



A Plan for Useful and Timely Family Medicine and Primary Care Research

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BACKGROUND AND OBJECTIVES: Our nation's health care system is changing. Nowhere is this more evident than in primary care, where fundamental improvements are necessary if we are to achieve the Triple Aim. Such improvements are possible if we can put useful and timely information into the hands of stakeholders to enable practical decision-making. To do this, family medicine and primary care researchers need to (1) build on our substantial current research foundation, (2) increase the relevance and pace of our research, (3) reconceive the research workforce to engage new partners, (4) disseminate findings more rapidly into the hands of those who can take action, and (5) build a "question-ready" research infrastructure to make this possible. Family medicine researchers face exciting opportunities: technical capacity to generate and manage large amounts of data; clinic- and system-level networks for testing innovations; digital health technologies for real-time and asynchronous monitoring and management of risk factors and chronic diseases; the know-how to make fast, local improvements in our systems of care; partnerships beyond those traditionally engaged in research that can multiply our capacity to generate new knowledge; and new methods for creating generalizable knowledge from the study of local efforts. This is a historic time for family medicine research. Now is the time to build on our past work, accelerate the pace, and capitalize on emerging opportunities that open an incredibly bright future.

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The American health care system is fragmented and dysfunctional.¹ Strengthening the primary care system would greatly mitigate these shortfalls² and move the United States closer to accomplishing the Triple Aim—better health, better health care, at lower cost.³ A robust research infrastructure is essential to equipping family medicine with the timely and relevant information it needs to play

a crucial role in US primary care transformation.

In this paper we offer examples of how family medicine can accelerate the generation of relevant knowledge needed to guide and power this transformation. We outline action steps for how family medicine, along with its partners and other stakeholders, can acquire and implement this knowledge. Our partners in this enterprise include researchers from many disciplines, all primary care

clinicians, the patients we serve, and the system leaders, payers, and policymakers operating in this space.

Much of traditional family medicine and primary care research is invaluable and should continue as is. In this paper, we emphasize new questions, problems, methods, and solutions, particularly those involving the partners listed above. Capitalizing on new opportunities and tackling current problems will mean a radical shift in how we conduct research. We need new knowledge about how we can work most effectively in primary care teams; which elements in primary care confer healing and health; how to best respond to patients' health priorities; how to organize and deliver digital health care; how to manage the

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health of populations; how to balance the technical revolutions in genomics, proteomics, and informatics with access to basic care and healing relationships; and a host of other problems too numerous to list.

If family medicine, in partnership with others in the primary care community, does not accept the challenge to find answers to these questions, we will miss this historic opportunity to improve the health and health care of our patients and communities. Family medicine, as the nation's largest producer of primary care, must take bold action now. This paper offers a place to start.

Action Areas and Steps

We outline four action areas for family medicine research to help primary care take its place as the foundation for a balanced, effective, and just health care system.

Action Area A: Increase the Relevance and Pace of Primary Care Research

Research creates new knowledge and helps people to make better day-to-day decisions. This action area has three parts: (1) sort and prioritize a research agenda according to relevance for stakeholders, (2) increase the pace of the research process, and (3) use methods and report results better suited to stakeholder questions, partners, and settings.

1. Sort and prioritize research according to relevance for particular stakeholders.

The issue: More relevant research questions can be asked than can be answered.

Background to inform action: Setting priorities for research questions, agendas, and funding streams occurs through advocacy, education, investigator-initiated work, and decisions made by funders. In partnership with stakeholders who will significantly gain if the US health care system achieves the Triple Aim, we can lead this priority-setting process.

Recommended action: Develop a prioritized family medicine and primary care research agenda.

Systematically use the literature together with direct inquiry to find the answers stakeholders need the most, and create from this a primary care research mandate. Publicize the resulting mandate within and beyond the FMAHealth initiative. This document should be “owned” by a group charged with keeping it up to date. This group should organize discussions with research funders and others who might become interested in funding certain kinds of research—along with the stakeholders themselves. This mandate should inform a robust primary care research agenda, guide emerging research infrastructure, and inspire the workforce, as outlined in subsequent sections of this paper.

2. Step up the pace of research processes.

The issue: The lag time between defining an important question and disseminating results is too long to meet the needs of the evolving delivery system.

Background to inform action: Suggestions for accelerating research include streamlining grant application and review processes, engaging stakeholders in rapid-learning research systems with partnerships across stakeholders, posing research questions to multiple networked practices, allowing discoveries within a study to influence the ongoing study design in a recursive manner, and expanding dissemination methods to get results quickly into the hands of users (eg, reducing publication lag times—Action Area C⁴). There are also new research designs, such as the platform trial, that are efficient strategies for evaluating multiple and changing treatments and cohorts on a continuous iterative basis.⁵

Recommended action: Host a summit of family medicine and primary care research funders and leading research organizations to: (1) encourage the adoption of known ways to speed grant review, funding, and implementation processes, (2) discover motivations and concerns that can open the way for adopting these

changes, (3) seek alignment on how we can best broaden research partnerships, and (4) expand acceptable study designs and research methods to make our research more timely and relevant.

3. Use methods suited to stakeholder questions, partners, and settings.

The issue: Tackling many of the most pressing primary care research questions will require innovative designs, methods, and data, and conducting studies in non-traditional settings with a much broader team.

Background to inform action: Family medicine and primary care researchers have rich and varied designs, tools, traditions, and laboratories, such as descriptive studies, randomized controlled trials (RCTs), practiced-based research networks (PBRNs), health services research methods, comparative effectiveness research, implementation science, pragmatic trials, rapid-cycle evaluation from quality improvement efforts, and primary care informatics. These provide a foundation, but we need new standards for achieving relevant, rapid, stakeholder-involved and replicable research. The Agency for Healthcare Research and Quality (AHRQ) Practice-Based Research Network (PBRN) Resource Center has developed a practical guide to the uses of and methods for conducting rapid-cycle research;⁶ this moves us in the right direction. Table 1 outlines some of the basic standards, distilled from recent literature and described in the “5Rs” framework.⁷ Table 1 also includes a “pre-flight checklist” for formulating research questions and designing studies.^{7,8}

Recommended action:

1. Promote the 5Rs as a general standard for family medicine and primary care research at all stages—from funding announcements and portfolios, to streamlining review processes, to conducting studies, to publication and dissemination.

2. Develop an “instruction kit” for emerging methods in real-world natural experiments. Some of these methods may not be familiar to

Table 1: The 5R's With Preflight Checklist for Family Medicine and Primary Care Research*

<p>1. Relevant to stakeholders</p> <ul style="list-style-type: none"> • Involve end users meaningfully from the outset in forming research questions and selecting outcomes. • Build an ultimate use perspective into all stages of the research process. <p><i>Design:</i> Are end users and involved stakeholders identified? Is there a plan to gather their questions, and what is important to them? <i>Implementation:</i> Are stakeholders involved in ongoing refinement? Are changes they suggest recorded and implemented? <i>Reporting:</i> Are diverse stakeholders involved in interpreting and reporting findings? <i>Dissemination:</i> Are the audience and likely users involved? Are findings expressed in meaningful language and channels that stakeholders use?</p>
<p>2. Rapid and recursive in application</p> <ul style="list-style-type: none"> • Accelerated study design, peer review, funding cycles. • Participate in rapid-learning research systems. • Allow discoveries within a study to influence study—short learning cycles; questions and answers evolve. • Pose questions to multiple networked practices <p><i>Design:</i> Is rapid cycle measurement built in? Is an approach in place to allow early discoveries to shape the study? <i>Implementation:</i> Is short-cycle learning influencing design and measurement? Is learning influencing the questions? <i>Reporting:</i> Are emergent findings shared on ongoing basis throughout study? Are adaptations made and reported? <i>Dissemination:</i> Are guidelines provided for tailoring results to future use and transport?</p>
<p>3. Redefines rigor</p> <ul style="list-style-type: none"> • Regard rigor as property of decisions, observations, and disciplined conduct of learning rather than of techniques. • Give attention to both external and internal validity <p><i>Design:</i> Are study concepts, measures, data, and analyses systematic? Multiple methods? Balance of internal-external validity? <i>Implementation:</i> Is systematic design actually followed and documented? Are checks for bias and superfluous connections done? <i>Reporting:</i> Are methods reported transparently, including checks for bias and superfluous connections? Are conclusions justified by standards of evidence? <i>Dissemination:</i> Is there description of how external and internal validity findings support wider use or not? Information needed for modification in other settings or populations?</p>
<p>4. Reports on Resources</p> <ul style="list-style-type: none"> • Report on as many of the relevant costs of interventions as possible, and do it with a standard vocabulary. • Intervention costs, clinician and staff time and energy, infrastructure and training costs; start-up costs, ongoing costs, opportunity costs, likely costs of re-creating in other setting. <p><i>Design:</i> Are intervention costs (monetary and other) measured? <i>Implementation:</i> Is cost data gathered on an ongoing basis? Using a standard vocabulary for different kinds of costs? <i>Reporting:</i> Are useful cost data of different kinds reported? Are cost estimates made for reproducing under different conditions? <i>Dissemination:</i> Are the intervention and estimated costs of modifications in new settings included?</p>
<p>5. Replicable</p> <ul style="list-style-type: none"> • Design for factors that may affect subsequent implementation in a different context. • Design to inform implementation and re-invention in different settings. • Report the “how” as well as the “what”—with contextual factors important to transport to other settings. <p><i>Design:</i> Is the study designed at the outset to inform implementation and reinvention? Are likely relevant settings identified? <i>Implementation:</i> Are contextual factors documented that are important to understanding what happened and why? <i>Reporting:</i> Are contextual factors relevant to reinvention in new settings reported, including likely variations? <i>Dissemination:</i> Are data-supported suggestions about contexts most relevant or reproducible included?</p>

* Adapted from Peek, Glasgow, Stange et al.⁷

clinicians and some researchers. Create “methods labs” that help investigators apply these designs.

3. Continue traditional trials, even as we reach for improvements

in their efficiency, speed, cost, and power. The need is as great as ever for well-designed clinical trials about better ways to manage the common clinical problems in primary care.

4. Convene research organizations and funders to adopt these standards.

Action Area B: Reconceive the Research Workforce to Include New Partners and Participants

We outline three broad action steps: (1) create a culture of curiosity and inquiry, (2) engage more stakeholders in the research process, and (3) attract and train research scientists from other disciplines.

1. Commit to creating a culture of curiosity and inquiry.

The issue: Improvement and growth will require culture change.

Background information for action: The creation or transformation of a culture is a deep and complex process. Culture encompasses the values, beliefs, attitudes, assumptions, and practices shared by a group of people.⁹ But there are straightforward elements of culture change that offer a starting point.

Recommended action: Create a culture of curiosity about how best to improve health and health care. For clinicians, this curiosity can be fostered if we prioritize research questions that can actually be answered, and the answers have value. Curiosity and inquiry should be linked to professional excellence through certification requirements, professional recognition, and even financial incentives. We can further nurture this curiosity by providing clinicians with the means to answer these questions, such as registries, reports, dashboards, and quality improvement approaches. Clinicians who actually find answers that improve their practices or the health of their patients should be celebrated and modeled. Their discoveries and innovations should become our new exemplars. A general change in attitude and behavior will follow. Similarly, we can create a culture that enables and encourages patients to do the same. Empowering our patients to know more about their health and how to be healthier will produce an additional impetus toward creating this culture of inquiry.

2. Engage More Stakeholders in the Process.

The issue: We need more stakeholders engaged in research to ensure the research is relevant.

Background to inform action: We already know from our experience with PBRNs that clinicians can and will collect data if it helps them care for their patients—especially if it is done as a normal part of practice—and especially if they are engaged in deciding what data to collect, how to interpret the data, and how to apply it to their individual patients and populations. Collecting data about one's practice, and acting on these data, is core to quality improvement. Electronic health records (EHRs) should be improved so that practice-level data, with appropriate benchmarks, is easily and immediately available to practices.

Recommended action: Every clinician practicing in the United States can and should become a partner in the expanded primary care research workforce; we should set this as an expectation, and we should reorganize our research workforce accordingly. This might best be done with a supportive national structure that both facilitates access to information and trains clinicians in the interpretation and use of such data. Additionally, we should advocate for the improvement of EHRs so that actionable data becomes easily available, or develop easily available workarounds.

With a modicum of training, patients as well as clinicians can influence the formulation of important research questions, speak into the feasibility of certain designs, collect data about interventions and their effects, and help us learn how to get this information into the hands of other patients who can act on it. If new payment models are designed to incent patients to make healthy decisions, we can count on them to be part of the research workforce that determines the value of these decisions.

As with patients and clinicians, so with employers and purchasers

who want more affordable care and healthier, more productive employees. This group of stakeholders has much to gain by partnering with researchers, and we must frame our invitation to them in language and values they understand. Partnerships between primary care clinicians, employers, health plans, and policymakers already exist with organizations such as the Patient-Centered Primary Care Collaborative (PCPCC), but the research dimension of these partnerships have not been defined and activated.

There is also a need to create new and deeper relationships with funders as partners in the research enterprise. For some studies, funders may remain separate from the development of studies and interpretation of findings. Increasingly, funders are becoming more active partners. We should survey stakeholders' needs, identify clusters of questions, match them to relevant funders, and invite a conversation to create new funding initiatives with funders to most effectively disseminate relevant findings. Patients and patients' families may also wish to help develop and fund primary care research initiatives of special interest to them.

3. Attract and Train Research Scientists From Other Disciplines as Partners.

The issue: Our research prospects would be improved with more partners from other disciplines.

Background to inform action: Our research benefits from contributions from many disciplines and a breadth of traditions. This inter-disciplinary approach should be continued and expanded.

Recommended action: Scientists and trainees from the basic medical sciences, informatics, epidemiology and other public health disciplines, the behavioral sciences, anthropology, statistics, economics, education, and others should be invited in as partners, learners, and mentors, and our research agenda should be expanded accordingly. All research projects should be scanned for inclusion of the relevant disciplines.

Action Area C: Get Research Findings into the Hands of Those Who Can Use Them

We outline two broad action steps: (1) design dissemination strategies into studies from the beginning, (2) augment traditional dissemination methods with new methods that increase impact and better target intended audiences.

1. Design ultimate use and transportability resources into studies from the beginning.

The issue: Researchers often wait until their study is completed to think about relevant stakeholders and target audiences, and this can limit the impact and relevance of findings.

Background to inform action: Creative and effective dissemination plans can be incorporated into research designs or demonstration projects from the beginning. For example, a study that aims to improve patients' experiences of their care might benefit from an embedded videographer-journalist to record patient stories about their care. These kinds of results are often far more helpful to patients, policymakers, and clinicians than a dry scholarly report, with tables and tests of significance.

Recommended actions: Pull together suggestions, guidelines, and exemplars of best practices. Advocate for innovative and widespread dissemination as a core part of all research grants. Make better use of the excellent literature on research application and dissemination, such as UCSF's repository on research dissemination,¹⁰ toolkits for research

dissemination,¹¹ and AHRQ materials.¹²

2. Broaden methods of dissemination and better target intended audiences.

The issue: We need more rapid and broad uptake of research findings, but rapid uptake of research findings is not simple. Clinics are busy, schedules are full, routines are set, change is hard.

Background to inform action: A research finding has value only when someone can see why and how to use it with such conviction and clarity that it overrides the good reasons to leave well enough alone. Moreover, different stakeholders have different opportunities and reasons to act on research or to even notice it. One person's knowledge is another person's noise.¹³ We customarily share research findings in peer-reviewed publications, white papers, conference presentations, consultations, webinars, and policy briefs. These methods of dissemination are suited for academic audiences, but they are not suited for all the stakeholders we wish to reach, nor do they necessarily inspire action.

Recommended actions: Research findings must be presented in ways that bridge the science to the application for additional, specific stakeholders.

We need to "translate" our results from academic journals into public discourse and directly into the care delivery system through digital technologies, decision support tools, point of care tools, and clinical population health management systems.

In order to better tailor messages to different audiences, we must teach researchers how to use alternative methods known to be effective for different audiences and help them become comfortable and adept at doing so. Table 2 highlights examples of additional dissemination methods and their benefits. We also need to teach stakeholder audiences how to process, present, and interpret research results in a way that is understandable to their peers and colleagues. Particularly, we must step up our efforts to equip primary care clinicians with the knowledge and skills to interpret and act on the medical literature.

Action Area D: Build a "Question-Ready" Professional Research Infrastructure

The issue: Policy-makers, community leaders, health care systems, primary care clinicians, and other innovators make changes in the health care system every day. We currently do not have the infrastructure or resources to research these changes rapidly in an organized and efficient way.

Background to inform action: Sometimes innovative health policies or systems of care are informed by evidence, but often they are not. These natural experiments must be studied rigorously, rapidly, and in partnership with the relevant stakeholders in order to learn what works and why. Researchers currently must spend years readying themselves to conduct studies (eg, obtain grant funding, build infrastructure and datasets, expand teams, acquire

Table 2: Additional Dissemination Methods

<i>Social media.</i> Researchers can blog and tweet in order to get the research into the hands of the public. The use of Google Plus, Facebook, LinkedIn, Pinterest, and still other platforms that haven't yet emerged can multiply the reach of research findings.
<i>Public relations experts,</i> for example, to write op-eds, blogs, or other interpretive pieces to accompany media reports of peer-reviewed publications. If done well, this could help put valuable information into many more hands more quickly than traditional academic methods.
<i>Impact statements</i> to accompany findings—statements that describe what the research should lead to or is good for and not just what it found. Distinguish research dissemination (getting it out the door) and research impact (what good it does). This is like moving away from "impact factor" of an article to "actual change on the ground" that resulted from the research.

additional training). If a new intervention is harming patients, we cannot afford to take years for those findings to come to light. If something is helpful, we should have a way to rapidly define its benefit and spread the innovation to benefit everyone possible.

Residents and faculty in all family medicine residency programs must show evidence of successful scholarly activity in order to retain their program's ACGME accreditation. Many programs have successfully met this requirement through journal clubs and through training that is focused on evidence-based medicine. But others have difficulty meeting this requirement, and the implementation of evidence-based findings in practice falls far short of ideal. The impact of quality improvement or original research projects are often marginal, the enthusiasm for this element of residency training is often low, and program directors complain about the difficulties in maintaining a local research and scholarship infrastructure on a constrained budget in the absence of technical support for research.

Recommended actions: Primary care needs state-of-the-art infrastructure (eg, laboratories, discovery clinics) and resources (eg, experts, technologies, data) that are ready to answer new questions in the real world and in real time. It is impractical to prescribe or even predict the final form these structures might ultimately take, but some provisional suggestions can be sketched today. We offer two examples.

First, for residents and faculty in all family medicine residency programs, who must show evidence of successful scholarly activity, consider a National Family Medicine Scholarship Institute—a “virtual university” that collects in one place everything programs need to accomplish meaningful scholarship, meet their accreditation requirements, and maximize the quality and learning value of the projects. This institute would include five core elements:

1. Intake staff to learn a program's interests and to map those to opportunities within the universe of research and scholarship possibilities.

2. Research educators—coaches—to provide basic education about the principles of research, the tasks for actual projects, the formal requirements and timelines, and the resources available to conduct such projects. These research coaches would ultimately co-produce a formal research or evaluation protocol, complete with a budget and justification. Most of these projects could be done at affordable costs.

3. A large library of databases, PBRNs, community-based participatory research networks, and other sources of data in a form usable for these projects.

4. A core of technical support consultants. Faculty and staff to help with institutional review board and other human subjects' protection issues, to solve implementation problems, to talk through complications with enrollment, measurement, and other issues that arise in the course of a project, to clean and analyze data, to produce results tables and to help disseminate results.

5. An evaluation and certification core. These individuals evaluate not only the individual projects to ensure they meet the accreditation criteria for scholarship but also evaluate the program as a whole for effectiveness, efficiency, and cost effectiveness.

Such a program would improve the quality of individual program efforts, produce usable answers for our field, link similar efforts into larger projects, transform the scholarship requirement from an onerous distraction to a core skillset for future family physicians, make much better use of limited residency program resources, and produce a clinician-researcher workforce equipped to answer difficult and important questions. This program would also serve as a fertile training ground for fellows and junior researchers wanting to network with national colleagues and gain valuable experience in

mentoring and conducting research with diverse teams.

A second example of how to meet family medicine's research infrastructure needs is a strategic national resource center (or network of centers and laboratories) for very large projects. It makes sense to consolidate the research resources presently housed in departments of family medicine and other locations into regional or national centers, particularly if these centers can host some of the very large datasets that are emerging today—datasets that take highly specialized knowledge and skills to use responsibly. Such an organization could not only raise the quality and amount of research but could also serve as a staging area and convener for assembling and deploying research teams. If this emerged into a network of centers, one of these centers could focus on tailoring to the needs of residents and residency faculty (as discussed in the first example above).

We should look closely at alliances with organizations that do not presently lead research efforts, but have the wherewithal and motivation to do so, such as the innovation fund proposed by the Institute of Medicine for graduate medical education reform, or foundations established by health care organizations, and explore the prospects for congruent research. Given that we already have a national Council of Academic Family Medicine (CAFM), and research is an organizational priority for most of its members, CAFM could be an attractive organization to host new research initiatives.

Conclusions

These are ambitious action areas and action steps. But these are unusual times. Never before have we seen such an alignment of constituencies that agree, at least in part, with each other—agree with us—on the need for a strong, comprehensive, coherent primary care research agenda that can answer our common, pressing questions.

This ambitious agenda deserves our closest attention, our focused collective wills, and our most strenuous creative efforts. These efforts are more likely than ever before to be rewarded.

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