Green Park Collaborative | USA

A partnership for innovation and effectiveness

Highlights of the 2015 Annual Meeting

April 30, 2015
Baltimore, Maryland

CMTP

The Green Park Collaborative is a major initiative of the Center for Medical Technology Policy

Green Park Collaborative: Going Deeper

The second annual Green Park Collaborative (GPC) Annual Meeting took place on April 30, 2015 at the World Trade Center in Baltimore, Maryland. While previous GPC Annual Meetings have focused on progress reports from its various consortia and working groups, this gathering revolved around three high-value topics: Core Outcome Sets for Clinical Research, Real World Evidence (RWE), and Promoting Evidence Development. These were explored through panel discussions and short presentations that highlighted recent developments within each field. Under the skillful facilitation of Cliff Goodman of the Lewin Group, these sessions promoted rich discussion and provided participants with the opportunity to engage actively in robust dialogue on the best ways to generate evidence relevant to key decision makers.

Getting Started

Sean Tunis, MD, MSc, President and CEO of the Center for Medical Technology Policy (CMTP) and Chair of the Green Park Collaborative's Advisory Committee, framed the day and the three panel discussions, providing an introduction to the evolving demands for additional clinical evidence, including unmet needs and opportunities ripe for GPC attention. In particular, he pressed the group to consider the field of "reimbursement science" as an area that GPC and CMTP should strive to create and support. This term, he said, emphasizes the analogy to "regulatory science," which the FDA and others define as "developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products." The objective of regulatory science is to "speed innovation, improve regulatory decision-making, and get products to people in need." GPC's work, Dr. Tunis noted, shares these objectives in the reimbursement domain, while adding the important objectives of population health and affordability.

Prior to the formation of GPC, there has been no obvious platform to support this type of social-scientific dialogue related to reimbursement decision making. Through GPC and other projects, CMTP is now creating an analogous body of work around payment and value. Reimbursement science focuses on developing new tools, standards, and approaches to assess the comparative effectiveness and value of products covered by public and private health plans. Like regulatory science, it aims to speed innovation, improve health outcomes, and ensure resources are spent wisely. In the absence of a CMS-driven federal platform for reimbursement science, GPC has begun to create spaces in particular disease areas or around particularly complex topics (e.g., next generation sequencing tests), in which this work can take place with input from all relevant stakeholders.

Engaging patients more dynamically

Pivoting from this provocative introduction, the day's Keynote Speaker, Sharon Terry, President and CEO of the Genetic Alliance, talked about "Patient Centered Research: From Rhetoric to Reality." She began with her dramatic story of becoming a "citizen scientist," when two of her children were diagnosed with a rare disease. She and her husband, both lay people, learned the science, patented a gene, got a test through the FDA, had their patent struck down, and now have a compound in clinical trials. Along the way, they have created the Genetic Alliance, a leading nonprofit health advocacy group whose network includes more than 1,200 disease-specific advocacy organizations, as well as thousands of universities, private companies, government agencies, and public policy organizations. Terry and the Alliance are intimately involved with PCORnet, PCORI's network of patient-powered and clinical data research networks, as well as a variety of new technologies designed to enable patient voice and patient engagement in the clinical research process. Big questions remain, she noted: "How do we create a culture of openness and sharing? How can we take friction out of our [data collection] systems? How do we know what's working? How do we animate the American public to take this issue more seriously?"

Three Dynamic Panel Discussions

Following this inspiring presentation, the bulk of the day was devoted to panel discussions that featured brief three-to-five minute talks from a variety of leaders from academia, industry, payers, and government (see page 4). Each panel prompted additional, and often energetic, conversation from the assembled.

Core Outcome Sets for Clinical Research

There are various ongoing efforts to develop core outcome sets, that is, an agreed upon minimum set of outcomes or outcome measures that should be reported in all trials in a specific research area. These are critical to providing a foundation for systematic evidence reviews and can provide a consistent way for payers to gauge the value of new products in ways that matter to patients, clinicians, and society more broadly. This panel covered efforts to develop core outcomes for several conditions and classes. There was a general recognition of the value of these sets for PCORI, for PCORnet, and for industry, though the work to realize this value is just beginning. There is currently a huge amount of heterogeneity in what gets measured. GPC may be an ideal platform from which to convene stakeholders to achieve agreement on standards for disease-specific core outcomes. One panelist further suggested that there was an opportunity for an entity like GPC to see if a "core set" of "core outcomes," across different disease states, can and should be established. There is also a corresponding urgency, other panelists noted, as patient-centered and comparative effectiveness research has caught fire in recent years to create the foundation for systematic reviews and other evidence development and help streamline reimbursement decisions.

Real World Evidence (RWE): Defining What "Good" Looks Like

Real world evidence, including the data harvested through electronic health records during every day clinical practice, represents a powerful opportunity for clinical research to help inform a range of decision-making. But what are the characteristics of RWE studies that are reliable enough to support reimbursement, formulary, and other payer choices? Panelists noted that the quality of RWE studies currently vary widely from peer-reviewed and credible to marketing-driven and suspect. "Good enough" RWE is too often "in the eye of the beholder." There is the need for a common vocabulary and common standards, reviewed by an impartial body—perhaps a role for GPC. Logistically, the panel noted, these reviews need to take place relatively quickly in order to be useful, particularly around post-approval decisions so they can shape therapeutic guidelines and other policies in real time. And RWE can be a critical complement to randomized control trials (RCT), when the real world (e.g., the patient population or setting) is different than the initial RCT.

A Path Forward for Promoting Evidence Development

When an innovative therapy is first marketed, payers often face uncertainty about whether it offers good value in a real world setting compared to the standard of care or in a broader, more heterogeneous population. CMS' Traditional Coverage with Evidence Development (CED) process offers one way to address these issues, particularly for device and diagnostic makers whose path to reimbursement may be bumpier post-approval than drug developers. While private payers have not been receptive to the traditional CED paradigm developed by Medicare, payers have been eager to encourage the development of better evidence to inform their coverage policies. As with the other issues of the day, challenges revolve around creating a better, more efficient infrastructure, informed and supported by multiple stakeholders that can enable the development of improved clinical evidence. GPC may have a role in creating forums and developing guidance that can facilitate CED for public payers and rethink the ways that commercial health plans can incentivize the generation of high quality evidence they require.

In Review, Looking Ahead

Following the final session, Dr. Tunis provided a brief review of the day's discussions, commenting on the range of evidence challenges raised. He noted that these issues will continue to evolve as the health system changes and concerns about value and cost continue to drive reimbursement policy decision making. There will continue to be the need to gather information that is relevant and meaningful for patients. There will be opportunities to develop cheaper, faster technologies that will help us generate credible real world and other evidence. Finally, there will always be the need for creative partnerships and stakeholder conversations among health systems, payers and others, as this work is complex and can't be done in silos or independently. It is this difficult but critically important work that GPC will press forward in the months and years ahead.

Program and Speakers

Welcome

Sean Tunis, MD, MSc, President and CEO, Center for Medical Technology Policy
Chair, Advisory Committee, Green Park Collaborative

Introductions and Facilitation

Cliff Goodman, PhD
Senior Vice President and Director, Center for Comparative Effectiveness Research, The Lewin Group

Keynote Presentation

Sharon Terry
President and CEO, Genetic Alliance

Core Outcomes Sets for Clinical Research

Panelists:

- **Clifton "Bing" Bingham, MD**, Associate Professor of Medicine, Director, Johns Hopkins Arthritis Center, Johns Hopkins Bayview Medical Center
- **Marcy Fitz-Randolph, DO, MPH**, Research Client Manager, PatientsLikeMe
- **Bryan Luce, PhD**, Chief Science Officer, Patient-Centered Outcomes Research Institute
- **Eleanor Perfetto, PhD**, Professor, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy

Real World Evidence – Defining What "Good" Looks Like

Panelists:

- **G. Caleb Alexander, MD, MS**, Associate Professor of Epidemiology and Medicine, Co-Director, Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health
- **Marc Berger, MD**, Vice President, Real World Data and Analytics, Global Health and Value, Pfizer Inc.
- **Jennifer Graff, PharmD**, Vice President, Comparative Effectiveness Research, National Pharmaceutical Council
- **C. Daniel Mullins, PhD**, Professor and Chair, Pharmaceutical Health Services Research Department, University of Maryland School of Pharmacy
- **Lewis Sandy, MD, MBA**, Senior Vice President, Clinical Advancement, UnitedHealth Group
- **Marcus Wilson, PharmD**, President, HealthCore

A Path Forward for Promoting Evidence Development

Panelists:

- **Naomi Aronson, PhD**, Executive Director, Clinical Evaluation, Innovation and Policy, Blue Cross Blue Shield Association
- **Michael Barlow**, Vice President, Palmetto GBA
- **Louis Jacques, MD**, Senior Vice President and Chief Clinical Officer, ADVI
- **Jack Lasersohn, MA, JD**, General Partner, The Vertical Group
- **Jeff Shuren, MD, JD**, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration
- **Eric Wichems, MEng, MBA**, President and Chief Executive Officer, Vertos Medical