Engaging With Stakeholders & Aligning With Health System Partners

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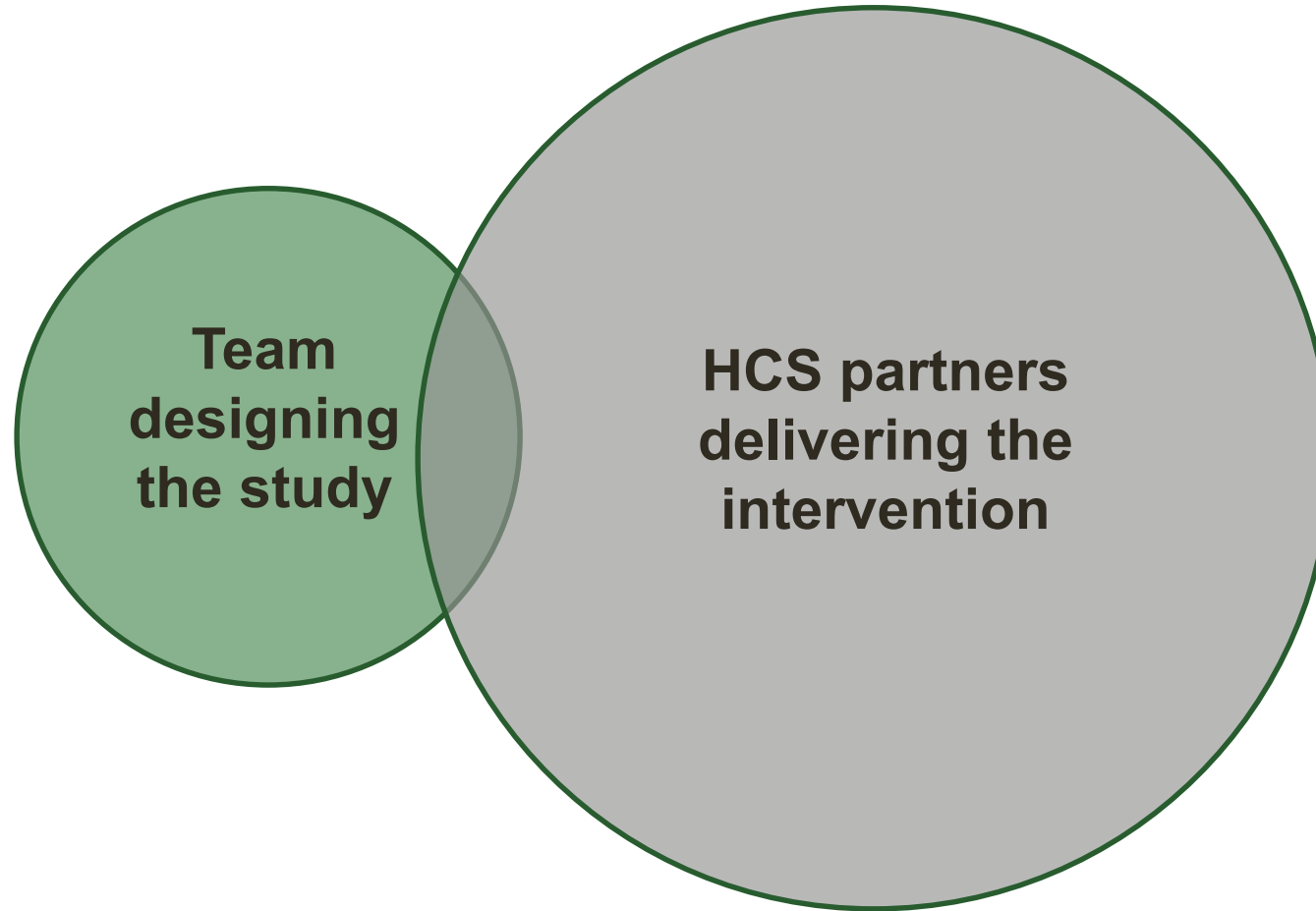
Learning goals

- Identify skills needed for a strong study team and consider the diversity of the team, including inclusive practices
- Describe the breadth of stakeholders to engage as partners and approaches for engaging them through all phases of the study
- Understand the real-world priorities and perspectives of healthcare system leaders and how to obtain their support
- Identify engagement practices to obtain patient and community perspectives
- Highlight challenges of partnering across diverse health systems
- Q & A with attendees

New: **Group Activity!**

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Important things to know

- ePCTs are a team sport
- Necessary expertise depends on the study aims and how the intervention will be implemented
- Plan for ongoing training—Clinical, IT, or other staff turnover may be high
- Plan for sustainability—If the intervention will be turned on at all sites at end of study, what are the plans to maintain or turn off intervention?

Who is involved?

Team designing the study

HCS partners delivering the intervention

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Potential team members

- Principal investigator, co-investigator
- Health system leader or executive
- Biostatistician
- Lead clinician (eg, pediatrician, behavioral specialist, radiologist, pharmacist, physical therapist)
- Clinical staff (eg, nurse, operations manager, business manager)
- IT specialist for EHR data extraction or clinical decision support tool design

- Implementation science researcher
- Site champion/liaison
- Practice facilitator
- Research assistant
- Project coordinator
- Research participant, patient, or patient advocate
- Society leadership

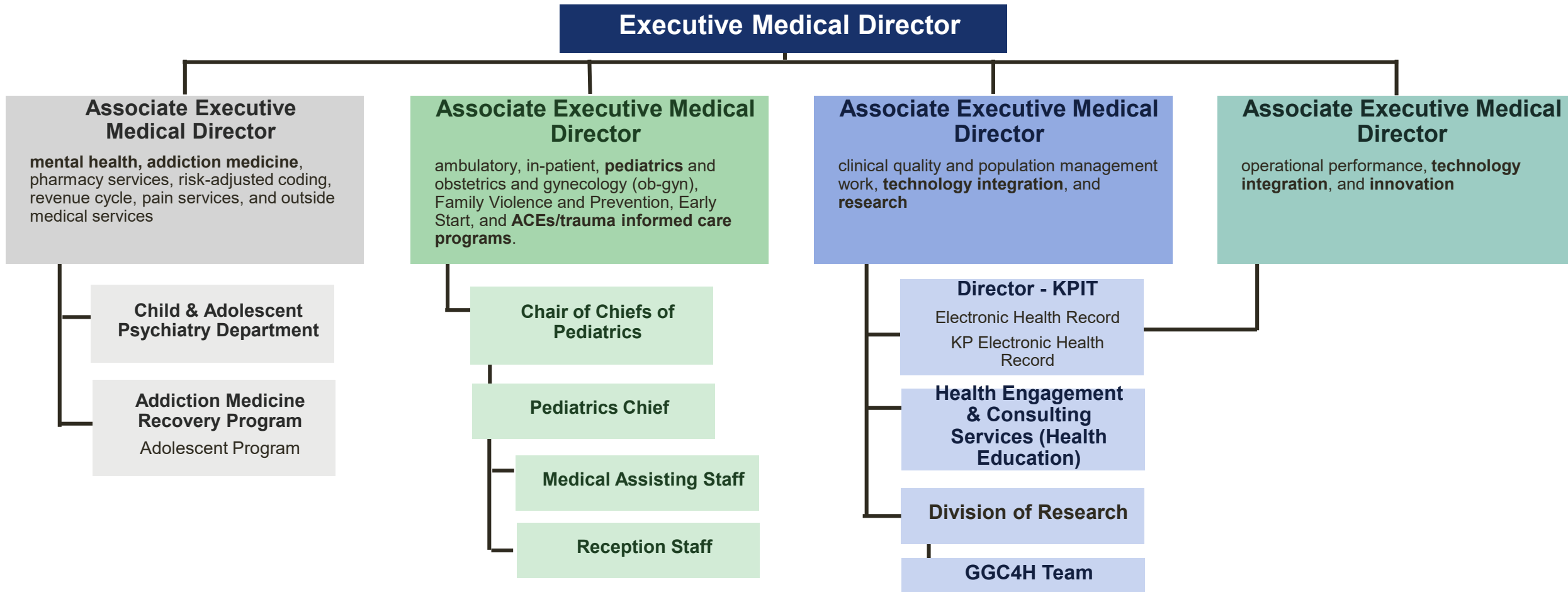NIH PRAGMATIC TRIALS COLLABORATORY
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Important things to do

- Identify the skills that are needed during the planning phase
- Recruit team members during the planning phase and engage them throughout for the duration of the trial
- Plan for staff turnover, especially clinical and IT
- Plan for dissemination, implementation, de-implementation at the start

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What skills will be needed?

- Best skill set depends on the study aims and how the intervention will be embedded in the healthcare system workflow
- Questions to ask:
  - What clinical specialties will be needed to carry out the intervention?
  - What roles will support clinic operations?
  - Who will be the liaison between HCS departments for interventions that are multidisciplinary?
  - What aspects of the trial will require IT staff expertise?
  - Will the trial need training videos, online materials, or toolkits?

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Kaiser Permanente Northern California

Executive Medical Director

Associate Executive Medical Director

mental health, addiction medicine, pharmacy services, risk-adjusted coding, revenue cycle, pain services, and outside medical services

- **Child & Adolescent Psychiatry Department**
- **Addiction Medicine Recovery Program**
  Adolescent Program

Associate Executive Medical Director

ambulatory, in-patient, **pediatrics** and obstetrics and gynecology (ob-gyn), Family Violence and Prevention, Early Start, and **ACEs/trauma informed care programs**.

- **Chair of Chiefs of Pediatrics**
- **Pediatrics Chief**
- **Medical Assisting Staff**
- **Reception Staff**

Associate Executive Medical Director

clinical quality and population management work, **technology integration**, and **research**

- **Director - KPIT**
  Electronic Health Record
  KP Electronic Health Record
- **Health Engagement & Consulting Services (Health Education)**
- **Division of Research**
- **GGC4H Team**

Associate Executive Medical Director

operational performance, **technology integration**, and **innovation**

Guiding Good Choices for Health: The study team engaged with all of these aspects of The Permanente Medical Group at Kaiser Permanente Northern California. These stakeholders represent a small fraction of the many relevant stakeholders in large, complex healthcare systems. Most systems are comprised of several different entities – e.g., medical group, health plan, hospitals/facilities, etc. + labor partners

Considerations for Training Front-Line Staff and Clinicians on Pragmatic Clinical Trial Procedures

EPCT QUICK START GUIDE FOR RESEARCHER AND HEALTHCARE SYSTEMS LEADER PARTNERSHIPS

This Quick Start Guide is designed to help clinical investigators successfully partner with healthcare system leaders to support the successful conduct of an embedded pragmatic clinical trial (ePCT) within their healthcare system. It provides advice from the Collaboratory and serves as an annotated Table of Contents, pointing readers to essential content in the *Living Textbook* regarding partnering to conduct an ePCT.

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journal homepage: www.elsevier.com/locate/hjdsi

Perspectives

Trials without tribulations: Minimizing the burden of pragmatic research on healthcare systems

Eric B. Larson [a], Chris Tachibana [a], Ella Thompson [a], Gloria D. Coronado [b], Lynn DeBar [b], Laura M. Dember [c], Stacey Honda [d], Susan S. Huang [e], Jeffrey G. Jarvik [f], Christine Nelson [g], Edward Septimus [h], Greg Simon [a], Karin E. Johnson [a,*]

Review article

Pragmatic clinical trials offer unique opportunities for disseminating, implementing, and sustaining evidence-based practices into clinical care: Proceedings of a workshop

Leah Tuzzio*, Eric B. Larson, David A. Chambers, Gloria D. Coronado, Lesley H. Curtis, Wendy J. Weber, Douglas F. Zatzick, Catherine M. Meyers

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How researchers approach stakeholders in traditional RCTs

Researcher reviews the literature

Researcher presents idea to researchers who understand the theory and can see how study fills gap

Researcher designs and conducts study, prepares manuscripts

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Researchers partner with stakeholders in ePCTs differently.

Important things to know 👓

- **Start engagement early**, even before you have a research question or study design
- Be patient: Relationships take time to build and nurture
- Consider whether your intervention will add value
- Expect changes and disruptions
- Engage stakeholders continuously

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Who will be impacted? Who are the decision makers?

Potential stakeholders have a variety of priorities, values, work cultures, and expectations:

- Healthcare delivery organization leaders
- Clinicians
- Operational personnel
- Patients, caregivers, patient advocacy groups

- Payers, purchasers
- Policy makers, regulators
- Research funders
- Researchers
- Product manufacturers

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Roles of stakeholders

1. Designing the trial

2. Successfully conducting the research

3. Disseminating the results

Roles of stakeholders

1. **Designing the trial**
2. Successfully conducting the research
3. Disseminating the results

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Choosing a salient question

We want to know what you need.
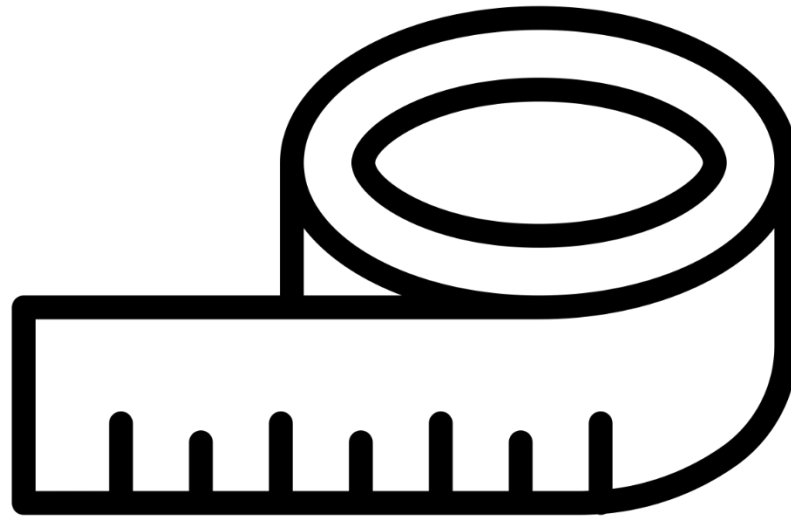*What research should we be doing?*
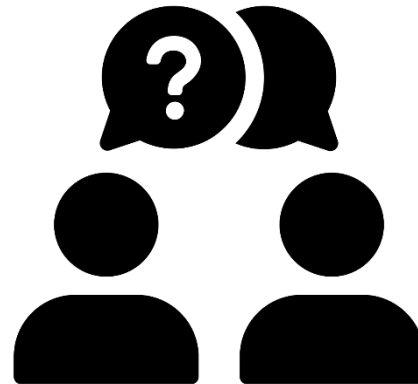
Source: Greg Simon, MD, MPH

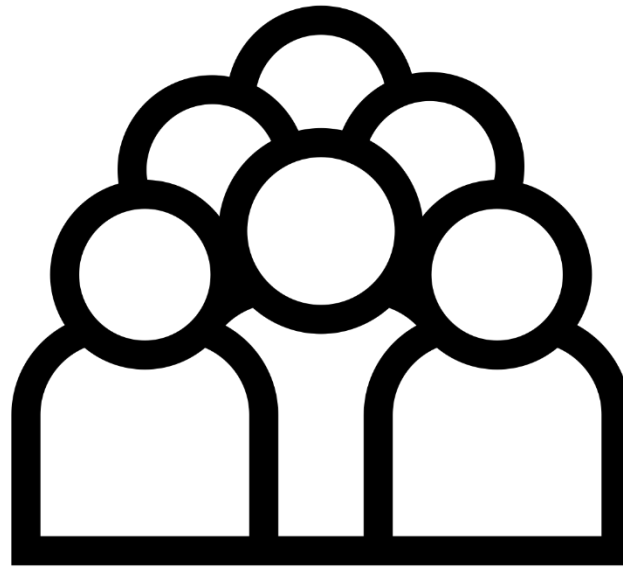# Designing the intervention for sustainment
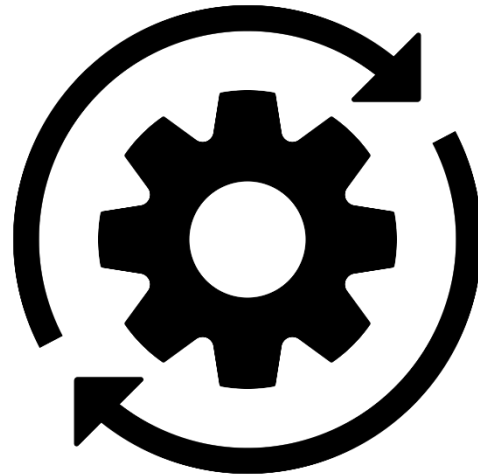
Designing the intervention to minimize burden for patients and clinicians
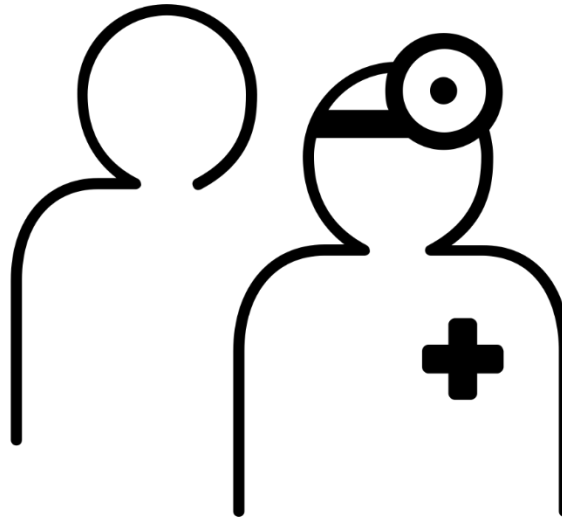
Selecting outcome measures

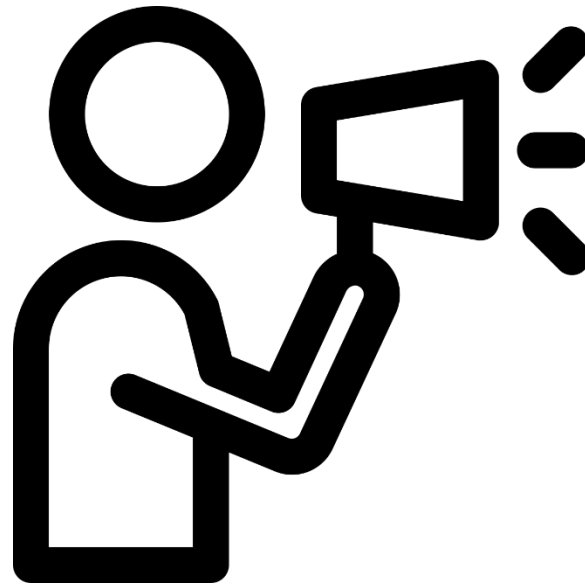# Determining inclusion and exclusion criteria

Roles of stakeholders

1. Designing the trial
2. **Successfully conducting the research**
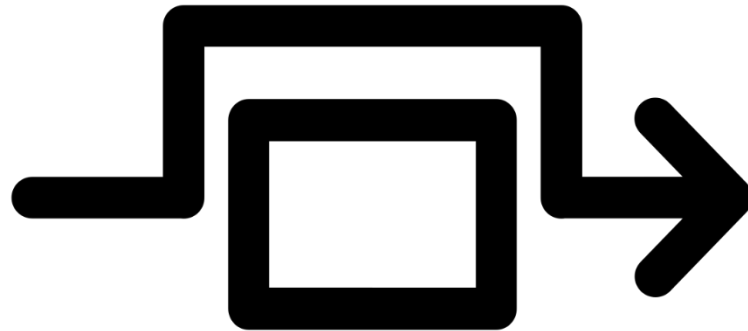3. Disseminating the results

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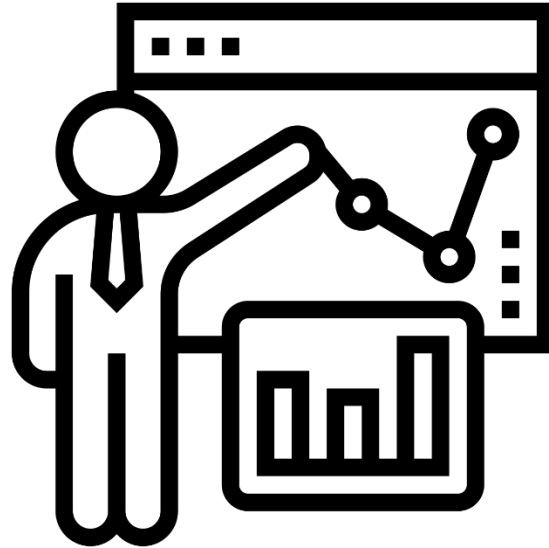
Develop recruitment strategies

Serve as study champions
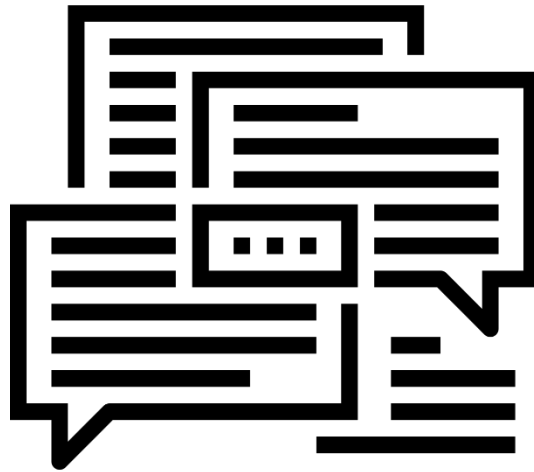
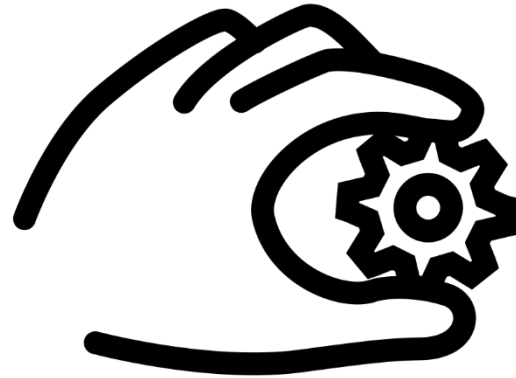# Track challenges and adaptations

Interpret study results

Roles of stakeholders

1. Designing the trial
2. Successfully conducting the research
3. **Disseminating the results**

Determine key messages for different stakeholder groups and identify avenues for dissemination

Support implementation or de-implementation

Consider changes to policies and guidelines

Roles of stakeholders

1. Designing the trial

2. Successfully conducting the research

3. Disseminating the results

Engaging Stakeholders Group Activity

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Group Activity Instructions

- Look at the **assigned letter (A, B, or C)** on your engagement activity sheet and find your small group

- Spend **5 minutes on your own** reading the prompt and jotting down some thoughts about the questions

- Spend **10 minutes as a group** discussing responses

- **Report back** to the large group

A Stakeholder Engagement Success Story: STOP CRC

- **Goal**: STOP CRC aims to improve rates of colorectal cancer screening in patients at Federally Qualified Health Centers

- **Problem**: Some patients lacked health insurance coverage to pay for follow-up colonoscopy after a positive fecal test.

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A Stakeholder Engagement Success Story: STOP CRC

- The advisory board included legislators who changed state law to require commercial insurance plans to cover follow-up diagnostic colonoscopy with no patient out-of-pocket costs

- Local community organizations provided free colonoscopy through a network of donated care

- Medicaid expansion resulted in higher insurance coverage rates

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Resource: Engaging stakeholders

Engaging Stakeholders and Building Partnerships to Ensure a Successful Trial

From the *Living Textbook of Pragmatic Clinical Trials*
www.rethinkingclinicaltrials.org

Design	Data, Tools & Conduct	Dissemination	Ethics and Regulatory
View Chapters >	View Chapters >	View Chapters >	View Chapters >

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Resources: Journal articles

- Concannon TW et al. Practical guidance for involving stakeholders in health research. *J Gen Intern Med*. 2019 Mar;34(3):458-463.

- Whicher DM et al. Gatekeepers for pragmatic clinical trials. *Clin Trials*. 2015 Oct;12(5):442-448.

- Johnson KE et al. A guide to research partnerships for pragmatic clinical trials. *BMJ*. 2014 Dec 1;349:g6826.

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Important things to do

- Engage stakeholders early and often
- Set expectations to work collaboratively and build trust from the beginning
- Use familiar language that stakeholders understand
- Get to know your stakeholders' values, priorities, and expectations
- Assess your partners' capacity and capabilities
- Track goals reached, challenges, and adaptations throughout the life cycle of your ePCT
- Show appreciation and celebrate accomplishments early and often to have sustained partnerships

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Questions?

Stakeholder roles in:

Design
- Question
- Intervention
- Outcomes
- Population

Conduct
- Recruitment
- Advocacy
- Challenges
- Interpretation

Dissemination
- Messaging
- Venues
- Implementation
- Guidelines

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