Advisory Panel on Clinical Trials
Fall 2019 Meeting

November 5, 2019

9:30 AM – 1:30 PM ET

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Goals for the Day

Andrea Troxel, ScD (Chair)
Professor and Director,
New York University School of Medicine

Anne Trontell, MD, MPH
Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Allie Rabinowitz, MPH
Senior Program Associate, Clinical Effectiveness and Decision Science, PCORI

Housekeeping

- Panelists who were not able to attend in person have access to dial in information.
- COI and Confidentiality.

COI Statement

Welcome to the CTAP Fall 2019 Meeting. I want to remind everyone that disclosures of conflicts of interest of members of CTAP are publicly available on PCORI's website and are required to be updated annually. Members of the CTAP are also reminded to update your conflict of interest disclosures if the information has changed. You can do this by contacting your staff representative, Allie Rabinowitz.

If the CTAP will deliberate or take action on a matter that presents a conflict of interest for you, please inform the Chair so we can discuss how to address the issue. If you have questions about conflict of interest disclosures or recusals relating to you or others, please contact your staff representative, Allie Rabinowitz.

Introductions

- Your name
- Your CTAP stakeholder role
- Your institutional or professional organization affiliation

PCORI Updates

Anne Trontell, MD, MPH
Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Follow Up From Previous Meeting and Chair Nominations

Allie Rabinowitz, MPH

Senior Program Associate, Clinical Effectiveness and Decision Science, PCORI

CTAP Spring 2019 Topic Follow Up: Returning Aggregate Results to Patients

- Currently: Applicant guidelines encourage awardees to return results
- PCORI Workgroup created to make this clearer and more prominent
- Goal: Have a strategy finalized and implemented for future PFAs

Chair Position Opening

- Next Fall 2020 - Position of Chair and Co-Chair will both be open
- Position entails:
  - Oversite and consultation of agenda development
  - During in-person meetings
    - Introduce topics
    - Keep to the agenda
    - Moderate discussion
- If you are interested in serving in the leadership of the panel or nominating a fellow member, please contact Allie Rabinowitz

- Questions ?

Understanding PCORI's Complex Interventions Standards: How Implementation Science Can Help

Andrea B Troxel, ScD (Chair)
Professor and Director of Biostatistics
Department of Population Health
New York University School of Medicine

Methodology Committee

Standards for Studies of Complex Interventions (SCI)

- Proposed October 2017
- Approved April 2018

Studies of Complex Intervention Standards

- **SCI-1:** Fully describe the intervention and comparator and define their core functions
- **SCI-2:** Specify the hypothesized causal pathways and their theoretical basis
- **SCI-3:** Specify how adaptations to the form of the intervention and comparator will be allowed and recorded
- **SCI-4:** Plan and describe a process evaluation
- **SCI-5:** Select patient outcomes informed by the causal pathway

Studies of Complex Intervention Standards

Of particular interest

- **SCI-2:** Specify the *hypothesized causal pathways* and their theoretical basis
- **SCI-3:** Specify how *adaptations* to the form of the intervention and comparator will be allowed and recorded

Studies of Complex Intervention Standards

Note that **SCI-2** and **SCI-3** are very closely linked

- **SCI-2:** The *hypothesized causal pathways* involve a proposal for how the intervention works, and what the critical features are
- **SCI-3:** The causal pathway will elucidate how *adaptations* the intervention and comparator may affect its impact

Studies of Complex Intervention Standards

Together, these two standards will inform a process evaluation to inform these questions

- **Implementation** science is a field that formalizes process evaluations and other ways of assessing reach, adoption, and scalability

Implementation Science

"The scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services"

Bauer, Damschroder, Hagedom, Smith, Kilbourne. An introduction to implementation science for the non-specialist. *BMC Psychol* 3(1): 32, 2015.

Implementation Science

- Process evaluation
  - Describes characteristics of the use of an EBP
- Formative evaluation
  - Uses data gathered to adapt and improve implementation
- Summative evaluation
  - Compilation of impact of an implementation strategy
  - May characterize economic impact

Implementation Science

- Especially relevant to complex interventions
- Considers barriers and facilitators of successful implementation
  - Systems level
  - Individual practitioner level
  - Participant level
- Considers effect of changes or adaptations
- Considers adoption, scalability

Implementation Science Frameworks

- Consolidated Framework for Implementation Research (CFIR)
- RE-AIM
- Proctor
- Precede-Proceed
- PRISM
- Many others…

CFIR

- Five major domains
  - Intervention characteristics
  - Inner setting
  - Outer setting
  - Characteristics of implementing individuals
  - Implementation process

Damschroder, Aron, Keith, Kirsh, Alexander, Lowery. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 4: 50, 2009.

RE-AIM

- Five dimensions
  - Reach
  - Efficacy / Effectiveness
  - Adoption
  - Implementation
  - Maintenance

Glasgow, Vogt, Boles. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *Am J Public Health* 89(9): 1322-7, 1999.
www.re-aim.org

Implementation Science Study Designs

- Hybrid Type I
  - Test health impact of EBP while collecting explicit data on implementation
- Hybrid Type II
  - Test both EBP effects on health outcome and implementation strategy effects on EPB use
- Hybrid Type III
  - Test ability of implementation strategy to enhance use of EBP while collecting data on health impact

Example

- cRCT of two multicomponent interventions for implementation of tobacco use treatment
  - TTR: training, toolkit, reminder system
  - Intervention: TTR + Village Health Worker referral
- Pre-trial, conducted formative assessment using CFIR
  - Identify potential barriers and facilitators
  - Inform modifications to optimize translation

VanDevanter, Kumar, Nguyen, Nguyen, Stillman, Weiner, Shelley. Application of the Consolidated Framework for Implementation Research to assess factors that may influence implementation of tobacco use treatment guidelines in the Viet Nam public health care delivery system. *Implement Sci 12*: 27, 2017.

Example

- Formative assessment
  - Semi-structured interviews with 40 providers and VHWs
- Interview guides covered
  - Intervention characteristics (current practices, relative pros/cons of proposed approach)
  - Outer setting (perceived need for services, role of Ministry of Health)
  - Inner setting (leadership engagement, compatibility with current workflow
  - Individual characteristics (provider knowledge, attitudes, beliefs)

Example

- Data analysis
  - Thematic content analysis
  - Mapping of themes to CFIR domains
- Results
  - Intervention characteristics: training, referral resource, complexity
  - Outer setting: patient needs, policies
  - Inner setting: implementation climate, competing priorities, workflow compatibility, learning climate, leadership engagement
  - Individual characteristics: collective efficacy, identification with organization

Discussion

- What designs are the most relevant for PCORI?
- What guidance can CTAP give to supplement the recommendations of the Methodology Committee?
- Do we have particularly good examples of hybrid designs to learn from?

Thank You

Supplementary Slides

Proctor

- Eight implementation outcomes
  - Acceptability
  - Adoption
  - Appropriateness
  - Costs
  - Feasibility
  - Fidelity
  - Penetration
  - Sustainability

Proctor, Silmere, Raghavan, Hovmand, Aarons, Bunger, Griffey, Hensley. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 38(2): 65-76, 2011.

Precede-Proceed

- PRECEDE
  - Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation
- PROCEED
  - Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development

Green, Kreuter. Health program planning: An educational and ecological approach, 4th Ed. New York: McGraw-Hill 2005.

PRISM

- Four primary elements
  - Program intervention
    - Organizational perspective
    - Patient perspective
  - External environment
  - Implementation and sustainability infrastructure
  - Recipients
    - Organizational characteristics
    - Patient characteristics

Feldstein, Glasgow. A practical, robust implementation and sustainability model (PRISM) for integrating research findings in to practice. *Jt Comm J Qual Patient Saf* 34(4): 228-43, 2005.

Break

11:15am – 11:30am

Challenges of PCORI Awardees: Notes from the Field

In-Depth Feedback Gathered From
PCORI's Pragmatic Clinical Studies Investigators

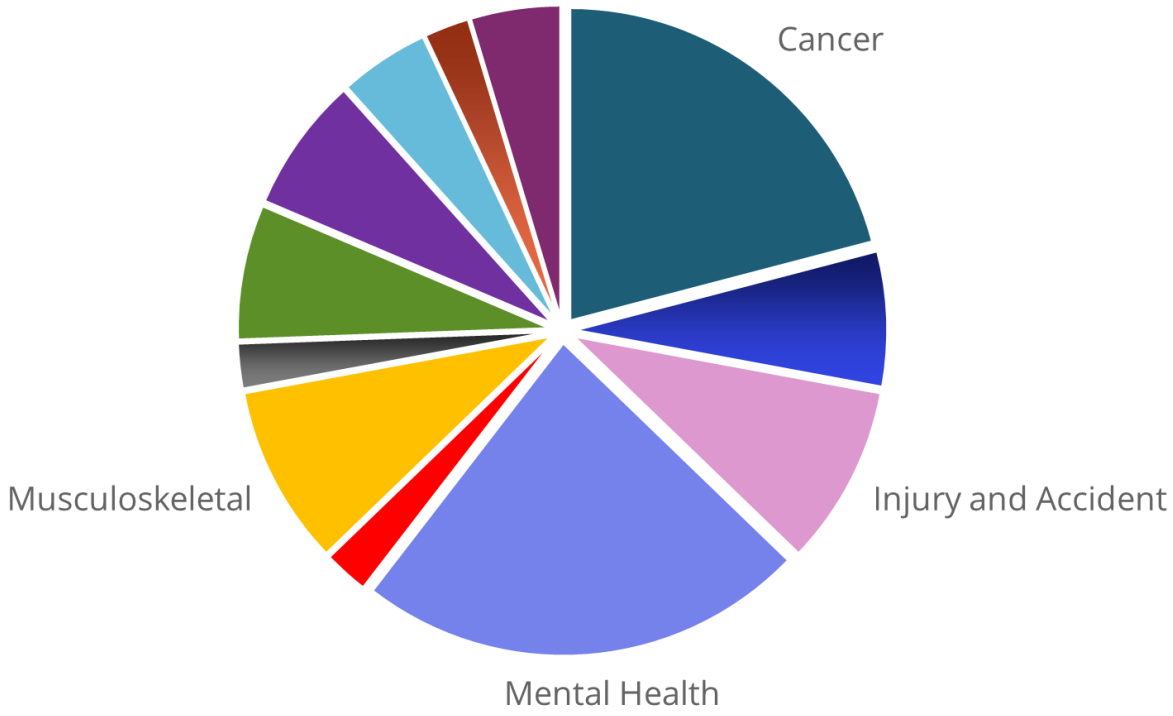
Do These Offer CTAP Future Opportunities for Input?

Anne Trontell, MD, MPH
Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Background on PCORI's Named Pragmatic Clinical Studies Portfolio

42 studies with 40 randomized trials

- Perhaps the world's largest single collection of named "pragmatic studies"
- Unique opportunity to learn & advance real-world evidence generation for ALL PCORI-funded studies
- Real-world implementation with scientific rigor is a common challenge



Cluster-Randomized = 14

Primary Non-inferiority design = 12

PCORI-Funded "Pragmatic " Studies Extend Beyond the Named PCS Portfolio

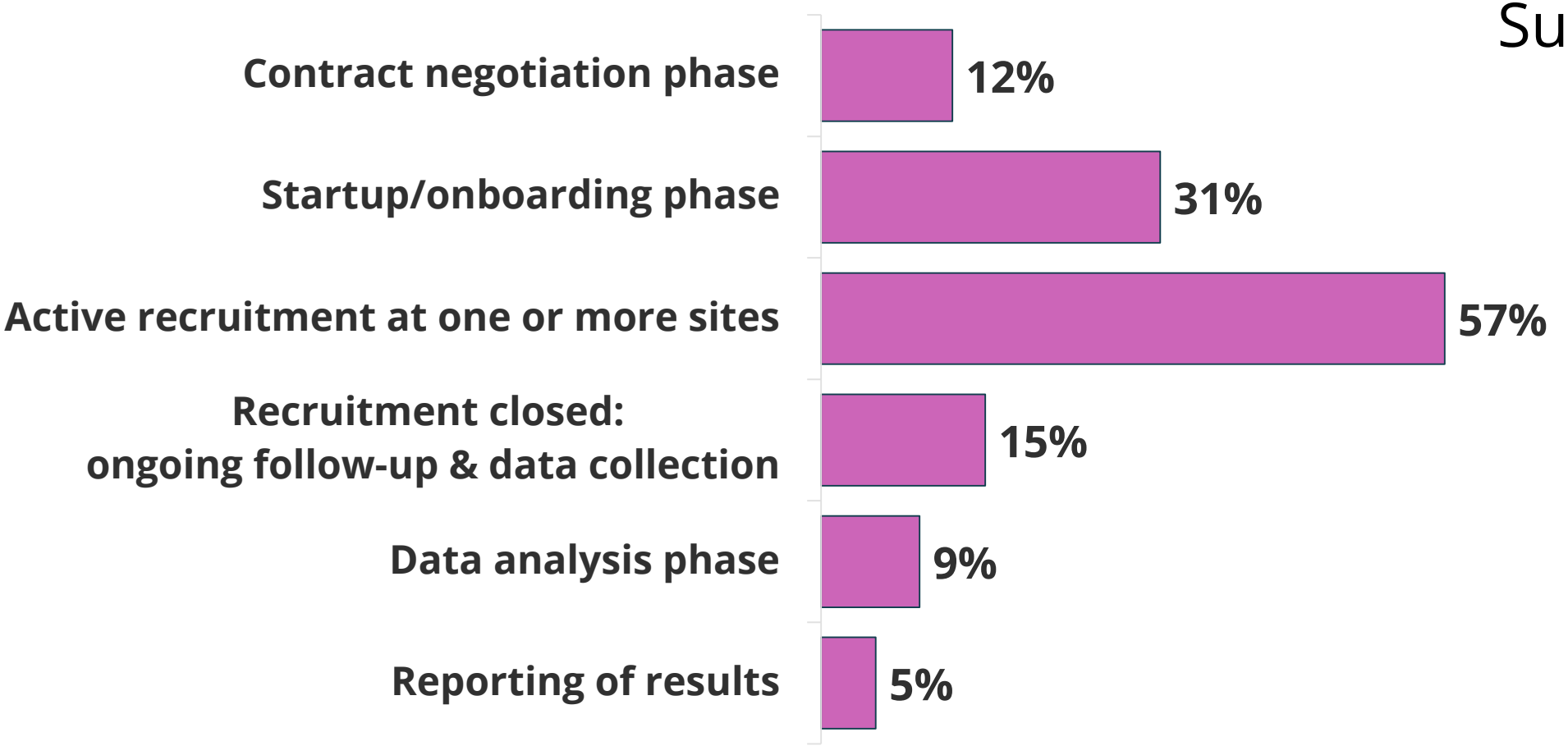
- Pragmatic studies have no fixed definition, most often described on a continuum of 9 domains where extent of pragmatism varies 1 to 5
- A liberal interpretation would include nearly all PCORI studies because PCORI requires all its funded research have a pragmatic focus
  - Real-world populations
  - Real-world settings of care
  - Relevant patient-centered outcomes
  - Engage multiple stakeholders as well as patients
- Thus, PCS investigator challenges are emblematic of other PCORI-funded research

Needs Assessment of Pragmatic Clinical Study Investigators

- To assess potential value of PCORI establishing a “learning network”
  - Structured networking approach for peer-to-peer learning through real/virtual meetings, collaboration, & shared resources
- Basis of feedback received July – September 2019
  - In-depth discussions: Awardees & PCORI stakeholders (n=8)
  - Awardee web survey: N=89 PIs/co-PIs + PMs/PCs
    RR= 84% (only 1 study unrepresented)
  - In person meeting of PIs/designees with ~80% of studies represented

Study Implementation Phase

Survey



“Getting it [the PCS] right [is a challenge]”
said one awardee to summarize
the tension and tradeoffs between achieving “pragmatism” and maintaining scientific rigor
in the study, adding,
“You can’t have it all in many cases.”

Challenges Volunteered by Survey Respondents

When asked for brief descriptions of any current study challenge(s), 57 respondents reported at least 1

Top 3 themes seen of challenges identified by all respondents

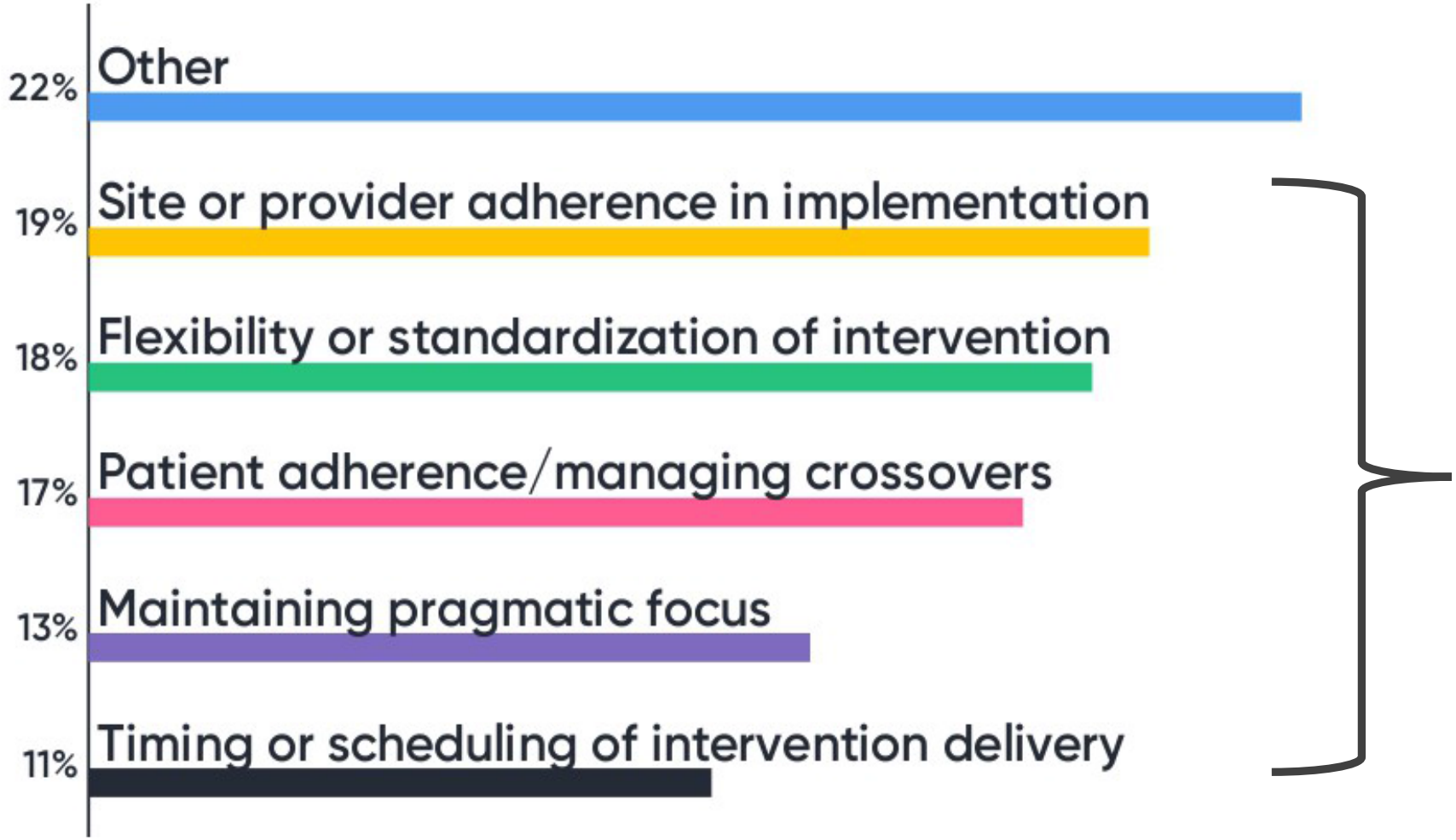
1. Flexibility and real-world implementation ← #1 for PIs
2. Patient recruitment, enrollment, and retention
3. Study site startup and onboarding ← #1 for PMs

In-person Meeting Focus: Top Identified Issues from Survey

- Challenges and questions
  - Flexibility/fidelity/standardardization of interventions and adherence
  - Recruitment/accrual/retention (RAR)
  - Study site startup & onboarding
- Interest in sharing experiences with stakeholder engagement

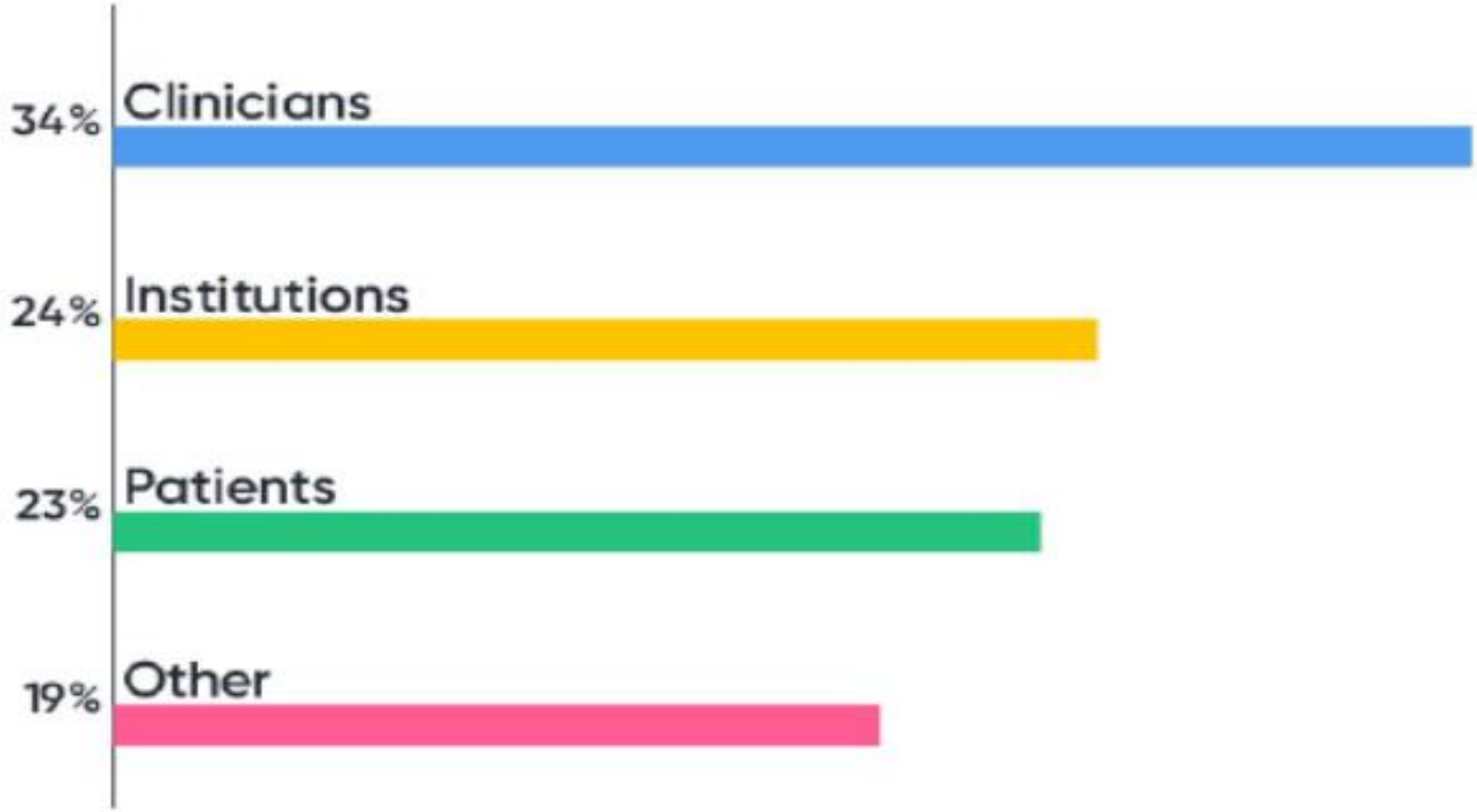
Flexibility and Fidelity: Distribution of Factors Contributing to Challenges

In-person Meeting Responses



Flexibility and Fidelity: Distribution of Leading Contributors to Challenges Seen

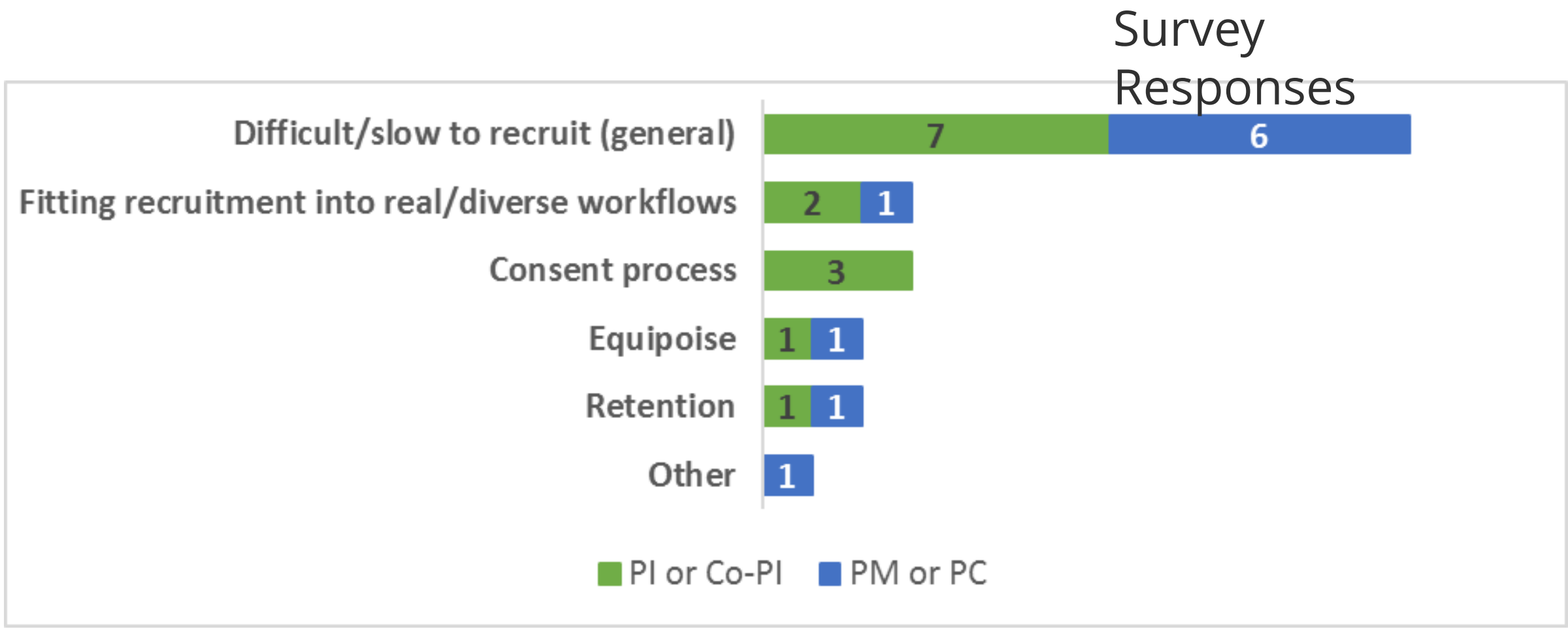
In-person Meeting Responses



Flexibility and Fidelity: Potential Opportunities for CTAP Input

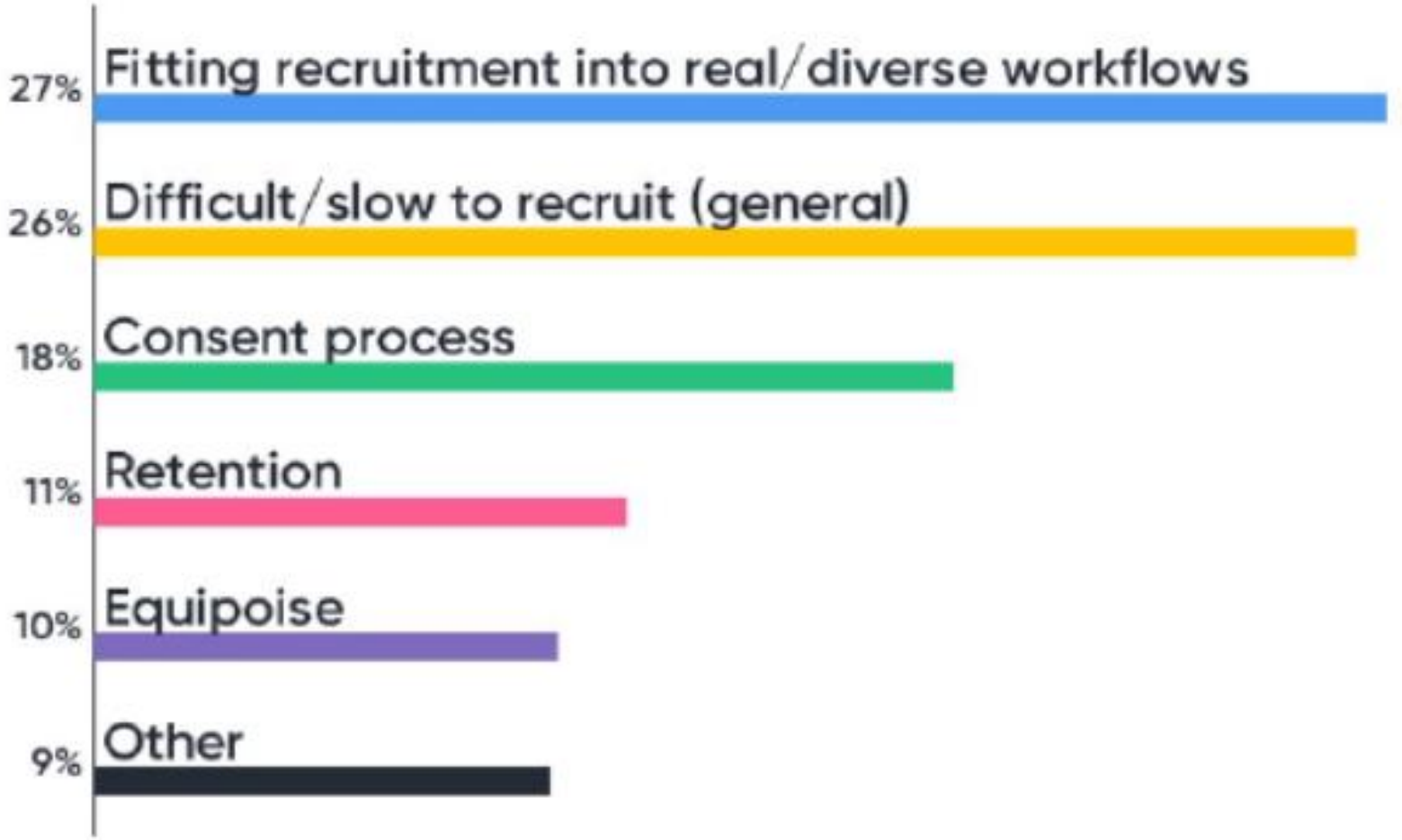
- Setting boundaries or “guardrails” around what is allowed in conduct
  - “Pragmatic” doesn’t mean “sloppy”
- Managing the range of differing expectations of collaborators
  - Laissez-faire or ”do what you want”
  - Over-enthusiastic quality improvement teams that want to “improve” the intervention and change it substantively
- Writing protocols that allow typical variation in the standard of care so variations are not construed as protocol deviations
- Methods to measure adherence

Recruitment and Enrollment: Challenges Experienced



Recruitment & Enrollment: Distribution of Contributing Factors to Challenges

In-person Meeting Responses



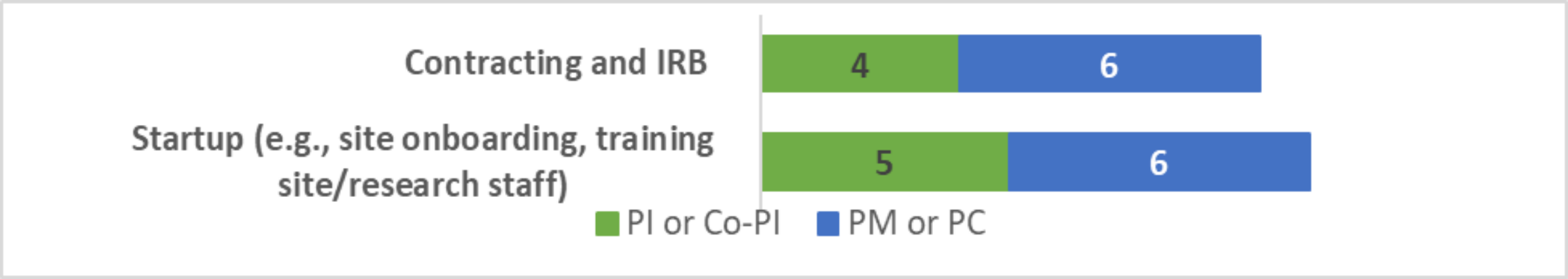
Recruitment and Enrollment: Themes Emerging from Discussion

PCORI Question: Are there common challenges to recruitment and enrollment that are unique to pragmatic studies?

- No/low experience of “real-world” clinical sites with fewer resources in terms of personnel, space, infrastructure to handle trial operations
- More experienced sites struggle with flexible implementation vs. tightly controlled interventions of conventional RCTs and industry trials

Study Site Startup and Onboarding: Challenging Aspects

Survey Responses



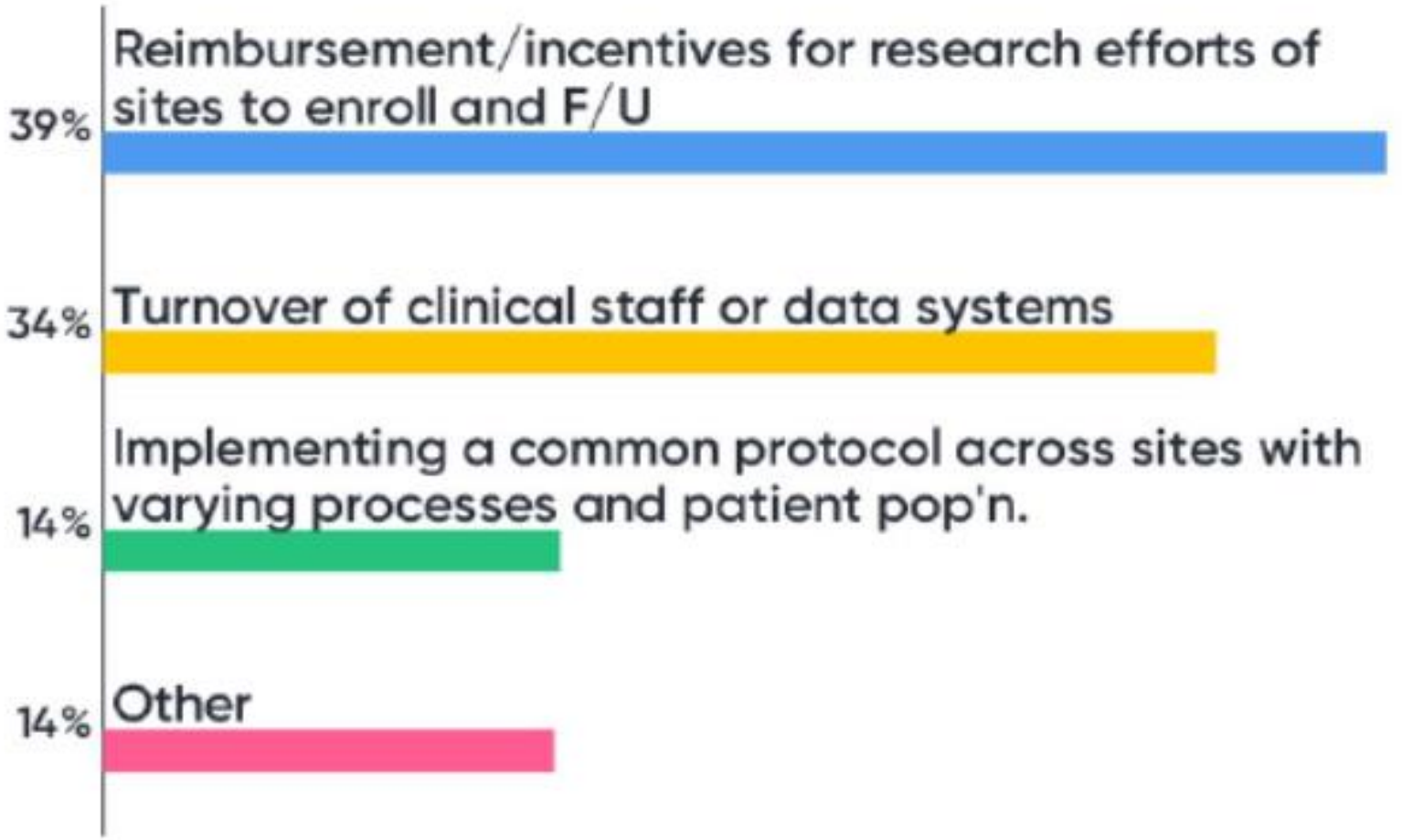
Study Site Startup and Onboarding: Main Sources of Challenges

What percentage contribution do these make to your study startup & onboarding challenges?

- Reimbursement/incentives/disincentives for **research efforts** of sites to enroll, carry out interventions, and follow up patients
- Turnover of clinical staff, leadership, or data systems (e.g. EHR upgrades)
- Implementing a common protocol across sites with varying clinical care processes, staffing, community factors, and patient populations

How Much do These Contribute to Your Study Startup/Onboarding Challenges?

In-person Meeting Responses



Stakeholder Engagement: Benefits

- Patient stakeholders were most often to be a source of study contributions
- Patient SH contribute perspective, understanding of obstacles, and language/framing suggestions (10)
- Help with recruitment & enrollment (4)
- Help in understanding/overcoming obstacles or barriers
- Input to make study design relevant

Other Challenges and Questions

- Despite good planning, unanticipated issues arise in the real world. How best to manage these (and quickly) as they arise?
- If something is not working and redesign seems necessary, how determine what to do?
- Deviations from the study plan and handling them analytically (e.g. XO due to “structural” vs. selection bias)
- How can technology (wearables, apps, etc) facilitate trials? Which of emerging options is best?

Next Steps for CTAP ?

- Exploration of specific issues at future meetings
- Lead-in to discussion of developmental, pilot, or phased research funding models
  - Can developmental or pilot studies mitigate challenges in real world research conduct?
  - Are there opportunities to facilitate real world research conduct with developmental, pilot, or phased/staged funding approaches?
    - Engagement activities with clinicians, patients, and health systems
    - Infrastructure support and training
    - Observational health services research on practice patterns, populations,etc.

Lunch

12:00pm

How Might Staged or Phased Research Projects Improve the Quantity, Quality, and Success of PCORI-Funded Trials?

Anne Trontell, MD, MPH
Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Allie Rabinowitz, MPH
Senior Program Associate, Clinical Effectiveness and Decision Science, PCORI

Courtney Clyatt, MA, MPH
Program Officer, Engagement, PCORI

Session Goals

To present and discuss preliminary PCORI research into different mechanisms of developmental/pilot studies or phased research funding to inform possibilities for PCORI 2.0

Reasons to explore developmental/pilot studies or staged/phased research funding

- To amplify and diversify impactful applications to PCORI such as
  - Head to head comparisons of clinical options (being explored by a PCORI Board workgroup)
  - Interventions delivered by or in primary care
  - Rare diseases
- To inform selection and management of PCORI's largest research investments

Plan for Presentation and Discussion

- Describe PCORI's current practices
  - Research awards
  - Engagement awards in support of research project development
- Present developmental/pilot and phased funding models used by other funding organizations (NIH, VA, and private foundations)
- Invite CTAP consideration and discussion
  - Members' experience of different models
  - Other models to explore
  - Benefits/downsides to different models
  - Optimal application of different funding models, including targeted use(s) of different models to achieve varying goals

Overview of PCORI Mission and Authorities

- Mission: 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.
- PCORI must use research contracts (not grants)
  - Operationally achieved with one contract for the entirety of the research project
  - Currently no staged or phased funding model in use
  - Contractual/logistical constraints discourage use of separate contract awards for study phases
- PCORI is a research funder not a sponsor
  - Oversight is of contracted research plan without direction of project activities

Overview of Current PCORI Funding Approaches : Research Awards

Broad Funding Announcements or "Broads" on PCORI's 5 strategic priority areas

- 3 to 5 years duration with total direct costs of $2 – 5 million
- Discrete, largely investigator-initiated, occasional research areas of interest

Pragmatic Clinical Studies also address 5 priority areas

- Up to 5 years duration with total direct costs up to $10 million
- Investigator-initiated + named priority areas of interest, occasional set-asides for special areas of interest

Targeted funding announcements on focused areas of interest

- Up to 5 yrs duration with total direct costs often ~$10 million, some higher

Effective 2017, all new awards >4.5 year duration have a formal assessment of progress via an administrative review

PCORI Engagement Awards To Support PCOR/CER

Patient-Centered Outcomes Research Clinical Comparative Effectiveness

Development of Multistakeholder Research Capacity and Applications

Courtney Clyatt, MA, MPH
Program Officer, Engagement

Pipeline to Proposal Program (P2P) to Support PCOR/CER

- Established in 2013 to support stakeholder partnerships and capacity building in research on health issues affecting their communities
- Goals
  - Increase stakeholder involvement in research, especially underrepresented communities and stakeholders
  - Increase patient-centered outcomes research applications
- Approach
  - Provide successive tiers of funding along with technical assistance support from PCORI contractors in 5 field offices

P2P Tiered Award Structures

Overall goal: Develop a high-quality research proposal to be submitted

Four cycles of awards using 3 tiers initially, then 2 tiers

Tier		Maximum Duration	Maximum Award	Purpose
I		9 mo	$15K	Partnership development
II		12 mo	$25K	Develop research capacity, partnerships, research infrastructure
III	A	12 mo	$50K	
	B	9 mo	$40K	*Develop research proposal

*Tier B was not awarded

P2P Results

- Of 123 Tier I awards, 64 progressed to Tier III proposal stage
- No funds were awarded for Tier B
- 1506 partnerships developed, many with deliverables to promote sustainability (governance, communications, & sustainability plans)
- 76% focused on health issues of racial & ethnic minorities
- # of successful research awards?

Key Lessons Learned

- P2P helped stakeholders to learn *how* to engage partners in pre-research
- P2P created a multi-stakeholder environment to conduct pre-research
- P2P partnerships successfully engaged underrepresented stakeholders in communities across the country
- P2P facilitated sustainability in developing governance documents, communication and sustainability plans

Other Engagement Support:
Eugene Washington Engagement Awards

Previous awards were directed to capacity building to do PCORI/CER and to support conferences/workshops/other formalized meetings

Currently available award types (each up to $100K, 1 year)

- Accelerating Adoption of Tools and Resources to scale up & enlarge engagement to increase capacity for PCOR/CER
- Community Convening Around PCORI to hold multi-stakeholder convenings for collaborations on PCOR/CER

Models Used By Other Funders

Allie Rabinowitz, MPH

Senior Program Associate, Clinical Effectiveness and Decision Science, PCORI

Methods Used to Explore Funding Mechanisms of Other Institutions

- Librarian-assisted literature search (mostly grey literature)
  - Databases: Google, Pubmed, Web of Science
  - Multiple & extensive search strategies used in each database
- Review of NIH descriptions of types of grant programs at https://grants.nih.gov/grants/funding/funding_program.htm
- Contacts and their recommendations of funders to contact
  - Michael Lauer, MD – Deputy Director of Extramural Research, NIH
  - Gail Pearson, MD, ScD – Associate Director, Division of Cardiovascular Sciences, NHLBI, NIH
  - David Atkins, MD, MPH – Director of Health Services Research & Development, Veterans Affairs

NIH Models

NIH Mission and Goals: Focus on Discovery and Knowledge Development

Highlights of NIH goals

- To foster fundamental **creative discoveries, innovative research strategies**, **and their applications** as a basis for ultimately protecting and improving health
- To develop, maintain, and renew scientific human and physical resources…. to prevent disease
- To expand the knowledge base in medical and associated sciences…
- To …promote…scientific integrity, public accountability, and social responsibility in the conduct of science

NIH Centers, Offices, and Institutes Use Varying Developmental Research Awards

- Funding mechanisms to develop research projects
  - Infrastructure and capacity building
  - Small grants programs
  - Planning grants
- Phased funding mechanisms
  - Exploratory/developmental grants with phased funding
  - Cooperative agreements with phased funding

Exploratory and Small Grants: P20 and R03

- P20 Exploratory Grants - intended to support
  - Planning for new programs
  - Expansion or modification of existing resources
  - Feasibility studies to explore various approaches to the development of interdisciplinary programs
- R03 Small Grants –limited, short-term funding to support a variety of projects including
  - **pilot or feasibility studies**
  - **collection of preliminary data**
  - secondary analysis of existing data
  - small, self-contained research projects
  - development of new research technology, etc.

NIH Planning Grant Program: R34

R34 Planning Grants support initial development of a clinical trial (or research project) to lead to a separate application for a full-scale trial

- Support development of essential elements of a clinical trial such as
  - establishment of the research team,
  - development of tools for data management and research oversight
  - development of a trial design or experimental research designs
  - finalization of the protocol
  - preparation of an operations/procedures manual
- Offer early peer review of the rationale and concept for the proposed clinical trial

NIH Phased Funding: R21 and R33

- R21: Exploratory/Developmental Grants
  - Encourage **new, exploratory and developmental research**
  - Support early stage, high risk/high reward projects which may represent a breakthrough in a particular area (also novel technologies).
  - Sometimes used for **pilot and feasibility studies**.
  - Support for research projects where **proof-of-principle** is not yet established
- R33: Exploratory/Developmental Grants Phase II
  - Used where proof-of-principle was established
  - Supports further maturation of innovative research initiated
  - Generally only R21 Awardees are eligible to apply for an R33

Collaboratory Staged Funding Mechanism: UH2/UH3 or UG3/UH3

- UH2/UG3: Phase 1 Exploratory/Developmental Cooperative Agreement
  - Used to establish the feasibility of a proposed large study
  - Done as cooperative agreements with substantial NIH guidance & input
  - If milestones and feasibility requirements are met, may transition to UH3
  - UH2 and UG3 grants differ in their funding amounts
- UH3: Phase 2 Exploratory/Developmental Cooperative Agreement
  - Supports the conduct of the research study initiated under the UH2/UG3
  - Only UH2/UG3 are generally eligible to apply
  - Continues cooperative agreement with NIH guidance and input

Veterans Affairs (VA) Model

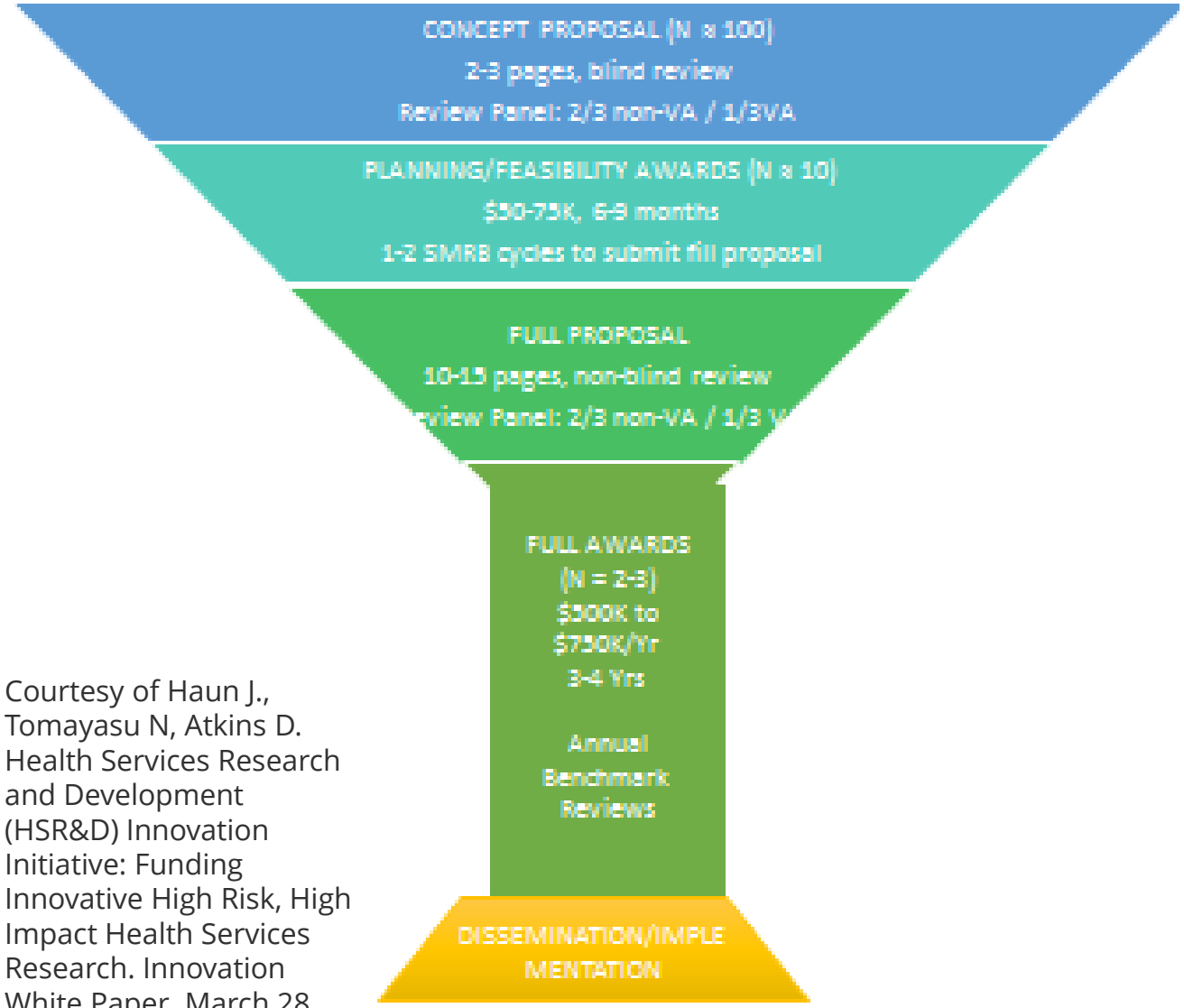
VA Health Services Research & Development Program (HSR&D)

- An intramural research program of the VA to identify, evaluate, and rapidly implement evidence-based strategies that improve the quality and safety of care delivered to Veterans.
- Recently established an Innovation Initiative seeking
  - Out of the box research with potential for disruptive progress
  - High risk/high reward projects
  - Rapid cycle review and progression of promising nascent innovations
  - Based upon exploration of other funding mechanisms to encourage innovation and to speed the uptake of promising interventions

VA HSR&D Innovation Initiative Phased Funding Model

- Target innovations: One that are unfamiliar/underexplored due to inexperience, limited data, or extrapolations of ideas from outside fields to healthcare
- Developed a purposeful approach to decrease barriers and encourage innovation:
  - Identify priority areas for innovation
  - Implement a rapid review process to evaluate and fund early studies based on predefined criteria
  - Use a cooperative agreement approach to ensure progress and support
  - Pre-define clear milestones of progress in phases for transitional funding to implement or scale up what has been proven effective

HSR&D Innovation Award Overview



Courtesy of Haun J., Tomayasu N, Atkins D. Health Services Research and Development (HSR&D) Innovation Initiative: Funding Innovative High Risk, High Impact Health Services Research. Innovation White Paper. March 28, 2019.

~100 Concept Proposal submissions (2 – 3 pages; blinded review)

~10 Planning/Feasibility Awards made to test feasibility and/or plan full submission ($50-$100K for 6 – 9 months)

Full Proposal (10- 15 pages; non-blinded review)

2-3 Full Awards made (~$500-750K ; ~3 years)

Dissemination/Implementation

Wellcome Trust

Wellcome Trust Mission Statement

"We will champion and support research through changing times. We will ensure the world is better prepared for the next epidemic. We will advance the global response to drug-resistant infections. We will harness the creativity of innovators across disciplines to deliver health impact. We will push R&D for health up the global political agenda."

Focus

- Preparation for global epidemics and drug-resistant infections
- Support innovations to have an impact on health

Wellcome Trust

Takes risks on approaches, methods, and themes to maximize new knowledge to support

- Improved understanding of health and disease
- Research grounded in the needs, values, and priorities of the populations affected
- Work with researchers & communities to identify health challenges
- Professional development of researchers
- Investments in facilities and resources, specifically professional meetings, conferences, travel, and networking
- Cooperation and collaborations across the research community, UK research networks, international partners

Wellcome Trust

Takes risks on approaches, methods, and themes to maximize new knowledge to support

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- Professional development of researchers
- Investments in facilities and resources, specifically professional meetings, conferences, travel, and networking
- Cooperation and collaborations across the research community, UK research networks, international partners

Wellcome Trust Funding to Develop Research Projects

- Seed Awards in Humanities and Social Science
  - Help to develop compelling and innovative ideas that will go on to form part of larger grant applications to Wellcome or elsewhere
- Small Grants in Humanities and Social Science
  - Small grants to enable researchers to build professional networks, develop new research agendas, and increase the impact of their work

Summary: Overview of Funding Mechanisms Examined by PCORI Staff

- Developmental research awards are done with varying goals
  - To foster novel, innovative, or high-risk research project development
  - To assess research feasibility before undertaking a larger research funding investment
- Small and/or time-limited research awards have multiple purposes
  - Proof-of-concept testing
  - Pilot/feasibility studies
  - Research planning/feasibility testing +/- re-competition to carry out research
- Tools used
  - Close, cooperative development of research with funding organization staff
  - Criteria or milestones to determine adequacy of progress
  - Rapid-cycle review of early stage research development

Questions for CTAP

- What other models of phased funding exist that PCORI might explore?
- How are different models best deployed to meet different potential goals?
  - To increase interest/volume of worthy research questions and applications
  - To improve selection of worthwhile investments in large research studies
  - To diversify or balance risks/rewards of PCORI's overall research portfolio
- What are the potential downsides of phased funding? How might they be overcome? Examples:
  - More work/obstacles for applicants
  - Longer timeframe to get to definitive results
  - Need for active PCORI guidance or "direction" of research development
  - Administrative/contractual burdens, delays, or other constraints

Wrap Up and Next Steps

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Thank you!