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Thank you for the opportunity to comment on the draft National Priorities for Research and Research Agenda. I have some general comments and observations and also some specific feedback on the draft priorities.

Patient-centered outcome research is a phrase that embodies the mission of PCORI. I would like to make several comments regarding that mission, its interpretation and how we measure its success. Understanding what ‘works’ and ‘does not work’ in health care is vital. This understanding will never be black and white. Among a variety of factors, patient attributes will always play a determinant role in the success of health technologies used and the methods employed to prevent disease, promote health, treat and cure disease and provide supportive care. Patient attributes are critical to the appropriate selection of effective and safe clinical interventions. In our efforts to improve the health of the nation, at the population and subpopulation level, which is a focus that I believe is appropriate for the work of PCORI, we must orient our research and communication efforts to include healthcare issues that are important to patients. This would include topic choice and research outcomes people/patients care about. This is not necessarily another way of saying “personalized medicine”, a term coined from the field of genetic testing and genomic-based pharmacotherapy. I also do not think it means or should mean a focus on an individual patient, with all his or her personal health history and status and experiential, intellectual, behavioral, social, ethnic and cultural characteristics. At the PCORI (research) level, we need to focus on populations and sub-populations, where these kind of factors will be explored and hopefully, provide guidance at all levels of care—individual, group, sub population and population.

Overall, PCORI has done a good job of being inclusive and trying to cast a wide net – trying not to exclude any populations, clinical areas, or study design types up front. I understand the approach of not specifying disease areas – that certainly sets PCORI apart from traditional NIH funding pathways. However, it does open the door for ‘ballot stuffing’ by well organized and generally well funded groups that focus on certain diseases, which may leave research on other important conditions unfunded. This approach also has implications for the review process because it may be challenging to assemble review groups that include clinical experts in the area addressed by each proposal. PCORI will be using the established NIH process, which was developed for use with the NIH funding approach, in which specific disease or interest areas are defined by the NIH and therefore the focus of the submitted proposals is narrow and predefined. It remains to be seen whether this process will work for PCORI proposals, which could be very diverse and likely will address some disease areas for which there are few expert reviewers within the group assembled for the PCORI proposal reviews.

Page 22 in the Features of the PCORI Research Agenda section, item #10 is “Measure eventual success by the impact on patient outcomes.” I would argue that the definition of success should

be much broader. There are a lot of other outcomes that would be beneficial for the country as a whole, even if individuals with a specific condition don't have better outcomes. These include improving efficiency of care (could free up resources for other types of patients – for example, caring for terminal cancer patients in hospice is a better use of resources than caring for them in a hospital setting and doesn't affect the final outcome); reduction in cost; reduced impact on the environment; improved healthcare worker safety, etc.

I also want to comment on the vital need to emphasize the impact the PCORI funded research, communication and dissemination efforts will have on behaviors and outcomes among everyday people and clinicians. We have an opportunity now to make a real difference, with a level of research funding for PCOR that we have never had before at a time when our nation's healthcare 'system' is in crisis and our nation's health is declining. We cannot squander this opportunity. To prevent this from occurring, we must emphasize and measure the impact of our efforts – not just measure in select research groups the safety and effectiveness of what is being evaluated, but also measure how and to what effect our findings are being used. It is not sufficient to create new, innovative ways of disseminating and communicating research findings and conclusions and documenting that subjects have received, and even used, the content and tools delivered. We must deepen our understanding of what things influence and result in uptake and change and how to sustain the most effective approaches, among everyday people and clinicians. To achieve these essential goals, we must measure uptake and the change in behaviors and outcomes that result. I also believe the clinical, operational and financial documentation of this "return on investment" will be essential in making the case to sustain and expand the PCOR focus----vital to our nation's health and wellbeing and the transformation of our broken healthcare system!

And finally, I have a comment regarding the Funding Model (page 21). Please consider allocating more money for communication and dissemination research. This could be accomplished by allocating the funding for Accelerating PCOR and Methodological Research at 10% and Communication and Dissemination Research at 20%. I understand that AHRQ will also be funded to disseminate research findings, but timely and effective communication and dissemination of research findings is one of the key barriers to use of research finding, and therefore research into more effective methods warrants substantial attention from PCORI. There is a substantial body of work about PCOR methods, much from international sources. There's no need to reinvent the wheel for all of these methods.

Thank you for the opportunity to review and comment on the draft. We look forward to a continuing dialogue with PCORI.

Respectfully,
Winifred S. Hayes
President, CEO
Hayes, Inc.

