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

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John Rice, PhD
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

- No Communication Disability
- Voice Only Disability
- Speech/Language Disability
- Speech/Language plus Voice Disability

Conditions: Hypertension, Cardiovascular disease, Stroke, Emphysema, Asthma, Cancer, Diabetes, Arthritis
Access to Healthcare

- Usual Source of Care when Ill:
  - No Communication Disability: 81.9
  - Voice Only Disability: 87.6
  - Speech/Language Disability: 81
  - Speech/Language plus Voice Disability: 79.4

- Usual Source of Care for Routine Care:
  - No Communication Disability: 86.3
  - Voice Only Disability: 90.6
  - Speech/Language Disability: 85.7
  - Speech/Language plus Voice Disability: 85.7

- Trouble Finding Provider:
  - No Communication Disability: 2.5
  - Voice Only Disability: 5
  - Speech/Language Disability: 5.7
  - Speech/Language plus Voice Disability: 10.3
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
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
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<td>1. % and representativeness of patients who participate</td>
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<td>2. Patient reported health related quality of life^a</td>
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<td>5. Patient self-efficacy</td>
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<td>6. Providers’ satisfaction with the quality of interaction^b</td>
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<td>1. Patient reported health related quality of life^a</td>
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<td>6. Healthcare utilization^c</td>
<td>6. Emergency department visit and hospitalization frequency</td>
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<td>Aim 3</td>
<td>Adoption</td>
<td>1. Percent and representativeness of healthcare team who participate vs. decline</td>
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<td>1. Healthcare team members’ acceptance and willingness to participate in</td>
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<td>1. Healthcare teams’ perceptions of and intentions regarding continuing the</td>
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^a, ^b, ^c: See notes for additional details.
## Data Collection and Sample Size by RE-AIM outcomes

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

- (a) Parallel cluster study
- (b) Parallel cluster study with a baseline period
- (c) Stepped wedge study
- (d) Stepped wedge study including transition period

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

Cluster

Time
0 1 2 3 4 5 6 7 8 9

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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

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