

August 16, 2021

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Executive Director  
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Dear Dr. Cook,

On behalf of the members of the American Society for Radiation Oncology (ASTRO) we applaud the Patient-Centered Outcomes Research Institute's (PCORI) commitment to research and evidence development that enables providers, patients, and caregivers to make informed decisions as they navigate the healthcare system and advocate for appropriate care. The recent publication of PCORI's five proposed National Priorities for Health serves as an opportunity to build on the strengths that PCORI has developed over the past decade. ASTRO appreciates the opportunity to comment on the proposed priorities, as many of them align with ASTRO priorities.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. ASTRO members also work with medical oncology and surgical oncology colleagues to provide multi-disciplinary care. This team-based approach provides a unique perspective from which we provide input on the inherently complex issues related to healthcare priorities that impact the delivery of care to patients with cancer.

Radiation therapy, while a high-value and efficient form of cancer treatment, is not always considered as part of a patient's cancer care plan even when appropriate and beneficial to the patient. Frequently, this is because of the referral-based nature of the specialty; the use of radiation therapy often depends on whether providers and patients are familiar with its efficacy. We applaud PCORI for serving as a repository of clinical evidence that can provide patients and providers with guidance to inform decision making, ultimately resulting in better outcomes. ASTRO looks forward to working with PCORI as it seeks to build on that foundation through the implementation of the proposed National Priorities for Health.

The following are ASTRO's comments regarding each of the priorities outlined in the proposal.

Priority: Achieve Health Equity

PCORI aims to expand stakeholder engagement, research, and dissemination approaches that lead to continued progress toward achieving health equity in the United States.

ASTRO commends PCORI's interest in expanding approaches to achieving health equity in the United States. Uncovering and understanding the barriers to health equity is a national imperative. Given that these inequities are driven in large part by a lack of investment and resources, we think this domain should receive a larger share of funding than the other priority areas.

We initiated our own analysis of how health inequities factor into the delivery of radiation therapy. ASTRO has conducted a preliminary analysis (unpublished) of Medicare data and found that despite having completed the treatment planning process, only about 2/3 of minority patients actually begin their radiation therapy treatments. Although the analysis of what causes this is not complete and further investigation is needed, evidence points to a myriad of factors, including lack of transportation or childcare, inability to take time off work, lack of connection with provider due to differences in demographics or societal beliefs, underinsurance/uninsurance, and limited social support (housing, access to fresh food, etc.) as key barriers.

Health equity issues are also relevant to rural populations seeking radiation therapy treatment. While approximately 15 percent of Americans live in rural communities, less than six percent of radiation oncologists practice in these communities. Rural communities across the country share common healthcare risk factors, including physician shortages, lower socioeconomic status, and remote locations, which contribute to limited access to care. Additionally, ASTRO has conducted an analysis which indicates that rural radiation oncology practices are less likely to have advanced technology that supports shorter, more cost-effective radiation treatment regimens for patients.

ASTRO welcomes the opportunity to engage with PCORI on opportunities to address healthcare disparities through improved patient engagement, as well as the establishment of supportive services that ensure patients receive necessary and appropriate care.

High priority topics for investigation in the oncology space include:

- Evaluation of treatment outcome inequalities in the most common malignancies: breast, lung, colorectal and prostate cancer
- Evaluation of access to care issues associated with different populations (e.g. racial, ethnic, gender, geographic, rural)
- Evaluation of how oncologic screening tests may differ in patients of color (normal range of PSA in people of color, etc.)
- Inclusion of diverse populations in studies related to new technologies (i.e., theranostics and radiopharmaceuticals, liquid biopsies, protons, FLASH radiotherapy, etc.)

Priority: Increase Evidence for Existing Interventions and Emerging Innovations in Health

PCORI aims to strengthen and expand ongoing Comparative Effectiveness Research (CER) focused on both existing interventions and emerging innovations to improve healthcare practice, health outcomes and health equity. ASTRO appreciates the need for this particular priority given the significant growth in new technologies and innovations that are designed to improve patient care.

Radiation oncology is a technology dependent and driven field of medicine. Advances in technology often result in improved patient experiences, which include more convenient, shorter treatment regimens coupled with fewer side-effects from treatment. Unfortunately, dynamics of the existing payment and coverage system frequently prevent patients from enjoying these advances. The existing fee-for-service system disincentivizes the use of shorter course therapy and often payer policies prevent patients – and society at large – from realizing the benefits afforded by technologies that decrease the burden of treatments, in terms of time, morbidity and cost of treatment.

Radiotherapy is often used as a substitution therapy for patients who are not candidates for other standard therapies, in both the oncologic and non-oncologic space. For example, patients with early-stage lung cancer often have significant comorbidities that preclude surgical resection. Stereotactic body radiotherapy (SBRT) has emerged as a standard non-invasive treatment for early-stage lung cancer. Multiple randomized trials comparing SBRT to surgery have failed to accrue due to the inherent difficulties in randomizing between invasive and non-invasive therapies and lack of patient and physician equipoise. Another emerging use of SBRT has been in patients who have life-threatening ventricular tachycardia (VT). Such patients are typically managed with ablation of the VT using invasive catheter ablation. However, after such interventions fail, or for those patients who are medically unfit for catheter ablation, no reasonable options exist. Recent studies have shown great promise for use of a single dose of noninvasive SBRT as a substitution therapy for catheter ablation in these patients. This new emerging paradigm follows an established history of radiotherapy as an effective substitution therapy to other invasive treatments for non-oncologic conditions such as coronary artery disease, trigeminal neuralgia, heterotopic ossification, keloids, and tremor. ASTRO is supportive of pragmatic CER in this area where radiation can be used as a substitution therapy.

While we recognize and support the advancement of the field, we are also aware that there have been instances in which tried and true methods of treatment have been cast aside for the latest technology that may yield little to no advancement in patient outcomes. A key example of this is the treatment of cervical cancer, which according to clinical guidelines should be treated with a combination external beam and brachytherapy to ensure optimal patient outcomes. Despite guidelines and clinical evidence, the use of brachytherapy with external beam radiation therapy has declined significantly in recent years.

ASTRO welcomes the opportunity to collaborate with PCORI on any research related to the use of existing and new interventions and innovations associated with cancer treatment and other diseases. We believe that opportunities exist to not only educate patients and providers, but also payers and even CMS on those interventions that are high-value and provide patients with high-quality care outcomes. Additionally, ASTRO thinks research on patient reported financial toxicity could be an important topic, including both out of pocket costs and lost wages due to recovery and side effects of treatment.

High priority topics for investigation in the oncology space include:

- Use of patient-centered telemedicine to improve access and relieve some of the burdens of care
- Collection of (electronic) patient reported outcomes (including financial toxicity) to improve and inform quality of care, the patient experience, and survivorship
- Expansion of the use of moderate hypofractionation
- SBRT and ultrahypofractionated interventions
- Radiopharmaceuticals

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

PCORI aims to enhance the infrastructure that facilitates patient-centered outcomes research (PCOR) to drive lasting improvements in health and transformation of both the research enterprise and care delivery.

ASTRO agrees that enhanced infrastructure is needed to accelerate patient-centered outcomes research. One area that ASTRO has prioritized in this domain is data standardization to improve data exchange. In 2019, ASTRO began working on data standardization with our [Minimum Data Elements for Radiation Oncology](#) publication; we also joined the Executive Committee of [mCODE](#) along with American Society for Clinical Oncology, the Alliance for Clinical Trials in Oncology, MITRE and the Society of Surgical Oncologists. We were early leaders in [CodeX](#) and have worked across ASTRO and the American Association of Physicists in Medicine to further expand and specify common oncology data elements focused on the radiation oncology space. In this collaborative, use-case approach, we have experience in achieving consensus and creating key standards for radiation therapy including treatment modality, technique, and dose delivered to volumes utilizing HL7-FHIR standards and SNO-MED codes. We believe that this substantial achievement ASTRO has accomplished with our partners will help enable future patient-centered research.

ASTRO has also worked with the Veterans Administration's Radiation Oncology Quality Surveillance (ROQS) pilot program. Under this pilot, ASTRO established Blue Ribbon disease panels for prostate, lung, breast, head/neck and rectal cancer to develop measures for quality surveillance. In total, 100 measures have been developed across the 5 disease sites as well as over a dozen harmonized measures for all cancer patients. The data elements needed to support these measures are being integrated into various clinical forms to enable passive capture of data and calculation of performance on the measures. While the measures themselves are not PROs,

we believe the ability to pair PROs with the robust and relevant process measures will provide insight as to which processes impact patient outcomes.

High priority topics for investigation in the oncology space include:

- Creation of a unique patient identifier to help track patients across various providers.
- Assessing proper safety parameters against cyber-crime
- Further development of oncology-specific data standards and informatics approaches to facilitate pooling of data and learning across health systems
- Establishing low-burden quality metrics linked to patient outcomes
- Wearable devices to track patient factors

Priority: Accelerate Progress Toward an Integrated Learning Health System

PCORI aims to foster actionable, timely, place-based, and transformative improvements in patient-centered experiences, care provision, and ultimately improved health outcomes through collaborative, multisectoral research to support a health system that serves the needs and preferences of individuals.

In addition to the data standardization efforts described above to facilitate data exchange, ASTRO is one of the few specialty societies that supports a patient safety organization. The Radiation Oncology - Incident Learning System (RO-ILS®) was conceived to facilitate safer and higher quality care in radiation oncology by offering a no-cost mechanism for providers to report on patient safety events that will facilitate shared learning in a secure and non-punitive environment. In addition to these efforts, ASTRO separately manages and administers a practice accreditation program for radiation oncology, the Accreditation Program for Excellence (APEX®). This program recognizes facilities that demonstrate compliance with industry-wide quality standards and are committed to delivering safe, high-quality care to their patients.

High priority topics for investigation in the oncology space include:

- Evaluation of various oncology accreditation programs (i.e., CoC, APEX, QOPI certification) to determine if they provide transformative improvements in patient-centered experiences
- Study reported incidents that impact patients to address the root causes of quality gaps

Priority: Advance the Science of Dissemination, Implementation, and Health Communication

PCORI aims to advance the scientific evidence for, and the practice of, dissemination, implementation, and health communication to accelerate the movement of CER results into practice.

ASTRO agrees with the importance of this priority. We develop clinical practice guidelines for physician audiences and we also have a patient website, [RTAnswers](#), where we share science-based information with patients. As discussed above, RO-ILS also produces [reports](#) for the radiation oncology community to disseminate and share learning from reported incidents. We

invest significant resources to develop these work products and think they offer the field needed and valuable information. We also believe more can be done to advance awareness and implementation of our guideline recommendations and that there are additional ways to effectively communicate with patients.

ASTRO also notes that in order to greatly improve health communication, it helps to increase the number of racially underrepresented physicians and healthcare workers as well as support cultural competence training to all healthcare workers. For our healthcare system to be more equitable, we must address the inherent biases already present and re-train all of our workers to be sensitive to the needs of our most vulnerable patients as well as hire more physicians and staff that represent the diverse populations we treat. We must also create strategies for racially underrepresented or vulnerable patients to have access to trained culturally competent advocates to help address questions and help them effectively navigate the healthcare system. These suggestions could help improve patient outcomes and also improve minority patient consent to join clinical trials.

High priority topics for investigation in the oncology space include:

- Use of telemedicine and access to broadband to remove barriers, logistic strain for follow up oncology visits
- How oncologists can better communicate with referring physicians and PCPs as part of survivorship care for our patients
- Non-English translations of guidelines and guidance materials
- Development of readable patient education for those with limited literacy skills, and appropriate grade level material for literate patients
- Patient-focused summary of ASTRO guidelines
- Design of effective cultural competence training to all healthcare workers

We appreciate the opportunity to provide comments. We fully support the national priorities that you propose, and hope you consider the topics we identified in each domain as timely in the oncology space.

Sincerely,



Laura Thevenot

Chief Executive Officer