Pragmatic Trials in Serious Illness

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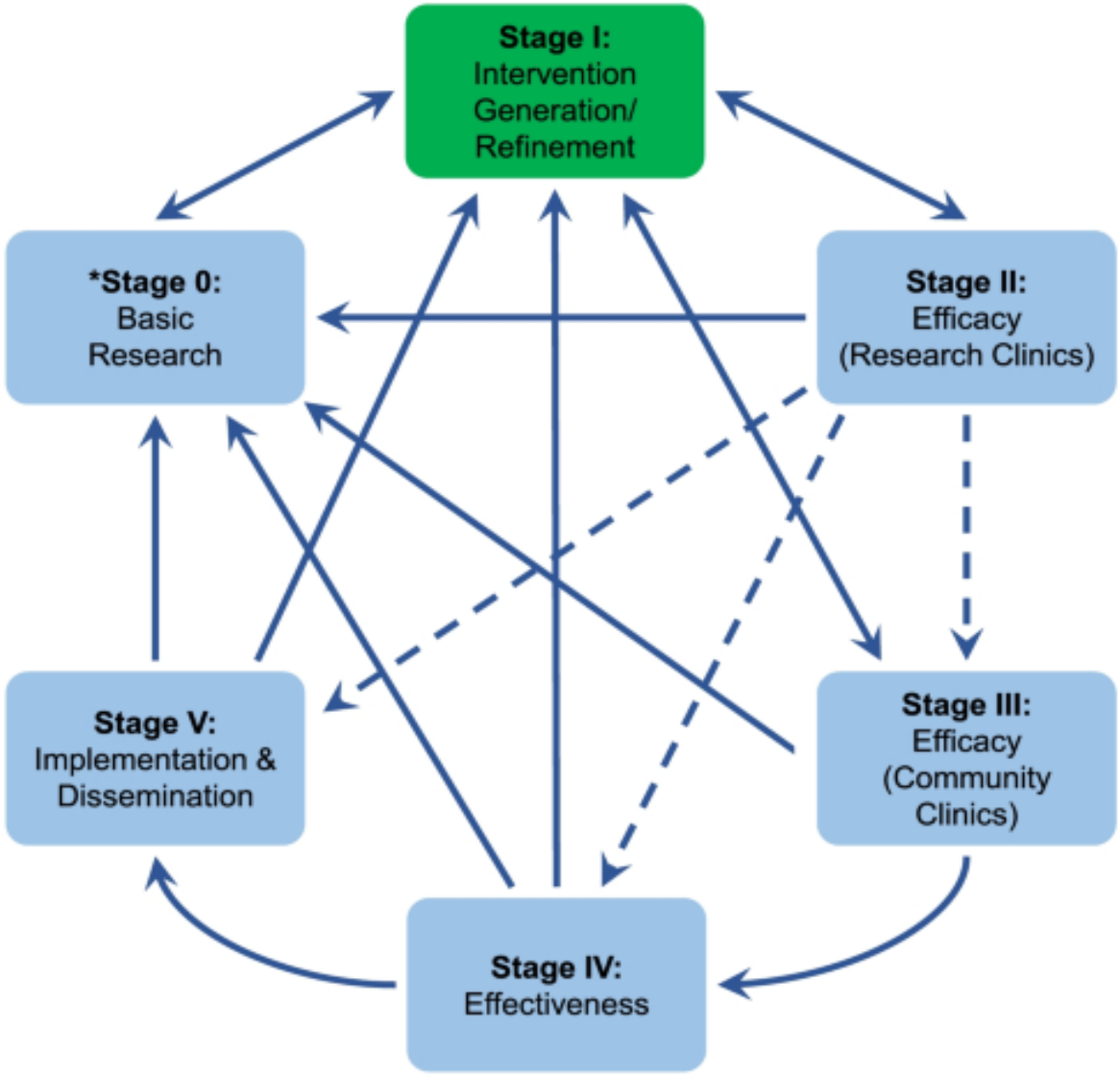
NIH Stage Model



NIH Stage Model

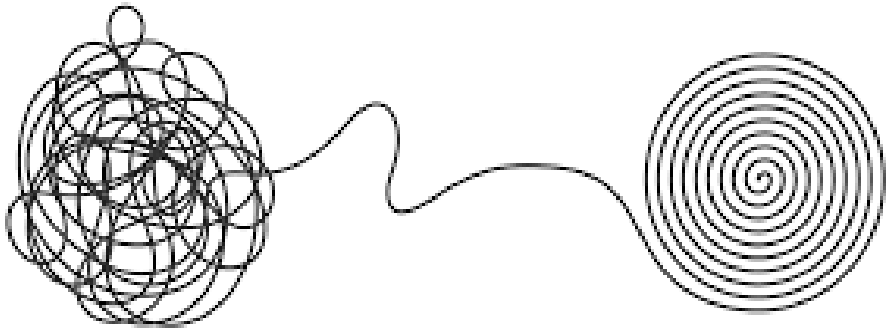
Pragmatic Trial Aim

~~Can this intervention work under ideal conditions?~~

Does this intervention work under usual conditions?

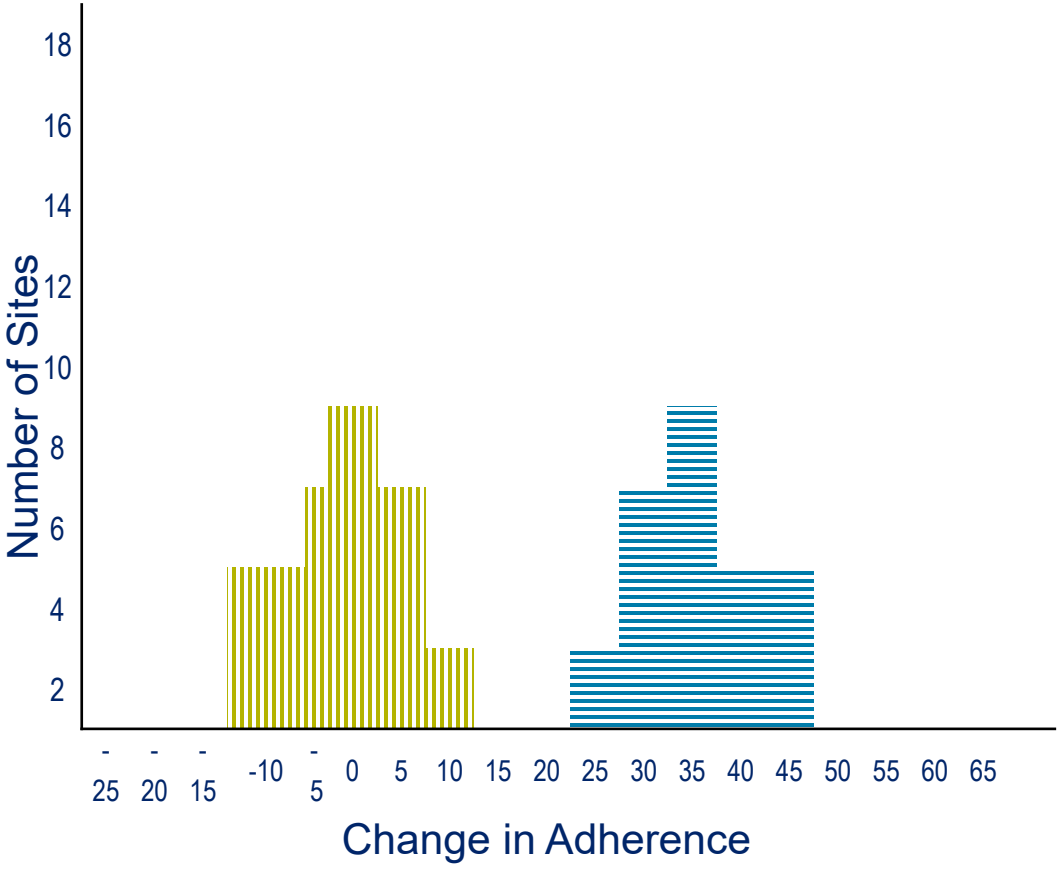
Complex health interventions

- Adaptation embraced, studied, and guided
- Complex causal pathways
- Average effect size estimate is not predictive, context sensitive
- Main effects often weak
- Outcomes strongly influenced by context
- Impacts are often indirect (mediated), thus variable and attenuated

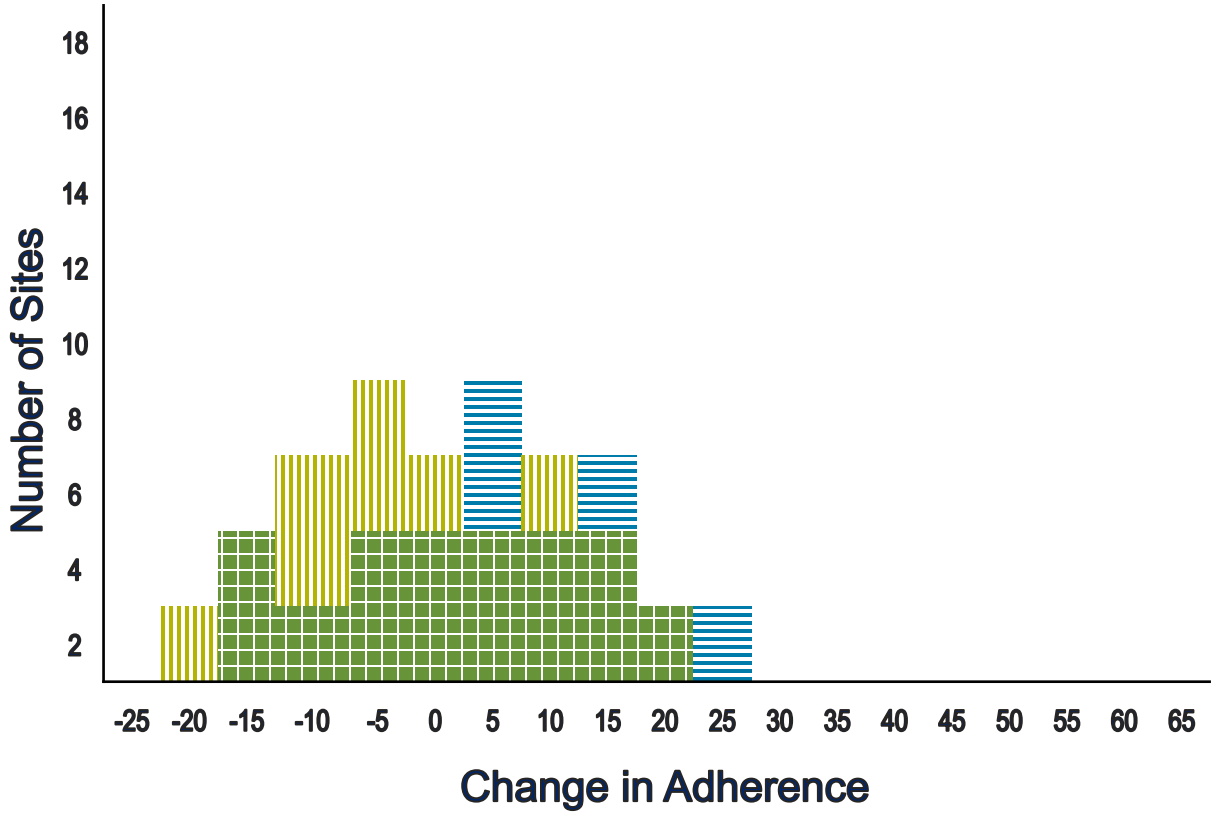


Interventions in Serious Illness

Strong effects, moderate variance



Weak effects, high variance



Evidence versus insights and guidance

Simple Interventions:
dichotomous approval or selection decisions (FDA, formulary, treatment):

Is it effective?
Does it work?
Which is more effective?

Complex Interventions:
insights and guidance for practice

How does it work?
Why? Where? When? For whom?
How can we enhance effectiveness?

Fidelity to Function

~~Manualized Interventions~~

~~Ignore or suppress adaptation~~

Specify core functions and menu of forms

Function:
purpose, intended effect(s); linked to needs

Form:

activity, format, operationalization

Emergency Departments LEading the transformation of Alzheimer's and Dementia care (ED-LEAD)

1U19AG078105-01A1 MPIs Chodosh, Brody, Grudzen and Shah

To study the effectiveness of three transitional care interventions, alone and in combination, for PLWD with serious illness in a cluster-randomized multifactorial trial embedded within 80 EDs on: ED revisits, hospitalizations, and healthy days at home following the index ED visit;

Emergency Departments LEading the transformation of Alzheimer's and Dementia care (ED-LEAD)

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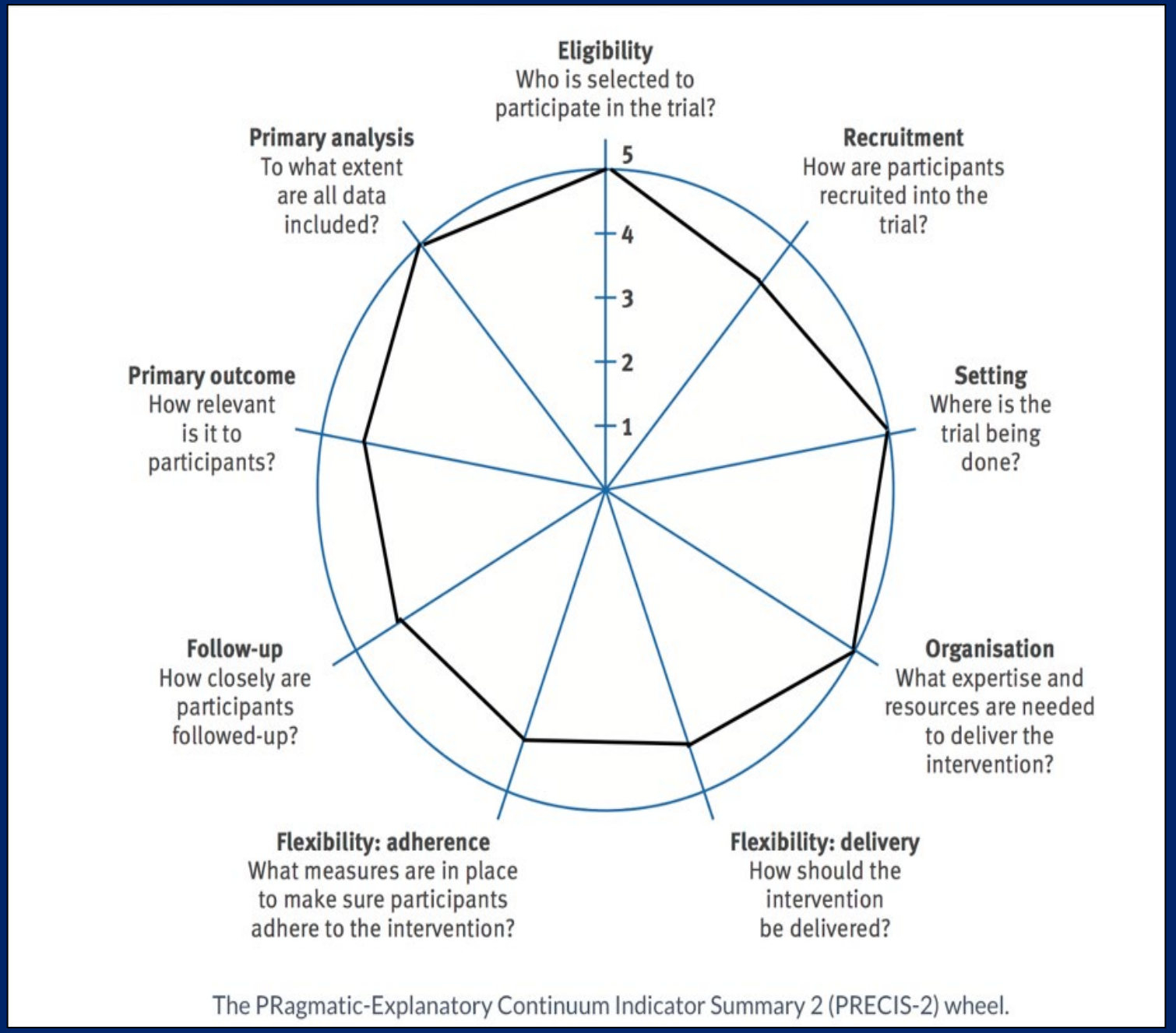
1) Emergency care redesign (UH3AT009844) of new and intentional workflows for emergency providers reinforced by digital alerts and structured collaboration between sites, already shown to increase identification of advance care plans and enlisted multidisciplinary support;
2) Nurse-led telephonic care program (PCORI) that increased advance care planning and connected patients to hospice; and
3) Community paramedic-led structured coaching intervention (R01AG050504) that reduced the odds of an ED revisit within 30 days by 75%.

Precis-2 Wheel:
Explanatory to Pragmatic Continuum



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

Precis-2 for ED-LEAD

Domain	Score	Rationale
Eligibility Criteria	5	Broad eligibility criteria include all older adults 66+ who present to a participating EDs with two ICD-10 codes for dementia in past 12 months; very few exclusions
Recruitment Path	5	No individual patient or care partner research consent or recruitment
Setting	5	EDs treat all patients regardless of insurance status or ability to pay
Organization intervention	5	Intervention will be delivered by existing emergency provider, telephonic nurse, and community paramedic workforce
Flexibility of the intervention — Delivery	4	Core components (e.g., identification and recognition of role of care partner) are standardized yet the delivery can be tailored to each ED based on their current workforce (e.g., EMT versus paramedic) and local electronic health record (EPIC versus Cerner)
Flexibility of the intervention — Adherence	4	Use current providers already working in health system; varying levels of contact hours depending on their role
Follow up	5	No additional patient or care partner follow-up as part of trial
Outcome	4	ED revisits, healthcare utilization in the 6 months following the index ED visit, and healthy days at home are all highly relevant to PLWD and CP participants and measurable via administrative claims data
Analysis	5	Intention to treat analysis regardless of compliance with per protocol sensitivity analysis

*1=very explanatory, 2= rather explanatory, 3=equally pragmatic/explanatory, 4=rather pragmatic, 5=very pragmatic

Form-Function Matrix for ED-LEAD

Function	Forms
Clinical decision support	• Interruptive alerts, passive banners • Consultation of additional teams (automated versus as needed) • Referral to community services (tailored versus comprehensive)
Interdisciplinary approach	• Mode of communication (face-to-face, electronic mail or health record, telephonic, instant message) • Provider type (physician, nurse, advance practice provider, community paramedic, social worker, pharmacist)
Training and education	• Mode of training (in person, online, videoconference) • Synchronous versus asynchronous • Traditional versus competency-based with opt-out
Audit and feedback	• Mode of delivery (instant messaging, electronic mail, electronic health record) • Feedback (case-based review, comparative assessment) • Level (provider, team, department, health system) • Incentives (recognition, monetary or non-monetary rewards)
Symptom assessment	• Mode of assessment (face-to-face, telephonic, tele-video) • Timing of assessment (ED visit, follow-up telephonic or home visit) • Patient versus proxy assessment • Length of assessment (short versus long form) • Types of assessment (physical functioning, mental health, social determinants of health)

Key Takeaways: Pragmatic Trials in Serious Illness

- Inherently complex, multicomponent transitional care interventions
- Core functions must be specified, tracked, and maintained with integrity
- Mixed methods required to provide the why, how, when, where and in whom the interventions work

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