Conducting Stakeholder-Engaged Research

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Wonderful Opportunity for Stakeholder Engagement!

• Thank you for telling us about yourselves! You have amazing interests and expertise.

• Research teams

• Disciplines--nursing, family medicine, rheumatology, epidemiology, Ob-Gyn, surgery, pediatrics, …

• Topics--obesity, pharmacogenomics, genetic testing, inter-hospital transfers, peritoneal dialysis, chronic autoimmune disease, fibromyalgia, rural health care, …
Goal: Enhance Skills for Stakeholder Engagement when Conducting Research

Structure:

• Have 3 presenters and Q’s for next 2 sessions

• Last hour we break into groups for expert consultations

• Consult on actual projects, using volunteered project descriptions
Objectives

• Identify common research challenges that can be addressed with stakeholder engagement

• Develop and implement meaningful stakeholder engagement agendas and activities to successfully address common research challenges

• Build and sustain stakeholder partnerships across the phases of research

• Incorporate stakeholder input in an iterative, feedback-driven process

• Assess whether IRB approval is needed for stakeholder engagement activities
Engaging Stakeholders to Address Common Challenges in Conducting Research

Session 3 – 50 minutes
No One Best Way to Engage Stakeholders

• Considerations
  – Align the engagement with the values of the team
  – Intensity and length of engagement
  – Resources for engagement
Dimensions of Stakeholder Engagement

- **Integrity of Engagement in Research**
- **Input from Existing Stakeholder Communities**
- **Research Participation**
  - Interviews
  - Focus groups
  - Existing literature
  - Surveys

- **Stakeholders on Research Team**
- **Blended Stakeholder Engagement Groups**
- **Patient Advisory Groups**

- **Length of Engagement**
  - One Time
  - 2-3 Times
  - > 1 Year
Templates

• The templates referenced in the following slides can be downloaded from the toolkit available here:

• https://www.hipxchange.org/SustainingEngagement
Aligning Stakeholder Engagement with Values

Template 1: Aligning Your Stakeholder Engagement with Your Intended Research Products

**Goal**

To help you identify what key research products you hope your research will produce and what stakeholder engagement could aid this.

Begin this process with the end in mind.

1. What are the products that you want to have at the completion of this research?

2. What are the products that are desired/required by your funder? Examples include: publications, toolkits, interventions, further grant applications, policy recommendations, and/or development of new data collection methods or measures.
How Much Money Do I Need to Engage Stakeholders?

Template 5: Creating a Budget for Stakeholder Engagement

Goal
To create a realistic budget along usual grant budget categories to support needed stakeholder engagement over the life of your project.

Personnel—who will develop materials to recruit stakeholders, recruit them, vet them, orient them to the research, set agendas and activities for them, collate stakeholder input, and integrate that input into the ongoing research?

Equipment and Supplies—what do you need to support stakeholder engagement (e.g. general supplies like paper, pens, nametags, envelopes, audio recorders, or flipcharts)?

Other Expenses—how much will you pay stakeholders for participation in your stakeholder activities, do you need to cover travel or parking, will you provide snacks or a meal, where will they meet and will there be a fee for room rental?

Review of budget issues identified in prior submissions:
1. Is your reimbursement to stakeholders adequate for their effort?
2. Are the stakeholder tasks as described in the budget justification consistent with descriptions of those tasks elsewhere in the research plan?
3. Does the budget justification include sufficient detail to assess its value?
4. If you are cost sharing stakeholder engagement activities with other projects, does your budget provide for and clearly describe what is being paid for from each source?

Based on materials from the Wisconsin Network for Research Support, UW School of Nursing.
Stakeholder Engagement Prior to Funding

Template 2: Stakeholder Engagement Prior to a Major Grant Application

Goal
To identify stakeholder input that would strengthen your future major grant (PCORI or NIH). This input might be gathered during a pilot grant prior to the larger grant application.

What would you and others on your team like to talk to stakeholders about before submitting a major grant application?

☐ Understanding the problem from different perspectives
☐ Defining relevant research questions
☐ Determining meaningful outcomes for patient/community stakeholders
☐ Reviewing and interpreting available preliminary data
☐ Designing study procedures that are implementable for both patient subjects and research sites
☐ Optimizing the feasibility of your intervention and its implementation
☐ Identifying feasibility of your data collection approach
☐ Identifying whether ongoing stakeholder engagement is needed throughout the study and, if so, what types of stakeholders to engage
☐ Creating effective plans for recruitment and enrollment
☐ Writing letters of support
☐ Budget needs for stakeholder compensation, food, travel, other costs
Other: (Fill in yourself)

Based on the boxes you selected above, what types of stakeholders or partners do you need to involve in developing your grant submission?

☐ Patients
☐ Caregivers
☐ Public
☐ Community or advocacy organizations representatives
☐ Clinicians
☐ Researchers
☐ Hospitals & health systems representatives
☐ Training institutions representatives
☐ Policy makers
☐ Payors
☐ Purchasers
☐ Industry representatives

Examples and definitions of these types of stakeholders can be found here: http://www.pcori.org/funding-opportunities/what-we-mean-engagement/pcori-stakeholders

(Template 2 continued on next page)
Tips for Demonstrating Engagement before Funding

• Engage with existing organizations
  – Advocacy groups
  – Healthcare leadership
• Narrow to key focus
• Frame pilots as engagement
• Get support letters that detail engagement product
• PCORI Pipeline to Proposal Awards
• ICTR-CAP Stakeholder and Patient Engaged Research Awards
Yay, I’m funded!!! Oh no…

• What challenges occur in conducting research?
Typical Challenges for Researchers

• Will I recruit and retain enough participants?
• Will hard to reach populations participate?
• Will the study succeed in the “real world” setting?
• Will my participants provide complete data?
• Will my results actually make things better?
Yay, I’m funded!!! Oh no…

- What challenges occur in conducting research?
Pediatric Type 1 Diabetes Self-Management

- About 190,000 children with type 1 diabetes
  - Only about 30% adequately control blood sugar
  - Can negatively affect quality of life

- Each family has unique barriers to managing diabetes

- Evidence-based strategies from randomized trials can improve blood sugar control, but few families use these
Why the Limited Use?

• Resources aren’t family-centered!!
  – *Respecting families’ wants, needs, and preferences and soliciting their input on the support they need to make decisions and participate in care*

• Not tailored to each family’s specific needs
• Multiple uncoordinated visits
• Requires missing school/work
Project Overview

• Compare usual diabetes healthcare to care enhanced by a family-centered approach
  – Resources offered either before or after clinic visit
  – Resources are matched to each family's needs, as determined by a short survey

• 200 youth 8-16 years of age and their parent(s)
Trial Design

Administer PRISM

Willing to be randomized for trial?

Excluded

Block randomized to Intervention?

Review parent and adolescent PRISM results

Single barrier identified

INTERVENTION: Next 4 Quarterly Visits to Usual Care (Multidisciplinary Clinic) Plus 4 Group-Based Family-Centered Self-Management Resource Sessions

Multiple barriers identified

CONTROL

No barrier identified

No
Stakeholder Engagement

To date, we have held over 50 advisory board meetings!
Project ACE Logo Designed by Child
Engagement Shaped Intervention Delivery

- Potential issues in the timing of group sessions:
  - Single parents
  - Job scheduling constraints
Impact of Engagement on Recruitment

- 73% of eligible families recruited
- Completed more rapidly than expected
- Exceeded recruitment goal
- Recruitment of hard to reach populations matches population demographics
Engagement Smoothed Clinical Integration of Study

CHALLENGE: Scheduling future clinic appointments and/or group intervention sessions
Simultaneous multi-stakeholder engagement
Blended Stakeholder Engagement?

• Experiences with blended stakeholder groups?

• Advantages?

• Potential challenges?
Weighing Out Doing Blended SE

• Advantages
  – Research implemented in or designed to change a system needs multi-stakeholder engagement
  – Efficiency can be improved with multi-stakeholder engagement
  – Aids implementation and dissemination

• Challenges
  – Ensure all voices are heard and valued--need skilled facilitators
  – Blended stakeholder groups can push change rapidly--need tight coupling with research team
Engagement Smoothed Clinical Integration of Study

CHALLENGE: Scheduling future clinic appointments and/or group intervention sessions

SOLUTIONS:
1. Schedule appointments and/or groups sessions in advance for next 6 months
2. Hold needed clinic appointments in reserve for participants to have available when scheduling next visit
Engagement and Retention

• Intervention group was planned as 4 group sessions
• 69% of participating families attended at least 3 of the 4 group sessions; 82% attended at least 2
• Rescheduled only 4 of 128 group sessions!
Engagement Informed Data Collection

- Decided process and timing for data collection and reminders
  - Phone reminder references email
  - 3 weeks before and 3 days before

- Revised outcome measures
Pediatric Hypoglycemia Anxiety Index

- Anxiety about low blood sugar matters
- Existing tools to measure this outcome are not sensitive
- Parent input has been instrumental in refining the survey tool
The Impact of Parent Feedback on the Hypoglycemia Anxiety Index

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<tr>
<td>Number of items added</td>
<td>5 items</td>
</tr>
<tr>
<td>Total % of items changed</td>
<td>100%</td>
</tr>
</tbody>
</table>
Impact of Engagement on Data Collection

- Over 24 mo, A1c lab every 3 mo, surveys every 6 mo
- 82% of A1c values were collected
- 84% of surveys were completed; <1% missingness
Stakeholder Engagement Activities in a Major Funded Grant

Template 3: Stakeholder Engagement Activities in a Major Funded Grant

Goal
To identify stakeholder input that you would like during your major grant (e.g., PCORI or NIH) when funded.

Stage 1: Planning
☐ Creating study name and/or logo
☐ Providing feedback on study design
☐ Providing feedback on proposed study implementation
☐ Defining characteristics of study participants (inclusion, exclusion criteria)

Stage 2: Conduct
☐ Developing or providing feedback on participant recruitment strategies
☐ Giving feedback and recommendations about recruitment material design
☐ Crafting language to explain the study (e.g., for recruitment materials or in-person scripts)
☐ Providing feedback on human subjects consent forms
☐ Developing or refining data collection strategies, instruments
☐ Developing strategies for subject retention over time
☐ Participating in data collection
☐ Participating in data analysis (e.g., reviewing survey data for authenticity, interpreting or coding interview transcripts, providing a validity check for qualitative research findings)
☐ Reviewing ongoing recruitment data and advising on issues
☐ Advising on economic sustainability for the intervention

Stage 3: Dissemination
☐ Interpreting research findings
☐ Advising on outlets for product dissemination (e.g., identifying non-traditional channels, developing partnerships with outside organizations)
☐ Providing stakeholder-relevant language for study products (e.g., articles, presentations, websites)
☐ Participating by stakeholders in publishing findings (e.g., writing journal articles, newsletters, websites or blogs)
☐ Presenting study results or processes at events (e.g., conferences, workshops) by stakeholders
☐ Working with health care organizations to implement effective processes into their clinic workflow
☐ Working with community or advocacy organizations to disseminate findings
☐ Other: (Fill in yourself)

Examples and definitions of these types of stakeholders can be found here:
http://www.pcori.org/funding-opportunities/what-we-mean-engagement/pcori-stakeholders
Engagement has Helped our Work…

• Recruit and retain participants
• Be engaging and accessible for hard to reach populations
• Balance the needs of participating families with the clinical constraints
• Collect high quality, complete data
Published Work


Questions?
Next Up

• Break
• Session 4
  – Agendas and activities for engaging stakeholders across the research trajectory
  – When are stakeholders considered human subjects
• Expert consults!
• Reception
Conducting Stakeholder Engagement Across the Study’s Life Cycle

Session 4 – 50 minutes
What is a Community?

• Persons joined by some commonality (e.g., occupation, health condition, site, age, ethnicity, etc.). No community is monolithic. Be aware of differences. Listen to voices.

  – Care providers in health settings
  – Patients and/or care partners
  – Indian reservation or public housing populations
  – Community organizations – Aging and Disability Resource Centers staff and/or clients
How Do You Access a Community

• With humility seek to understand that community

• May choose co-investigators for this very reason

• Who are community leaders? What are its needs/ strengths? Ask how can I leave it better than I found it?

• ID trusted messengers on your behalf
  – Advocacy or community advisory groups
  – Church leaders
  – Clinic staff/hospital leaders
  – Community agency leaders/staff
Engaging Stakeholders Across the Research Trajectory

**Preparatory Stage**
- Agenda Setting & Funding
  - Provide feedback on research questions and outcomes
  - Review and interpret preliminary data
- Study Design & Procedures
  - Provide feedback on research methods and survey design
  - Collaborate on intervention design
- Study Recruitment
  - Recruitment design and material development
  - Generate participant retention strategies

**Execution Stage**
- Data Collection
  - Pilot test study instruments
  - Monitor data collection process and accuracy
  - Monitor and troubleshoot intervention process
- Data Analysis
  - Interpretation of findings

**Translational Stage**
- Dissemination
  - Dissemination of research findings to clinicians and researchers
  - Dissemination of research findings to advocates, patients, and families
- Implementation
  - Development of tools and guidelines for clinical practice
  - Integration of process changes into clinical practice
- Evaluation
  - Ongoing feedback on process and product
  - Evaluative feedback on the effectiveness of PRISM-based tailoring
ACE Meeting Agendas Aligned with Study Stage

- **Meeting 2** *(8/18/14)*
  - Help us explain random assignment to families when recruiting
  - How can the recruitment process be improved; Study involvement private

- **Meeting 3** *(12/17/14)*
  - How address issue of kids not wanting to miss school
  - Help on appointment reminders (method and message)

- **Meeting 4** *(4/16/15)*
  - PCORI encourages D and I: What should ACE consider disseminating?
  - New issue: How to help set the agendas in clinic visits?

- **Meeting 5** *(9/10/15)*
  - What should we tell others about developing & sustaining Blended Boards?
  - How to implement/disseminate “PRISM” assessment & tailored groups (in and out of clinics)

- **Meeting 6** *(12/16/15)*
  - What does “usual care” mean to you at your clinic?
  - Feedback on computerized question prompt list (QPL)
Sustainability Requires Respect

- **Decide Key Values for stakeholder meetings:**
  - Co-learning; all voices equally credible
  - Create sense of group; community over time
  - Flatten hierarchies--round tables; first name tags
  - Reinforcing for all to come
  - Everyone feels valued
    - Establish shared values about nature of stakeholder boards early and each meeting reinforces.
    - Has to be meaningful, clear, and fun if possible
Select Meaningful Questions & Agendas for Stakeholders

1. What 2 priority Q’s do we need help with in near future?

2. What is expertise of board members re: possible Q’s?

3. Why are these Q’s particularly good for (ex. “Blended” Board)?

4. Would answer take us back to IRB?

5. Can we implement what they tell us? (If no, don’t ask)
Example of Input from Stakeholders

• How to explain Randomization & Keep ‘Control’ Families?
  – We role played long script that we planned to use in clinic.
  – Board said, “Tell the families the computer did it.”
  – Never use the words “just”, “only”, or “unfortunately” when describing the control condition
  – Present both experimental conditions and control as equally important and helpful to study
  – Don’t use jargon (“screener, eligibility, quality”)
Iterative Process Sustains Collaboration

Advisory Boards
- Engage in meaningful dialogue
- Generate feedback, ideas, & effective solutions
- Get member buy-in & commitment

Research Team
- Review feedback
- Revise plans
- Address issues & implement solutions
- Generate new meaningful questions
Plan Schedule of Meetings

• 5:30-6:00 Buffet
• 6:00-6:10 Welcome; **How we used your input!** - BC
• 6:10-6:20 Project Update (Data, recruitment) - GJ
• 6:20-6:35 Play with a Purpose – K and K
• 6:35-6:40 Introduce Q 1 with context, role play, data BC/GJ
• 6:40-7:10 Divide up (or not) into regions (Milwaukee vs. Madison), Age (kids vs adults) and then address question – All
• 7:10-7:15 Report back to whole group - All
• 7:15-7:20 Bio Break and give checks - GJ
• 7:20-7:55 Introduce Q 2 with context, role play, data - BC
• 7:55-8:00 Next meeting time (month; ask when doodle) - GJ
To Sustain SE Logistics are Key

• Easy place for all to meet--They chose to meet between 2 cities!
  - Oconomowoc (Use hotel meeting room)

• Easiest time to meet--They chose 6-8 pm week night
  - Kids need to head home in time for school night
  - We doodle dates ahead (we ask when to send doodle each meeting)

• Buffet dinner provided, people sit and chat before meeting

• For ACE we paid everyone AT each meeting ($100. kids, parents, clinicians)

• For Contraceptive Decision Aid Project--Uptown popcorn and meaningful activity

• Need facilitators at each meeting (good note taker)
Q’s to Shape SE Planning: Similar to Q’s in our Breakout Consultations

1. What are the values (a) of research partners; (b) of facilitators re: stakeholder process?

2. What are your approaches (timeframe, mode, activity) you will use to involve stakeholders?

3. Agenda: What research design, execution or translation question would you like stakeholder feedback on?

4. What practical issues must you address to do this?

5. What outcomes occur as a result of the stakeholder feedback? (a) what stakeholders offered; (b) what research outcome occurred as a result
QUESTIONS!