAE</td>
<td>DentaQuest Partnership for Oral Health Advancement</td>
</tr>
<tr>
<td>Jodi Holtrop, PhD, MCHES</td>
<td>University of Colorado School of Medicine</td>
</tr>
<tr>
<td>Monica Perez Jolles, PhD</td>
<td>University of Southern California</td>
</tr>
<tr>
<td>Eve Kerr, MD, MPH, MACP</td>
<td>Ann Arbor VA Medical Center, University of Michigan</td>
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<tr>
<td>Stephen Kimmel, MD, MSCE</td>
<td>University of Pennsylvania</td>
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<tr>
<td>Heather Kitzman, PhD</td>
<td>Baylor Scott and White Health and Wellness Center, Baylor University</td>
</tr>
<tr>
<td>Tracy Lieu, MD, MPH</td>
<td>Kaiser Permanente Northern California</td>
</tr>
<tr>
<td>Brian Mittman, PhD</td>
<td>Kaiser Permanente Southern California</td>
</tr>
<tr>
<td>Huong Nguyen, PhD, RN</td>
<td>Kaiser Permanente Southern California</td>
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<tr>
<td>Thearis Osuji, MPH</td>
<td>Kaiser Permanente Southern California</td>
</tr>
<tr>
<td>Carly Parry, PhD, MSW, MA</td>
<td>Patient-Centered Outcomes Research Institute</td>
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<tr>
<td>Lisa Rubenstein, MD</td>
<td>RAND, University of California Los Angeles</td>
</tr>
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<td>HealthPartners and HealthPartners Institute</td>
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