CANCER LEADERSHIP COUNCIL

**A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER**

March 15, 2012

Joe Selby, M.D., M.P.H
Executive Director
Patient-Centered Outcomes Research Institute

Re: Draft National Priorities for Research and Research Agenda

Dear Dr. Selby:

The undersigned organizations, representing cancer patients, physicians, and researchers, are pleased to provide comments on the Patient-Centered Outcomes Research Institute (PCORI) Draft National Priorities for Research and Research Agenda (version 1). We commend PCORI for developing five broad priorities for patient-centered comparative clinical effectiveness research. We offer advice to PCORI and the research community regarding promising research initiatives that are consistent with these research priorities and that would, consistent with the PCORI mission, "offer patients and caregivers the information they need to make important healthcare decisions."

Assessment of Prevention, Diagnosis, and Treatment Options

The PCORI Proposed Research Agenda identifies as a priority area research that is related to the assessment of prevention, diagnosis, and treatment options. The agenda states that the research should focus on "biological, clinical, economic, and geographic factors that may affect patient outcomes." We recommend as a special area of emphasis research projects that would evaluate strategies to ensure the best possible patient outcomes from use of targeted cancer therapies.

Important advances in the understanding of cancer have contributed to the development of targeted cancer therapies that block the growth and spread of cancer by interfering with specific molecules involved in tumor growth and disease progression. These treatments may offer significant benefits to cancer patients, sometimes without the side effects of chemotherapy or radiation therapy.

However, the appropriate use of such targeted therapies may depend on timely and accurate diagnostic testing of individuals to ensure that they will benefit from the treatment. There are economic, medical practice, and educational and communication barriers to the proper utilization of diagnostic tests that inform the use of targeted therapies, and evaluation of these obstacles and identification of strategies for addressing them might be the focus of research supported by PCORI.

Improving Healthcare Systems

Research on management of the late and long-term effects of cancer and cancer treatment

Consistent with the PCORI research agenda that focuses on ways to improve access to care, receipt of care, coordination of care, self-care, and decision-making, we recommend research on management of late and long-term effects experienced by cancer survivors. Cancer survivors may experience a wide range of side effects of cancer and cancer treatment, varying in their impact on quality of life and in their severity. Although the side effects experienced by adult cancer survivors will vary by cancer diagnosis and treatment received, these effects might include cardiovascular disease, fatigue, cognitive impairment, psychological distress, infertility, and lymphedema. Cancer survivors may also be at risk of a cancer recurrence or second primary cancer. The side effects experienced by childhood cancer survivors are also significant.[1] The Institute of Medicine (IOM) found that, "As many as two-thirds of childhood cancer survivors are likely to experience at least one late effect, with perhaps one-fourth of survivors experiencing a late effect that is severe or life threatening."[2] Among the late effects experienced by childhood cancer survivors are neurocognitive and psychological, cardiopulmonary, endocrine, musculoskeletal, and second malignancies.

Cancer survivors—whether diagnosed as children, adolescents, or adults –face serious challenges associated with the management of the late and long-term effects of their cancer and treatment for cancer. We recommend a number of research initiatives that would investigate optimal strategies for managing the co-morbidities experienced by cancer survivors. These projects might be focused on:

- Evaluating the impact of written treatment summaries and survivorship plans on the receipt of appropriate care for management of effects of cancer and care treatment; the coordination of all elements of health care monitoring and side effects management; self-care by survivors; and decision-making about nature and scope of survivorship care.
- Assessing the optimal site of care for survivors of childhood cancer and the transition from pediatric to adult systems of care and the impact of such transitions on childhood cancer survivors and their health outcomes.

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[1] Institute of Medicine, From Cancer Patient to Cancer Survivor: Lost in Transition, 2006.

[2] Institute of Medicine, Childhood Cancer Survivorship: Improving Care and Quality of Life, 2003.

Research to determine the best health care teams for management of complex care

Cancer care is typically multi-disciplinary and often long-term. The challenges associated with cancer care delivery are becoming even greater, with the development of oral, self-administered therapies that raise adherence issues and targeted therapies that require access to diagnostics to guarantee appropriate use of the therapy. In addition, cancer patients may encounter difficulties in understanding their financial responsibilities for care. Further complicating the cancer care situation is the projected deep shortage of oncologists.

Patient navigators have in some settings played a role in assisting cancer patients in management of their care. Questions still arise regarding the appropriate training for navigators and the scope of their engagement in the system of care. In addition, other sorts of cancer care teams – perhaps utilizing navigators but relying on other health professionals in addition to physicians –are being utilized in a range of health care systems. We recommend research initiatives that would evaluate the impact of cancer care teams of different composition (including navigators and health professionals collaborating with physicians) on care delivery, quality of care, and patient satisfaction with care.

Research related to provider acceptance of new technology, treatments, and practice standards

Cancer care in the United States has always evolved rapidly, with researchers providing information about new uses of approved therapies, innovators bringing new products to the market, and surgeons introducing enhancements into practice. In recent years, cancer patients have become aggressive consumers of information, monitoring research developments carefully to integrate them into their care. The process for incorporating new treatments into the standard of care has been strained by the pace of discovery and the consumer command of information about possible new treatments.

We identify two recent developments in cancer care to illustrate the challenges facing cancer care providers in incorporating new standards of care into their practice. New therapies that are targeted to individuals with a specific molecular profile require use of a diagnostic test to determine those who will benefit from a particular therapy, a testing process that may in some circumstances present substantial burdens. The American Society of Clinical Oncology (ASCO) recently released a Provisional Clinical Opinion recommending the incorporation of palliative care into oncology care, a change in practice that will require adaptation and adjustment.

We recommend research into effective means of disseminating information about new practice standards to health care professionals and dissemination of the same information to patients. This research will support changes in the health care delivery system for better coordination of care and also access to best available care.

Communication and Dissemination

We applaud PCORI for the substantial emphasis on improved communication to facilitate patient engagement and decision-making. There is strong support among cancer patient advocates, physicians, and caregivers for the development of a written cancer care plan outlining all elements of active treatment and symptom management and coordinating all aspects of cancer care, to be provided to the individual patient by his or her care team. Such written care plan—to be updated when there is a significant modification in treatment, a change in the individual's condition, or a transition to long-term survivorship –is considered an aid to patient decision-making and involvement in the care process and a means to facilitate the coordination of care provided by multiple physicians and care teams.

We recommend research on several elements of the cancer care planning process, to ensure that there is broad provider acceptance of this practice and guarantee that the plans that are communicated to patients are adequate to support informed decision-making.

We urge:

- Research to determine the most effective professional education strategies for encouraging the adoption of cancer care planning as an essential element of cancer care delivery.
- Evaluation of the elements that are critical for inclusion in the written care plan, to ensure that the document is adequate to support decision-making but also consumer-friendly.
- Investigation of solutions to potential challenges related to development and delivery of cancer care plans to underserved populations, including minority populations.

Research on these issues will strengthen the quality of cancer care plans, facilitate their incorporation in practice, and empower patients for participation in their care.

Addressing Disparities

We commend the decision to include disparities as part of the research agenda and are pleased that PCORI will consider disparities related to race/ethnicity and other causes of disparities in disease incidence and survival, including socioeconomic status, gender, and geographic location. Research has shown that these different disparities influence the time of cancer diagnosis as well as outcomes. For example, African Americans are more likely to be diagnosed with and die from cancer than any other racial or ethnic group. In addition, as reported by the American Cancer Society, "Persons with lower socioeconomic status (SES) have disproportionately higher cancer death rates than those with higher SES, regardless of demographic factors such as race/ethnicity." [3] Research in this area holds the promise of reducing disparities, including the disparities seen in diagnosing cancer at an early stage, when odds for survival are typically higher.

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[3] American Cancer Society, Cancer Facts & Figures, 2012.

Accelerating Patient-Centered and Methodological Research

We are pleased that the PCORI agenda includes research on the use of registries and clinical data networks to support research about patient-centered outcomes. We believe there is promise in the use of registries and databases to document patterns of care and the effectiveness of health care interventions over time. To achieve that end, it is appropriate for PCORI to invest in research to 1) improve the quality of clinical data in registries and databases, 2) identify options for design of effective and efficient databases and registries, and 3) develop strategies for enhanced health professional and patient utilization of registries.

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We appreciate the opportunity to comment on the first version of the PCORI research agenda and look forward to additional occasions to offer our input into the PCORI research program. Our research recommendations are specific to cancer patients and providers, as that is our area of expertise and experience. However, our proposals are generally appropriate as recommendations for research on chronic disease management more generally. We also realize that the demands on the PCORI budget are great, as the research program must address a wide range of research topics and priorities.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
College of American Pathologists
International Myeloma Foundation
The Leukemia & Lymphoma Society
LIVESTRONG
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network