



NIH Collaboratory

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Assembling an ePCT Team

Robin Boineau, MD, MA

National Centers for Complementary and Integrative Health
National Institutes of Health

Essentials of Embedded Pragmatic Clinical Trials Seminar

A decorative vertical strip on the left side of the slide, composed of a grid of small squares in various shades of blue.

Learning goal

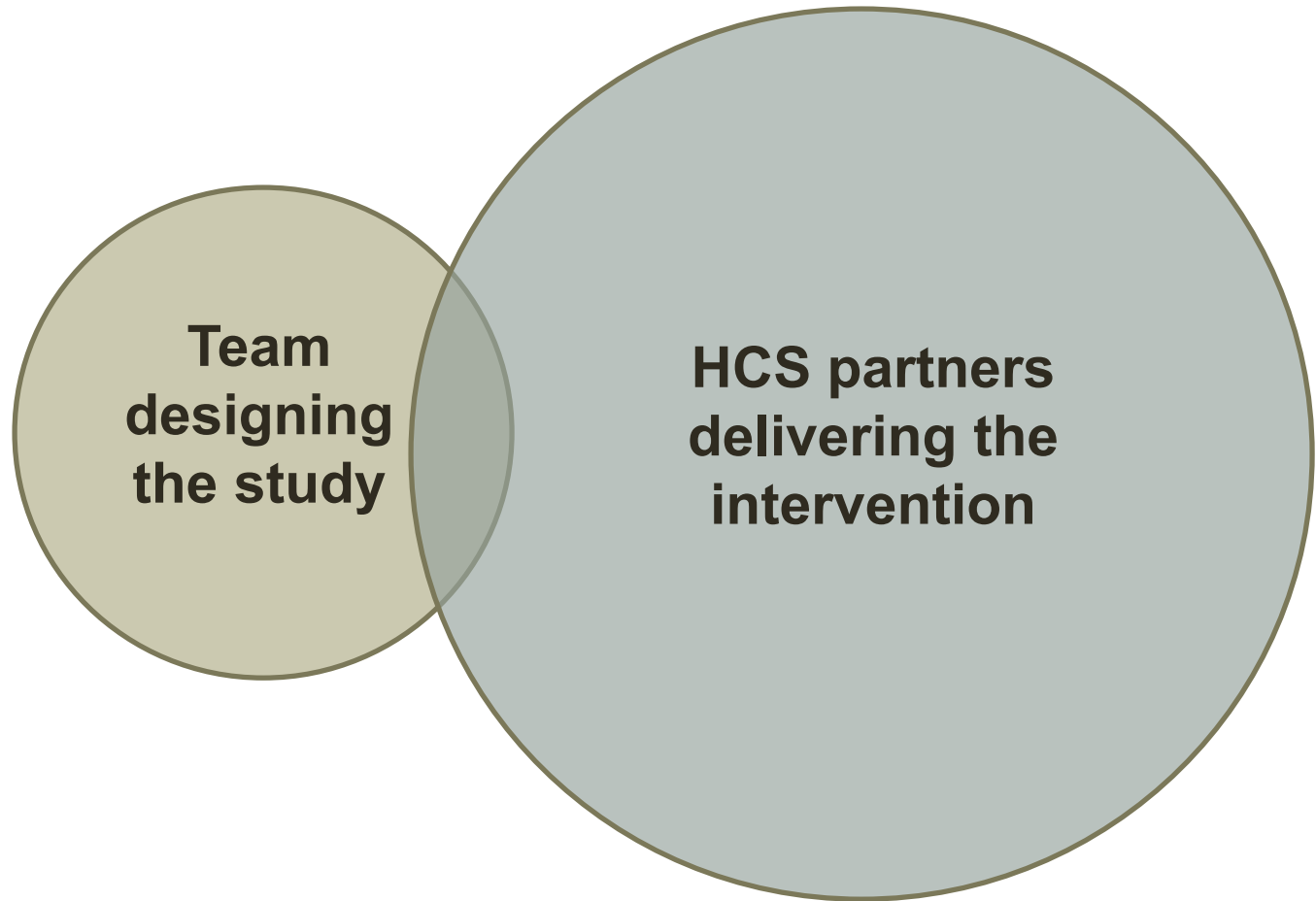
Identify skills needed for a strong study team



Important things to know

- PCTs are a team sport
- Necessary expertise depends on the study aims & 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?



Potential team members

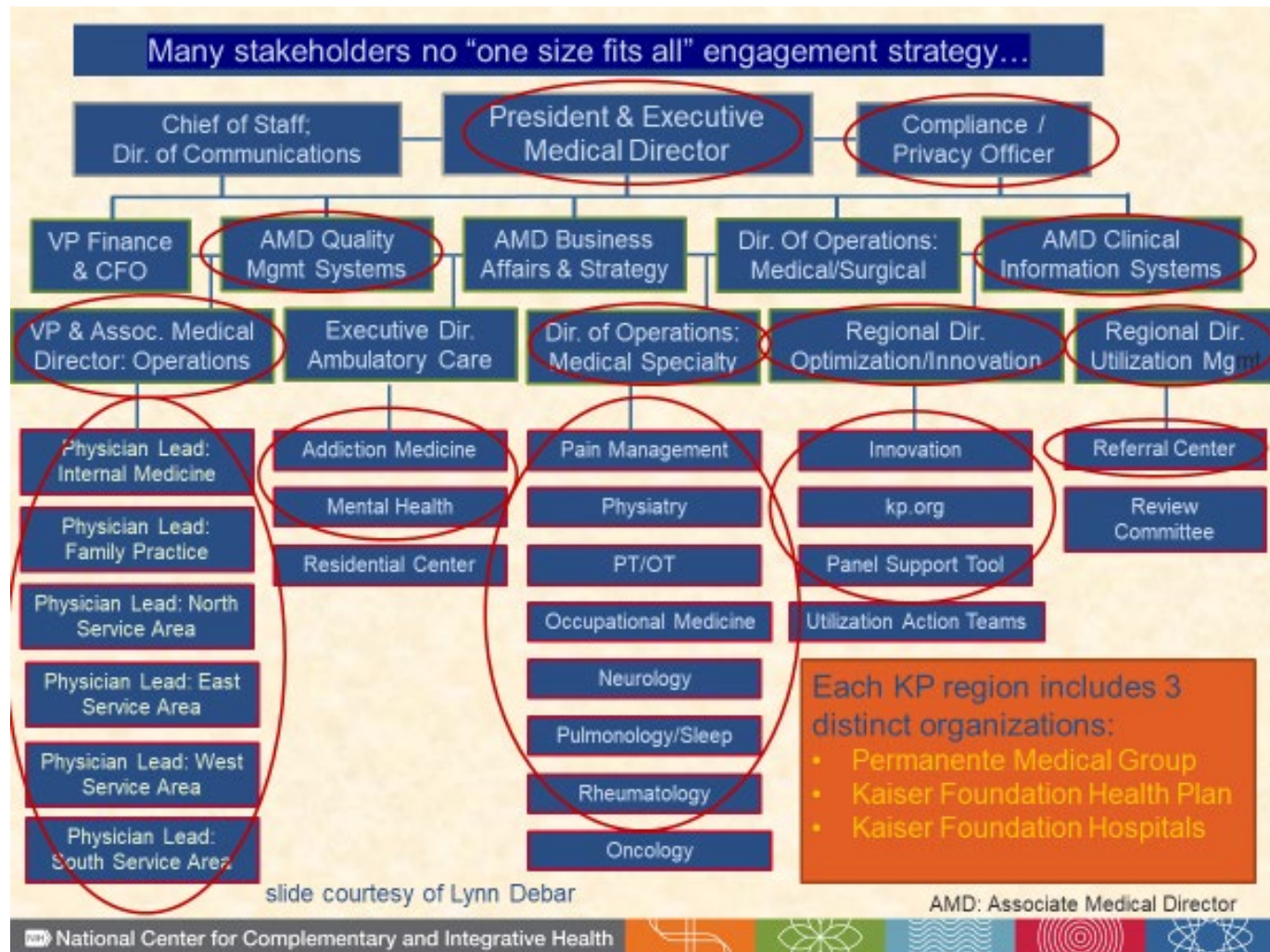
- Principal investigator, co-investigator
- Health system leader or executive
- Biostatistician
- Lead clinician (eg, pediatrician, behavioral specialist, radiologist, pharmacist, physical therapist)
- Clinical staff (eg, nurse, operations manager, business manager)
- IT specialist for EHR data extraction or clinical decision support tool design
- Implementation science researcher
- Site champion/liaison
- Practice facilitator
- Research assistant
- Project coordinator
- Research participant, patient, or patient advocate
- Caution: Society Leadership

What skills will be needed?

- Best skillset depends on the study aims & how the intervention will be embedded in the HCS 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?

Collaborative Care for Chronic Pain in Primary Care (PPACT)

PI: Lynn Debar, Kaiser Permanente Washington Health Research Institute





Important things to do

- Identify the skills that are needed during the planning phase
- Recruit team members during the planning phase & 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