Campfire Session: CARNATION

Lynn L. DeBar, PhD, MPH (Contact MPI, KP Center for Health Research)
Nicole Cook, PhD (MPI, OCHIN)
Andrea Cook, PhD (Biostatistician, KP Washington Health Research Institute)

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Where We Are Now

- Data pull for outcome ascertainment and recruitment completed.
  - Analysis in process. Decision points: orders vs. services received.

- Complex cross-department and organization study team built
  - Advisory Group recruited; Co-design meeting held & interviews completed

- Implementing learnings: need provider EHR tool to enable IPM Care Coordinator tailored Compass Rose tools and workflow
  - Developing Provider SmartSet, BPAs – to sustain and scale IPM workflow package beyond study period and clinics

(Trial background information in meeting folders/eBinder)

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Challenges Scorecard

Challenge	Level of Difficulty*					
	NA	1	2	3	4	5
Regulatory issues (e.g., IRBs, consent)		X				
Study design issues (e.g., ICC, power, sample size, confounders)				X		
Using community-centered research methods		X				
Engaging with patient partners to inform the study				X		
Engaging with clinicians and health systems to identify or recruit participants						X
Engaging with clinicians and health systems to deliver the intervention					X	
Data access (e.g., approval, privacy, security) and data management planning			X			
EHR integration and/or data extraction, including data management and quality assessment				X		
Collecting prospective data, including PROs					X	
Optimizing intervention sustainability and planning for sustainment		X				

*Your best guess: 1 = little difficulty; 5 = extreme difficulty

Challenges So Far

- PCP EHR tools needed to enable whole-person HICP care and IPM Care Coordinator workflow (not originally forecasted) – timeline implications
- Data limitations impacting analytic-related decisions (what IPM services are available in each local health center context? How can we best collect outcome data?)
- Each health center is independent and has local needs; catch-22 on needed detail on specific health center operations and collaborative planning for trial
- Collaboration between CHR and OCHIN for complex implementation science trial with tailored EHR tools is challenging and expensive (balance with potential impact of replication and scalability)
- Envisioned IPM Care Coordinator role must be somewhat flexible as health center models vary tasks for care coordination, referrals, navigation, etc. (constant balance of “PRAGMATIC” science)

Ongoing Issues

- Outcome data (GCPS-R)/ tools, related EHR tools & workflows
  - Need to plan carefully to ensure that implementation outcome not circular
- How to best build out IPM Care Coordinator role and implementation supports for replication and scalability
- Timeline
  - Having all HIT infrastructure, champion and IPM care coordinator roles and implementation supports defined for optimal recruitment and trial implementation.
  - What modifications are needed/acceptable/feasible?

Questions for the Group

- Benefits / liabilities of seeking 6-month extension with funds to include pilot / ensure full recruitment of clinics for trial and related planning

- Refining analytic-related decisions in absence of concrete data?

- How does one work in this time of uncertainty re: public clinic funding and PCPs stretched to breaking point to recruit clinics?

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®