AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

March 15, 2012

Joseph V. Selby, M.D., M.P.H.
Executive Director
Patient-Centered Outcomes Research Institute
1701 Pennsylvania Ave., NW,
Suite 300
Washington, DC 20006

Dear Dr. Selby,

On behalf of the American Academy of Otolaryngology- Head and Neck Surgery Foundation (AAO-HNSF), I am writing to respond to the Patient-Centered Outcomes Research Institute's (PCORI) draft National Priorities for Research and Research Agenda. The Academy is the world's largest organization representing specialists who treat the ear, nose, throat, and related structures of the head and neck. The Academy represents more than 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas. The Academy commends PCORI for embracing a transparent process that allows stakeholders to play a key role in PCORI activities.

The AAO-HNSF appreciates the efforts of PCORI in developing its draft of national priorities for research and research agenda and its desire not to exclude any specific patient population, disease or condition from consideration. The AAO-HNSF believes that PCORI's research agenda should focus on areas with significant opportunity for quality improvement. As such, research should be steered to areas that will promote appropriate care, increase shared decision making and where large, undesired variation in practice exists.

The AAO-HNSF also recognizes the importance of the patient engagement in patient-centered outcomes research (PCOR). Further, we would like to highlight the role of consumer advocacy groups in driving more patient-centric research. For several years, the AAO-HNSF has included educated healthcare consumers, from relevant consumer advocacy groups, during the development of our clinical practice guidelines (CPG). In our experience, consumers have played a substantial role in developing CPG recommendations and framing the discussion from the patient/consumer's perspective.

An area that remains a concern is how comparative effectiveness research (CER) studies will be interpreted. While the study design needs to fit the study aim, and all CER studies may not need to be the highest level of scientific rigor and design (e.g. RCT), the concern lies in how results from studies will be used. Results from one study, especially if it is not conducted with rigor, involving large volumes (or ample enough for statistical power, risk adjustment, etc.), and

representative patient populations and provider settings (i.e. patients seen in academia are not generally representative overall and thus a broader network of provider types/skill levels is important), should not be used to make or support broad sweeping changes in treatment coverage, management guidelines, etc. The level of methodological rigor used in the AAO-HNSF CPG development and the ranking of evidence to make decisions on how strong or weak a study is in terms of making recommendations, should be used as a frame of reference to create a criteria for how CER evidence and studies can be used for various reasons.

The Academy supports the need for CER with the caveat that a guidance on interpretation of study results and the degree to which certain levels of research can and should be used for treatment and coverage decisions needs to be outlined in advance of further CER promotion and funding. If CER truly wants to benefit the patient, this guidance is imperative such that patients are not limited in potentially appropriate treatment options and providers are not limited in the care they provide using the best available evidence. The AAO-HNSF appreciates the opportunity to provide input to PCORI. PCOR has the potential to improve the quality of information available to physicians and patients, and when examined appropriately may address rising health care costs and change behavior. The AAO-HNSF looks forward to working together with PCORI to ensure the needs of otolaryngologists are addressed and represented in PCOR and CER.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO