Overview

To initiate our accelerated effort to develop targeted funding announcements, PCORI staff reviewed existing research from multiple sources to identify gaps in comparative effectiveness research (CER), obtaining 488 topics and questions. We reviewed and ranked these topics, applying balancing criteria, and presented 11 topics to PCORI’s Program Development Committee for approval. In December 2012, PCORI’s Board of Governors approved the topic of obesity treatment options in diverse populations as one of five topics for potential development into a PCORI Funding Announcement (PFA).

On April 16, 2013, PCORI convened an ad hoc workgroup meeting on obesity treatment options in diverse populations in Washington, DC, to gain a multifaceted perspective on high-priority research topics, identify critical gaps in research, and distinguish research topics with the potential to produce long-lasting, high-impact results. The ad hoc workgroup included patient advocates, researchers, stakeholders, and other webinar guests. Public comment was welcomed prior to, during, and after this meeting.

The workgroup discussed five themes and over 40 research gaps (see Table 1 at the end of this summary) that contribute to disparities in obesity treatment. Using a consensus-based process, the workgroup then identified the following four key research gap areas in obesity treatment options in diverse populations: (1) communication, (2) healthcare systems/integration of care, (3) effectiveness of treatment options, and (4) behavior.

These topics will be presented to PCORI’s Board of Governors for approval to potentially develop funding announcements in one or more of the research gap areas.

Approximately 65% of the US adult population is overweight (BMI ≥ 25) and 30% are obese (BMI > 30).

Non-Hispanic African Americans have the highest rates of obesity (49.5%) compared with Mexican-Americans (40.4%), all Hispanic people (39.1%), and non-Hispanic Whites (34.3%).

Almost 17% of US children and adolescents are obese.

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions.

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1 Available at pcori.org/about-the-accelerated-process
Background

PCORI is interested in identifying research questions that evaluate important choices faced by patients and that have a good chance of providing evidence that can reduce uncertainty, support decision making, change practice, and improve patients’ health outcomes. PCORI views these gaps in the evidence base on obesity treatment options in diverse populations as an area where we can contribute to improving health outcomes.

Obesity prevalence in the United States, among both adults and children, has increased to epidemic proportions over the past 30 years. Based on body mass index (BMI) guidelines, approximately two-thirds of adults are considered overweight (BMI between 25.0 and 29.9) or obese (BMI of 30.0 or higher). Disparities in rates of obesity exist. For example, African Americans, Hispanics, and Native Americans have disparately higher prevalence of obesity than their White counterparts. For additional information, please see Opportunity Snapshot: Obesity Treatment Options in Diverse Populations. Although the society, individual, and healthcare burden of obesity has been well-documented, little progress has been made on the identification of effective long-term obesity prevention and treatment strategies.

In December 2012, PCORI’s Board of Governors approved the topic of obesity treatment options in diverse populations as one of five topics for potential development into PCORI Funding Announcements. To learn more about the process followed to select these topics, see Summary of Accelerated Process to Generate Targeted PCORI Funding Announcements.

PCORI convened an ad hoc workgroup to help identify research gaps and questions in this topic area. The workgroup participants represented diverse perspectives, including researchers, patient advocates, other stakeholders, and PCORI science and engagement staff. See a list of participants and detailed biographies. For more on the workgroup selection process see Methodology for Selecting Workgroup Members for Obesity Treatment Options in Diverse Populations.

Meeting Summary

The workgroup meeting began with an opening, introduction of meeting participants, and overview of targeted PCORI funding announcements from Dr. Romana Hasnain-Wynia, Director of PCORI’s Addressing Disparities Program. The moderator of the workgroup, Dr. William Dietz, former Director of the Division of Nutrition, Physical Activity, and Obesity at the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention, presented an overview of current obesity prevalence data in the United States, as well as disparities in obesity prevalence and outcomes among diverse populations. Dr. Dietz also presented information from “Obesity Education for the 21st Century” and highlighted three critical areas for improvement in obesity treatment research: (1) changing the delivery model to include multidisciplinary teams versus one-on-one patient-physician interactions; (2) improving the delivery of care by making it more cost-effective

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2 Available at pcori.org/funding-opportunities/funding-announcements/obesity-treatment-options-in-diverse-populations/#snapshot
3 Available at pcori.org/assets/PCORI-Accelerated-Process-to-Generate-Targeted-Funding-Announcements.pdf
4 Available at pcori.org/assets/PCORI-Obesity-Treatment-Options-Workshop-Participants-041613.pdf
5 Available at pcori.org/assets/PCORI-Obesity-Treatment-Options-Workgroup-Biographies-041613.pdf
6 Available at pcori.org/assets/PCORI-Accelerated-PFA-Methodology-Workgroup-Treatment-Options-Obesity1.pdf
and accessible; and (3) training physicians to address obesity, including focus on behavior change, community-based interventions, and more effective healthcare strategies.

**Research Presentations**

Following the moderator’s presentation, workgroup participants presented their perspectives on obesity-related topics. These are summarized below and available here.  

- **“Obesity Prevention” by Alice Ammerman, DrPH, RD, Professor, Department of Nutrition, University of North Carolina**

Research suggests that the integration of technology with public health efforts has helped with achieving substantial weight loss. To build on these successes, the role of properly trained healthcare providers as advocates for the use of technology in obesity treatment strategies will be critical. In addition to innovative technological strategies, another way to encourage healthy behaviors is to use upstream influences. For example, South Carolina has a program where physicians are able to write prescriptions for patients to receive vouchers on fruits and vegetables purchased at farmers’ markets. This is one example of a local initiative to encourage healthy eating. On a more widespread scale, there are ongoing activities to address obesity, including policy improvements, family-based obesity prevention and treatment education, exercise promotion, and programs for challenging social norms to create environments that influence patients to make healthier decisions.

- **“Eat Smart, Move More” by H. Vondell Clark, MD, MPH, AIM-HI Advisory Panel Member, American Academy of Family Physicians**

Research focused on obesity treatment should involve three critical areas for improvement: life priorities, home education, and the larger community. To overcome obesity, the medical industry should increase its focus on identifying ways to move the medical community away from responding to obesity-related conditions as a primary treatment strategy to the active engagement in the treatment of obesity itself. Another place where a shift in focus could make a difference in outcomes is in focusing on changing the environment rather than trying to change patient behaviors. Changing the environment may help maximize benefits of obesity treatment strategies. There is a need to better understand the factors of change, including identifying specific facilitators and barriers to patients’ healthy behaviors, such as eating and exercise. Healthcare providers must spend time to understand those things that a patient is or is not willing to give up. Determining a patient’s value system, perhaps with the use of a tool or instrument, to understand the best treatment options for each patient may be beneficial in obesity treatment.

- **“Let’s Move” by Nicole Dickelson, MPH, Office of Minority Health Representative for Let’s Move!**

The US Department of Health and Human Services (DHHS) is interested in addressing the prevalence of obesity in the United States. One initiative in which DHHS is involved is the First Lady of the United States Michelle Obama’s “Let’s Move” campaign, which has the goal of reducing childhood obesity. The DHHS also has partnerships with a network of providers and community health workers that have been effective in delivering care in diverse populations. Understanding that many individuals receive their primary care in community-based settings, DHHS has dedicated significant focus to community-based

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7 Available at pcori.org/assets/PCORI-Obesity-Treatment-Options-Workgroup-Presentations-041613.pdf
and faith-based interventions. For example, the Center for Faith and Community-Based Partnerships reported that, in some communities, people are more receptive to messages received from community or faith-based leaders, rather than messages from a physician. Some patients also feel more comfortable with practices that include faith-based models, rather than traditional medical models of health care.

- **“Bariatric Surgery” by Ninh Nguyen, MD, Chief, Division of GI Surgery, University of California, Irvine**

More attention should be focused on comorbidities that occur with obesity, such as hypertension and diabetes, rather than treating the obesity itself. For example, when an obese patient requests medical advice from a physician, the physician may treat the patient’s diabetes, but fail to adequately address the cause or mediator of the diabetes (i.e., the obesity). Furthermore, a review of medical websites relating to obesity shows that the sites mention the management of hypertension and glucose, but lack information and guidance on obesity treatment options. The medical community must identify the best interventions to address those with severe obesity, including medical management, lifestyle modifications, and surgical procedures, as well as understanding the patient characteristics that indicate a particular intervention should be implemented. Obesity-related surgery has been a medical option for the past 50 years. There have been many improvements in procedures, such as minimizing the invasiveness and reducing recovery time for these surgeries. These improvements have resulted in increases in surgical obesity treatment procedures. In 1998, the number of procedures performed was approximately 10,000; however, today over 150,000 operations are performed each year, with the most common being the gastric band procedure and gastric bypass surgery. Despite a significant increase in the number of surgeries, there remain disparities in the effectiveness and outcomes, such as: (1) higher complication rates among African-Americans post-surgery; (2) less effectiveness among men than among women; and (3) greater initial weight loss, but less weight maintenance in African-Americans compared to their White counterparts.

- **“Medical Weight Management” by Donna Ryan, MD, FACP, Professor Emeritus, Pennington Biomedical Research Center**

The topic of weight loss is becoming increasingly popular in the pharmaceutical, device, and counseling industries. Overall, there is more movement towards weight management and helping primary care physicians better inform and work with patients to achieve weight loss. To address obesity, primary care physicians must be more in tune with patients, which means having a better understanding of their current health and lifestyle behaviors, and being able to effectively communicate the benefits and procedures to achieve weight loss. Effective motivating messages that primary care physicians can use to help their patients achieve weight loss require testing with focus groups to judge perception and overall patient satisfaction among diverse populations.

Developing tools to support obesity treatment is also essential to improving outcomes in diverse populations because physicians often have limited time to provide counseling and training to patients to achieve weight loss. Training may only be best achieved by educating physicians, as well as partnering with commercial and community programs such as YMCA or faith-based groups. When this type of model is established, technology must be implemented so that data systems can be linked to electronic health records (EHR) in primary care facilities. Another way to improve outcomes in obesity treatment may be to develop incentives for individuals’ long-term weight management.
Family-centered outcomes of childhood obesity treatment have not been incorporated into medical practice. The widespread use of mobile technologies could potentially be leveraged to promote family involvement in childhood obesity treatment. Primary care settings are often ill-equipped to deal with the multifactorial condition of childhood obesity. Currently, the most practiced model for managing childhood obesity and the associated mediators, such as social, cultural, and contextual issues, revolves around BMI and weight maintenance, rather than parent- and child-centered concerns such as keeping up in fitness class, improving self-esteem, reducing bullying, and fitting into clothes. Quality of life and mental health are some of the more family-centered outcomes that may be improved by the introduction of new, innovative treatments for childhood obesity.

Lifestyle interventions to combat obesity include improving diet, increasing exercise, and other behavioral modifications to improve health. An important note is that modest weight losses can have a significant impact on a patient's health status, including improvement in diabetes control. The medical community should dedicate resources to understand the reasons that patients do not access available treatment options, with the goal of reducing the barriers to the treatment options. For example, if transportation to a facility is a barrier, providing transportation may improve patient behaviors. It may be effective for physicians to refer patients to community-based weight-loss programs, such as the YMCA, or to other reputable programs available through the Internet to achieve weight loss. These resources could be used to motivate and educate the patient, while clinicians can monitor and encourage patients to continue best practices during appointments.

The medical community should place more focus on training physicians to understand the physiological, environmental, and psychological aspects of weight loss and weight gain to improve weight maintenance. Physical activity is critical, so the medical industry must determine how to focus on long-term programs and methods to keep patients engaged. An often overlooked opportunity is treating obesity during critical times where weight gain may be more prevalent, such as before, during, and post pregnancy. Understanding and implementing interventions to ameliorate excessive weight gain surrounding pregnancy may potentially have a positive effect on reducing the burden of obesity across generations.

Patients make trade-offs between benefits and risks of their behaviors. Using an interactive website that takes patient data and provides information on how weight has implications for other health outcomes could help patients make more informed decisions about treating their obesity. Customized patient assessments, telemedicine options, and tools to assist with patient decision making are necessary to improve outcomes in obesity.
Ted Kyle, BS Pharm, MBA, The Obesity Society

Obesity is often neglected as a health condition by both patients and physicians, until obesity-related illnesses emerge. Healthcare providers need to help patients adopt behaviors that encourage weight loss, rather than merely telling patients to “lose weight.” Substantial, customized, or evidence-based methods for losing weight are not usually communicated. In addition, healthcare providers need to be more aware of biases against obesity and develop ways to reduce those biases. The medical community should develop tools to improve obesity education and dispel myths regarding obesity treatments.

“Payers Viewpoint” by Eliza Ng, MD, MPH, America’s Health Insurance Plans

Obesity is associated with many diseases, especially cardiovascular disease. One ongoing challenge to obesity treatment has been the healthcare payment system, which may not cover some obesity treatments. With recent healthcare reform, there may be new opportunities for engagement of populations (e.g., value-based insurance design, which provides coverage for interventions for the most appropriate population). Patients also need to engage in behaviors that promote a healthy weight.

“Pharmacotherapy for Obesity” by Gary Palmer, MD, MBA, Eisai Pharmaceuticals

BMI is often used by physicians as an indicator of obesity. BMI is not always the best tool to characterize the status of specific patients. Therefore, physicians should explore alternative methods to detect obesity, as well as to highlight associated cardiovascular risk factors, including hypertension.

“Bariatric Surgery” by Sajani Shah, MD, Covidien

As a surgeon conducting bariatric operations over the past six years, I see patients who are interested in obesity treatments other than surgery. I have 90 minutes with patients to discuss reasons they are seeking surgery. Typically, patients seeking bariatric procedures have tried some sort of medical or lifestyle-based weight-loss program. However, by the time patients reach my office, they have a BMI over 40, with additional comorbidities, including diabetes. A challenge in the healthcare community is determining how to encourage primary care physicians to discuss obesity-related issues with their patients, including referring patients to medical or surgical weight-loss programs if their BMI is high. Primary care physicians are often not convinced that surgical procedures are the best treatment option, due to side effects of surgery. In addition, physicians must understand how African-American and Hispanic women perceive body image, which may be different than their White counterparts, and take that into account when presenting weight-loss options.

Joann Donnelly, MA, BCC, YMCA of Greater Boston

The YMCA has implemented several diabetes and obesity prevention programs including family-based interventions. The YMCA setting has been conducive to obesity treatment programs because people feel comfortable going to a place that does not resemble a medical setting. The YMCA weight-loss initiatives have found that: (1) patient perception is important in obtaining good outcomes; patients who feel judged for being overweight may not respond to treatment; (2) cultural and language barriers between providers and community members from diverse backgrounds must be overcome for obesity treatment to be effective; (3) healthy behavior coaching can be as effective for families as it is for one-on-one interactions; (4) people will not exercise in their community if violence exists in the neighborhoods;
providing places for people to exercise is important in unsafe communities; and (5) the effects of stress, poverty, and other related environmental factors that contribute to obesity need to be better understood.

- "School-Based Health Care" by Hayley Lofink, PhD, National Assembly on School-Based Health Care

Today, hospitals, federally qualified health centers, health departments, school districts, and other organizations are sponsoring “health clinics” in elementary and middle schools to allow children to access health care more easily. These clinics have been established in urban and rural areas in almost every state in the United States. These health clinics can help to promote healthy behaviors because, by providing care in a comfortable and familiar setting rather than a clinical setting that can induce anxiety, children are more likely to go and receive health care, which could include obesity treatment or prevention. School-based health settings are also a way to engage a robust healthcare team that includes nurses, community workers, and health education workers who can implement programs that promote healthy behaviors. Training the appropriate workforce to deal with obesity prevention and treatment, especially in diverse cultural, economic, and social settings, is needed.

- Karen Miller-Kovach, MBA, MS, RD, Weight Watchers International, Inc.

Weight Watchers is a consumer organization that centers on daily lifestyle choices rather than on obesity as a medical issue. This program also includes an evidence-based weight-loss model and standardized programs. An important aspect of Weight Watchers is that it employs role models to assist with the delivery of community-based programs to promote healthy food options. The medical industry must identify ways to increase adherence to obesity prevention programs, which may include developing new technologies, such as smartphone applications. In addition, to affect obesity outcomes, healthcare providers must determine how to partner with community health workers to provide coaching in clinical settings and to extend care beyond the clinical setting.

- Joe Nadgowski, Obesity Action Coalition

When treating obesity, patients want to know what the best therapy is for their lifestyle, race/ethnicity, demographic, or other social aspect. These aspects are important to identify the appropriate treatment options based on the patient’s unique need. Another area requiring attention includes comorbidities. A lot of focus has been placed on non-insulin patients, but the medical industry must also determine what support can be provided to diabetic patients who are insulin-dependent. Today, there are also a number of fee-for-service programs that may help motivate patients to make healthier and better decisions because they are sharing the costs.

- Webinar Participants

Webinar participants were able to present questions and comments during the meeting. The following is an overview of the comments received from the webinar participants:

- Sources of support for patients during their obesity treatment process
- Culturally sensitive and effective obesity interventions for diverse populations
- Critical periods for obesity intervention (e.g., pregnancy)
• Roles of incentives to improve patient adherence to obesity treatment and improve engagement
• Comprehensive obesity medical management programs
• Roles for non-physician practitioners or community health workers to assist with obesity treatment programs. (e.g., community-based support groups for fitness and wellness)
• Use of a patient-centered approach to obesity treatment including consideration of cultural challenges to access, adherence, and effectiveness of weight-management programs.

Action

The workgroup followed a two-step process to narrow broad research ideas into a concise list of well-defined high-priority research questions for potential PCORI funding:

**Step 1: Identify Priority Areas of Interest**
Workgroup participants and the public provided over 40 research and information gaps across five main topic areas listed below:

- Communication
- Integration of care
- Healthcare systems
- Effectiveness of treatment options
- Behavior

**Step 2: Narrow List of Research and Information Gaps and Tailor Questions**
From the broad list of identified research and information gaps, the workgroup narrowed down the list of research and information gaps and developed questions that PCORI could address through comparative effective research. The narrow list of research and information gaps is available here.⁸

Next Steps

The topics identified during the targeted workshop will be presented to PCORI’s Board of Governors for potential approval of a targeted funding announcement in obesity treatment options in diverse populations.

*Meeting summary prepared by Romana Hasnain-Wynia, Cathy Gurgol, and Amy Grossman. Posted June 6, 2013, and available on PCORI’s website.*⁹

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⁸ Available at pcori.org/assets/PCORI-Obesity-Treatment-Options-Workshop-TopTopics-041613.pdf
⁹ Available at pcori.org/events/targeted-pfa-workgroup-webinar-obesity-treatment-across-diverse-populations/?type=past
### Table 1: Compiled Research Questions/Gap Areas

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<th>Obesity Treatment Options in Diverse Populations</th>
<th>Prioritized Research Questions/Gap Areas</th>
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| **Communication**                               | ▪ Compare innovative approaches (e.g., communication tools, decision-support tools, links between PCP and community resources that promote healthy behaviors) to effectively implement weight-loss interventions in physician offices that improve prevention/treatment outcomes for: (1) childhood obesity and (2) targeted populations: rural, racial/ethnic groups, males/females  
▪ Compare mobile/remote (telehealth) applications or smartphone apps used to prevent/treat obesity |
| **Healthcare Systems**                          | ▪ Can scalable systems linked to the PCP EHR deliver lifestyle intervention counseling as part of the PCP visit?  
▪ How do we design interventions around social/contextual issues that may influence obesity (poverty, violence, neighborhoods), and what type of training do people need?  
▪ Which obesity interventions that take into account different racial/ethnic cultures are best? Should interventions be delivered by PCP, dietician, nurse, trained interventionist, psychologist, other? Should interventions be provided in medical home, community, clinic, etc.? Effect of culturally selected provider?  
▪ Are there clinical and behavioral interventions that can be introduced in school-based health center settings to address the needs of racial and ethnic minority children and adolescents residing in settings where there are significant social and environmental barriers to overall wellness, healthy living, and physical activity? Effectiveness of treating obesity without the presence of risk factors or comorbid conditions  
▪ Development and validation of population measures to demonstrate changes or impact on quality of life and other patient-reported outcomes that would help to increase the research devoted to obesity and increase the motivation to reimburse interventions to reduce obesity  
▪ How can we minimize the impact of weight bias in considering the treatment needs of diverse populations with obesity?  
▪ What systems can be put in place for patients to be able to make more informed decisions about bariatric surgery, medical management, other options for obesity treatment?  
▪ How can we develop and deploy a public health workforce capable of treating the complexity and scale of obesity? How can we build a more diverse workforce that utilizes nurses, nurse practitioners, community health workers, and health educators to deliver childhood obesity prevention and weight-management programs?  
▪ Should we be looking to develop and use more sophisticated criteria to characterize obese individuals that help to “medicalize” the condition and differentiate the potential associated health risks? Are there other frameworks that are available or can be developed to produce a spectrum for the disease and include consideration of impact on health and functioning? Alteration of obesity from a risk factor for other diseases to establishing obesity as a disease or condition recognized by the medical community. |
### Integration of Care
- Can we improve patient outcomes by providing readily available community-based services (such as the YMCA) to manage obese patients?
- How effective are family-based and/or faith-based obesity treatment programs?
- In what areas of life (home, school, community,) do most families find the most difficult challenges to making the healthy choice the easy choice? The logical extension from a behavioral economics perspective would be, “What is the evidence base to support healthy defaults in those settings?”
- Compared to usual glucose-centric diabetes management, can weight-centric medical management produce durable type 2 diabetes remission in OW/OB?

### Effectiveness of Treatment Options
- Comparative effectiveness of efficacy between surgical and non-surgical treatment of obesity and targeted population
- Pharmacological research: comparative effectiveness and safety of the various treatment options, pharmacological treatments as adjunct vs. stand-alone treatment. Which obesity treatment modality (behavioral, pharmaceutical, holistic, surgical, and staged) is the best for a specific patient classified by demographics, socioeconomic status, age, gender, comorbidities?
- Does adherence to Mediterranean diet improve health outcomes in Hispanic population in the US-Mexico border?
- What is the best way to treat obese asthmatics—pharmacological and/or lifestyle modifications?
- Will obesity treatment (efforts to help quickly bring BMI to within normal limits) for obese triple negative breast cancer survivors at high risk of recurrence reduce risk of breast cancer recurrence?
- HIV-infected people now suffer from obesity (not wasting), and it may be due to inflammation, behavioral, anti-HIV medications, co-infections. Is HIV-associated obesity a targeted topic? Existing treatments for obesity (calorie restriction, physical activity, gastric bypass) have not been studied in HIV, so their safety and effectiveness are unknown in HIV
- What obesity treatment modality is most effective for patients with specific comorbidities/condition related to obesity, especially if their condition requires medication associated with weight gain?
- What is the best intervention to improve cardiovascular risk factors (dyslipidemia and HTN), type 2 DM, and sleep apnea in severely obese subjects (BMI > 35) with dyslipidemia, HTN, DM, or sleep apnea randomized to medical management with lifestyle modification compare to medical management with lifestyle modification and bariatric surgery (sleeve or bypass)
- What is the best intervention to optimally control type 2 DM in obese patients (BMI 30–40) with type 2 DM on medications: diabetes support with lifestyle modification compared to diabetes support with lifestyle modification and bariatric surgery (sleeve or bypass)?

### Behavior
- How do we reduce the high rates of non-adherence to traditional behavioral weight-management programs?
- Compare innovative approaches for maintaining weight-loss achievements after a lifestyle intervention
- Determine barriers and compare innovative approaches to increase participation of diverse populations in effective weight-loss programs
- Compare weight-gain prevention interventions at the time of pregnancy to break the vicious cycle of obesity transmission to the next generation