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"People Focused, Healthcare Simplified"

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On behalf of Philips Healthcare ("Philips"), I am pleased to have the opportunity to comment on the Patient-Centered Outcomes Research Institute ("PCORI") Draft National Priorities for Research and Research Agenda (the "Draft Research Agenda"), which is currently subject to public comment.

Philips is organized across four main businesses: Imaging Systems (X-ray, computed tomography (CT), magnetic resonance (MR) imaging, nuclear medicine and ultrasound); Patient Care and Clinical Informatics (patient monitoring, hospital respiratory systems, children's medical ventures, cardiac care systems, healthcare informatics and image management services); Home Healthcare Solutions (sleep management and respiratory care, medical alert systems, remote cardiac services, remote patient management); and Customer Services (consultancy, clinical series, education, equipment financing, asset management and equipment maintenance and repair).

PCORI is charged with identifying national priorities for research; creating a research agenda based on those priorities; funding research consistent with the identified priorities; and providing patients and their caregivers with useful research findings. We understand that the Draft Research Agenda is PCORI's initial document focused on fulfilling this charge.

We would like to offer the following comments and observations:

- The Draft Research Agenda's lack of specificity makes it difficult to proffer useful comments. However, we agree that it is prudent to refrain from focusing exclusively on particular conditions, interventions or research methods. On the other hand, it appears clear that Congress intended PCORI's processes and specific priorities to be transparent and subject to comment. For this reason, we urge PCORI to establish a mechanism to disseminate its more specific priorities for public comment once these become clear. Because the Draft Research Agenda is so general, we also believe that it is important for PCORI to solicit comments on individual projects before significant research awards are made. Otherwise, we are concerned that the research agenda will be set de facto by those choosing to respond to PCORI solicitations.

- It appears that PCORI is proposing to dedicate significant resources to areas that also are being addressed by other governmental agencies. For example, the new CMS Innovations Center is focusing to a large extent on improving healthcare systems (which, according to the Draft Research Agenda, will also absorb 20% of PCORI funding); AHRQ is dedicating substantial research to effective patient communications; and identifying and addressing disparities has been a subject of some interest to other sectors of HHS, including both NIH and AHRQ. To the extent that PCORI extends the scope of its research activities into these areas, each of which is complex and resource-intensive, PCORI's potential impact in the area of comparative effectiveness and outcomes research will be diluted. To this end, we urge PCORI to coordinate closely with other agencies engaged in similar research.

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- In conducting comparative assessments of health care technologies and services, PCORI should refrain from assessing diagnostics based on the same outcomes measures used to assess therapeutics. Outcomes of diagnostic interventions differ from those for therapeutics; diagnostic interventions are intended to resolve diagnostic dilemmas or stratify and monitor patients for the purpose of making treatment decisions. Diagnostics should not be held to therapeutic outcomes, but instead must be measured against their intended use, such as the ability to diagnose a condition, measure disease progression, or help determine a treatment plan. Additionally, if endpoints are too distant or difficult to gather, or the clinical protocol and evidence gathering too cumbersome, the participating sites will not be representative of "community practice" and any conclusions would be biased.

  The accepted approach in the evaluation of diagnostic technologies includes sequential evaluation of the following six levels of efficacy: *(a)* technology, *(b)* diagnostic accuracy, *(c)* diagnostic thinking; *(d)* therapeutic planning; *(e)* patient outcomes, and *(f)* society.[1] With regard to diagnostic imaging, for example, Level 1, or "technical efficacy," generally relates to parameters that can be precisely measured in a laboratory with optimal conditions, such as spatial resolution, quantum mottle, necessary exposure time, and radiation dose. Level 2, or "diagnostic accuracy efficacy," relates to the sensitivity and specificity of the test, as well as its positive and negative predictive values. Level 3, or "diagnostic thinking efficacy," is used to measure the effect of diagnostic test results on the thinking of physicians. Level 4, "therapeutic planning efficacy" focuses on comparing intended patient care strategies prior to the test with intended patient care strategies after the test. Level 5, or "patient outcome efficacy," can really only be assessed in a prospective Randomized Controlled Trial ("RCT"), in which some patients undergo the test but others do not, and patient outcomes in the two groups (test vs. no test) are compared. Level 6, or "societal efficacy," relates to whether the social benefit of a test is acceptable in relation to its cost.

  For most diagnostic technologies, assessments should be conducted at Levels 1, 2, and 3, since the critical question is the technology's impact on physician decision making. In this regard, we note that Level 4 efficacy questions are extremely challenging, since it is often difficult to determine what would have been done without the results of a diagnostic test once those results are available and study designs attempting to address this problem through various "blinding" techniques are generally viewed by physician participants as artificial. Level 5 outcome studies require a RCT, in which some patients undergo the test but others do not, and patient outcomes in the two groups are compared; however, such RCTs are difficult to perform and are associated with challenging practical, analytic, and ethical issues. For these reasons, we urge PCORI to focus any studies relating to a diagnostic technology on the technical capability of the test, its diagnostic accuracy, and its impact on physician decision making.

[1] G. Scott Gazelle, MD, MPH, PhD; Pamela M. McMahon, BS; Uwe Siebert, MD, MPH, MSc; Molly T. Beinfeld, MPH. "Cost-effectiveness Analysis in the Assessment of Diagnostic Imaging Technologies," *Radiology* 2005; 235:361–370.

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We further urge PCORI to direct at least some portion of its funding to defining the level of clinical and cost effectiveness evidence to be required of new technologies and to establishing the "baseline" standards against which new technologies are to be measured. Leaders in innovation need some level of certainty with respect to the standards against which new technologies are to be evaluated. In addition, in light of the obstacles facing RCTs in today's rapidly changing environment, additional research is needed regarding alternative, least-burdensome, clinical evaluation methodologies that can discern the impact of various diagnostic technologies on clinical decision making in real-world settings. To the extent that PCORI focuses its research activities on improving research methods, PCORI should keep in mind the difficulties inherent in conducting RCTs and should focus on exploring research methodologies that offer practical and cost-effective methods of demonstrating the differential impact of various diagnostic technologies on physician decision making and diagnostic accuracy.

- In assessing methods to communicate the results of PCORI studies to patients, PCORI should carefully consider the need to ensure that media reports do not distort study findings, and should consider the effectiveness of controlled distribution of PCORI findings to health care professionals who are in the best position to interpret the results of these studies in light of patients' individual needs and circumstances. PCORI findings should be released to the media or by PCORI directly to patients, only in those limited circumstances where it can be anticipated that the findings will not be misinterpreted by a lay audience. Special care should be taken in disseminating findings that are limited to a particular subgroup of patients or to those with particular clinical conditions, to avoid the possibility that the findings will be more broadly and inappropriately applied by those with no medical training. Responsible reporting should inform and help consumers weigh benefits and risks in their lives, not paint a black and white world of good and bad. For example, there is no credible evidence available to support that a single imaging study causes cancer. Yet, many media reports have taken an overly simplistic, half-informed approach to reporting about imaging tests using ionizing radiation, which could result in some patients making the wrong decision about a potentially life-saving diagnostic test or treatment.

We appreciate the opportunity to submit these comments on the Draft Research Agenda, and look forward to working with PCORI as it works to refine its research priorities over coming years.

Sincerely yours,

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