Board of Governors Meeting
via Teleconference/Webinar

August 18, 2015
12:00-1:30 p.m. ET
Welcome and Introductions

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Joe Selby, MD, MPH
Executive Director
## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
</tr>
</thead>
</table>
| 12:00-12:05  | Call to Order, Roll Call, and Welcome  
               Consider for Approval: Minutes of July 21, 2015 Board Meeting                         |
| 12:05-12:20  | Consider for Approval:  
               Slate of PCORnet Obesity Demonstration Awards                                             |
| 12:20-12:35  | Consider for Approval:  
               Slate of Winter 2015 Large Pragmatic Studies Awards                                      |
| 12:35-1:20   | Consider for Approval:  
               • Treatment-Resistant Depression  
               • Long-term Opioid Treatment for Chronic Pain  
               • New Oral Anti-coagulants                                                                |
| 1:20-1:25    | Annual Meeting Update                                                                        |
| 1:25         | Wrap Up and Adjournment                                                                        |
Board Vote

Call for a Motion to:
• Approve the July 21, 2015 Board Meeting Minutes

Call for the Motion to Be Seconded:
• Second the Motion
  • If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Voice Vote:
• Vote to Approve the Final Motion
  • Ask for votes in favor, opposed, and abstentions
PCORnet Obesity Observational Research Initiative Awards

Joe Selby, MD, MPH
Executive Director

Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure
Project Development

• Topic generation and prioritization was coordinated through the PCORnet Obesity Task Force and included input from the PCORnet community, patients and stakeholders in the target population, outside experts, obesity experts, and observational researchers.

• Two topics were prioritized by the Obesity Task Force and sent to the Advisory Panel on Disparities for comment and approval:
  • Comparative effectiveness of bariatric surgery interventions
  • Comparative effectiveness of alternative antibiotics on weight outcomes in pediatric populations

• PFA development was approved by the Science Oversight Committee on January 6, 2015

• Both topics were approved by the Board for PFA development on January 27, 2015
Goals of the PFA

There were three main goals of the limited PFA:

1. **Support research on important unanswered clinical questions** faced by patients and their clinicians using PCORnet’s Distributed Research Network and associated processes and programs.

2. **Test and evaluate the capacity of PCORnet’s data infrastructure** and report on the readiness of PCORnet’s data infrastructure for observational research.

3. Provide an opportunity for PCORnet investigators, patients and stakeholders **to organize and collaborate in a multi-site study** and develop efficient, collaborative processes for doing so.
Review Criteria

- The following criteria were used to evaluate the submitted applications:
  1. Technical merit
  2. Patient-centeredness
  3. Patient and stakeholder engagement
  4. Infrastructure testing and evaluation plan
Application Review

- Application underwent rigorous technical and merit review
- Application was reviewed by a panel of external merit reviewers including patients, researchers, and other stakeholders
- Following PCORI process, additional information was requested from applicants based on concerns and questions raised in merit review
- An Advisory Panel on Clinical Trials subcommittee comprised of merit review panelists, Methodology Committee members, and other experts has been formed to advise PCORI in protocol refinement and monitoring the trial on an as needed basis
## Slate Summary

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Total Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bariatric Study</td>
<td>$4,499,999</td>
</tr>
<tr>
<td>Short- and Long-term Effects of Antibiotics on Childhood Growth</td>
<td>$4,499,142</td>
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</tbody>
</table>
Study Aims:

1. To what extent does weight loss and regain differ across three bariatric surgical procedures: Roux-en-y gastric bypass, adjustable gastric banding, and sleeve gastrectomy at 1, 3, and 5 years?

2. To what extent do these bariatric procedures differ on improvements in diabetes risk at 1, 3, and 5 years?

3. What is the frequency of major adverse events following these three different bariatric surgical procedures at 1, 3, and 5 years?
 Obesity Observational Research Initiative  
*Short- and Long-term Effects of Antibiotics on Childhood Growth*  

**Study Aims:**

1. Compare the effects of different types, timing, and amount of antibiotic used in the first 2 years of life on body mass index (BMI) and risk of obesity at ages 5 and 10 years.

2. Compare the effects of different types, timing, and amount of antibiotic used in the first 2 years of life on the rates and patterns of childhood growth during first 5 years of life.

3. Explore how the effects of different types, timing, and amount of antibiotics on childhood BMI, obesity risk, and growth vary according to patient socio-demographic, clinical, and maternal characteristics.
## Slate Overview: Obesity Observational Research Initiative

<table>
<thead>
<tr>
<th>PFA</th>
<th>Announced</th>
<th>Proposed Total Budget*</th>
<th>Average Project Budget*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity Observational Research Initiative</td>
<td>$9,000,000</td>
<td>$8,999,141</td>
<td>$4,499,570</td>
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</table>

*Total budget = direct + indirect costs

All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.
Call for a Motion to:

- Approve funding for the recommended slate of awards for the PCORnet Obesity Observational Research Initiative PFA

Call for the Motion to Be Seconded:

- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Large Pragmatic Studies to Evaluate Patient-Centered Outcomes
Winter 2015 Cycle Award Slate

Christine Goertz, DC, PhD
Chair, Winter 2015 Selection Committee

Bryan Luce, PhD, MBA
Chief Science Officer
Winter 2015 Pragmatic Studies
Cycle Overview and Slate
Recommendation
Winter 2015 Pragmatic Studies PFA

• Goal of PFA:
  • Fund pragmatic clinical trials, large simple trials, or large-scale observational studies that compare two or more alternatives for
    – Addressing prevention, diagnosis, treatment, or management of a disease or symptom
    – Improving health care system-level approaches to managing care
    – Eliminating health or healthcare disparities
  • Up to $10M in direct costs and up to 5 years duration
  • Funds available up to $90M total costs
Winter 2015 Pragmatic Studies

Merit Review Criteria

1. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
4. Patient-centeredness
5. Patient and stakeholder engagement
Slate Overview – Winter 2015 Pragmatic Studies

Process Overview

• 132 Letters of Intent (LOIs) submitted and reviewed
  • 32 LOIs invited to submit full application (24% of all LOIs)
  • 24 applications submitted (75% of invited) and reviewed at Merit Review

• Convened post-Merit Review methodology consultation panel with the assistance of our Methodology Committee and Advisory Panel on Clinical Trials

• We are proposing to fund 4 projects
# Winter 2015 Pragmatic Studies Funding Slate

4 Recommended Projects*

<table>
<thead>
<tr>
<th>Project Title</th>
<th><strong>1, 3</strong></th>
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<tbody>
<tr>
<td>Comparing Outcomes of Drugs and Appendectomy (CODA)</td>
<td></td>
</tr>
<tr>
<td>Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural Federally Qualified Health Centers (FQHCs)</td>
<td><strong>1, 3</strong></td>
</tr>
<tr>
<td>Comparative Effectiveness of Pulmonary Embolism Prevention after Hip and Knee Replacement (PEPPER): Balancing Safety and Effectiveness</td>
<td><strong>2</strong></td>
</tr>
<tr>
<td>Integrating Behavioral Health and Primary Care</td>
<td><strong>1, 3</strong></td>
</tr>
</tbody>
</table>

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

** 1: PCORI Priority; 2: IOM CER 100; 3: AHRQ Future Research Needs—priority areas are not mutually exclusive
Project #1
Comparing Outcomes of Drugs and Appendectomy (CODA)

Research Question

- Is the use of an antibiotics-first approach "as good as" an appendectomy for treating uncomplicated appendicitis?

Study Design/Sample Size/Population

- RCT with a parallel observational cohort; 1,552 adults presenting with a diagnosis of uncomplicated appendicitis (CT, ultrasound, or MRI confirmed) at 10 practice sites in a state’s CER Translation Network

Outcomes

- Primary: Rates of subsequent appendectomy in the “antibiotics first” arm, and the patient’s experience with appendicitis and its treatment using the European Quality of Life-5 Dimensions instrument at 90 days
- Secondary: Gastrointestinal quality of life index, PROMIS, Global Health Short Form, Decision Regret Scale; signs, symptoms, and safety events related to appendicitis

Total Budget: $12,911,011
Project #1 (cont.)
Comparing Outcomes of Drugs and Appendectomy (CODA)

• Engagement
  • Patient advisory network, partnerships with 2 national clinical specialty groups, engaged leadership of major insurance companies (commercial insurers as well as Medicaid and Medicare)

• Potential Impact
  • The project will provide accurate estimates of the comparative effectiveness of antibiotic therapy for acute appendicitis. It also will provide new evidence about recurrence of symptoms in patients who do and do not undergo appendectomy. This information will help to guide decision making by patients and their providers.
Project #2
Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural Federally Qualified Health Centers (FQHCs)

• Research Question
  • What is the comparative effectiveness of a tele-psychiatry, collaborative care intervention versus a tele-psychiatry, enhanced referral program for individuals with complex psychiatric disorders?

• Study Design/Sample Size/Population
  • Adaptive randomized trial; 1,000 patients (post-traumatic stress disorder (PTSD) only, bipolar disorder only, and combined PTSD and bipolar disorder); Community health center patients from rural and underserved areas who report symptoms of PTSD and/or bipolar disorder

• Outcomes
  • Primary: Patient self-reported health-related quality of life
  • Secondary: Access to care, therapeutic alliance with providers, patient activation, satisfaction with care, appointment attendance, medication adherence, self-reported clinical symptoms, medication side-effects, and progress towards life goals
Project #2 (cont.)
Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs

- Total Budget: $11,776,419
- Engagement
  - Study developed in partnership with patients and providers at community health centers as part of Academic Community Implementation Partnership and the Mental Health Integration Program
  - The Consumer Advisory Board of the study includes: 5 patients with PTSD or bipolar disorder, and 3 staff from consumer advisory groups and the Policy Advisory Board (comprised of national organizations)
- Potential Impact
  - Help make decisions between the two main interventions where remote mental healthcare integrated into FQHCs is expected to have greater reach, but lower effectiveness and referral to tele-psychiatry is expected to have lower reach, but greater effectiveness
  - Improve health-related quality of life for community health center patients and reduce health disparities across rural America
Project #3
Comparative Effectiveness of Pulmonary Embolism Prevention after Hip & Knee Replacement (PEPPER): Balancing Safety & Effectiveness

• Research Question
  • After total hip and knee replacement, what is the clinical effectiveness of three commonly used regimens to prevent venous thromboembolism (blood clots) and death: uncoated aspirin, or low intensity warfarin, or rivaroxaban? Are any of these three regimens preferable for improving patient-reported outcomes and safety due to fewer adverse bleeding events and surgical complications such as reoperation, infection, and stiffness arising from wound hematomas?

• Study Design/Sample Size/Population
  • Randomized, non-blinded three group study; 25,000 patients across 25 sites; patients 18 years or older having primary or revision hip or knee replacement

• Outcomes
  • Primary: Aggregate clinical pulmonary embolism/deep vein thrombosis and all-cause mortality
  • Secondary: Bleeding and patient-reported outcomes
Project #3 (cont.)
Comparative Effectiveness of Pulmonary Embolism Prevention after Hip & Knee Replacement (PEPPER): Balancing Safety & Effectiveness

- Total Budget: $13,535,266

- Engagement
  - ~165 senior citizens with advanced arthritis considering hip or knee replacement and a patient advisory board assisted in development of research question, study comparators, outcomes, and engagement strategies. Steering Committee members include patients, stakeholders, and national patient advocacy groups. A data safety monitoring board with patient members and an outcomes assessment committee will be involved throughout the study.

- Potential Impact
  - Study findings could inform and transform the use of therapies to prevent blood clots associated with hip and knee replacement.
Project #4
Integrating Behavioral Health and Primary Care

- **Research Question**
  - Does increased integration improve patients outcomes as compared to simple co-location of providers, improve outcomes?

- **Study Design/Sample Size/Population**
  - Cluster randomized trial; 1,800 patients; adults with both physical and behavioral health problems receiving primary care in private practices, academic medical centers, community health centers, and accountable care organizations

- **Outcomes**
  - **Primary**: Emotional distress (anxiety and depression), fatigue, pain, physical function, sleep disturbance, social participation (via PROMIS-29)
  - **Secondary**: Provider communication and empathy, patient self-management, treatment adherence, utilization, time lost due to disability, disease-specific outcomes
Project #4 (cont.)
Integrating Behavioral Health and Primary Care

• Budget: $18,509,211

• Engagement
  • Patients, advocates, behavioral and primary care providers, and policy makers are represented on the research team
  • Stakeholder advisory group including 3 national clinical specialty groups

• Potential Impact
  • Help health systems determine the added value of integrated behavioral health care over co-located care
  • Improve functional outcomes for people with both physical and mental health conditions
Slate Overview – Winter 2015 Cycle
Pragmatic Studies PFA

<table>
<thead>
<tr>
<th>Pragmatic Studies PFA</th>
<th>Announced</th>
<th>Proposed Total Budget*</th>
<th>Average Project Budget*</th>
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<tr>
<td>Large Pragmatic Studies to Evaluate Patient-Centered Outcomes</td>
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<td>$56,731,907</td>
<td>$14,182,977</td>
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*Total budget = direct + indirect costs

All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.
Board Vote

Call for a Motion to:

- Approve funding for the recommended slate of awards for the Winter 2015 Cycle Pragmatic Studies PFA

Call for the Motion to Be Seconded:

- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Targeted PCORI Funding Announcement Development

Christine Goertz, DC, PhD
Science Oversight Committee Chair

Bryan Luce, PhD, MBA
Chief Science Officer
Pathway to a Funding Announcement

Staff use Tier 1 and Tier 2 review criteria to determine topic eligibility, producing List 1

Science Oversight Committee (SOC) reviews and endorses topics for topic briefs, producing List 2

SOC reviews topic briefs and approves them for Advisory Panel review, producing List 3

Advisory Panel (AP) reviews topic briefs using Tier 3 review criteria, producing List 4

SOC reviews AP results and staff recommendations; endorses topics for further refinement, producing List 5

Staff and SOC use Tier 4 review criteria to assess questions; SOC assigns questions to targeted or Pragmatic Clinical Studies PFA, producing Lists 6 and 7

Board reviews and approves questions for targeted PFA

SOC reviews and approves questions for Pragmatic Clinical Studies PFA

Approved

Approved
Approved Targeted PFAs (List 6)

- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
- Treatment Options in Uterine Fibroids (Administered by AHRQ)
- The Effectiveness of Transitional Care
- Clinical Trial of a Multifactorial Fall Injury Prevention Strategy in Older Persons (Administered by NIA)
- Obesity Treatment Options Set in Primary Care for Underserved Populations
- Optimal Maintenance Aspirin Dose for Patients with Coronary Artery Disease
- Testing Multi-Level Interventions to Improve Blood Pressure Control in High-risk Populations (Administered by NHBLI)
- Clinical Management of Hepatitis C Infection
Targeted PFA Pipeline

• For Board Vote Today
  • Treatment-Resistant Depression
  • Long-Term Opioid Treatment for Chronic Pain
  • New Oral Anticoagulants

• Currently on List 5 – Approved for further Development and Refinement
  • Chronic Low-Back Pain
  • Multiple Sclerosis
  • Integration of Mental Health into Primary Care
  • Diabetes
Treatment Resistant Depression
**Definitions**

**Severe depression** causes considerable agitation, loss of self-esteem and feelings of uselessness and guilt. Symptoms are multiple, disabling, and interfere with functioning in work, school, social, and domestic settings such that they are obvious to others. Patients may suffer from delusions, or hallucinations. Severe depression is a major risk factor for suicide.

**Treatment-resistant depression** is a subset of patients with depression who haven’t responded to two or more adequate courses of antidepressant treatment.
Impact of Major Depression

• An estimated 30.4 million adults (13.9% of the US adult population) suffer from at least one major depressive episode in their lifetime

• Major depression accounts for more than 20,000 suicides each year

• Up to one-third of patients with Major depression do not respond to multiple types of anti-depressant medications
Evidence Gaps

- Pharmacological management
- Behavioral, cognitive, and other psychological therapies
- Specific populations:
  - The frail and physically ill
  - Patients with incurable cancer
  - Children and adolescents
  - African Americans and Hispanics
The workgroup included 36 participants.

Of the 56 questions submitted, staff identified four broad issues for the workgroup to consider:

- Clinical treatment options
- Treatment engagement and adherence
- Access to treatment
- Alternatives to face-to-face treatment
Proposed Research Question

For patients with treatment-resistant depression who haven’t responded to two adequate trials of antidepressant medications, what is the comparative effectiveness of augmentation strategies vs. switching to other treatments?

• **Populations:** Ethnic and racial minorities; comorbid medical or mental illness

• **Interventions:** Antidepressant medications; antipsychotic medications; transcranial magnetic stimulation and other neurological treatments; psycho-behavioral treatments; complementary and integrated therapies

• **Comparators:** Augmentation vs. switching; psychosocial vs. medication

• **Patient-Centered Outcomes:** Short- and long-term patient functioning, quality of life, depression symptoms, wellness, side effects of treatment, possible suicide ideation

• **Project Period:** 3-5 years

• **Settings:** Primary care and specialty mental health settings

• **Research Commitment:** 2-3 studies, up to $30M
Board Vote

Call for a Motion to:
- Approve up to $30M for Treatment-Resistant Depression for development

Call for the Motion to Be Seconded:
- Second the Motion
  - If further discussion, may propose Amendment to the Motion or an Alternative Motion

Roll Call Vote:
- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Long-Term Opioid Treatment for Chronic Pain
Chronic pain, defined as pain lasting longer than 3 months, is extremely common, debilitating, and costly

- Affects more than 100 million Americans

Opioids can be an effective treatment for chronic pain in carefully selected and monitored patients

Concerns about Opioid Use:

- Opioid prescriptions have increased 3-fold over the last 20 years
- In 2013, there were over 16,000 deaths due to prescription opioids
- Opioids are associated with a number of harms including: overdose, abuse, addiction, diversion, sedation, impaired cognitive function, depression, constipation, and nausea
  - Prolonged use of high-dose opioids has been associated with tolerance, abuse, addiction, hormonal effects, and immunosuppression
Evidence Gaps

- Long-term effectiveness of treatment options and dosing strategies:
  - No comparative effectiveness studies of opioids vs. non-opioid therapies (pharmacological or non-pharmacological) for outcomes >1 year
  - Little available evidence on the effectiveness of dose escalation, withdrawal/tapering strategies, short-/long-acting opioids
- Harms and adverse events including misuse and abuse of opioids:
  - No long-term studies examining the comparative effectiveness of strategies for managing patients who abuse prescription opioids
- Risk mitigation strategies:
  - No long-term studies evaluating the effectiveness of risk mitigation strategies for improving outcomes related to over-dose, addiction, or misuse
Summary from the June 9th Multi-stakeholder Workgroup

- The workgroup included 47 participants
- Of the 78 research questions that were submitted by the invited stakeholders, staff identified two categories for the workgroup to consider:
  - Panel 1: Pharmacologic Treatment Options and Dosing Strategies
  - Panel 2: Multimodal Treatment Options, Risk Mitigation Strategies, and Opioid Dependency

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<tr>
<td>Clinicians</td>
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<tr>
<td>Hospitals/system</td>
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<td>Industry</td>
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<td>Policymakers</td>
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<td>Researchers</td>
<td>7</td>
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<tr>
<td>Coalitions</td>
<td>2</td>
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Proposed Research Question 1

Among patients on high-dose long-term opioid therapy, what are the comparative effectiveness and harms of continuing opioid therapy alone vs. opioid therapy plus non-opioid interventions (pharmacological and/or non-pharmacological)?

- **Population:** Patients with chronic non-cancer pain on high-dose, long-term opioid therapy
- **Comparators:** Opioid therapy alone vs. opioid + non-opioid interventions (pharmacological, non-pharmacological options)
- **Outcomes:** Opioid dose reduction, pain control, functional status, health-related quality of life, opioid misuse, safety, mortality, reduction in medical side effects
- **Follow-up:** >1 year
- **Study Design:** Randomized controlled trial
- **Project Period:** 3-5 years
- **Subgroup Analysis:** How does effectiveness vary based on:
  - Patient comorbidities: mental health disorders, past or current substance use disorders
Proposed Research Question 2

Among patients on moderate/low-dose long-term opioid therapy, what are the comparative effectiveness and harms of strategies used to limit dose escalation?

- **Population:** Patients with chronic non-cancer pain on moderate/low-dose long-term opioid therapy
- **Comparators:** Protocols to limit dose escalation vs. standard risk mitigation strategies
- **Outcomes:** Opioid dose, tolerance, pain control, functional status, health-related quality of life, opioid misuse/addiction, medical side effects
- **Follow-up:** >1 year
- **Study Design:** Randomized controlled trial
- **Project Period:** 3-5 years
- **Potential Subgroup Analyses:** How does effectiveness vary depending on:
  - Patient comorbidities: mental health disorders, past or current substance use disorders

- **Research Commitment for Questions 1 and 2:**
  - 2-4 studies, up to $40M
Board Vote

Call for a Motion to:
- Approve up to $40M for Long-Term Opioid Treatment for Chronic Pain for development

Call for the Motion to Be Seconded:
- Second the Motion
  - If further discussion, may propose Amendment to the Motion or an Alternative Motion

Roll Call Vote:
- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
New Oral Anticoagulants (NOACs)
Overview

• Oral anticoagulants are used in several serious health conditions, including atrial fibrillation, deep vein thrombosis, and pulmonary embolism.
• Four new oral anticoagulants (NOACs) have been approved since 2010 (dabigatran, rivaroxaban, apixaban, and edoxaban). NOACs now account for 62% of new prescriptions.
• The fixed, once- or twice-a-day dosing and lack of need for monitoring for NOACs make them more convenient than warfarin, which requires frequent monitoring and dose adjustment. When used in the setting of atrial fibrillation, NOACs are associated with a lower incidence of serious bleeding which also accounts for their increased use.
• NOACs have been found to be non-inferior to warfarin for extended treatment after venous thromboembolism (VTE) to prevent recurrence. All four have now been approved by the FDA for the treatment of VTE.
Evidence Gap

• Clinical guidelines (ACCP 2012) calling for 3-6 months of anticoagulation treatment for deep vein thrombosis/pulmonary embolism are evidenced-based, but the evidence for extended treatment and choice of agents is lacking

• Comparisons among NOACs and with warfarin for extended treatment are lacking in terms of both VTE recurrence and bleeding rates
Summary from the June 9th Multi-stakeholder Workgroup

- The workgroup included 31 participants
- Of the 50 questions submitted, staff identified four categories for the workgroup to consider:
  - Medication adherence
  - Dosing strategies
  - Comparative benefits and harms among the NOACs
  - Comparative benefits and harms of NOACs vs. warfarin
Proposed Research Question

How do different strategies for extended anticoagulation treatment compare for patients who have completed a course of treatment after an initial episode of deep vein thrombosis or pulmonary embolism?

- **Population:** Patients treated for deep vein thrombosis or pulmonary embolism who have completed guideline-based treatment (at least 3 months), including elderly patients and those with renal dysfunction
- **Comparators:** Extended treatment comparing NOACs and/or warfarin
- **Patient-Centered Outcomes:** Recurrent VTE and bleeding
- **Project Period:** 5 years
- **Setting:** Community outpatient
- **Study Design:** Randomized clinical trial
- **Research Commitment:** 2-3 studies, up to $30M
Board Vote

Call for a Motion to:

- Approve up to $30M for New Oral Anticoagulants for development

Call for the Motion to Be Seconded:

- Second the Motion
  - If further discussion, may propose Amendment to the Motion or an Alternative Motion

Roll Call Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Annual Meeting Update

Bill Silberg
Communications Director
Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Directors