PCORI Engagement Webinar: 
*Emerging Approaches for Structuring Multi-Stakeholder Engagement in PCOR Projects*

Thursday, July 21, 2016 | 12:00-1:15 p.m. (ET)
Agenda/Ground Rules

• PCORI overview: mission and strategic goals, approach for patient and stakeholder engagement in research
• Introductions and presentations from featured PCORI projects
• Q&A

• Lines muted during presentation
• During Q&A portion, operator will open phone lines
• Submit questions via the Q&A function at anytime during the webinar
• Please respond to follow up survey!
Our Mission and Strategic Goals

PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Our Strategic Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence research funded by others to be more patient-centered
We Fund Research That…

What we mean by…

“Patient-centeredness”

• The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
• Research questions and outcomes should reflect what is important to patients and caregivers

“Patient and stakeholder engagement”

• Patients are partners in research, not just “subjects”
• Active and meaningful engagement between scientists, patients, and other stakeholders
• Community, patient, and caregiver involvement already in existence or a well-thought-out plan
# The PCORI Approach to Engagement - Our Engagement Rubric

## PCORI’s Framework for Engagement in Research: The Engagement Rubric

<table>
<thead>
<tr>
<th>Planning the study</th>
<th>Conducting the study</th>
<th>Disseminating study results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POTENTIAL ACTIVITIES</strong></td>
<td><strong>POTENTIAL ACTIVITIES</strong></td>
<td><strong>POTENTIAL ACTIVITIES</strong></td>
</tr>
<tr>
<td>Developing research questions</td>
<td>Drafting or revising study materials</td>
<td>Identifying partners for dissemination</td>
</tr>
<tr>
<td>Selecting relevant outcomes</td>
<td>Participating in study recruitment</td>
<td>Participating in dissemination efforts</td>
</tr>
<tr>
<td>Define study population characteristics</td>
<td>Participating in data analysis</td>
<td>Presenting information about the study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>REAL-WORLD EXAMPLES</strong></th>
<th><strong>REAL-WORLD EXAMPLES</strong></th>
<th><strong>REAL-WORLD EXAMPLES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient organization surveys members on treatment preferences</td>
<td>Patients develop informed consent to make it understandable to participants</td>
<td>Research team holds stakeholder summit to speed implementation of findings</td>
</tr>
<tr>
<td>Clinicians suggest a third arm to study based on variability in practice</td>
<td>Patient representative serves on data safety monitoring board</td>
<td>Research team introduces study at a patient advocacy conference to inform community of the research</td>
</tr>
</tbody>
</table>

## PCOR Principles

- Reciprocal Relationships
- Co-Learning
- Partnerships
- Transparency, Honesty, Trust

**Reciprocal Relationships:** Demonstrated when roles and decision-making authority of all research partners are defined collaboratively and clearly stated

**Co-Learning:** Researchers help patient partners better understand the research process, and researchers will learn about patient-centeredness and patient/stakeholder engagement

**Partnerships:** The time and contribution of patient and other stakeholder partnership is valued and demonstrated through compensation, cultural competency, and appropriate accommodations

**Transparency, Honesty, Trust:** Major decisions are made inclusively and information is shared readily among all research partners

---

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
Learning Objectives for Today’s Webinar

At the conclusion of this webinar, participants will be able to:

• Discuss various approaches for structuring research projects that engage patients and stakeholders.

• Recognize the unique considerations research teams face when engaging patients and stakeholders as research partners.

• Explain the value patients and stakeholders bring to research projects through a variety of engagement structures and processes; from identifying research questions, to designing and conducting studies and developing dissemination plans to make them more patient-centered, and potentially increasing uptake of findings.

• Identify barriers and challenges that may arise when establishing a patient-centered research structure, and approaches to overcoming them.
Early Supported Discharge for Improving Functional Outcomes After Stroke

Sabina Gesell, Ph.D.
Assistant Professor, Wake Forest School of Medicine
Co-Investigator, COMPASS Study

PI: Pamela Duncan, PhD, PT
The COMPASS Study
Sustainable Methods, Algorithms, and Research Tools for Delivering Optimal Care Study (SMART DOCS)

Clete A. Kushida, M.D., Ph.D.
Professor, Stanford University Medical Center
Principal Investigator – SMART DOCS

Deborah Nichols, M.S.
Director of the Data Coordinating Center – SMART DOCS
Randomized Trial of a Multifactorial Fall Injury Prevention Strategy: A Joint Initiative of PCORI and the National Institute on Aging of the NIH

Martie Carnie
Senior Patient Advisor at Brigham and Women's Hospital

Maureen Fagan, DNP, WHNP-BC, FNP-BC
Brigham and Women's Hospital
Associate Chief Nurse, Connor's Center for Women and Newborn-OB/GYN
Executive Director, Center for Patients and Families

PI: Shalender Bhasin, MD & Thomas Gill, MD & David Reuben, MD
Goals

• Engagement structure of a large pragmatic trial
• Promising practices of stakeholder engagement in a large pragmatic trial
Engagement structure of a large pragmatic trial
The COMPASS Study
Comprehensive Post-Acute Stroke Services (COMPASS) Study

• Changing stroke systems of care
  • Goal: To evaluate the comparative effectiveness of a patient-centered, transitional care model that provides both structure and processes for post-acute care of stroke patients versus usual care
  • Outcomes: functional outcomes, caregiver strain, hospital readmissions
• 40 hospitals in North Carolina
• 6000 diverse stroke patients discharged home from acute care
• Broad-based stakeholder engagement
Engagement Structure

- Team members are experienced in collaborating with stakeholders
- Shared leadership and commitment to engagement
  - Most study team members work with stakeholders
  - Credibility within stakeholder communities
  - Not all stakeholders interact with all investigators
- Oversight of engagement activities is centralized
  - Faculty “engagement officer” (30% FTE)
  - Dedicated research coordinator (100% FTE)
  - Administrative support (ongoing and additional as needed)
Promising Practices of Stakeholder Engagement in a Large Pragmatic Trial
1. Create a Roadmap
# Roadmap for Stakeholder Engagement

<table>
<thead>
<tr>
<th>ENGAGEMENT PERIOD</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STUDY OVERSIGHT</strong></td>
<td>1. Participate in study committees</td>
</tr>
<tr>
<td><strong>INTERVENTION DESIGN</strong></td>
<td>1. Design intervention components</td>
</tr>
<tr>
<td></td>
<td>a. Medication Management</td>
</tr>
<tr>
<td></td>
<td>b. ...</td>
</tr>
<tr>
<td></td>
<td>2. Develop messaging to patients and providers</td>
</tr>
<tr>
<td></td>
<td>3. Training of community-based clinicians</td>
</tr>
<tr>
<td></td>
<td>4. Draft job description for post-acute care coordinator</td>
</tr>
<tr>
<td></td>
<td>5. ...</td>
</tr>
<tr>
<td><strong>OUTCOME MEASUREMENT</strong></td>
<td>1. Provide input on consent process and wording of consent forms</td>
</tr>
<tr>
<td></td>
<td>2. ...</td>
</tr>
<tr>
<td><strong>RECRUITMENT &amp; RETENTION OF HOSPITALS &amp; PATIENTS</strong></td>
<td>1. Help design a patient-facing informational brochure about the study</td>
</tr>
<tr>
<td></td>
<td>2. ...</td>
</tr>
</tbody>
</table>
2. Designate an “Engagement Advocate” in each study committee
Engagement Advocate

- We designated and trained one researcher in each study subgroup to be the “Engagement Advocate”
- To intentionally look out for any additional opportunities for engagement (not outlined in the roadmap)
- To notify the engagement team who implements / delegates/ documents
3. Embed stakeholders in study committees
Stakeholders in Study Committees

• Patients and other stakeholders are active in study committees
  • in the Steering Committee and all study subgroups
  • based on their interests and skills
  • to have continuous input and support decision-making across the research process.
4. Map engagement activities to a social-ecological model
Stakeholder Groups Involved in the Planning of COMPASS

- **Public Policy**
  - Advocacy Organization, Policy Makers
  - Participated in 23 engagement activities

- **Community**
  - Community-Based Services, Clinicians, Industry
  - Participated in 53 engagement activities

- **Institutional**
  - Hospitals & Health Systems, Training Institutions
  - Participated in 58 engagement activities

- **Social Network**
  - Family Caregivers
  - Participated in 19 engagement activities

- **Individual**
  - Patients
  - Participated in 20 engagement activities
5. Track the engagement process
REDCap Engagement Tracker
# REDCap Dashboard

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Stakeholder Input Requested/Reported</th>
<th>Stakeholder Invited</th>
<th>Stakeholder Involved</th>
<th>Stakeholder Input Incorporated</th>
<th>Stakeholder Informed</th>
<th>Coding and Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>95</td>
<td>Patient and Caregiver eCare Plan Feedback Session, 2016-01-26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Richard Hopson provides feedback on OT/PT-related insurance documents, 2015-11-16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>97</td>
<td>NC Alliance for Effective Care Transitions 2016 Summit, 2016-01-26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>98</td>
<td>SHAPE Focus Group, 2016-01-19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Julie Wiggins reach out to Alleghany Memorial for recruitment, 2016-01-12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>Home Health Stakeholders providing feedback on Medicare Insurance Coverage of PT/OT services, 2016-01-22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>101</td>
<td>Core engagement group provide input on patient brochure for control group, 2016-01-28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>102</td>
<td>January 6, AAA Statewide Directors Meeting, 2016-01-06</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>103</td>
<td>Update on COMPASS Education and Training Plan, 2016-01-06</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>104</td>
<td>Stroke Survivors give feedback on Performance Measures/90 - phone survey, 2016-01-08</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please describe the <strong>primary</strong> level of engagement involved in this activity?</td>
<td>- Information Sharing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Consultation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Collaboration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Patient/stakeholder direction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please describe the <strong>secondary</strong> level of engagement involved in this activity?</td>
<td>- Information Sharing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Consultation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Collaboration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Patient/stakeholder direction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presenter/Leader(s):</td>
<td>Sabina Gesell, Lynette Staplefoote-Boynton, Lauri</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did a stakeholder co-present (Y/N)?</td>
<td>- Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated number in attendance:</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase of study:</td>
<td>- Planning/Design</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Conducting and Monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Dissemination and Implementation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe stakeholder input on study: (Please indicate if this input has been incorporated or is being evaluated. Type in N/A if not applicable.)</td>
<td>See input page</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you face any challenges with engaging these stakeholders?</td>
<td>- Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has input been vetted by representatives of the Executive Committee?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Was stakeholder input incorporated in the study?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Describe impact of stakeholder input on study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>See vetted recommendations</td>
</tr>
<tr>
<td>Vetted_Recommendations_Sanford Focus Group</td>
</tr>
<tr>
<td><a href="https://www.dropbox.com/s/q69ug7woedgnf/vetted_Recommendations_sanford%20focus%20group.docx?dl=1">https://www.dropbox.com/s/q69ug7woedgnf/vetted_Recommendations_sanford%20focus%20group.docx?dl=1</a></td>
</tr>
<tr>
<td>Patients in focus groups stressed the message of how important it is for all providers to adopt</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social Ecological Model Representation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(To be filled out by Engagement Team)</td>
</tr>
<tr>
<td>Public Policy</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
SMART DOCS: A Stakeholder Engagement Approach for Clinical Trials

Clete A. Kushida, M.D., Ph.D.
Deborah A. Nichols, M.S.
July 21, 2016
SMART DOCS Goals

Introduce a new Patient-Centered Outcomes and Coordinated-Care Management approach for sleep medicine

- New tools and technologies
- Access to information
- Collaboration
- Primary care integration

Compare the new (PCCM) approach to a conventional (CONV) sleep medicine practice in a clinical trial

- Health care performance ratings
- Disease-specific outcomes
- Global health measures
- Health care utilization
Randomized Clinical Trial

Includes new adult patients with signs/symptoms of a sleep disorder

1,836 Participants

Who are our Stakeholders?

Clinicians, Nurses, Researchers, Scientists, Patients, Hospital Administration, Professional Association Leadership, Patient Advocacy Groups, Industry Leaders
Align Stakeholder engagement activities with a typical clinical trial lifecycle
SH Engagement Phases

PCORI Engagement Rubric

- Planning
- Conducting
- Disseminating

SMART DOCS Clinical Trial Phases

- Design
- Recruit
- Analyze
Story 1: Design – Recruit

Hybrid Communication: Webinars + Stakeholder Portal

- Secure Login Site
- Collaborative Environment

Stakeholder Involvement During Design – Recruit Phase

- Finalize study outcomes and technologies
- Input on PCCM Patient Portal design/content
- Create patient educational materials

Necessity: Up-To-Date Reports

- Interactive visualizations
- Encourage data exploration by Stakeholders
Collaboration - Dashboard

Live Reports
Study Information
Calendars
Document Libraries
Links
Feedback Forum
Terminology
Announcements

SMART DOCS
Study Management
Project Management
EDIT LINKS

Overview

The SMART DOCS Stakeholder Portal provides diverse study content that enables collaboration about the study. It includes:

- Study Documents and content
- Visualizations and access to data reports using the Dashboard
- Announcements of upcoming events and study milestones
- Calendar of meetings
- Links to related websites such as my portal and manuscripts

It is available to SMART DOCS Stakeholders on a secure, permissioned basis and data are de-identified.

We also invite your input, ideas, and guidance within the Feedback Forum or Expert Advice Page accessed using the panel on the left. Any feedback you provide is considered important and is greatly appreciated.

SMART DOCS PCCM Approach

**PCCM Approach**

- **New technologies**
  - PICO + eHealth (smart/portal)
  - Acupuncture + (some training)
  - SMART DOCS - my portal
  - OM [acupucture]
  - Blood Genetic Tests
  - Saliva DnaG Tests (bioanalyte)

Announcements

- May SMART DOCS Stakeholder Call 5/21/15
  - 5/21/2015 7:07 AM
- Final SMART DOCS Participant Enrolled/Randomized on 4/21/15!
  - 5/21/2015 1:35 PM
- Educational Content Input by 3/16/15
  - 5/21/2015 12:15 PM
- SMART DOCS Manuscript Published 2/1/15
  - 5/21/2015 1:32 PM

Calendar

- March SMART DOCS Stakeholder Call - Option 1
  - 3/4/2015 3:00 PM
- March SMART DOCS Stakeholder Call - Option 2
  - 3/4/2015 5:00 PM
- May SMART DOCS Stakeholder Meeting - Option 1
  - 5/21/2015 8:00 AM
- May SMART DOCS Stakeholder Meeting - Option 2
  - 5/21/2015 2:30 PM
- Sleep 2015
  - 6/4/2015 8:00 AM
- Academy Health Annual Research Meeting
  - 6/14/2015 8:00 AM

Add new event

Links

- SMART DOCS my sleep portal
- Login for use by Stakeholder Team members.
- Adobe Connect Meeting Room
- For use during Stakeholder Calls
“Slicers” enable data exploration by the visualization user.
How many female participants were randomized?
How many females in race categories were randomized?
Story 2: Recruit – Analyze

Hybrid Communication: Webinars + Stakeholder Portal

• Secure Login Site
• Collaborative Environment

Stakeholder Involvement During Recruit – Analyze Phase

• Monitor – “My Sleep Portal” Patient Content
• Analyze – Patient Sleep Education Preferences

Necessity: Agile Approach for Stakeholder Engagement

• Interactive data visualizations
• Metrics for decision making
• Iterative feedback conveys value
Research/Stakeholder Team created 68 unique sleep education documents accessible on a patient web portal “My Sleep Portal”
How many educational documents were created for “My Sleep Portal” by category?
### Count of Documents Uploaded by Month

- Count of Educational Documents by Month: 1/1/2014
- Count of Sleep Disorder Documents: 16
- Count of Sleep Tests Documents: 9
- Count of Sleep Therapy Documents: 9
- Count of Sleep/Wake Tips Documents: 18

### Count of Documents by Repository, Category, and Type

- **Educational Documents**: 68
- **my sleep portal**: 68
- **Sleep**: 17
  - **Sleep Disorders**: 16
    - Circadian Rhythm Sleep Disorders: 4
    - Hypersomnias - Excessive Daytime Sleepiness Disorders: 2
    - Insomnias: 1
    - Other Sleep-Related Conditions or Disorders: 2
    - Parasomnias - Sleep-Related Behavior Disorders: 4
    - Sleep-Related Breathing Disorders: 1
    - Sleep-Related Movement Disorders: 2
  - **Sleep Tests**: 9
  - **Sleep Therapy**: 9
  - **Sleep/Wake Tips**: 18

### Delayed Sleep Phase Disorder

**What is it?** Delayed Sleep Phase Disorder is a circadian rhythm sleep disorder characterized by an inability to fall asleep and awaken from sleep until substantially later than desired/socially acceptable times.

**Key symptoms?** Extreme difficulty falling asleep at a desired/socially acceptable bedtime with significant difficulty awakening in the morning, confusion, and drowsiness. Once sleep onset occurs, sleep is reported to be normal in duration and quality but the timing of sleep is not typical (e.g., falling asleep at 3 a.m. and waking at 11 a.m.).

**What causes it?** The exact cause is unknown, but there is some evidence that biological changes during puberty promote a delay in the normal daily rhythm of alertness which encourages later bedtimes and rise times. In addition, social factors in adolescents reinforce late bedtimes. Up to 40% of individuals with this condition may have one or more family members that also have a history of this condition.
Which sleep disorders documents were viewed most often by patients?
Obstructive Sleep Apnea

What is it? Obstructive sleep apnea is a breathing disorder which results from airway (i.e., the throat) collapse during sleep.

Key symptoms? Daytime sleepiness/tiredness, loud and disruptive snoring, and witnessed breathing pauses are the most common symptoms. Other symptoms include a dry mouth/throat upon awakening, morning headaches, and night sweats. Children may have daytime symptoms that mimic those of attention deficit-hyperactivity disorder (ADHD).

What causes it? The cause is not fully understood; however, any condition which narrows the airway from the nose to the voice box increases the risk for sleep apnea. These conditions (such as obesity, enlarged tonsils) including those anatomical abnormalities form are also play a role, since the disorder tends to run in families.

How common is it? Approximately 24% of men and 9% of women have evidence of sleep apnea, and about 2–3% of children also have the condition.

Risk factors? Being overweight is a strong risk factor. It increases a women’s risk. Frequent use of alcohol or smoking increases the risk of all forms of sleep apnea.

Associations and consequences? People with obstructive sleep apnea are at risk for a variety of medical conditions (including high blood pressure, heart failure, stroke, and cardiovascular diseases), difficulty in concentration and focus, and accidents at work. It may also lead to a possibility of delayed growth.

How is it diagnosed? Although a patient’s history often necessary to confirm the diagnosis and measure severity at home, but in either case, the patient wears a device to monitor chest and abdominal wall movements, heart rate, oxygen saturation, and breathing. Based on these measurements, the severity of the condition is assessed.
Do patients prefer accessing sleep education materials on a web portal or by watching an interactive video?

SMART DOCS Interactive Dashboard: www.comethub.org/sd/SitePages/Sleep%20Education.aspx
Story 3: Disseminate

Hybrid Web Presence: Stakeholder Portal and Website

- **Stakeholder Website**
  - No login
  - Enables sharing (email links)
Stakeholder Engagement

If you build it, some will come...
For others, you will have to convince them to participate.
Lessons Learned

- **Social Media**
  - Collaborative project environment

- **Interactive Data Visualizations**
  - Highly graphic to convey complex information

- **Establish Metrics**
  - Measure and use to make decisions

- **Agile Methods**
  - Iterative; can identify issues quickly and react

- **Content Marketing**
  - Target objectives to impact behavior

- **Engagement is Important, But Not Easy**
  - Effective when devote sufficient resources

Visit: [http://www.COMETHub.org](http://www.COMETHub.org)
Authentic Patient and Stakeholder Engagement in the STRIDE Study

Maureen Fagan, DNP, MHA, FNP-BC
Executive Director, Center for Patients and Families
Associate Chief Nurse, OB/GYN/NICU
Brigham & Women’s Hospital

Martie Carnie, Senior Patient Advisor
Brigham & Women’s Hospital
STRIDE (Strategies To Reduce Injurious falls and Develop confidence in Elders)

- Pragmatic multi-site randomized control trial on fall prevention for adults aged 70 and older
- Study goal is to reduce injurious falls in elders
- Committees & Subcommittees
- National Patient Stakeholders Council (NPSC)
- Local Patient Stakeholders Council (LPSC)
Why Involve Patients in STRIDE?

- Brings important perspectives from end users
- Inspires and energizes research staff
- Keeps research staff grounded
- Provides iterative process with aims and research question
- Offers opportunity for qualitative analysis in addition to existing quantitative methods
- Brings connectivity of lived experience to the research question
- Contributes to dissemination process & education of general public and/or relevant patient populations
NPSC & LPSC Structure

• National Patient Stakeholder Council (NPSC)
  ▫ Purpose of the NPSC is to:
    • Serve in consultative capacity to local council
    • Integrate the input from the 10 local councils and communicate that to the trial PIs and committees
    • Coordinate activities for formulating final research questions, study design, monitoring study progress, and disseminating results
  ▫ Comprised of patients and stakeholders from each of the 10 sites

• Local Patient Stakeholder Council (LPSC)
  ▫ Purpose is to monitor local study progress and provide input at each stage of the research project
  ▫ Comprised of older adults with fall experience, caregivers of older adults, researchers, clinicians, community organization representatives and local fall prevention experts
STRIDE Patient and Stakeholder Engagement Process

• Preparing environment for patient-researcher partnership
  ▫ NPSC leadership met with PIs to clarify patients role on council and discuss importance of including their voice in the study
  ▫ Addressed facilitators and barriers for engagement

• Recruiting Patients and Stakeholders
  ▫ NPSC leadership shared methods for recruiting patient and stakeholders including qualifications and expectations

• Council Training
  ▫ NPSC leadership went to the 10 LPSC sites to provide in person training on being partners in research
  ▫ Training focused on team building and understanding of the research process
**STRIDE Patient and Stakeholder Contributions**

- **Patient and Stakeholder input includes:**
  - Providing feedback at every level & phase including the Pilot Study
  - Reviewing and editing all patient facing materials and documents for the study
  - Participating on all STRIDE Committee meetings outside of NPSC/LPSC

- **Two patient/caregiver representatives were invited to share and showcase the contribution of NPSC/LPSC at the end of Year 1 study**
Lessons Learned

- Strong NPSC leadership with knowledge on patient engagement
- On site meetings with NPSC leadership allowed for:
  - Assessment of local sites
  - Assisted with recruiting LPSC members onto NPSC and STRIDE committees
  - Set stage for bi-directional communication, mutual understanding of study and trust
- Site Coordinator is essential
- Sustaining patient engagement
“Embrace the opportunity to do research differently”
- Joe Selby, MD, MPH

Executive Director, Patient Centered Outcomes Research Institute
Thank you!


Maureen Fagan
mfagan@partners.org
617-732-6636

Martie Carnie
martiecarnei@hotmail.com
Q&A
Additional Resources

- **PCORI’s Methodology Standards PC-1 to PC-4**

- PCORI has developed other resources to help guide your engagement activities, housed on the “What We Mean by Engagement” page on the PCORI website

- Engagement Resources include:
  - Framework for Financial Compensation of Patient, Caregiver and Patient Organization Stakeholders
  - Engagement Rubric
  - Sample Engagement Plans
  - PCORI Stakeholder Groups
  - Short Videos on Engagement in Research
Thank you!

www.pcori.org  twitter  
info@pcori.org  YouTube