ARTICLE

Infrastructure

Leveraging the Clinical Translational Science Award Network to Advance Family Medicine Research

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In this commentary, the authors present opportunities for the family medicine's strategic plan for research to build and expand research infrastructure by leveraging the federally funded Clinical and Translational Science and Clinical and Translational Research Awards programs. These include engaging patients and communities historically underrepresented in research throughout the research design, development, implementation, and dissemination process; building and expanding practice-based research networks; leveraging research resources, facilities, trainings, and mentorship opportunities; obtaining pilot funding; using informatics expertise to improve care quality; and embedding dissemination and implementation science expertise to promote the use of evidence-based interventions in real world clinical primary care settings. (J Am Board Fam Med 2024;37:S122–S128.)

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In recognition of the importance of extending the opportunity for research participation to communities historically underrepresented in research, conducting clinical research in primary care settings is receiving increased National Institutes of Health (NIH) attention.[1] Concurrently, national family medicine organizations such as Association of Departments of Family Medicine (ADFM) and North American Primary Care Research Group (NAPCRG) are developing a family medicine research roadmap and strategic plan.[2,3] Infrastructure development is 1 of 3 key strategic priorities in this plan. In this commentary, the authors discuss how the discipline of family medicine has a significant opportunity to build and expand its national research infrastructure and reach by leveraging national translational research infrastructure.

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Established in 2006, the NIH Clinical and Translational Science Awards (CTSA) program was developed to accelerate the translation of research discoveries toward improved clinical care and the resulting health outcomes.[4] From the program's outset, academic family medicine leaders recognized collaborations with CTSAs as an opportunity for the discipline to "contribute to the mission of NIH and to move forward to expanding and completing medical knowledge in frontline practice."[5] They urged family medicine departments across the US to become involved in the community engagement components of these awards and beyond to "activate the potential of bidirectional translation"[5] between family physicians and basic scientists and relevance of research to patients and communities. However, a 2009 survey[6] found the majority of US family medicine departments were not substantively involved in local or national CTSAs. At that time, 12 of the 38 funded CTSAs had family medicine faculty in leadership roles —primarily in the areas of research training, practice-based research networks, and community engagement.[6] Although recent departmental surveys have not continued to assess this landscape, anecdotally, family medicine faculty hold leadership roles within several CTSAs, and these roles have expanded into areas such as informatics, and dissemination and implementation science. Family medicine faculty now also serve as CTSA Associate Directors, and a family physician leads the University of New Mexico CTSA as a Principal Investigator (author NP).

In 2024, over 60 US institutions across 30 states and the District of Columbia receive multi-million, multi-year CTSAs from the National Center for Advancing Translational Science (NCATS),[4] the NIH institute administering the CTSA program. These institutional CTSA-funded "hubs" partner together and, with contributors at the local, regional, and national levels, provide research education, training, resources, services and multi/interdisciplinary linkages to increase the output and innovation of translational research and dissemination of its findings. Hubs also provide seed funding for smaller-scale and pilot research projects, which can lead to more robust discoveries that promote individual and community health.

A mechanism for funding of the CTSAs issued in 2021 (UM-1 RFA)[7] set a new trajectory for the CTSAs and differed from the previous ones in several key ways. In particular, CTSAs were required to focus on translational science, defined as "the field that generates innovations that overcome the long-standing challenges along the translational research pipeline,"[8] and enabling research projects to become health solutions more quickly and efficiently. Several of the broad principles within the translational science field map well to skills and approaches used in family medicine practice. For example, NCATS calls for the CTSAs to prioritize initiatives that address unmet patient and population health needs, produce generalizable solutions for common and persistent challenges across diseases or conditions, leverage broad expertise, integrate knowledge, and use boundary-crossing partnerships.[8] These principles are core to family medicine; through this lens, its departments and faculty are well-positioned to support and leverage CTSAs and translational science discoveries.

In addition to the NCATS CTSA Program, the Institutional Development Award (IDeA) program was authorized by Congress in 1993 to enhance biomedical research capacity in the 23 states and Puerto Rico that have historically lower rates of NIH grant funding. Clinical and Translational Research Awards (CTRA) are available to institutions in those states, and similarly provide funding for research, workforce development and infrastructure enhancement. Network Awards, a category of these Awards, require partnership with clinics interested in research, such as those organized in a Practice Based Research Network.[9] As such, family medicine departments in IDeA states who do not have a CTSA similarly should examine opportunities available to partner with institutions who have or will be applying for these Awards.

As described below, the authors believe the current CTSA/CTRAs' program goals are well-aligned with the national family medicine research strategy.[2,3] Several opportunities present particularly strong areas of strategic alignment and can serve as foundations for the expansion of family medicine-based research. These opportunities were identified through discussions with attendees at the NCATS program meeting, the MWCTRIN program annual meeting and the Association of Departments of Family Medicine Research Summit. They are listed below in approximate order of existing engagement; areas where family physicians are already more engaged are listed first.

Opportunity #1: Community Engagement with Those Interested and/or Affected

CTSA/CTRA funding announcements acknowledge that translational research requires teams with

a wide range of expertise and perspectives relevant to a given area, from researchers and clinicians, to patients, community members and other partners. They also include an explicit commitment to addressing conditions that disproportionately affect rural, minority and other underserved populations. A special communications article by NCATS[10] additionally calls for examining the translational research process with a diversity, equity, inclusion, and accessibility (DEIA) lens to ensure inclusion of diverse perspectives, including from populations and groups that have historically been underrepresented in research. Engagement of diverse interested and/or affected individuals, for example patients as advisor-partners in all aspects of research, from study design and conduct, to result dissemination, implementation, and policy applications, is critical for understanding and addressing the needs and preferences of minoritized, underrepresented groups. Involvement of these key individuals in the research process can increase the relevance of study interventions and outcomes, with a potential for increased acceptability and uptake of evidence-based approaches and, ultimately, improved health of individuals and communities. This can also contribute to a more equitable access to effective treatments, reducing health disparities now experienced by many currently-underserved populations. The NIH[11] and the Patient-Centered Outcomes Institute (PCORI)[12] have started prioritizing patient and other interested/affected individuals' engagement in research as critical components of closing the long lag between research discovery and its real-world applications. For example, these individuals can help shape research by providing input on design and approach,[13] as well as by becoming involved as research team members to bridge the gap and build trust between researchers and academic institutions and (prospective or existing) study participants, promoting improved enrollment and retention, including among hard-to-reach populations.[14]

Family physicians care for individuals and families across the lifespan, from "cradle to grave," and are often actively and intimately involved in caring and serving as health advocates for the entire communities, particularly within rural areas. They treat the broadest range of conditions and illnesses among all specialties, and comprise the largest health care workforce within primary care, with the most clinic-based patient visits.[15] Family medicine is also the specialty most available in rural counties in the US[15,16] Because most health care in the US is delivered by primary care clinicians, and family medicine dominates this workforce, it is not surprising that a large proportion of populations categorized as vulnerable, marginalized or underserved are cared for by family physicians.[15–17] As such, family physicians and family medicine as a specialty are perfectly positioned to conduct research that is meaningful and acceptable to patients and impactful on a public health level. With appropriate support, such as through CTSA/CTRA-provided resources and services, family medicine and primary care practices and clinicians can advance clinical and translational research, and community engagement toward better health.[18,19] They can offer patients the opportunity to collaborate in research studies as participants or advisors.

Opportunity #2: Practice Based Research Networks

Primary care practice-based research networks (PBRNs) play a crucial role in advancing health care and improving patient outcomes.[20] These networks are comprised of health care teams collaborating with researchers and serve as a means for bridging the gap between academic research and real-world clinical practice. Primary care PBRNs generate valuable insights into treatment effectiveness, preventive measures, and health care policies in everyday clinical scenarios. This research can inform evidence-based decision making, enhances the quality of care, and tailor medical practices to the unique needs of their communities. Further, primary care PBRNs foster a culture of continuous learning among health care professionals, encouraging them to adapt and adopt the latest innovations, ultimately contributing to the overall well-being of patients and medical knowledge advancement. The Agency for Health care Research and Quality (AHRQ) has supported PBRNs through competitive grant programs and hosts a PBRN registry on their website. Over 100 PBRNs affiliated with Family Medicine providers were registered through AHRQ.[20]

Primary care PBRNs are mechanisms for improving the delivery of primary health care services worldwide. To this end, primary care PBRNs present opportunities for CTSAs and IDeA CTR Network programs alike. By leveraging PBRNs,

CTSAs can enhance translational research efforts, facilitating the rapid translation of scientific discoveries into clinical practice. Similarly, for IDeA state CTR programs, primary care PBRNs offer a unique opportunity to engage underserved communities, ensuring the inclusivity of research initiatives, and the equitable distribution of health care innovations. In fact, recent funding announcements for CTRs require integration of community engagement and outreach offered by PBRNs.[21] As such, there is an opportunity for Departments to collaborate with those engaged in these awards to build or grow a PBRN.

Opportunity #3: Research Training, Education, and Workforce Development

CTSA/CTRA-holding institutions offer advanced research funding, infrastructure, resources, and expertise. Family Medicine-based researchers with research skills ranging from modest to expert can immediately benefit from such resources. CTSA/CTRAs also offer training programs for all levels of medical professionals. Faculty within CTSA/CTRA-holding institutions have direct access such training. For those without a CTSA/CTRA, it offers a model from which to develop key elements of structured, actively mentored research training.

The current CTSA UM-1 RFA funding cycle continues to emphasize active trainee mentorship, grant-writing workshops, and networking, all geared toward helping faculty build successful careers as translational scientists. It also emphasizes a shift toward expanding trainings to include all potential members of research teams, including staff and community members. Programs in many CTSA/CTRAs now include opportunities for individual and team science training, collaboration across different disciplines, and faculty and staff career growth.

CTSAs additionally support mentored, longitudinal research training and career development for medical students (predoctoral), and residents and fellows (postdoctoral), along with their nonclinician counterparts, some CTSA support dedicated programs such as TL1 fellowships that provide clinical and translational science (CTS) training.[22] These 1 to 2-year programs provide funding (modest stipend and coverage of training-related expenses), structured settings, coursework, and mentorship. Resources provided by CTSAs can also facilitate success of federally-funded formal mentored research training programs such as 2 to 3-year NIH or NRSA supported T32 awards.[22] For early career faculty ("early stage investigators"; ESIs), CTSA resources offer formal 2 to 3-year training under the KL2 career development award mechanism.[23,24] CTSAs are also making a strong push to transition to community based participatory research. The authors (AZ, DR) have had particular success in their center through the CTSA Community Engaged Research Core, which provides career training through a fellowship program, resources, and mentorship inclusive of community stakeholders, along with other stakeholder training.

The career-development model offered by CTSA/CTRAs (modest funding, career development awards and research mentorship, and research protected time) can also be used by departments in centers without a CTSA/CTRA. For example, academic family medicine departments can create revenue-neutral (or near-neutral) research fellowships for ESIs interested in gaining research training, securing ample protected time for research and academic career advancement critical to becoming an independent clinician-scientist. Without a deliberate approach to securing protected time, clinical care responsibilities highjack early career faculty's time, energy, and efforts. A faculty member who does a modest amount of clinical work (20 to 40% FTE), especially if hired at a clinical instructor level, can pay for, or substantially offset, the cost of research/career development protected time (60 to 80% FTE). Active mentorship informed by progressive mentorship structures such as those offered by the National Research Mentorship Network,[25] and collaboration with ongoing research-related resources such as those offered by CTSA/CTRAs, help ensure success.

For all trainees and supporting entities, academic medical centers with or without CTSA/CTRAs are associated with medical schools and universities that provide nearly limitless learning opportunities. These include traditional in-person courses and a growing number of virtual courses and other resources. Lectures, seminars, and workshops are now often recorded and cached for later use by those unable to attend in person. Collective digital training repositories such as the DIAMOND portal[26] offer numerous research training materials that can be curated to create a comprehensive research training curriculum. Fellowships can leverage trainings to improve research capabilities, covering areas such as study design, data analysis, research methodology, regulatory compliance and research ethics.

Opportunity #4: Research Services and Pilots

CTSA/CTRA programs offer services to assist at many stages of the research conduct process, ranging from consultation on design, implementation of community-engaged and clinical trial studies, analysis, and dissemination. Services may be free or purchased depending on each hub's institutional arrangements. Often these are available on a fee-for-service basis to those outside a specific institution. Given the nature of these core services, transactions occur in a time-limited way. Using these services to assist in the design, analysis, or conduct of primary care studies rather than replicating this infrastructure within a department may be a cost-efficient approach, as the longitudinal responsibility for salaries and fringe benefits under these models are not borne by a faculty investigator or Department.

All CTSA/CTRA programs offer pilot funding programs, which offer an opportunity for catalyzing additional larger-scale research funding. Pilot opportunities may be general, focusing on a particular population, or focused on specific priority areas. Priority areas that are well-aligned with family medicine research programs include community and interested/affected individuals' engagement and outreach and dissemination and implementation. Departments should consider assisting faculty with the application process for pilot funding through mechanisms such as aid with budget preparation, assistance in identifying collaborators, and internal peer review before submission.

Opportunity #5: Alignment for Health Informatics Adoption and Integration

Health informatics has become a key component of translational research and is a rapidly expanding part of the CTSA programs. It often refers to the use and adoption of clinical informatics and information technology using existing electronic health records (EHRs), biogenetic data, and advanced statistics with machine learning/artificial intelligence (ML/AI), to augment and automate decision making processes for clinicians, patients, and health systems as a whole.[27] Within family medicine, the incorporation of health informatics could be transformational from the perspective of influencing quality and outcomes. Recent studies have demonstrated the benefits of informatics-driven interventions in chronic disease detection[28] and management.[29] Yet, many existing informatics advancements have been developed for specialty care, and it has been challenging for family practitioners and investigators to access and integrate health informatics for primary care research and clinical practice. As a result, despite overall efforts in advancing health informatics over the past decades, we are just beginning to understand the role of health informatics for primary care-related applications.

Through active collaboration with family medicine departments, the CTSA's research ecosystem, rich in technical and regulatory expertise, and data security protections, could assist primary care clinicians with accessing and securely "processing" the EHR and population health data necessary for quality improvement and scientific discovery endeavors. This assistance could include support for data storage, query and reporting interfaces, improved algorithms and technology, and the enterprise-level data governance and stewardship. As availability of big data for population health and health services research increases, CTSA hubs can become the foci of core resources to help address the need of increased computational power and technical skills. Such technical assistance would help primary care clinicians effectively access and use big data toward improvements in continuity care and care coordination, the hallmark features of primary care.[30]

In the era marked by exponential growth of the AI-based technology, tools, and applications, primary care research and practice should include this technology to process real-world clinical data toward better health care and patient outcomes, as well as to minimize potential harm associated with some sensitive features of the data and analysis. The CTSA's supports can be essential for ensuring appropriate analysis (especially when using AI) of big data and result interpretation to reduce the risk of data and algorithmic biases, which, albeit unintentionally, may propagate the negative stereotypes and further aggravate marginalization and health disparities experienced by some populations.[31,32] Moreover, concerns have been raised that health informatics techniques have often been developed without clinical and other vital partners, and rarely use data from community health care settings where primary care clinicians practice.[33,34] CTSAs could help engage relevant partners to develop a comprehensive roadmap and resources to both support research and decision processing in clinical care, and include necessary infrastructure updates

and training opportunities. The expected continued growth in the health informatics field will require progressively increasing capacity and technical expertise with better data/technology adoption in primary care to conduct high-quality research using real-world primary care data. Family medicine informaticists are well poised to collaborate with the CTSA network to partner in these endeavors.

Opportunity #6: Clinical and Translational Science Research Programs

With the explicit focus on translational science, an opportunity exists for larger scale funding from CTSAs to examine solutions to barriers to disseminating evidence-based interventions in real world clinical, public health and community settings. Departments have an opportunity to proactively collaborate with CTSAs in these endeavors, thereby enhancing both their research missions and the quality of clinical care that is provided. For example, dissemination and implementation (D&I) science is required in the new funding opportunity announcement. Family medicine departments could collaborate with CTSAs to hire faculty with this research expertise who focus on primary care. Guided by theory-informed models, faculty with D&I expertise can provide actionable insights that support the implementation process through assessing factors such as readiness and capacity to implement an evidence-based intervention; providing detailed implementation plans that are tailored to different settings; monitoring implementation success through data collection and analysis; and planning for sustainment through quality improvement and financial analysis.[35]

Opportunity #7: Apply for a New CTSA

As a final big picture idea- what would it look like to have a CTSA or CTRA specifically focused on translational science in primary care? Given expanded interest in primary care research alongside establishment of new medical schools with a primary care-centered mission, perhaps the discipline of family medicine leadership could consider a bold strategy of partnering with one or more of these schools to support future applications. Such a demonstration project could help establish best practices for the discipline and leverage these translational networks while simultaneously advancing the field of primary care research.

In summary, the goals of family medicine and, in general, primary care, are well-aligned with the mission and vision of the NIH supported CTSA/CTRA programs. Departments can leverage the resources provided and thereby support and grow their research endeavor; this in turn advances translational science and the application of its discoveries toward effective dissemination and improved human and public health.

To see this article online, please go to: http://jabfm.org/content/37/S2/S122.full.

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