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March 13, 2012

Joe V. Selby, MD, MPH
1701 Pennsylvania Ave., NW
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Washington, DC 20006

Re: PCORI Draft *National Priorities for Research and Research Agenda*

Dear Dr. Selby:

The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the Patient-Centered Outcomes Research Institute's (PCORI) draft *National Priorities for Research and Research Agenda*. Neurosurgery is supportive of PCORI's mission to conduct comparative clinical effectiveness research in a transparent manner that encompasses stakeholder input. We are pleased that PCORI has initiated the development of defining national research priorities and a research agenda for patient-centered outcomes research.

We were a bit disappointed, however, that PCORI's draft priorities and research agenda does not include specific clinical conditions for additional research, but merely describes broad categories of research. The lack of specificity makes it very difficult, if not impossible, to provide useful and meaningful comments. While the overall framework is appropriate, it still does not address or explain the specific clinical areas that PCORI believes should serve as the initial research priorities. Without an open, public process for acquiring comments and input from physicians and clinical experts on specific research topics and questions, it will be difficult for PCORI to construct a unified agenda that answers the research questions for which clinicians and patients have the most interest.

That said, neurosurgery is extremely pleased that PCORI has referenced registries as a source for evaluating and studying comparative effectiveness research. Clinical data registries are valuable tools that support evidence development, performance assessment, comparative effectiveness studies, and the adoption of new treatments into routine clinical practice. Registries can provide high-quality evidence on par with randomized clinical trials while offering the added value of documenting patient experiences in everyday clinical practice rather than under strict eligibility and treatment protocols. Regularly observing patient responses to treatment can provide important insights into which healthcare strategies work best in actual practice.

Neurosurgery, through its clinical data registry program, the NeuroPoint Alliance (NPA), has recently launched *The National Neurosurgery Quality and Outcomes Database (N²QOD)*. This resource will allow any U.S. neurosurgeon or orthopedic spine surgeon, practice group, or hospital system to contribute to and access aggregate quality and outcomes data through a centralized, nationally coordinated clinical registry. The primary goals of this registry are to:

- 1) Establish risk-adjusted national benchmarks for the cost and quality of common neurosurgical procedures.
- 2) Allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real-time and, in doing so, facilitate the development of new care initiatives.
- 3) Generate both quality and efficiency data to support claims made to public and private payers.
- 4) Demonstrate the comparative clinical effectiveness of neurosurgical procedures.
- 5) Facilitate the conduct of essential multicenter trials and other cooperative clinical studies.

We are presently conducting a pilot registry involving approximately 40 leading practice groups from all regions of the United States, including academic and private groups in both rural and urban settings. The primary aim of this 12-month pilot is to demonstrate the feasibility of collecting high-quality, validated, aggregate practice data on a national scale. NPA has initiated the registry effort with a lumbar spine module because of the pressing need expressed by many groups around the country for outcomes data in this practice area. Furthermore, N²QOD is the first and only national registry in the U.S. assessing one-year quality of life after surgical treatment. As the registry grows, we will be adding additional subspecialty modules to evaluate care in the areas of cerebrovascular, trauma, tumor, pain and functional neurosurgery.

The current spine portion of the registry project, called the National Spine Surgery Quality and Outcomes Database (S²QOD), has been developed in conjunction with several national spine-care stakeholders including multidisciplinary spine care providers, patient advocacy organizations, payer groups, employers, quality care researchers and epidemiologists. This comprehensive quality project will be conducted jointly with orthopedic spine groups. The S²QOD contains a number of unique and important structural features, including clinical variables that allow for appropriate risk adjustment and patient-reported outcomes and utilization metrics along with longitudinal follow up, the latter of which will allow for determination of the sustainability of treatment effects. Through longitudinal follow-up, the S²QOD has the capability and intent to assess effectiveness of care. Collecting and reporting on validated outcomes that are important to, and reported by, the patient, such as pain, quality of life, function, and satisfaction, will enhance the information gleaned through this effort.

Given that the direct and indirect costs associated with back pain and other spinal disorders exceed over \$100 billion annually, **we encourage PCORI to consider supporting research projects such as the S²QOD, which hold a great deal of promise in evaluating spine care treatments.**

Finally, we wish to take this opportunity to make a few comments on one aspect of PCORI's new definition of Patient Centered Outcomes Research (PCOR). Our comments relate to the last element of the PCOR definition, which states:

- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, **resource availability**, [emphasis added] and other stakeholder perspectives.

We are very concerned about PCORI interjecting "resource availability" into PCORI's research work – certainly at this stage when PCORI is just getting off the ground and has yet to prove that it can appropriately carry out its clinical effectiveness research agenda. As you will recall, there was considerable controversy surrounding the creation of PCORI, and many of the opponents feared (and still fear) that this would merely be an organization that would make recommendations for rationing care based on costs and resource use. As stated on your website:

Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and

their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options.

Nothing in this description involves cost effectiveness research or an evaluation of resource use or availability. Resource use is not an appropriate element of *clinical* comparative effectiveness research, which focuses on which treatment works best, for whom, and under what circumstances. Inclusion of cost or resource use in the PCORI research agenda will diminish the credibility of the important work PCORI is doing. Therefore, **PCORI must not move forward with an agenda or research priorities that incorporate cost or resource utilization.**

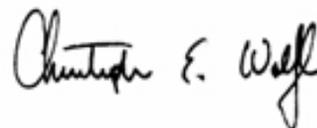
Neurosurgery shares with the public a sense of urgency and responsibility to meet the challenges of creating a sustainable healthcare system. We look forward to working with all relevant stakeholders – including the PCORI -- to promote a coordinated, national effort to define and develop patient-oriented outcomes measures and general practice data collection tools. Our ultimate goal is to develop a national quality-care competency to improve the quality, safety and value of neurosurgical care.

The AANS and CNS appreciate the opportunity to provide feedback on PCORI's draft research priorities, and we look forward to contributing to the work of PCORI. We urge PCORI to maintain an open and transparent process as it moves along with defining its priorities and research agenda. Thank you for considering our comments. Please feel free to contact us if you have any questions or need further information.

Sincerely,



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American Association of Neurological Surgeons



Christopher E. Wolf, MD, President
Congress of Neurological Surgeons

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