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Improving Communication and Healthcare Outcomes for Patients with Communication Disabilities: A Stepped Wedge Cluster Randomized Trial

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Agenda

- Discuss the long road to funding
- Engagement of stakeholders
- Overview of study and outcomes
- Stepped-wedge study design

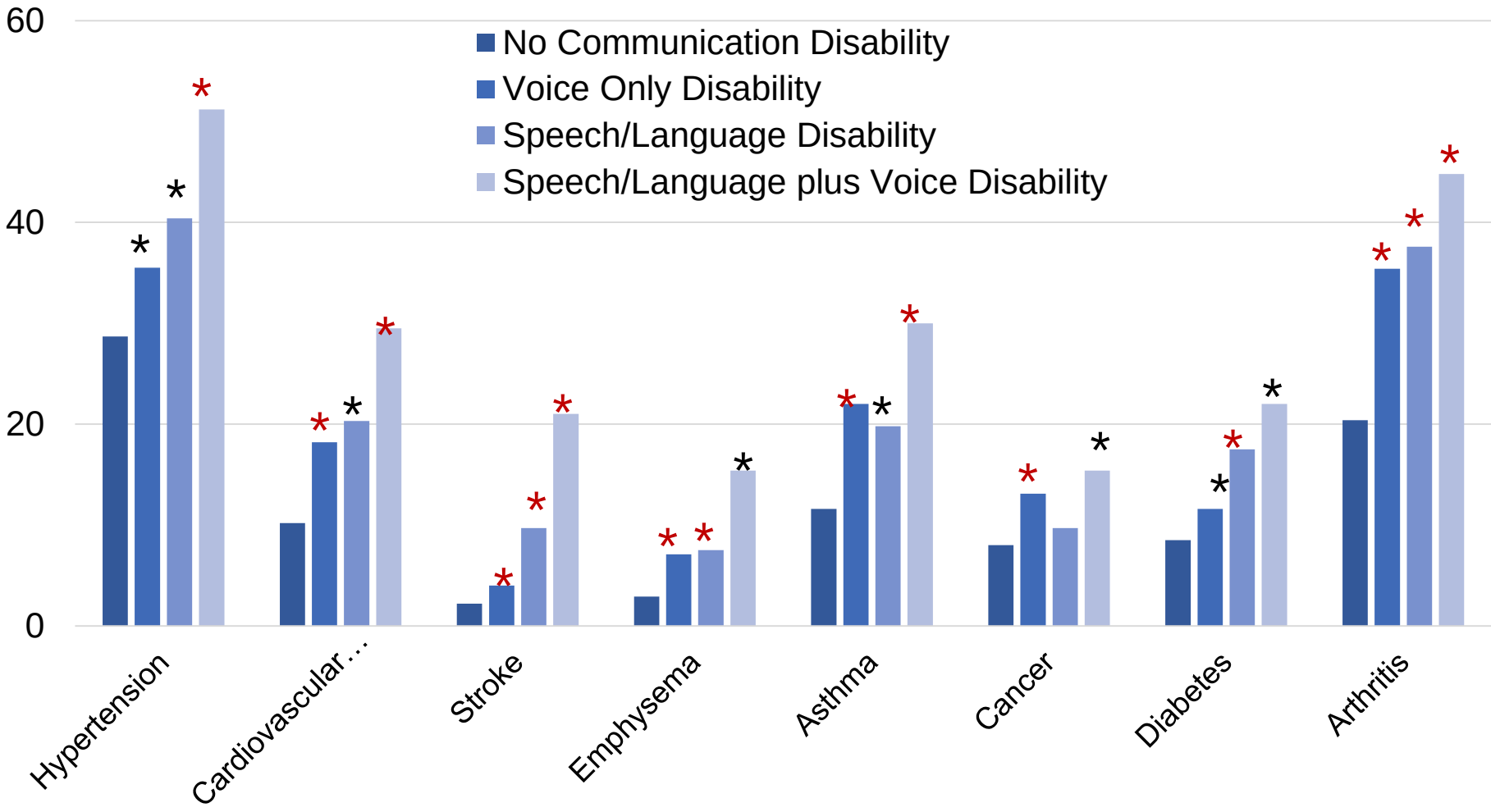
Communication Disabilities

- Includes:
  - Speech – producing speech sounds
  - Language – comprehension and expression
  - Voice – producing vocal sounds
  - Hearing
- Represents 14% of the US adult population
- CDs can have numerous etiologies
  - E.g., aphasia from a stroke, aphonia due to laryngectomy, developmental stutter, etc.

Disability Healthcare Disparities

- Patients with communication disabilities
  - 3x more likely to experience an adverse medical event
  - Rate satisfaction with quality of care lower

Health Outcomes: % by Type of Chronic Conditions



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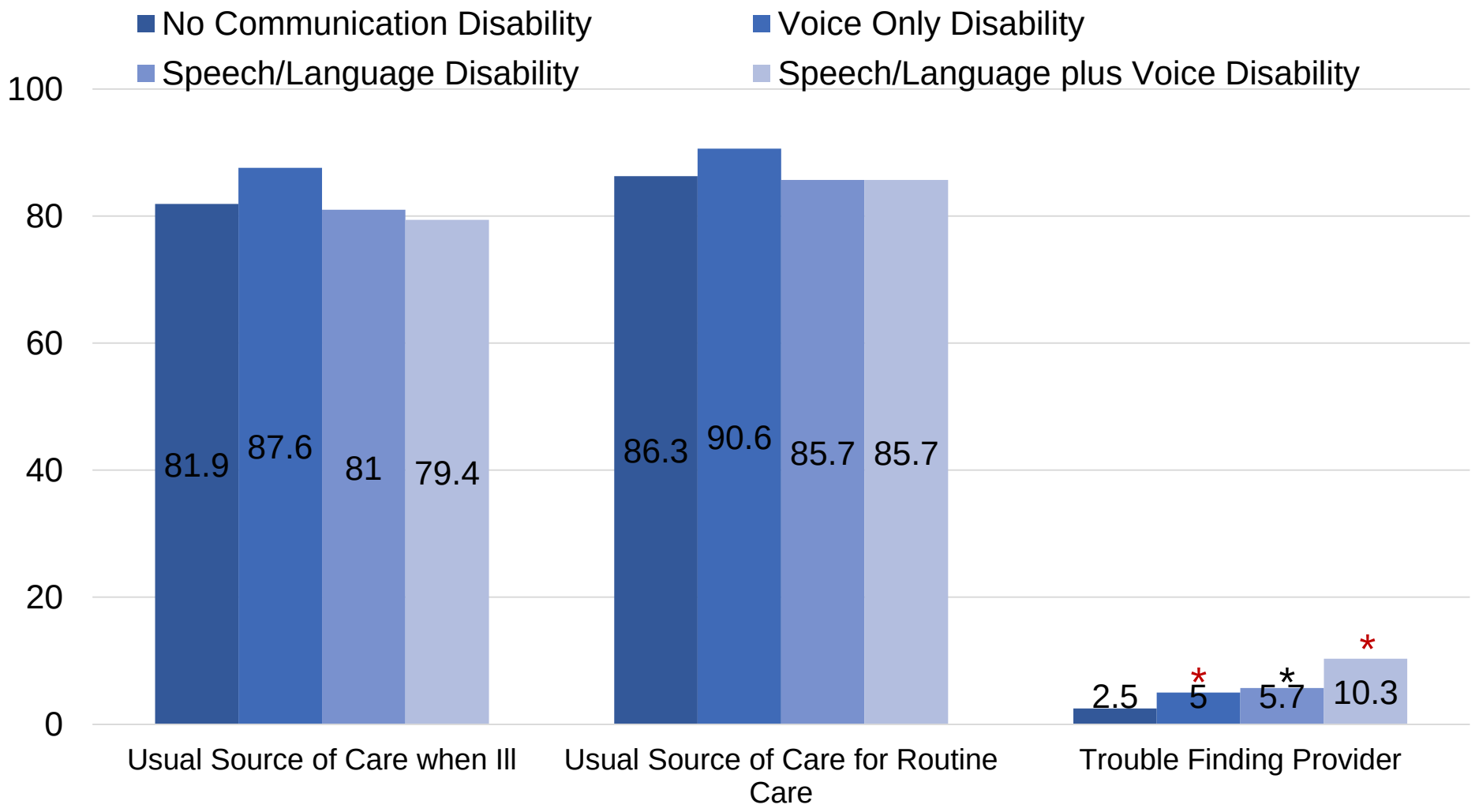
Access to Healthcare



It all began over a decade ago…

- Followed "hunch" from clinical and personal experience
- 2011 - Conducted a qualitative study of individuals with speech disabilities regarding communicating with their healthcare providers
  - Stories of multiple barriers
  - Woman created a one-page description of her communication abilities but had implementation challenges
- 2013 - Conducted study with persons with aphasia in which we video recorded their clinical encounters, did video elicitation interviews and surveyed the providers

2014

- Engaged with Partnerships for Improving Patient Care (PIPC) – consortium of disability advocacy groups
  - Travelled to DC to meet with Stakeholders several times
  - Discussed their priorities and did several rounds of ideas
- Submitted first proposal to the Addressing Disparities section of Patient-Centered Outcomes Research Institute (PCORI)
- Rejection

Resubmissions

- 2017 – submitted the proposal
  - Rejection
- 2018 – submitted the proposal
  - Rejection
- 2019 – submitted the proposal
  - SUCCESS!
- July 2020 – June 2023

Stakeholder Challenges

- Discrepancies between what stakeholders and what reviewers wanted for outcomes
- Tricky to keep the stakeholders engaged for 5 years with so many rejections
  - Set expectations, especially for length of time
  - Regularly met in person
  - Submitted other grants (Engagement Award)
  - Active communication

Study Objective

We will compare the effectiveness and implementation of 2 interventions to increase primary care* providers' use of evidence-based communication strategies**, improving the quality of their communication with patients with communication disabilities.***

*Not focused on a specific medical condition

** Communication strategies examples: maintain eye contact, use meaningful gestures, write down key words while speaking

***Any and all communication disabilities included, except for individuals who use Sign Language

Interventions in Comparative Effectiveness

- Provider education (Intervention A)
  - Adapt evidence-based curriculum from medical student education
  - Goal: Review communication strategies and how to use
- Patient-directed tool (Intervention B)
  - Empower patients to share their requested communication strategies with providers
  - Based on the "Ask Me Three" and the tool that the participant in the initial qualitative study created
  - Paper and electronic versions

Study Sites

- UCHealth
- Mayo Clinic
- University of Illinois Chicago
- University of Michigan

- 2 primary care clinics at each of the sites

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Investigators and Stakeholders

- Megan Morris
- John Rice
- Russ Glasgow
- *Dan Matlock*
- Stacie Daugherty
- Ryan Pollard
- Shannon Seacrest

- Jenna Duffecy
- *Bernice Man*
- *Rachel Caskey*

- Sean Phelan
- Joan Griffin
- *Mioki Myszkowski*

- *Mike McKee*

Stakeholders

- Sara Biorn
- Bob Williams
- Toni Iacolucci
- *Carmen Lewis*
- Tina Cordero

Aims

- **Aim 1**: Adapt the 1) healthcare team-directed intervention and 2) patient-directed intervention for multiple primary care settings, maximizing feasibility, scalability and sustainability for future dissemination.
  - Currently in the midst of this process
- **Aim 2 and 3**: A vs. A+B
  - The trial which will start this summer

Guided by RE-AIM

- **Aim 2:** Compare the reach and effectiveness of the interventions on patient- and health-system reported experience in primary care practices across 4 healthcare systems using a stepped-wedge randomized controlled trial.

- **Aim 3:** Examine the adoption, implementation, and short term sustainability of the interventions.

INTERACT Study Outcomes

- Aim 2: Patient-level outcomes
  - Reach
  - Effectiveness
- Aim 3: Provider- and organization-level outcomes
  - Adoption
  - Implementation
  - Maintenance

		Outcome measure	How will measure
Aim 2	Reach	1. Patients with CD who agree to participate in Intervention B	1. % and representativeness of patients who participate
	Effectiveness	1. Patient reported health related quality of life[a] 2. Patients' reported experience with the clinical visit[a,b] 3. Providers' use of communication strategies[b] 4. Patient self-efficacy 5. Providers' satisfaction with the quality of interaction[b] 6. Healthcare utilization[c]	1. PROMIS Global Health Measure survey 2. Patient Perception of Quality of Care survey 3. RIAS coding of the video-recorded encounters 4. PROMIS Patient Self-Efficacy for Management of Chronic Conditions 5. Physician Satisfaction with Primary Care Office Visits survey 6. Emergency department visit and hospitalization frequency
Aim 3	Adoption	1. Healthcare team members' acceptance and willingness to participate in Intervention A	1. Percent and representativeness of healthcare team who participate vs. decline
	Implementation	1. Healthcare teams' perceptions of the implementation 2. Time required to implement the interventions 3. Fidelity and adaptation of the interventions	1. Qualitative interviews and focus groups 2. Time-driven activity based analysis 3. Video-recorded clinical encounters
	Maintenance	1. Healthcare teams' perceptions of and intentions regarding continuing the intervention following the trial.	1. Interviews and focus groups with healthcare teams and leadership

Data Collection and Sample Size by RE-AIM outcomes

	Month 0 ⟵		⟶ Month 18
Reach	Patients who agree to participate (% and characteristics)		
Effectiveness	Patient surveys at time of visit and 1 week post (24/step/clinic, total n= 1728)		
Effectiveness, implementation	Video-recorded clinical encounters (4-5/step/clinic, total n=324)		
Effectiveness	Clinician survey (4-5/step/clinic, total n=324)		
Effectiveness	EHR review and patient-report 6 month post intervention (60/clinic, total n=480)		
Implementation, maintenance	Focus groups (1/clinic, n=8) Interviews (2-3/clinic, n=24)	Focus groups (1/clinic, n=8) interviews (2-3/clinic, n=24)	Focus groups (1/clinic, n=8) interviews (2-3/clinic, n=24)
Adoption	Providers/staff who participate in training (% and characteristics)		
Implementation	Time and resources required to implement the interventions (report monthly)		

Reach

- Reach defined as proportion of patients with CD who agree to participate in the patient-directed intervention (Intervention B)
- Also interested in characteristics of participators
- **Binary** outcome at the patient level
- Measured/estimated by a proportion at the clinic level
- Data will also be collected on those who refuse to complete the tool
  - basic demographics (age, gender, type of CD)
  - reasons for non-participation

Effectiveness

- Primary outcomes
  - Patients' reported experience with their clinical encounter (Patient Perception of Quality of Care **survey**)
    - Immediately after appointment
  - Patients' reported health related quality of life (PROMIS Global Health Measure **survey**)
    - 7 days after appointment

Effectiveness

- Secondary outcomes
  - Patients' self-efficacy for management of chronic conditions (PROMIS Patient Self-Efficacy for Management of Chronic Conditions **survey**)
  - Providers' use of patient-centered communication and communication strategies (RIAS **coding** of the video-recorded encounters)
  - Providers' perceptions of communication during the encounter (Physician Satisfaction with Primary Care Office Visits **survey**)
  - Patients' emergency department use and inpatient hospitalizations - 6 month (**count** outcome)

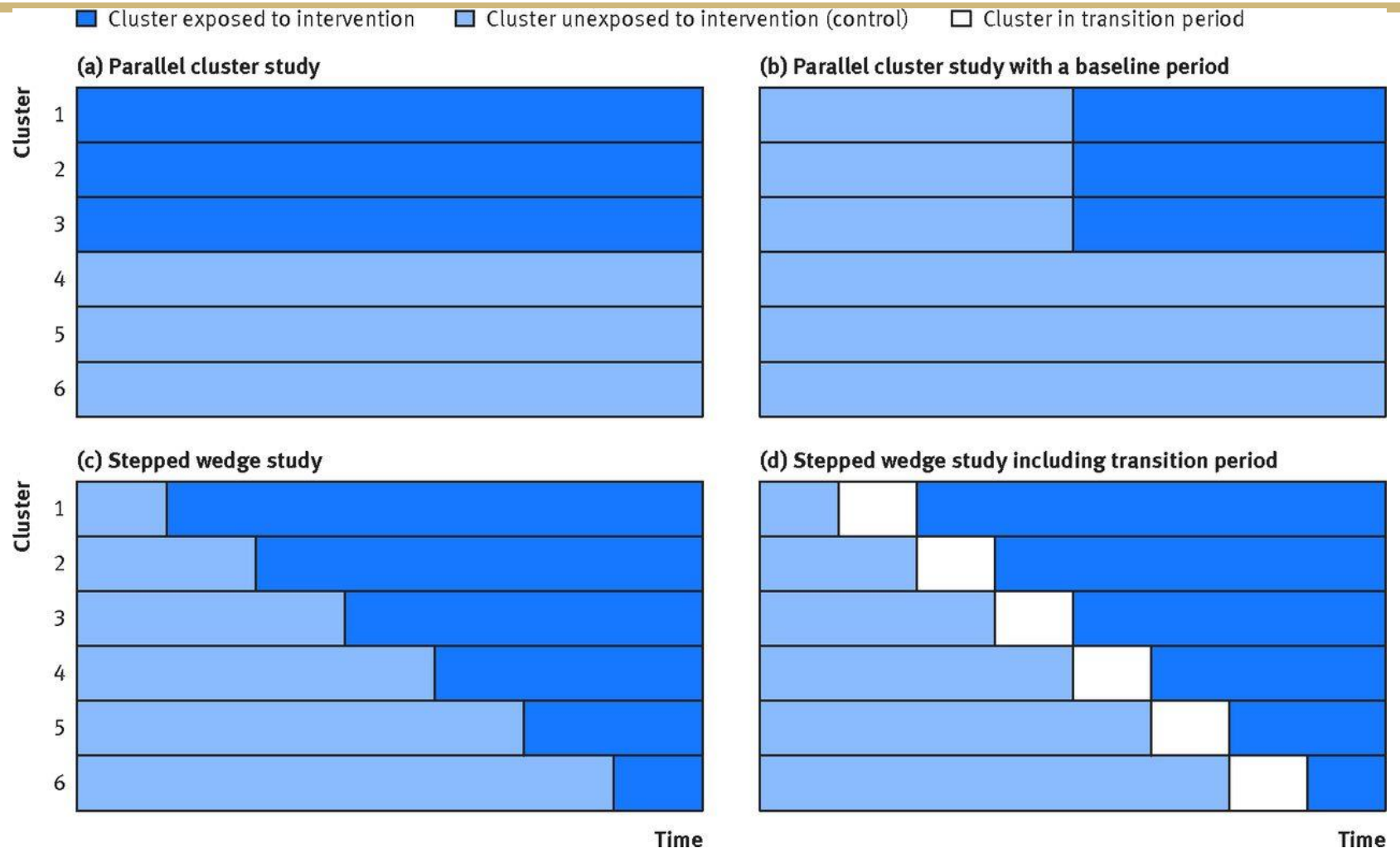
Study Design

- Cluster-randomized studies
- Stepped-wedge design
- Analytic considerations

Cluster-randomized trials (CRT)

- Alternative to classical notion of individually randomized (at patient level) studies
- What is a cluster?
  - Hospital
  - Clinic
  - Health system
- Reasons for use of CRTs
  - Levels of randomization and outcomes assessment don't match
  - Intervention can't be delivered to individual patients

Types of CRT



Hemming K, Haines T P, Chilton P J, Girling A J, Lilford R J. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting *BMJ* 2015; 350 :h391

Stepped-wedge design basics

- Every cluster provides pre and post intervention observations (acts as their own control)
- When ICC is large, stepped wedge design will have more power than a parallel CRT
- Transition period (during which no observations are collected) reduces power substantially

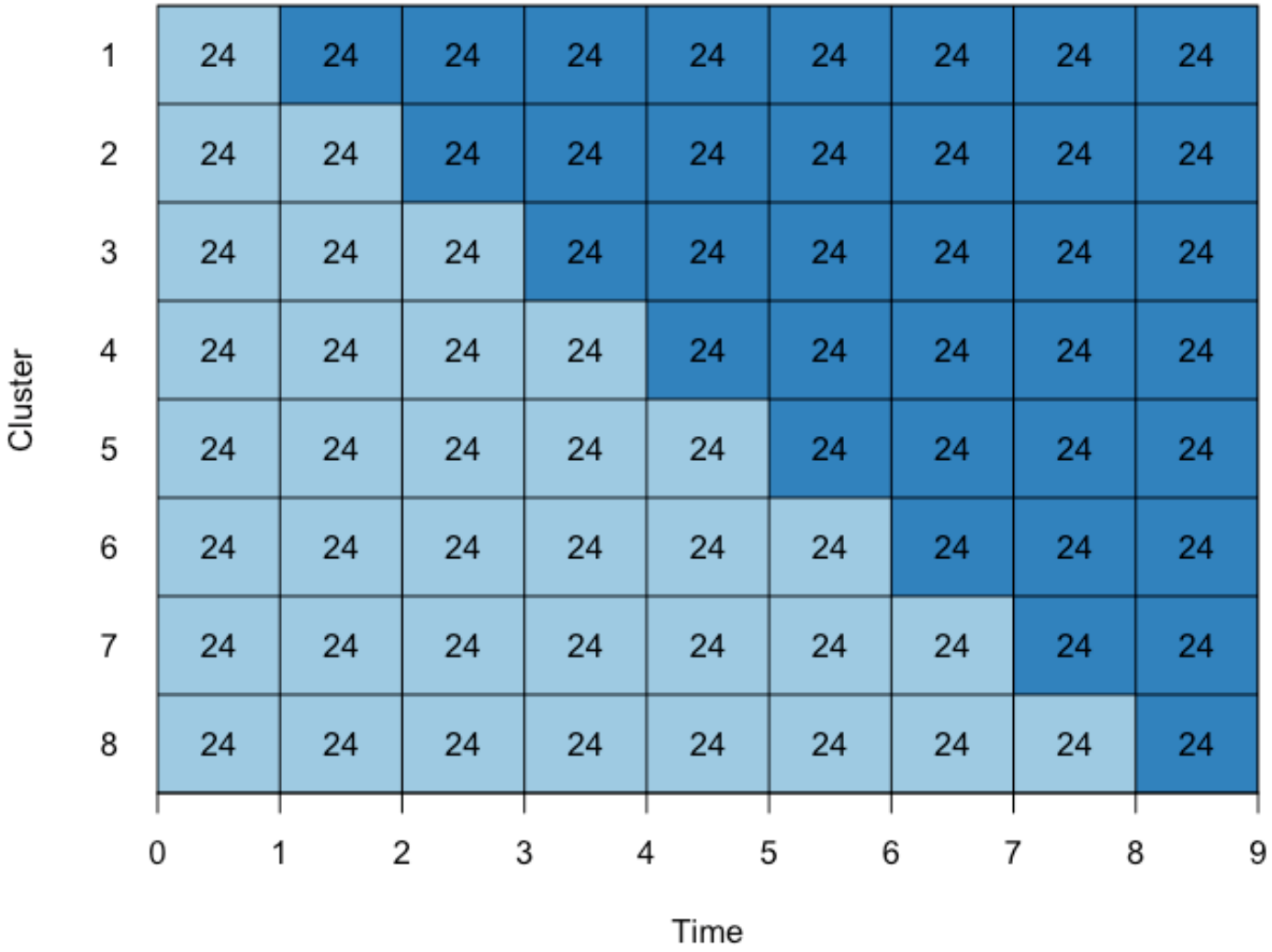
Pros and cons of stepped-wedge studies

- Can be beneficial to participation when all clusters want to receive the intervention, as otherwise some will be randomized to control
- Logistical challenges greater than for CRT due to the time dimension
- Analytical complications can result if outcome at the patient level needs to be assessed over a long period of time
  - Examples include time-to-event outcomes, changes over time within a patient
  - possible for the patient to be exposed to both control and intervention conditions

INTERACT's design

- 2 interventions
  - A: healthcare team-directed
  - A+B: patient-directed
- 8 clinics within 4 health systems to be randomized, but want to assess some outcomes at the patient level
- Stepped-wedge
  - All clinics receive intervention A at baseline
  - Clinics receive intervention B in randomized order
  - All clinics begin with intervention A only and end with intervention A+B

INTERACT stepped wedge design



Statistical model for stepped-wedge data

$$\mu_{ij} = \mu + \alpha_i + \beta_j + X_{ij}\theta$$

- Conditional mean at time *j* for cluster *i* is

$$Y_{ijk} = \mu_{ij} + e_{ijk}$$

- Patient (individual) level

Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials. 2007 Feb;28(2):182-91. doi: 10.1016/j.cct.2006.05.007. Epub 2006 Jul 7. PMID: 16829207.

Analysis of stepped-wedge trial data

- Outcomes can be in many forms
  - Examples: continuous, binary, counts
  - Form of model changes but analytic approach is similar
- Analysis can occur at cluster level or individual level
  - Cluster-level analysis is usually limited to simplest settings (normal outcome, equally sized clusters)
  - Individual-level analysis is much more flexible
- Methods include (generalized) linear mixed models (GLMM) and generalized estimating equations (GEE)

Importance of time effect

- Can use "within-cluster analysis" to estimate treatment effect if there is assumed to be no effect of time on the outcome
  - Take differences in means between control and intervention conditions within each cluster
- If there is a time effect, then this estimate will be **biased**
- Need to include a time variable (categorical) in regression models to avoid this

Acknowledgements

- Patient-Centered Outcomes Research Institute
- Study team

Patient Perception of Quality of Care survey

- Patients asked to complete this at two time points
  - immediately following their clinical encounter
  - within a week following their clinical encounter
- 14 items
- 2 subscales
  - Provider's Bedside Manner
  - Provider's Work
  - Both subscales include questions about quality of communication
- All items scored on 5-point Likert scale (strongly disagree → strongly agree)

PROMIS Global Health Measure survey

- Administered within a week of clinical encounter by phone or internet
- Shown previously to be sensitive to change and able to detect intervention effects
- 10 items scored on 5-point Likert scales
  - Including 3 items asking the patient to rate pain, fatigue and emotional wellbeing for the past 7 days