Working Together to Improve the Quality of Reimbursement Science

2015 Progress Report

The Green Park Collaborative is a major initiative of the Center for Medical Technology Policy
Creating a Collaborative Path to 21st Century Cures

Since our inception in 2013, the Green Park Collaborative-USA (GPC) has focused on improving clinical research by cultivating collaboration between drug and device developers, private and public payers, clinicians and the patients they serve. In our second year of operation, GPC made real progress toward our goals. We developed disease-specific consortia in the areas of oncology and diabetes, and issued Effective Guidance Documents focused on these conditions. We also initiated broader discussions and strategies—via webinars and workshops—to address cutting-edge topics in reimbursement science, the work of developing new tools, standards, and approaches to assess the comparative effectiveness and value of products in order to inform coverage decisions by public and private health plans.

Simply put, the goal of our collective efforts is to get new therapies to patients faster and more efficiently, and this means a commitment to doing things differently from all the stakeholders involved. We are pleased to report that even Policymakers are beginning to take notice. The Energy and Commerce Subcommittee on Health in the U.S. House of Representatives recently introduced the 21st Century Cures Act, a bipartisan bill that could radically alter how drugs and devices are regulated in this country. Last year, representing the GPC Advisory Committee, I testified in front of the congressional subcommittee that allowing more conditional coverage may help accelerate innovation, particularly in the areas of medical devices and diagnostics.

At our 2015 annual meeting, GPC will further explore the rapidly evolving field of comparative effectiveness research (CER) and the importance of identifying core outcome sets that will assist innovator companies to efficiently develop additional evidence of effectiveness and value. We will also explore new models and approaches to clinical research that can generate “real world evidence” (RWE) without significantly undermining rapid access to products that address unmet health needs. In addition, we will review potential new topics for GPC projects, including treatment crossover in oncology clinical trials, and a further focus on next generation sequencing.

This report offers an overview of GPC’s recent accomplishments and other efforts. We continue to welcome new sponsors to join us in this critical work and offer special thanks to those who made the past year such a success.

Sean Tunis
President & CEO, CMTP
Chair, Green Park Collaborative Advisory Committee
At our 2015 annual meeting, GPC will further explore the rapidly evolving field of comparative effectiveness research (CER) and the importance of identifying core outcome sets that will assist innovator companies to efficiently develop additional evidence of effectiveness and value.
Throughout the past year, the Green Park Collaborative-USA (GPC) used its unique role as a neutral forum to discuss critical health issues, establish ways to improve clinical research, and most importantly, take action. GPC provided a number of exceptional opportunities for stakeholders to connect with others in industry, research and government, and to develop solutions to difficult challenges associated with the coverage and reimbursement of new medical products.

Expanding the Evidence for Next Generation Sequencing Testing

Over the past year, GPC has focused extensive efforts on exploring coverage and reimbursement challenges related to next generation sequencing (NGS)-based testing in oncology. As a first step, GPC hosted a launch meeting in coordination with the Roundtable on Consensus Standards for Multiplex Cancer Genomic Testing, the American Society of Clinical Oncology (ASCO), the Association for Molecular Pathology, and the College of American Pathologists. Stakeholders included representatives from health plans, Center for Medicare and Medicaid Services (CMS), NGS test developers, Food & Drug Administration (FDA), patient groups, oncology guideline organizations, clinical oncology groups, drug/biologic companies, and others.

This July 2014 meeting launched a project focused on improving the evidence available for coverage and reimbursement of NGS-based tests in oncology. Since the fall of 2014, the team has connected regularly via phone conference, and in November of 2014, GPC convened a follow-up multi-stakeholder meeting to discuss the methods and standards for evaluation of the clinical utility of NGS-based testing. This meeting in turn kicked off a series of discussions that will take place through the spring of 2015 and will culminate in the issuance of an Effectiveness Guidance Document (EGD). A complete summary of the July meeting is available on the CMTP website.

Complementing these efforts, Sean Tunis published an op-ed in Clinical OMICs, summarizing GPC’s efforts to develop guidance on study design for NGS. The next stakeholder meeting is set for April 2015, and the EGD on Clinical Utility of Next Generation Sequencing (NGS) will be issued in the first half of 2015.

Hepatitis C Drugs: Evidence to Demonstrate Effectiveness and Value

In the past year, there have been exciting developments in the treatment options available for Hepatitis C patients. While new treatments have come to market that are faster, simpler, and more effective, they are very expensive. In July 2014, GPC hosted an expert webinar focused on the evidence needed to demonstrate the comparative value of these new drugs. More than 200 participants joined in to hear from subject matter experts representing public health authorities, pharmaceutical companies, and private and public payers.

Speakers included Poonam Mishra from the Food and Drug Administration, Gregg Alton of Gilead Sciences, and Steve Pearson from the Institute for Clinical and Economic Review. Following the presentations, participants explored learnings from the first wave of new drugs now available to treat this disease. The webinar also enabled a wide range of stakeholders to discuss the level and type of evidence needed to inform both clinical and policy decisions related not only to these hepatitis treatments, but other high-cost, high-value drugs.

Exploring Obesity and Overweight Interventions

In January 2015, GPC, in collaboration with the FDA and America’s Health Insurance Plans (AHIP), hosted a one-day workshop to explore the steps needed to improve research on the comparative effectiveness and value of interventions for treating obesity, one of the United States’ most significant public health challenges.
Leaders from the FDA, CMS, the Department of Veteran Affairs, and state Medicaid agencies joined with private insurers, health systems executives, internists, surgeons, researchers, patients, professional societies’ leadership, and representatives of pharmaceutical and medical device companies to discuss how study designs can best evaluate weight loss devices and compare them to other treatment options, including drug therapies.

Participants identified several priority focus areas including determining responsive patient subgroups, long term data on outcomes, better understanding of the relationship between various levels of weight loss and other clinical outcomes, and how best to use registries to collect relevant data. The group agreed that the current approach of stakeholders working in independent silos is not sufficient, and that all would benefit from more open discussions on the needs of various parties and how best to satisfy them. GPC and its partners are now working to determine the best options and format in which to continue this conversation.

Comparing Therapeutic Sequences in Advanced Cancers EGD

The GPC Oncology Consortium developed an EGD that provides recommendations on how to conduct studies to compare sequences of therapies for treating advanced cancer when a range of options exist, but evidence is lacking on the optimal choices. By focusing on the outcomes that matter to patients, including aspects of patient burden often not systematically studied, the resulting studies should help to inform the decisions of patients, clinicians, payers, and others. These recommendations are also likely to provide a good starting point for adaptation outside of the United States health system. Released in March 2015, the EGD’s principles and recommendations were based on a multi-step process that involved topic selection through semi-structured interviews, review at meetings of the Oncology Consortium, and a series of meetings of a subgroup of experts including oncologists, epidemiologists, biostatisticians and data experts, outcomes researchers, and patient advocates. These experts came from the life sciences industry, major health plans, academic medical centers, and community clinical practices, among other organizations.

Improving Late Phase Studies for Type 2 Diabetes EGD

GPC’s Endocrine-Metabolic Diseases Working Group produced an EGD on Patient Reported/Centered Outcomes in Late Phase Drug Studies in Type 2 Diabetes in July 2014. The EGD provides guidance for improving the design, conduct, and reporting of these studies (both pre- and post-approval). Prospective clinical study design recommendations reflect payers’ evidentiary expectations, as well as the perspectives of patients, clinicians, and other decision makers. The recommendations cover four major areas: population, outcomes, methods, and reporting for patient stakeholders. A manuscript based on the EGD is in preparation for publication.

Helping to Build 21st Century Cures

In January 2015, the Energy and Commerce Committee’s Subcommittee on Health introduced a draft of the 21st Century Cures Act, a bipartisan bill proposing changes to how drugs and devices are regulated and approved. This bill is the result on nine months of discussion, including more than 20 roundtables and congressional hearings. Sean Tunis was asked to provide testimony to the committee in May 2014 where he emphasized that new approaches are needed to accelerate biomedical innovation.

The legislation includes dozens of proposals to encourage innovation, including provisions that encourage new models of approval for drugs and devices. This includes increased use of accelerated approval, approvals for limited populations (based on smaller data sets with indications for specific subgroups), and adaptive approvals (which allow for evidence generation across the life cycle of a drug, granting approvals in expanded patient populations as additional evidence is collected.)

The discussion draft of the bill is an early proposal intended to generate further debate. GPC will remain vocal in its support of effective new models for coverage with evidence development as the draft moves into legislation.
GPC TIMELINE

2013

05.01 - GPC-USA launch meeting
06.14 - Donna Messner named Oncology Consortia Lead
09.19 - Inaugural Meeting of Oncology Consortium, EGD topic selected (sequence and timing of oncology therapies)
10.23 - Inaugural Meeting of Endocrine-Metabolic Diseases Consortium; EGD to focus on patient centered outcomes in diabetes
11.12 - First Annual Meeting of GPC USA
12.16 - Technical Working Group for diabetes EGD convenes
03.26 - Technical Working Group for EGD on sequence and timing of oncology therapies convenes

2014

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Advisory Committee — Ex Officio

- **David Atkins, MD, MPH (SES EQV)** — Department of Veterans Affairs
- **Tanisha V. Carino, PhD** — Avalere Health
- **Patrick H. Conway, MD, MSc** — Centers for Medicare and Medicaid Services
- **Rachael L. Fleurence, PhD** — Patient-Centered Outcomes Research Institute (PCORI)
- **Jason Gerson, PhD** — Patient-Centered Outcomes Research Institute (PCORI)
- **Grant D. Huang, MPH, PhD** — Department of Veterans Affairs
- **Michael S. Lauer, MD, FACC, FAHA** — NHLBI DCVS
- **Peter Marks, MD, PhD** — Food and Drug Administration
- **Jeffrey Roche, MD** — Centers for Medicare and Medicaid Services
- **Murray Sheldon, MD** — Food and Drug Administration
- **Tamara Syrek Jensen, JD** — Centers for Medicare and Medicaid Services
- **Robert Temple, MD** — Food and Drug Administration

**Guidance for Treatment Switching in Clinical Trials**

Planned for late 2015, GPC will host a workshop to explore the topic of treatment switching in the design and analysis of oncology trials. This event will be a follow-on to the efforts of Bellberry, an Australian nonprofit, that first explored the issue at a 2014 congress in Adelaide, Australia. Hosted in collaboration with Bellberry, the workshop will address key issues first identified at the Australia meeting within the context of a North American health care system, and will also work toward consensus on optimal approaches to managing treatment switching in oncology trials. A range of stakeholders will participate, including patients and patient advocates, representatives from payers, health systems, the pharmaceutical industry, FDA, clinical guideline and compendia developers, health technology assessors, researchers and others. The meeting will kick off a nine to 12 month process leading to an Effectiveness Guidance Document with specific recommendations on managing treatment switching in the design, conduct, analysis, and reporting and assessing evidence in oncology drug trials when treatment switching has occurred.

**Annual Meeting**

The 2015 GPC Annual Meeting will take place on April 30th, in Baltimore, Maryland; a welcome reception will be held the evening before. All GPC members are welcome to attend. The Annual Meeting will focus on three high-value topics: Coverage with Evidence Development (CED); Real World Evidence (RWE); and Core Outcome Sets for Clinical Research. These topics will be explored through panel discussions and short presentations that will highlight recent developments within each field, and promote discussion surrounding associated issues and challenges. This dialogue will help determine the roadmap for GPC activities for 2015 and beyond.
About GPC

GPC, a major initiative of the Center Medical Technology Policy, is a multi-stakeholder forum that was established to guide the generation of clinical evidence needed to better inform healthcare treatment and coverage decisions in the United States. GPC members include a diverse mix of payers, life sciences companies, patients, clinicians, researchers, and regulators. GPC convenes working groups to develop condition and technology-specific study design recommendations that focus on real-world effectiveness and value, meet the evidence expectations of payers, and are informed by the views of patients and clinicians. Participation is by invitation only.

About the Center for Medical Technology Policy

CMTP is an independent, non-profit 501(c)(3) organization that aims to make health care more effective and affordable by improving the quality, relevance, and efficiency of health care research. CMTP focuses on the design and implementation of comparative effectiveness research to produce information that helps patients, clinicians, and payers make informed treatment and policy decisions. CMTP provides a trusted forum in which a broad range of stakeholders can collaborate to identify important research questions, design appropriate studies, and develop innovative partnerships to implement these studies.