PIPC Partnership to Improve Patient Care

May 12, 2020

Ms. Yvette Venable
Vice President of Patient Engagement
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Dear Ms. Venable:

We are writing to applaud the creation of your position as Vice President for Patient Engagement at the Institute for Clinical and Economic Review (ICER) and to offer to partner with you in your work. The undersigned are organizations that engage patients, people with disabilities and caregivers, many of which are deeply engaged in patient-centered outcomes research and the implementation of patient engagement strategies in other organizations. We hope to work with you to ensure that ICER develops and implements a robust and meaningful patient engagement framework.

Over the years, many of our organizations have provided comments to ICER urging the organization to align with innovative leaders in the field of patient engagement and value assessment. Among our recommendations, we have encouraged ICER to:

- Partner with patients and people with disabilities to develop innovative measures of value that account for patient differences and priorities and do not have the discriminatory implications of quality-adjusted life years (QALY) and similar metrics that do not capture outcomes that matter to patients;
- Work with patients to ensure that real-world evidence is available and included in ICER's assessments, even if it means delaying the reviews of drugs for which prices and indications are yet to be finalized and during a period when quality of life data are yet to be published. This is important to assure the assessment achieves real-world validity and appropriate translation into a value determination for real people with a disease, chronic condition, or disability;
- Engage patients to identify the condition-specific preferences of health-related quality of life (HRQOL) for ICER assessments so that they reflect value to patients with the condition;
- Partner with patients on strategies to develop or identify evidence on heterogeneity of treatment impact -- it has been well established that reporting of differential value assessment across subgroups will lead to substantial health gains, both through treatment selection and coverage;
- Share comments from patients and people with disabilities publicly at each stage of the process and provide direct and public responses to their input;

- Ask patients to identify clinicians who specialize in serving the patient populations under discussion and rely on their expertise in the value assessment process;
- Identify appropriate disease specialists and disease-impacted patients and allow them to serve as voting members for all reviews;
- Engage patients in a process to determine the minimum data requirements for ICER assessments so that premature reviews do not do them harm;
- Extend comment periods for patient stakeholders who often did not budget or plan for ICER's assessment and therefore require significant time and resources to ramp up their ability to meaningfully participate in the process.

For a value assessment entity, the foundation of a successful patient engagement framework is a truly patient-centered mission and methodology that captures value to the patient. As examples, we urge you to advocate internally for patient representation on ICER's advisory and governing boards, as well as voting committees, and for meaningful incorporation of patient input into ICER's base models. We look forward to working with you to implement patient-centered assessment methods such as those described above, combined with a strong patient engagement framework. As you look to implement a patient engagement framework alongside a more patient-centered assessment methodology, we urge you to engage with patient stakeholders early and often, and to look to the experts in the field of patient engagement.

As experts, the Patient-Centered Outcomes Research Institute (PCORI) has done tremendous work in consultation with patients and people with disabilities to define the elements of patient engagement and to ensure that patients and their representatives are appropriately trained to meaningfully engage in research. Most importantly, they are implementing engagement meaningfully and in real time. One of PCORI's most important remits is to provide appropriate guidance to researchers through its patient engagement framework, which is routinely updated based on real world experience and in consultation with its Patient Engagement Advisory Panel. This work has provided a foundation for cultural change throughout the research infrastructure as patient-centeredness has become an expectation for research institutions more broadly.

Many of our organizations also have been engaged with the FDA in its own evolution in patient engagement, particularly through Patient-Focused Drug Development. They have a prescriptive framework for the patient role in research, as well as 200 patient representatives being hired as special government employees, trained specifically on the medical research lifecycle, and engaged in a prescriptive manner throughout the entire process. The FDA also has an entire framework for patient-focused drug development that evolved into the FDA-wide Patient Council bringing together all Centers and Offices to ensure that the patient perspective is consistently integrated in regulatory decision-making over the total product lifecycle.

More recently, we are seeing leadership in patient engagement from independent entities that recognize the need for methodological improvements to capture the patient voice in value assessment. For example, the Patient-Driven Values in Healthcare Evaluation (PAVE) Center, which is a Center of Excellence in Patient-Driven Value Assessment, is dedicated to promoting value-based decision-making through a diverse multi-stakeholder collaboration. They engage patients from an extensive network of partners to build technical expertise in patient-centered outcomes research, education, and dissemination. PAVE has also partnered with the National Health Council (NHC), an organization with expertise in developing educational tools for patients and patient advocacy organizations, to train patients and ensure they have the tools needed to engage productively in the research process. We strongly encourage you to collaborate with and learn from these and other organizations[1] as you embark on your new role.

As organizations that have worked across the spectrum of health care – including life sciences innovation, payer decision-making and value assessment – with missions to improve the quality of life for patients and people with disabilities, we hope that you will engage with us and take advantage of our real-world patient engagement experiences and lessons learned. Do not hesitate to reach out to us and to the experts in this field described above as you consider patient engagement frameworks that may be fit for use within ICER.

Sincerely,

ACCSES
Albie Aware Breast Cancer Foundation
American Association of People with Disabilities
American Autoimmune Related Diseases Association (AARDA)
Association of University Centers on Disabilities
Asthma and Allergy Foundation of America
Axis Advocacy
Boomer Esiason Foundation
Brain Injury Association of America
Bridge the Gap - SYNGAP - Education and Research Foundation
Cancer*Care*
Center for Autism and Related Disorders
Children with Diabetes
Cure SMA
Cutaneous Lymphoma Foundation
Cystic Fibrosis Research, Inc. (CFRI)
Davis Phinney Foundation for Parkinson’s
Depression and Bipolar Support Alliance
Diabetes Patient Advocacy Coalition
Dynamic Therapy and Wellness Services, Inc.
Epilepsy California

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[1] www.thevalueinitiative.org, https://mdic.org

Epilepsy Foundation
Epilepsy Foundation New England
FORCE: Facing Our Risk of Cancer Empowered
Global Genes
Global Healthy Living Foundation
Global Liver Institute
GO2 Foundation for Lung Cancer
Health Hats
Healthcare Leadership Council
Heart Valve Voice US
Hepatitis Education Project (HEP)
ICAN, International Cancer Advocacy Network
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Pemphigus and Pemphigoid Foundation
Jaime M. Sanders
Kids with Heart National Assn for Children's Heart Disorders, Inc
Livpact
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Men's Health Network
MLD Foundation
National Alliance on Mental Illness
National Diabetes Volunteer Leadership Council (NDVLC)
National Infusion Center Association
National MPS Society
National Organization for Rare Disorders
National Viral Hepatitis Roundtable (NVHR)
NBIA Disorders Association
Northwest Parkinson's Foundation
Partnership to Fight Chronic Disease
Partnership to Improve Patient Care
PFCCpartners
RASopathies Network
Rosie Bartel
Sick Cells
Sickle Cell Consortium
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
Tuberous Sclerosis Alliance
U.S. Pain Foundation
United Cerebral Palsy National
United Spinal Association
Whistleblowers of America