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Harold and Muriel Block
INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH
at Einstein and Montefiore

# EXPLORE

## *Center for **Ex**cellence in **P**romoting **L**HS **O**perations and **R**esearch at **E**instein/Montefiore*

## Planning and Conducting *Stakeholder Studios* to Inform Research Design and Implementation

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# Rationale for EXPLORE

- Researchers are increasingly aware of the limitations of reductionism in clinical and population health research
- Our traditional methods are ill-equipped to capture and make sense of the dynamic complexity and full contextual reality of our contemporary circumstance
- We need research strategies that:
  - Move us beyond our distinct disciplines
  - Helps us to see “the big picture” more clearly
  - Foster a Science of Improvement: *Institute for Health Care Improvement*, IHI)

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# Science of Improvement (IHI) for Populations

Triple Aim:

1. Improve the health of the population
2. Enhance the patient experience of care (including quality, access, and reliability)
3. Reduce, or at least control, the per capita cost of care

Three Questions:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What changes can we make that will result in improvement?

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# Dissemination and Implementation of Evidence-based Practices in Population Health

Promote the systematic uptake of research findings and other evidence-based practices into routine practice

(Bauer, Damschroder et al., 2015)

Research Approach:

1. Mixed methods (qualitative and quantitative)
2. Stakeholder-engaged (patient-centered, participatory)
3. Transdisciplinary (team-based, collaborative)
4. Systems-oriented (multi-level, translational: $T_0 \rightarrow T_4$)

| T0 | T1 | T2 | T3 | T4 |
|---|---|---|---|---|
| Basic (Lab\|Animal) | Efficacy (Phase 1) | Effectiveness (Phase 2\|3) | Comparative Effectivness | Community & Population |

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# Working Passionately … Separately to Improve Health


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# “Centeredness” vs. “Engagement”

## Centeredness

- Examination of outcomes and preferences assessed from the stakeholder’s perspective (e.g.,PROs)
- Research questions and outcomes that are important to stakeholders

## Engagement

- Stakeholders as research partners
- Active, meaningful deliberation among researchers, patients and other stakeholders
- Specified roles, responsibilities, and rewards for stakeholders

# IOM Recommendation for CTSAs:

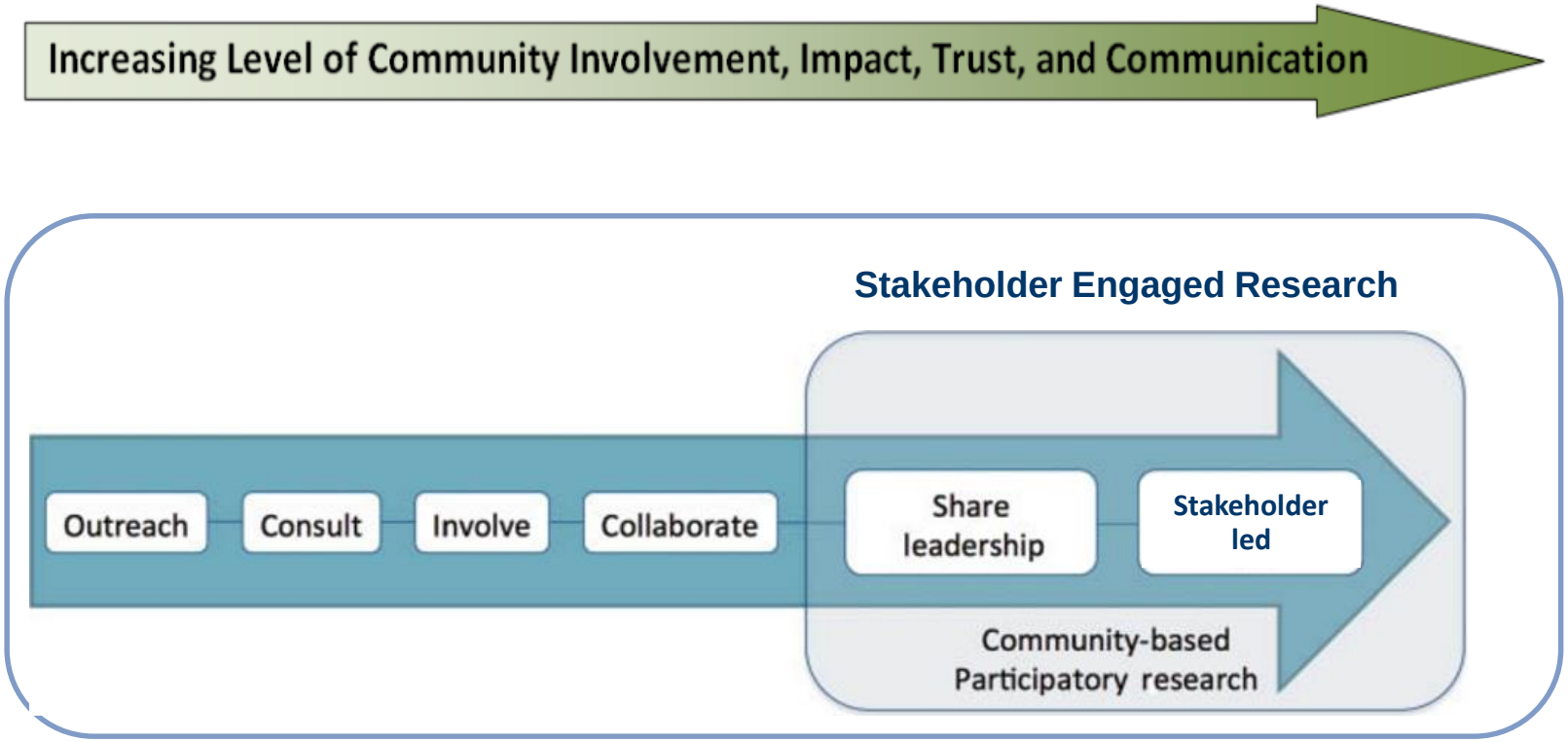
# Ensure Stakeholder engagement in all phases of research

**Figure.** Enhancement of Comparative Effectiveness Research (CER) Through Continuous Patient Engagement

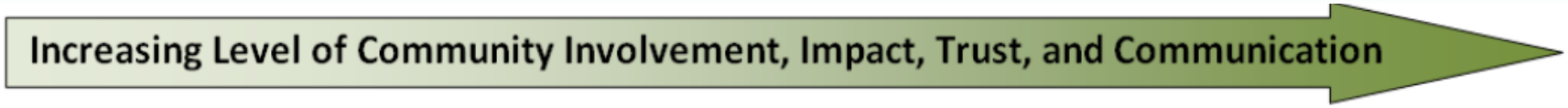
| Step in CER Process | Purpose of Patient Engagement |
|---|---|
| Topic solicitation | ■ Identify topics that are important to patients, caregivers, and the community<br>■ Propose topics to be investigated |
| Prioritization | ■ Solicit feedback on relevance and priority of topics<br>■ Discuss the urgency of addressing topics |
| Framing the question | ■ Ascertain questions' relevance and usefulness<br>■ Assess "real-world" applicability |
| Selection of comparators and outcomes | ■ Identify comparator treatments of interest<br>■ Identify outcomes of interest<br>■ Incorporate other aspects of treatment |
| Creation of conceptual framework | ■ Provide a "reality check"<br>■ Verify logic of conceptual framework<br>■ Supplement with additional factors not documented in the literature |
| Analysis plan | ■ Verify importance of factors and variables<br>■ Ascertain whether there is a good proxy for a specific concept<br>■ Inquire about potential confounding factors |
| Data collection | ■ Determine best approaches for data collection (eg, trial, registry, medical charts)<br>■ Assist with selection of data sources |
| Reviewing and interpreting results | ■ Assess believability of results<br>■ Suggest alternative explanations or approaches<br>■ Provide input for sensitivity analysis |
| Translation | ■ Interpret results to be meaningful<br>■ Document which results are easy or difficult to understand<br>■ Indicate which results are counterintuitive |
| Dissemination | ■ Facilitate engagement of other patients<br>■ Help other patients to understand findings |

Mullins, C. D., A. M. Abdulhalim and D. C. Lavallee (2012). "Continuous patient engagement in comparative effectiveness research." Jama 307(15): 1587-1588.

# Spectrum of Stakeholder Engagement in Research



# Engagement Continuum




| Outreach | Consult | Involve | Collaborate | Shared Leadership |
|---|---|---|---|---|
| *Some Community Involvement*<br><br>*Communication flow is from one to the other, to inform*<br><br>Provides community with information.<br><br>Entities co-exist.<br><br>Outcomes: Optimally, establishes communication channels and channels for outreach | *More Community Involvement*<br><br>*Communication flows to the community and then back, answer seeking*<br><br>To get information or feedback from the community.<br><br>Entities share information<br><br>Outcomes: Develops connections | *Better Community Involvement*<br><br>*Communication flows both ways, participatory form of communication*<br><br>Involve more participation with community on issues.<br><br>Entities are cooperating with each other.<br><br>Outcomes: Visibility of partnership established | *Community Involvement*<br><br>*Communication flow is bi-directional*<br><br>Form partnerships with community on each aspect of project from development to solution<br><br>Entities form bi-directional communication channels<br><br>Outcomes: partnership building, trust building | *Strong Bi-directional Relationship*<br><br>Final decision making is at community level<br><br>Entities have formed strong partnership structures<br><br>Outcomes: Broader health outcomes affecting broader community. Strong bi-directional trust built. |

Reference: Modified by DJ McCloskey and from the International Association of Public Participation

# Purpose of Stakeholder Engagement Studios

- Engaging community members, patients, caregivers, and other stakeholders in research is complex
- Most clinical and translational researchers are not prepared to identify, recruit, and convene stakeholders in research
- Via Studios, members of the researcher's population of interest serve in as consulting experts, typically focused on improving research procedures and outcomes

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# Key Elements of a Studio

- One-time event, typically in early evening, always with food and drink served
- Starts with researcher's brief presentation of the project and poses specific questions to the stakeholder experts
- Stakeholder expert discussion that follows is guided by a neutral facilitator to elicit authentic and constructive feedback
- Advance prep/coaching to support the role of the researcher and stakeholder experts is essential

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# Studios are Not Human Subjects Research

| | Studio | Focus Group Interview |
|---|---|---|
| Purpose | Inform development, implementation or dissemination of research | Qualitative data collection |
| Approach | Bi-directional discussion | Uni-directional |
| Participants | Consultants<br>Identified as experts based on lived experience | Research subjects<br>Screened for eligibility |
| Facilitator | Neutral: could be community member;<br>Not affiliated with research project;<br>Uses techniques to balance power;<br>Uses guide for conversation: can diverge if relevant. | Research team member;<br>Uses pre-approved script: cannot diverge |
| Preparation | Coaching for research team<br>Orientation for stakeholder experts | IRB approval required;<br>Consenting of research subjects |
| Compensation | Consulting fee | Participant incentive |
| Use of input | Participant comments and recommendations summarized<br>CE Studio Team may help researcher interpret and apply recommendations | Participant comments transcribed and qualitatively analyzed |

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# Stakeholder Studio Planning, Implementation and Outcomes


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# Studio Roles and Responsibilities

- Project Lead/Principal Investigator Presents a succinct slide set (Powerpoint) to 'pitch' the planned project or research to participating stakeholders, calling out specific issues or challenges to be addressed during the studio. This presentation is no longer than 10 minutes/10 slides.
- Navigator Responsible for planning and conducting the pre-studio researcher meeting. A boundary spanner with experience working in organizational settings and communities, and familiar with research practices.

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# Studio Roles and Responsibilities

- Facilitator Creates a neutral environment for open discussion between the researcher and the stakeholder experts.
- Stakeholder Advisory Committee Serves to provide on-going guidance and organizational support. Vets all SE Studio requests to assess appropriateness for Studio. Assists investigators with identifying stakeholders to fit needs of research project. Members have experience with patient-centered outcomes research, clinical practice improvement processes, community public relations, participatory action research, and program evaluation.

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# Assessing the Project-Specific Need to Conduct a Studio

1. What challenges are you anticipating (recruitment, retention, invasiveness)?
2. Is there a specific demographic that will be more difficult to reach (age, class, ethnicity)?
3. What parts of the study are most arduous (consenting; activity)?
4. What is your expected timeline for having results?
5. Do you know what outcomes are of most importance to the target population?

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# PRIME-Studios GitHub Site

https://github.com/dlounsbu/PRIME_studios

- A repository for current materials to support planning and conducting Studios
- Project management tool: Wiki pages; Track issues
- Rebranding and tailoring Meharry/Vanderbilt Studio Toolkit
  - Scheduling and Follow-up Timelines
  - Metrics (evaluation summaries)
  - Promoting the CE studio
  - Appendices: Comm Navigator Job Description; FAQs for Researchers; Sample Research Presentation; Expert Orientation Guide; Tools for Recruiting Community Experts; Sample Forms (Tracking database); CE Studio Costs; Researcher Evaluation Survey; Sample CE Studio Summary and Recommendations; Sample CE Studio Flyer (for recruitment)

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# Justina Groeger
# Mentors: Joanna Starrels and Sharon Rikin

Project To improve the quality of opioid prescribing within the Montefiore Healthcare System

2019-04-26: Initial studio planning meeting:

JG shared her background and interests, including her experience at CDC and her interest in epidemiology and public health.

Key study population is patients admitted for knee/hip replacement 65+.

JG described the need to conduct formative research to better understand prescription differentials at discharge, with the goal of developing a standardized approach to tailored care for three populations: (1) Opioid naive, (2) Opioid prior for joint pain management, and (3) Patients with existing opioid dependency/addiction.

EMR dashboards that would inform discharge prescribing would be a tool to develop and test, over time.

JG will draft a protocol for this formative research activity.

Key stakeholders who could inform JG's first research activity would be Nurses/Physician Assistants. Providers (MDs) are also a priority stakeholder group.

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# Kaitlyn Philips
# Mentors: Michelle Gong and Inessa Gendlina

Project: Sepsis recognition and management at Montefiore

2019-05-06: Initial Stakeholder Studio Planning Meeting

Major problem: Over dx of sepsis in ER

Fever, white count, heart rate, and respiratory issues are all symptoms.

Organ failure is associated with sepsis: So, pull admissions data and related information for patients who develop organ failure.

Proposed studio: To elicit concepts that would reduce over dx of sepsis in ED. To explore possible research designs/design issues to support these concepts.

Key stakeholders: ED attending physicians, ED nurses, other ED staff (residents, hospitalists).

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# Kevin Fiori
# Mentor: Michael Rinke

Project: Enhancing health system capacity to address unmet social needs in patients requiring complex primary care services

2010-05-07: Initial Stakeholder Studio Planning Meeting

KF presented preliminary three aims:

> Aim 1: Identify a predictive model of UNMET SOCIAL NEEDS to CLINICAL OUTCOMES. Can SCREENING TOOL effectively classify patients/families?
>
> Aim 2: Design workflow for clinic staff and Community Health Workers (CHWs) that uses SCREENING metrics from Aim 1 to flag AT-RISK patients and to prompt some addition action (i.e., referral to CHW; OUTREACH)
>
> Aim 3: Demonstrate that SCREENING, REFERRAL, and INTERVENTION improves clinical outcomes

Data source: With screening data for approximately 35K patients, statistical modeling (regression; SEM) will look for associations with key outcomes in a population of MMC primary care patients with complex chronic disease (CCD).

Once this modeling is complete, use results to inform a research design to support Aim 2.

Organize stakeholder studio with CHW and primary care clinic staff to obtain their input about preferences regarding 'packaging' of SCREEN TOOL and proposed research design.

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# Vijay Yanamadala
# Mentor: Chandan Guha

Project: Patient centered outcomes are a fundamental aspect of our research in spinal cord injury.

2019-04-23: Initial studio planning meeting

VY to discuss concepts for proposed research. RD (Assistant) joined via Zoom.

Proposed concept is broad. VY described a potential expansive program of research to understand and address how to (1) detect spinal mets, (2) classify patients with mets as high or low risk, (3) coordinate referrals and treatment planning among multiple providers, including neurologists, medical oncologists, radiologists, orthopedic surgeons, and rehab specialists.

The concept of organizing an image repository and of designing machine learning algorithms to screen and classify was one important, initial theme to the proposed study.

A studio with referring providers would be useful.

VY is working to draft his initial research activity protocol.

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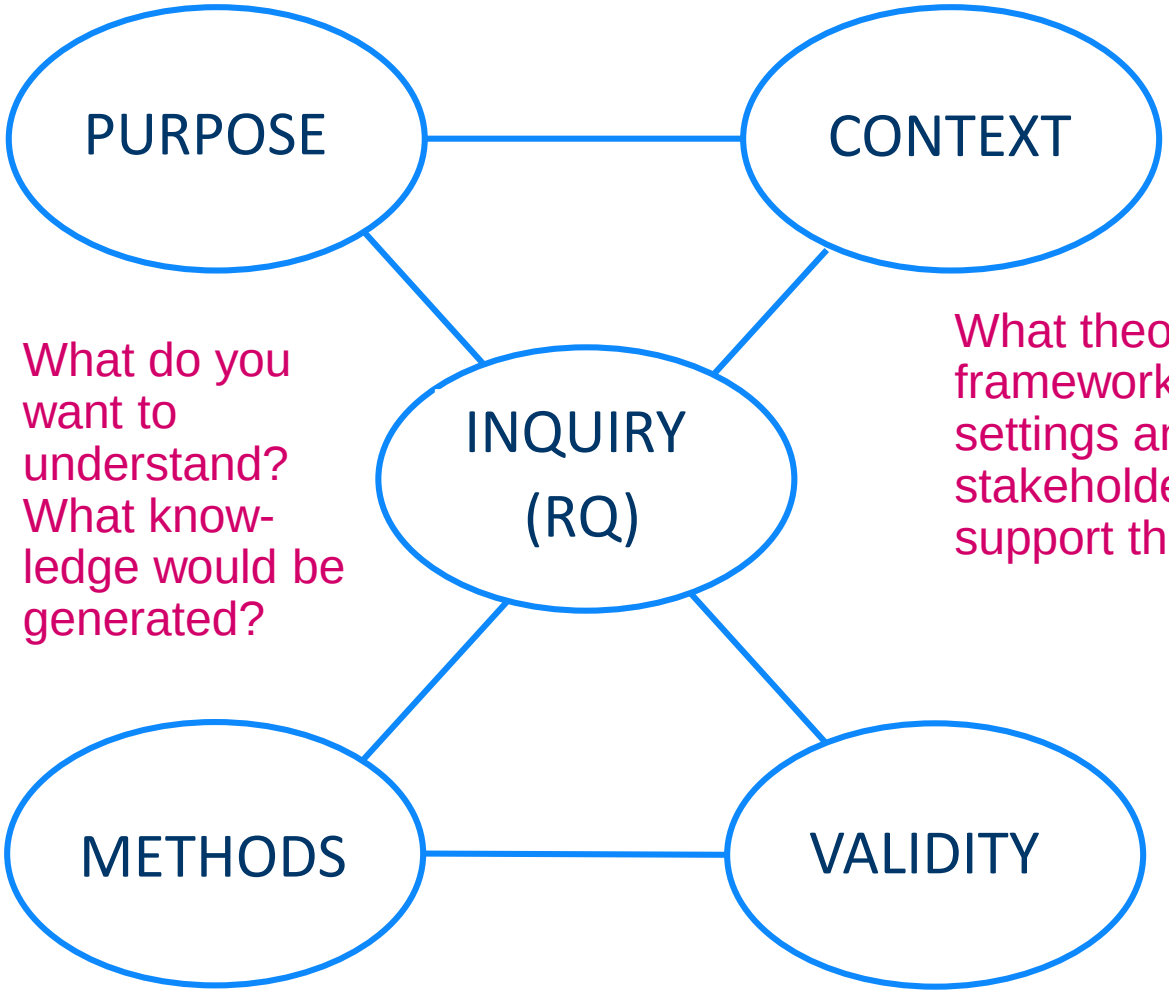
# Maxwell's Interactive Model of Research Design




What are the ultimate aims, goals of this study?

What do you want to understand? What know-ledge would be generated?

What theory or framework and/or settings and stakeholders will support the study?

What is your approach? Your design? Type(s) of data to be collected? Analytic approach?

How might results be limited or wrong?

# Tentative Schedule

- Who goes first? Second? Third? Fourth?
  - Team readiness
  - Accessibility of stakeholders
  - Design-related contingencies
  - Anticipated clinical milestones and/or study opportunities
- Homework:
  - Create personal Github account (to add you as a repository collaborator)
  - Draft 10 min/10 slide studio pitch (Due date?)
- Future studio planning meetings

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# THANK YOU!

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