August 24, 2021

Nakela L. Cook, MD, MPH Executive Director Patient-Centered Outcomes Research Institute 1828 L Street NW, Suite 900 Washington, DC 20036

Submitted electronically to: NPPC@pcori.org

Dear Dr. Cook:

We are writing on behalf of the Council of Academic Family Medicine (CAFM) which collectively includes family medicine medical school and residency faculty, community preceptors, residency program directors, medical school department chairs, research scientists, and others involved in family medicine education and research. Participating in CAFM are the Society of Teachers of Family Medicine, the North American Primary Care Research Group (NAPCRG), the Association of Departments of Family Medicine (ADFM) and the Association of Family Medicine Residency Directors (AFMRD.) CAFM offers the following specific suggestions to the recent PCORI request for comments on their draft national research priorities.

We think this document has made great strides in advancing changes that would support a more global understanding of health care that is not disease-specific but is more attuned to whole person care and communities. However, we think the descriptions within each priority and many of the strategies and examples would benefit greatly from acknowledging the role primary care plays in achieving each priority and we support an explicit additional priority related to primary care.

Broadly, our comments reflect a recommendation that PCORI add an additional national priority – **Improving the Primary Care System**. We think more emphasis on primary care can help PCORI achieve the goals outlined in its draft priorities. Below we site many reasons for this recommendation, and we include additional recommendations for the current draft priorities. We have numbered the current priorities for clarity purposes, even though we know they aren't in a priority order.

The need for a new, additional national primary care priority:

Since its inception, PCORI has been on the leading edge of medical research – uniquely identifying patient and stakeholder engagement as its driving force for comparative effectiveness research. Primary care, and particularly family medicine, has been on the forefront of participatory engagement in research and practice, and primary care research can address many of the goals included in PCORI's draft national priorities. Therefore, it is critical to prioritize research funding focused on strengthening primary care to ¹achieve these priorities.

Primary care is the largest delivery platform in the US, accounting for one out of every three physicians.ⁱ,ⁱⁱ It is also the first level of contact for individuals, the family, and the community. Yet, primary care is not mentioned once in the priorities, the strategies identified to pursue those priorities, or in the illustrative examples of endeavors to be undertaken to address the priorities. Hospitals are

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mentioned three times, and public health nine times. In fact, primary care provides a platform where public health, communities, and large health care delivery systems like hospitals intersect.

The COVID-19 pandemic has caused an unprecedented upheaval in our health system. In each sphere of care, new pressures and changes have required innovation and adaptation. CDC data show that among known COVID-19 patients, just over 80% remain in ambulatory care, and do not require hospitalizationⁱⁱⁱ. The ambulatory care space has been deeply affected by COVID-19 and the impact on primary care and family medicine needs to be evaluated regarding new payment changes, training, care modalities and particularly research.

The title of the recent National Academy of Sciences, Engineering and Medicine (NASEM) report, *Implementing high-quality primary care: Rebuilding the foundation of health care*^{iv} says it all – there is a great deal of work to be done to rebuild the foundation of our nation's health care. Among the areas of support needed to accomplish this is research to address questions that are critically important for primary care outcomes and a population-based understanding of illness and disease. While the report is directed at government agencies, it also emphasized the fact that "Primary care is the only health care component where an increased supply is associated with better population health and more equitable outcomes. For this reason, **primary care is a common good**, which makes the strength and quality of the country's primary care services a public concern^v. As such, and with PCORI's work authorized and funded by the federal government, we believe PCORI has a duty to expand it efforts in this research domain and focus a priority on primary care research.

Primary care providers serve as partners in managing chronic disease, gatekeepers to successive tiers in the healthcare system, and act as health educators. Primary care is often a critical intermediary between medicine and public health, bringing healthcare closest to where people live and work, and contextualizing patient needs against the sociocultural backdrop of the world in which they live. This degree of personalization unique to primary care rests on an intimate understanding of a community's social and cultural fabric. As almost half of all visits in the US are in the domain of primary care this provides a unique perspective and opportunity to add to an ongoing knowledge base of comparative effectiveness. The primary care physicians and team's distinct and unique advantage for contributing new information related to patient level care is the contact with all members of the family, direct experience with both healthy and ill patients in all stages of disease, long-term follow-up, and multidisciplinary approach to care.

Primary care research encompasses much more than typical biomedical or biological sciences research – including qualitative, behavioral science, epidemiology, ethnography, and their interdisciplinarity. Because of these differing theoretical orientations, methodologies, and methods, primary care research can be very complex. However, primary care research is often inadequately acknowledged and valued due to its complexity and focus on methods beyond traditional biomedical ones.

Notably, the Rand Corporation, funded by Congressional appropriations through the Agency for Health Care Research and Quality (AHRQ), recently studied health services and primary care research (PCR) and determined there were "two overarching research gaps in PCR: Core functions of primary care to holistically address patient needs, and primary care transformation and role in the wider health care system."

Dr. Jean Kutner, a general internist researcher and President of the Society of General Internal Medicine, wrote that "PCR can inform our attempts to enhance the quality, effectiveness, and value of clinical care, while also addressing important issues such as health care disparities and the care of underserved populations. More PCR is needed to examine the core functions of primary care and transform the role of primary care in the health care system, including its role in reducing disparities." This area is amenable to outcomes effectiveness research which is the core of PCORI's mission.

As Dr. John Westfall, et al, wrote in a commentary^{ix} about the Rand Study, a key component of the study was identifying gaps in primary care research. For example, "A core gap identified is a lack of research on the "basic science" of primary care. That is, "what's actually going on in primary care." This basic science of primary care is needed to understand the core functions of primary care, create and disseminate care models that deliver those functions, and engage patients to assure care is holistic and comprehensive. The 4 Cs of primary care: first contact, comprehensiveness, continuity, and coordination were mentioned but not universally accepted. As a core area of study, the basic science of primary care may help us understand how primary care leads to improved individual and population health outcomes."

Primary care is an essential foundation of an effective, equitable and high- quality health care system. Our COVID experience has highlighted the fragile and vulnerable nature of the primary care system in the United States and its need for more research to help it address many problems within our healthcare system, including inequities in health care. For all of these reasons, we suggest a new, additional priority focused on primary care. — **Improving the Primary Care System**. This should include adding knowledge related to clinical primary care as well as systemic changes important to improving the delivery of primary care in the United States. Many of our comments below provide additional support for this request. Although primary care can aid in meeting the draft priorities, as currently proposed, they do not go far enough. We have additional recommendations for each of the priority areas outlined in the draft.

Priority #1 – Increase Evidence for Existing Interventions and Emerging Innovations in Health

"PCORI aims to strengthen and expand ongoing CER focused on both existing interventions and emerging innovations to improve healthcare practice, health outcomes, and health equity."

We support both the priority and the discussion and rationale PCORI has included in its first proposed national priority, yet we have concern that while "care settings" is mentioned in the rationale, there is no clear indication that within this priority, in order to achieve better outcomes and better health equity, that community-based settings and especially primary care settings are included. We realize PCORI doesn't want its priorities to be limited in scope, yet we think an emphasis on identified key settings and populations is crucial to achieving the goals established in the draft priority.

In addition, the strategies listed to accomplish meeting the priority also don't identify significant and fundamental settings needed to achieve this work. We would like to see these settings emphasized in the Strategy section accompanying the first priority, and the rationale. Strategies 2. and 6. would benefit from the addition of this language. For example, in Strategy #2 the addition of primary health care would be beneficial; for #6, the addition of "from community practices to primary care to tertiary care" after the word settings, would be helpful. We are extremely heartened to see Strategy #4, "expand the scope of stakeholders engaged in PCORI's work from topic inception through implementation of the results," included in this priority. Over the years we have seen that PCORI has limited its methodology and its approaches to patient engagement; this change will maximize PCORI's potential and its greater connection to primary care and more complete patient engagement.

We have recommended that PCORI embrace comprehensive engagement, where patients are partners throughout the entire research process and not just at the initial and final phases, and that the elements that have been or will be undertaken collaboratively be clearly delineated within proposals and letters of support. Our past observation is that PCORI's reviewers consider studies that dynamically evolve in response to ongoing patient and stakeholder feedback to be less rigorous. Data that PCORI shared with CAFM demonstrate that scores for family medicine proposals are worse after in-person discussions (family medicine scores fall by 6.3 points compared to 3.7 for non-family medicine proposals). While the reasons for this finding are undetermined, we hypothesize that our approach to participatory research is misaligned with the views of some reviewers. We also suspect that the lack of generalist reviewers may contribute as well. So, we are pleased that PCORI is recognizing this issue and including this change in its priority.

We recommend the addition of another "Example of Illustrative Areas and Activities that Could be Explored under Priority #1." Suggested language is, "Expand prioritization of problems such as medical complexity / multi-morbidity, polypharmacy / de-prescribing, palliative care, and undifferentiated symptoms, as well as meta-issues, such as interventions aimed to improve patient-clinician communication, vaccine resistance, social determinants of health, screening rate improvement, and other issues that span across disease or organ-system categories."

Priority #2 - Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research

"PCORI aims to improve the nation's capacity for health research. Goals include expanding: the use of real world data. . . diversity, etc."

There is a large body of evidence and consensus among experts that improving access to primary care results in better health outcomes, while reductions in the supply of primary care physicians results in an increase in deaths due to preventable causes. A case to and utilization of primary care services also mitigates health disparities and advances health equity. Primary care physicians are also more likely to ultimately practice in rural and underserved areas. While primary care physicians and practices have been shown to lower mortality, morbidity and cost, there has not been a great deal of support for research within primary care to identify the nature of the impact of primary care, and what changes are needed to help expand this knowledge to impact population and individual health. However, primary care is not mentioned as a goal explicitly or implicitly.

Data show that much of PCORI's research, while patient-centered, has focused on rare diseases, rather than on the place where most people get most of their care, most of the time – in primary care settings. A recent study by Balster, Merenstein et al. shows that, while over half of all physician visits occur in primary care, only about one-quarter of PCORI trials had any relation to primary care, and less than one-third of the \$1.1 billion investment in PCORI is applicable to primary care patients^{xv}. In addition, based on our analyses of PCORI data, family medicine departments have received 0.5% of the \$6.32 billion that PCORI distributed. In addition, it is clear that NIH funding for primary care research has also been extremely limited. Studies have shown that only .3% of grants, and .2% of dollars from NIH have gone to family medicine departments – the largest primary care specialty. We suggest that priority 2 acknowledge this discrepancy.

Unlike other specialties which developed to encompass new areas of research knowledge or technology, family medicine developed in response to a broadly perceived lack of adequate primary care, before an active research base was established. The deficiencies in an active research base continue to be an issue for the discipline of family medicine and directly linked with this, the other disciplines involved in primary care. The infrastructure for primary care research needs to be updated and in order to realize the full potential of improvements in primary care processes and outcomes requires research *specifically focused on how clinical care is delivered in primary care settings*.

In this priority's rationale, PCORI states that it is uniquely positioned to strengthen and connect the elements of the health research enterprise...and then goes on to list multiple elements of research infrastructure, stating, "It involves people – patients, communities, clinicians, researchers, purchasers, policy makers, and representatives of payers, industry, hospitals and health systems, and training institutions – who collectively represent the health and research workforce as well as information (knowledge and data) and methods." While one could argue that the terms clinicians and researchers are broad and inclusive, we believe it is important to call out the areas of infrastructure that are important to address PCORI's goals of improving health equity, health outcomes and health care. Primary care research should be identified as a key element to achieving the goal PCORI has articulated. Primary Care is a crucial part of the front line of care and services within the healthcare system. While hospitals and health systems are referenced, primary care practices are not.

Similarly, one of the examples PCORI highlights as "Illustrative of Areas and Activities that could be explored under this priority states: "Build a strong and sustainable PCOR workforce pipeline that represents the diverse backgrounds of individuals in the health research ecosystem. This includes patients, communities, clinicians, researchers, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions that together represent the research workforce." Again, this language should be amended to include workforces in additional key settings such as primary care, not just hospitals.

Dr's Bartlett and Dube write that, "Currently, primary care is situated as an extension of our hospitaloriented health care system with fragmentation of information and challenges with sufficient and equitable access. The COVID-19 pandemic and ensuing crisis in care has provided an opportunity to flip the orientation of our health care system to ensure that primary care is at the hub as an anchoring point for provision of care. Much like an engineering stress test, the COVID-19 pandemic has pushed health care systems to the limit and clearly identified areas of failure. The current model of health care is still...fundamentally organized around hospital care with a focus on disease diagnosis and treatment. While health promotion and disease prevention receive some attention, only a small fraction of funding for research and care has ever been attributed to these areas. It is now possible to gather, structure, and analyze more significant quantities of data with greater efficiency than ever to support solutionoriented health care systems strongly grounded in primary care, thereby enabling performance and resilience for individuals and populations as well as for our economy and society."xvi An example of the enhancement of current infrastructure is at the nexus of artificial intelligence (AI) and primary care. Dr. Winston Liaw writes that "primary care artificial intelligence has failed to transform primary care due to a lack of engagement from the primary care community....Even though its history spans 4 decades, primary care artificial intelligence remains in the "early stages of maturity" because few tools have been implemented. Changing primary care is difficult when only 1 out of every 7 of these papers includes a primary care author."xvii PCORI can help support the development of transdisciplinary teams of primary care researchers and artificial intelligence researchers to develop new conceptual frameworks transcending historic disciplinary boundaries.

An additional area of research infrastructure needed for primary care research is related to practice-based research networks (PBRNs). As Drs. Green and Hickner write, "Primary care researchers and practitioners extended the participatory approach from institutional settings and solo practices to multiple practices with their organization of PBRNs." These networks of (typically) primary care practices have infrastructure needs that are unique and different from the bricks and mortar infrastructure costs of typically biomedical research laboratories. We recommend to you a study which surveyed PCORI recipients of pilot project awards. The authors, Nease, et al, discuss the infrastructure needs of community-based participatory research, and the domains of those infrastructure needs. Dr. Green sums this up nicely, stating, "If we want more evidence-based practice, we need more practice-based evidence" The property of the property of

One area that could be included in this section as an "Example of Illustrative Areas and Activities that Could be Explored under this Priority" relates to the current "laboratory of PBRNs." Currently, PBRNs do not get laboratory support through indirect costs. All the costs of running a practice-based research lab are taken from the direct grant revenue, which is a problem for fully funding this type of research. An example that could be included would be for PCORI to fund a task order or study relating to identifying the costs of running a practice-based research laboratory.

Priority #3 – Advance the Science of Dissemination, Implementation, and Health Communication

"PCORI aims to advance the science of, and practices that support, the real-world use of research results... to better inform health decisions. . . look at how to best communicate about and share study results and get results to patients, clinicians, and others to use in their health decisions."

We support the inclusion of this priority in PCORI's draft national priorities. It attempts to address one of the most intractable areas of biomedical and health care research. We have a few specific recommendations to help PCORI reach its goals in this priority. Communication with patients and dissemination of findings goes hand in hand with the ties between primary care physicians, interdisciplinary teams and their communities.

We know that complex decision-making in primary care, where community and patient comanagement, interdisciplinarity, multiple body systems and co-morbidity feature in every clinical decision, requires the type of contextualized evidence that needs to be driven by the people and setting which will ultimately need to use it. Participatory research that puts the end user (patient, community, provider, policymaker) at the heart of the evidence creation process, is now seen to be the principal mechanism behind knowledge translation, patient-centered care and practice-based research networks -- all hallmarks of modern primary care.

Westfall, et al, write that "Practice-based research networks are most commonly collections of primary care practices that work together to ask and answer health questions for their patients and communities and are an integral part of the translational pathway from discovery to practice to community health.... Practice-based research networks can gather and combine data from dozens of communities, hundreds of practices and thousands of patients to address health equity and disparities across the full spectrum of community and public health to clinical and primary care."xxii

We encourage PCORI to emphasize the work of PBRNs to help advance this priority. We recommend adding PBRNs to the strategies as a method for achieving the goal, and the other strategies listed, and we also recommend inclusion of use of PBRNs in the Examples listed.

Priority #4 -- Achieve Health Equity

"PCORI aims to advance health equity in the United States."

We applaud the inclusion of this priority in the draft national priority areas. Many physician and research organizations are increasing efforts at addressing racism and health equity in medicine and beyond, into disadvantaged communities and addressing disparities in health care.

We recommend adding language to the 5th strategy under this goal: Identify and fund the professional development and increase the engagement of investigators of color, investigators with disabilities, and populations who are historically underrepresented in research endeavors.

One recommendation we have for addressing this goal is to include efforts at training underrepresented minorities in medicine to increase the percentage of URM students, residents, and faculty who have the skills to produce scholarly research. An example of this type of effort can be found on the Society of Teachers of Family Medicine (STFM) website:

https://www.stfm.org/facultydevelopment/onlinecourses/webinars/urmscholarship/

In addition, though, we recommend that rural communities are clearly identified as an underrepresented area. It is the clearest example of a geographic inequity in health care and professional health workforce development and should be identified as clearly as the other categories in this strategy.

In the previous section we discussed the utility of PBRNs to address dissemination, implementation and communication issues regarding PCOR research. We wish to highlight here the utility of PBRNs to address health disparities and improve health equity. Westfall, et al, showed that "PBRNs are ideally suited to both rapidly assess issues of health equity and study interventions designed to reduce health disparities. Because of their direct linkage to and relationships with practices that serve diverse communities and populations, PBRNs provide an opportunity to investigate the impacts of race, ethnicity and social determinants on health. PBRNs are also an ideal laboratory for studying interventions to address health equity issues, particularly those that are well suited to delivery in primary care settings. Finally, it is important to emphasize that PBRN practices can often serve a sentinel function, alerting investigators to the presence of important health equity issues while also providing a laboratory for the investigation and confirmation of suspected health equity issues."

We recommend that PCORI call out PBRNs as a key component in the health research spectrum that will aide in accomplishing research important to achieving health equity. In addition, we recommend adding an "Example of Illustrative Areas and Activities that Could be Explored under this Priority" specifically related to using PBRN's to advance this priority.

In addition, strategy 2 should be strengthened by the identification of community health centers and smaller primary care practices. These are often the only source of care in medically under-resourced areas and are important venues for stakeholder engagement.

Lastly, we recommend that PCORI make every effort to increase the involvement of minority populations, including persons of color, persons from rural communities, and persons from other disadvantaged backgrounds on its own review panels. We recommend that this be included as a new strategy to address this priority and note that PBRN networks and practices might be a useful place to identify these individuals.

Priority #5 – Accelerate Progress Toward an Integrated Learning Health System

"PCORI aims to support a learning health system, or LHS, that works to improve patients' experience with health care and their health..."

We support the inclusion of this priority in the draft National Priorities. We agree that supporting a learning health system would be beneficial to aid in the improvement of patients' experiences with health care. We also agree that many spheres of influence are important to facilitate this effort. However, we are concerned that the priority lists "health care", public health, etc. without identifying areas that would prove the most fruitful in helping large portions of the population. As referenced earlier, more than half of all health visits are primary care. Emphasizing and targeting primary care can have a larger impact than other areas within health care. Focusing on specific diseases handled mostly in tertiary care settings misses a key area of health delivery -- primary care.

We support language included in several of the strategies in this priority that specifically call out communities and whole person care, which we think is important. We recommend that community health centers, primary care practices and PBRNs all be considered important partners in this effort.

In addition, we recommend the addition of two potential "Examples of Illustrative Areas and Activities." One would be "Integrate community health workers into primary care practice and the second would be "Improve primary care capacity for continuous quality improvement to engage communities."

One of our member organizations, the North American Primary Care Research Group (NAPCRG) hosts a Practice-based Research Network (PBRN) work group which explores the role of PBR laboratories and learning communities in the development of new model practices. It is currently using a collaborative strategy to develop research best practices specific to the context of practice-based research. The group also considers advocacy needs of Practice Based Researchers. If PCORI wishes to connect with this group, information about it can be found at: https://www.napcrg.org/resources/casfm/practice-based-research/

Another NAPRCRG work group, the Participatory Health Research (PHR) work group promotes and supports collaborative research partnerships in primary care together with patients, communities and other stakeholder partners. Their goals include jointly collaborating on products that increase understanding and capacity for a participatory approach in primary care research; supporting primary care researchers and professionals undertaking participatory research; and advocating for participatory research policy within relevant research and healthcare organizations. If PCORI wishes to connect with this group, information about it can be found at: https://www.napcrg.org/resources/casfm/participatory-health-research/

Conclusion:

We support the amount of thought and effort that went into the drafting of these priorities, strategies to accomplish them, and examples to illustrate the work to be undertaken within each priority. Over the years we have consistently requested that PCORI concentrate more on questions of concern to communities and populations, especially in the area of primary care. We think this document has made great strides in advancing changes that would support a more global understanding of health care that is not disease-specific but is more attuned to whole person care and communities. However, we think the descriptions within each priority and many of the strategies and examples would benefit greatly from acknowledging the role primary care plays in achieving each priority and support an explicit primary care priority.

Should you have any questions about our comments, or if you wish to continue a dialogue on these points, please contact CAFM Director, Government Relations, Hope Wittenberg at <a href="https://hww.neg.edu.n

Sincerely,

Aaron Michelfelder, MD

and Michelfelden

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