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Adaptive Designs in Implementation Research: Lessons Learned via the VA Suicide Risk Identification Strategy National QI Project

QUERI Implementation Research Group Cyberseminar

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Nazanin Bahraini, PhD
Rocky Mountain MIRECC for Suicide Prevention

ROCKY MOUNTAIN MIRECC

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Our Team

Investigators:
Bridget Matarazzo
Lisa Brenner
Jeri Forster
Edd Post
Steve Dobscha
Catherine Barry
Katherine Dollar

Data & Analytics:
Trisha Hostetter
Sam King
Janelle Keusch
Christina Wade

OMHSP Partners
Matthew Miller
Jesse Burgard
Edgar Villarreal
Lisa Kearney

Implementation (TA, Email Support, Audit & Feedback and External Facilitation):
Jane Stanton
Tiara Peterkin
Audrey Cobb
Daniel Reis, PhD
Suzanne McGarity
Christie Machan
Megan Harvey
Elizabeth Spitzer
Marissa Fielstein
Liz Velasquez
Ashley Dzaman
Carolyn Gass
Jane Wood

Research Study Designs Used in Implementation Science

- Randomized Control Trial
- Cluster Randomized Trials
- Stepped-Wedge Designs
- Hybrid Designs
- Mixed Methods
- Intervention Optimization Designs

[Overview of Study Designs in Implementation Science]

What are Adaptive Designs?

Clinical trial design that allows for **prospectively planned modifications** to one or more aspects of the design based on data from participants in the study

Can be used for both exploratory and confirmatory clinical trials

“Planning to be flexible” (Shih, 2006)

Why Adaptive?

Allows researchers to address more complex issues, including participant heterogeneity, intervention ordering, and combining interventions

Variable Responses

Intervention Optimization

Potential time and Cost Savings

Sequential Multiple Assignment Randomized Trial (SMART)

A multistage design that involves a particular sequence of interventions delivered at specific times.

SMART Designs used to develop an optimized, adaptive intervention.

What intervention option should we offer first?

What is the impact of augmenting intervention A with intervention B?

Should the first-stage intervention differ based on treatment setting?

What is the best way to define response/non-response to an intervention?

Are there interaction effects based on the order/sequence of delivery?

Bringing SMART Designs to Implementation Science

Amy M. Kilbourne, PhD, MPH

VA Quality Enhancement Research Initiative (QUERI)

Dept. of Psychiatry, University of Michigan

SMART & Adaptive Designs for Implementation Studies - YouTube

Key Components of a SMART Design

Participants are:

- Randomized to a
- Specific sequence of interventions
- Based on defined decision rules that
- Incorporate participant data

Figure. An Example of a SMART Design

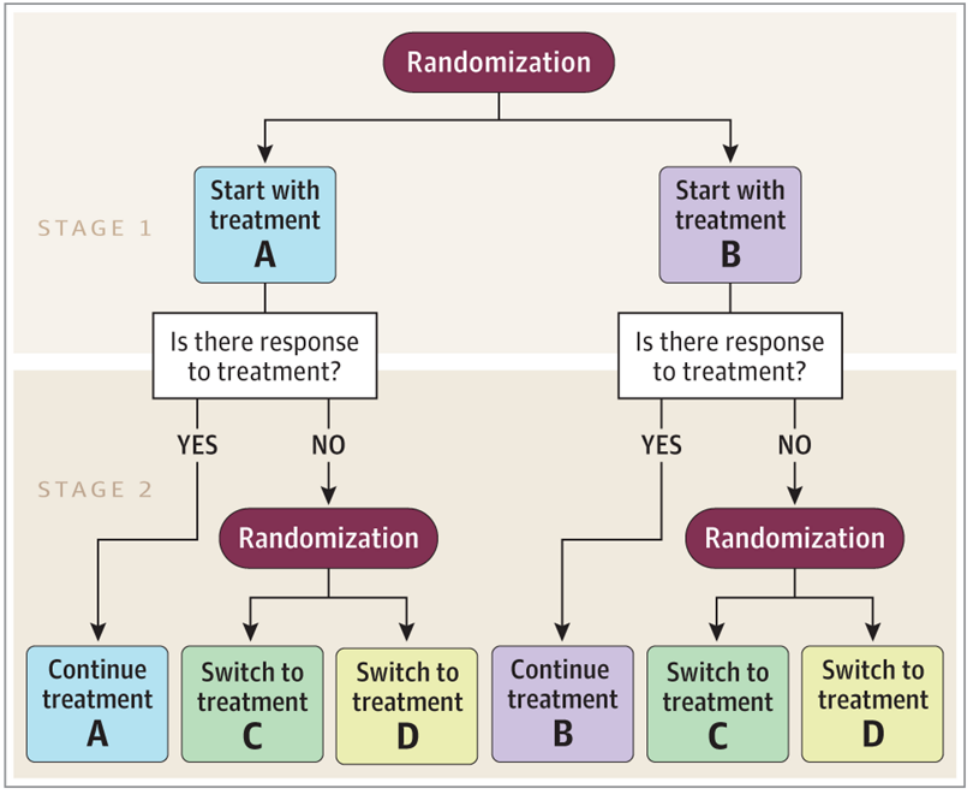


Figure from: Kidwell KM, Almirall D. Sequential, Multiple Assignment, Randomized Trial Designs. *JAMA.* 2023;329(4):336–337

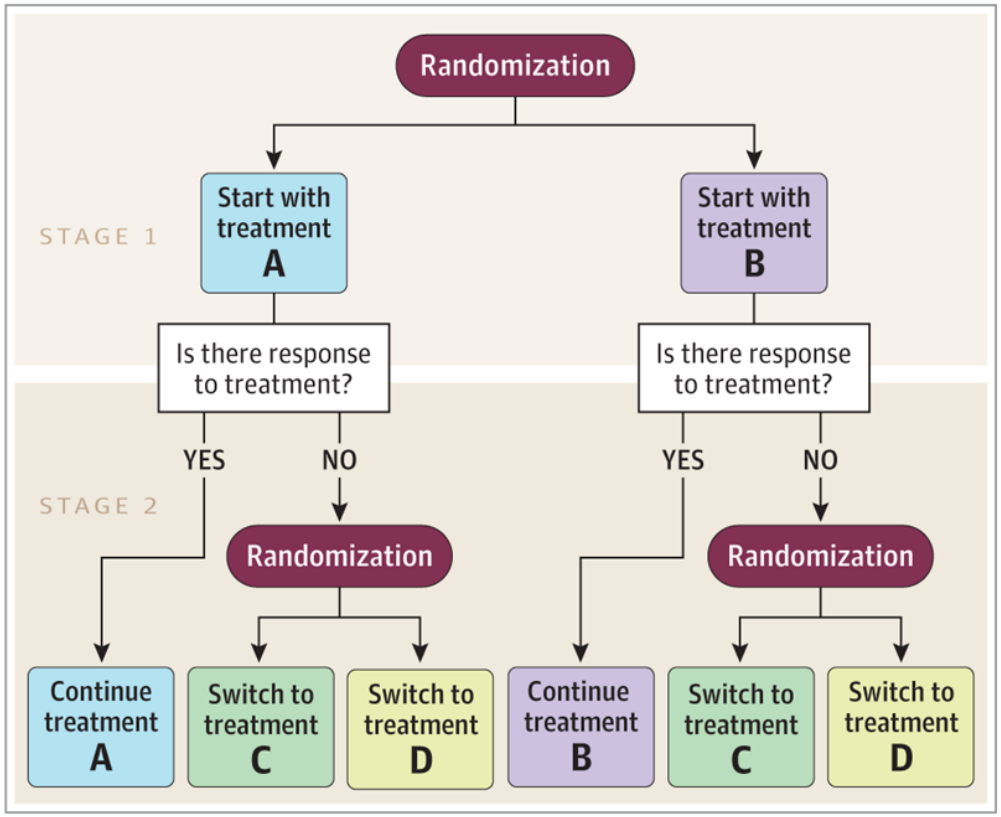
Multiple Intervention Pathways

1. Participants that starts with treatment A and respond stay with treatment A

2. Participants that start with treatment A and do not respond are switched to treatment C

3. Participants that start with treatment A and do not respond are switched to treatment D

Figure. An Example of a SMART Design



4. Participants that starts with treatment B and respond stay with treatment B

5. Participants that start with treatment B and do not respond are switched to treatment C

6. Participants that start with treatment B and do not respond are switched to treatment D

Figure from: Kidwell KM, Almirall D. Sequential, Multiple Assignment, Randomized Trial Designs. *JAMA.* 2023;329(4):336–337

Answer Multiple Questions

What is the best stage 1 treatment?

What measures should be used to make stage 2 treatment decisions?

For patients who do not respond to treatment A, should treatment be changed or intensified?

For participants that do not respond to treatment B, what is the best stage 2 treatment?

Figure. An Example of a SMART Design

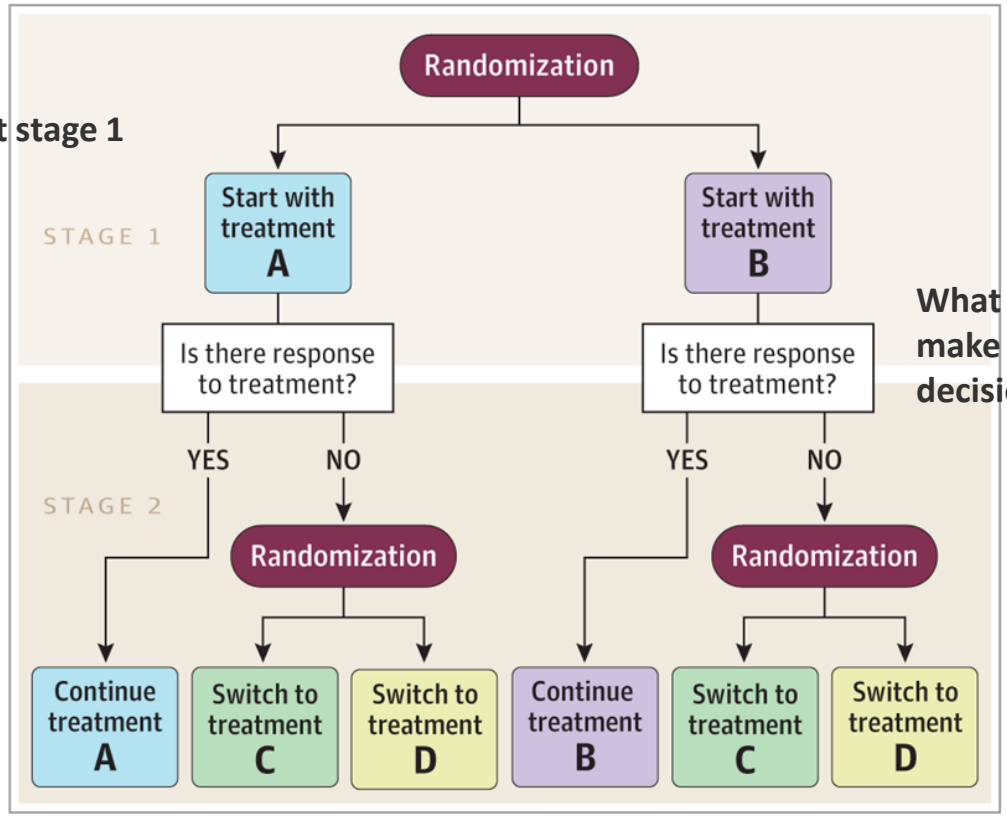
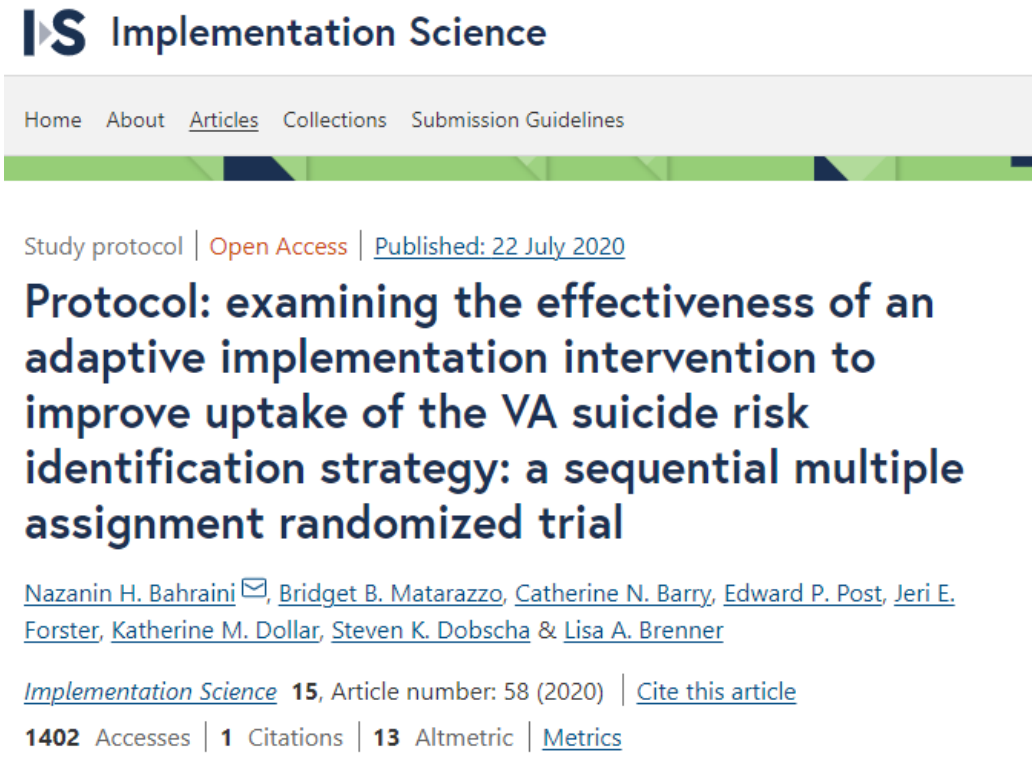


Figure from: Kidwell KM, Almirall D. Sequential, Multiple Assignment, Randomized Trial Designs. *JAMA*. 2023;329(4):336–337

Application of SMART Design to National Quality Improvement Project (QUERI PEC 19-303)

Project Objective

Develop an ***adaptive implementation strategy*** to improve the implementation of the Risk ID universal screening and evaluation requirements in ambulatory care settings



Implementation Science

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Study protocol | Open Access | Published: 22 July 2020

Protocol: examining the effectiveness of an adaptive implementation intervention to improve uptake of the VA suicide risk identification strategy: a sequential multiple assignment randomized trial

Nazanin H. Bahraini, Bridget B. Matarazzo, Catherine N. Barry, Edward P. Post, Jeri E. Forster, Katherine M. Dollar, Steven K. Dobscha & Lisa A. Brenner

Implementation Science **15**, Article number: 58 (2020) | Cite this article

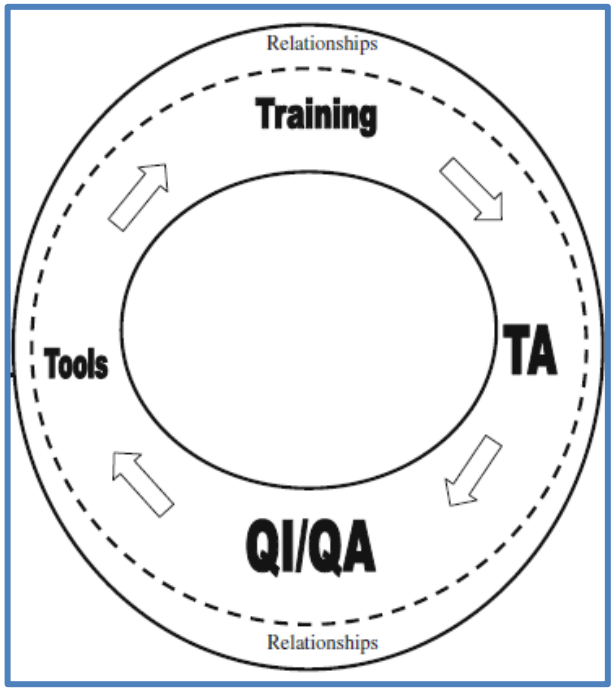
1402 Accesses | **1** Citations | **13** Altmetric | Metrics

Universal Screening

Focused on the universal suicide risk screening requirement in ambulatory care settings (January 2021)

2. **Universal Screening Requirement:** All Veterans should be screened annually with the Columbia-Suicide Severity Rating Scale (C-SSRS) Screener. Annual suicide risk screening will be facilitated though the clinical reminder system. The annual suicide risk screen reminder should be satisfied by appropriate staff, at a Veteran's encounter, when it is due. This reminder should be satisfied ***regardless of other setting-specific requirements*** for suicide risk screening and/or evaluation. A positive C-SSRS requires the timely completion of the Comprehensive Suicide Risk Evaluation (CSRE).

Level I: Implementation As Usual



Tools

- SharePoint Site
- FAQ
- CSRE Toolkit

Training

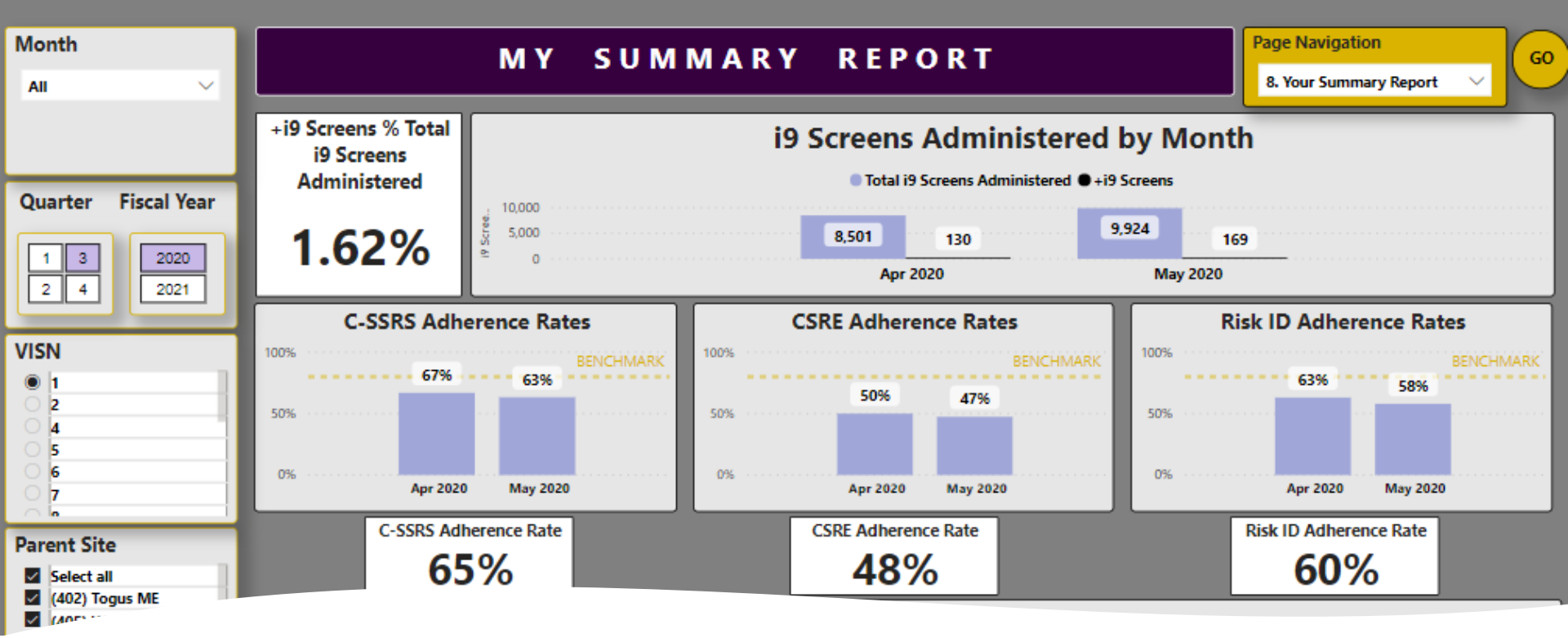
- Webinars
- TMS Training
- Ongoing Trainings

QA/QI

- Notes templates and reminders
- Fallout report
- Pilot metrics

Technical Assistance

- Facility Champions
- Email Support
- Weekly TA calls



Level II: Audit and Feedback

- [Risk ID Power BI Dashboard]
- Individualized performance data
- Toolkit/tutorial to help facilities understand how to best use the tool
- Monthly Summary Reports with Tailored Feedback

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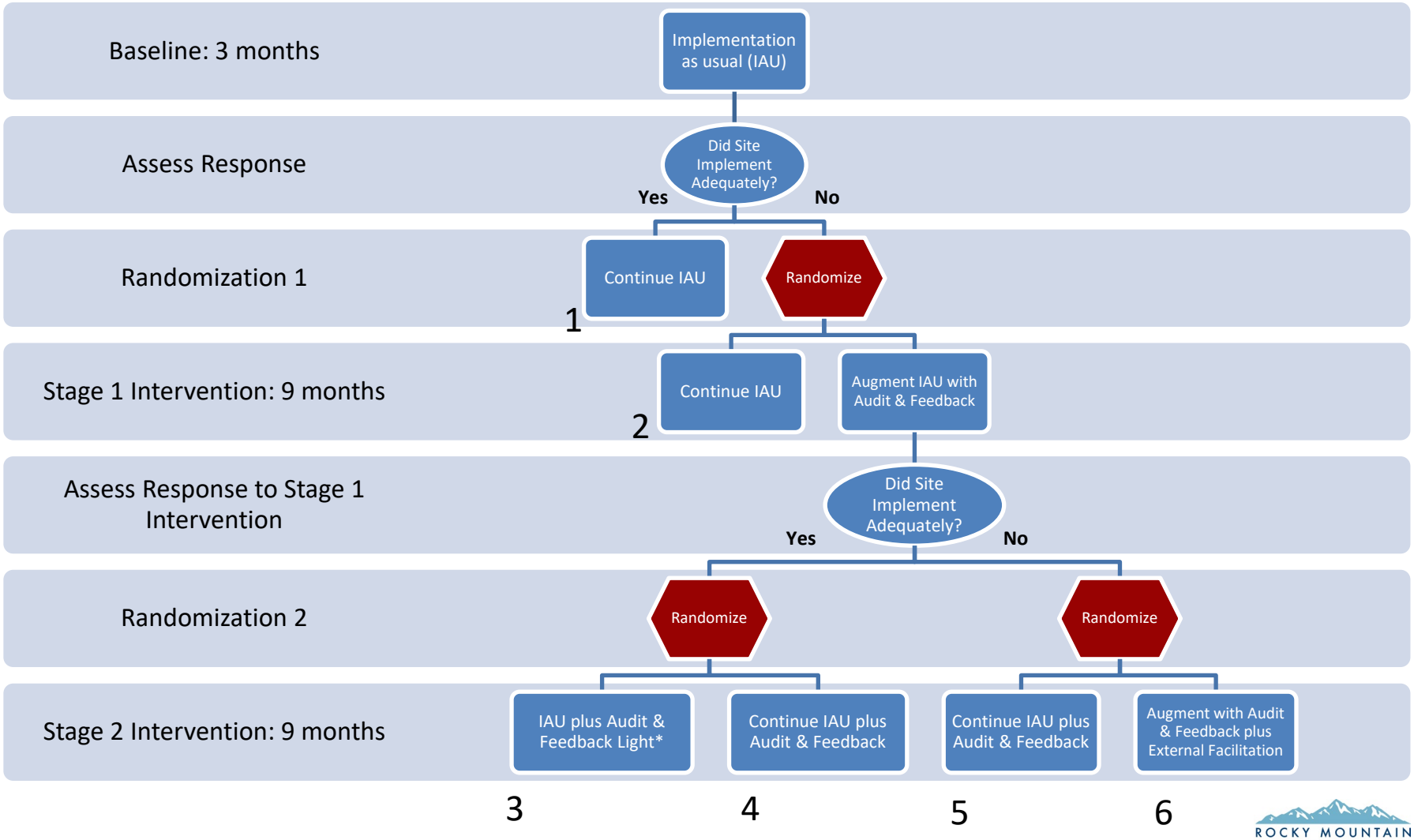
Level III: External Facilitation

- Engage leadership and key stakeholders
- Site Visit
- Assess barriers and facilitators
- Interactive Problem Solving and Support
- Tailored Implementation plan
- Monitor Progress

Implementation Focused SMART



**In November of 2021, dashboard access added to IAU*

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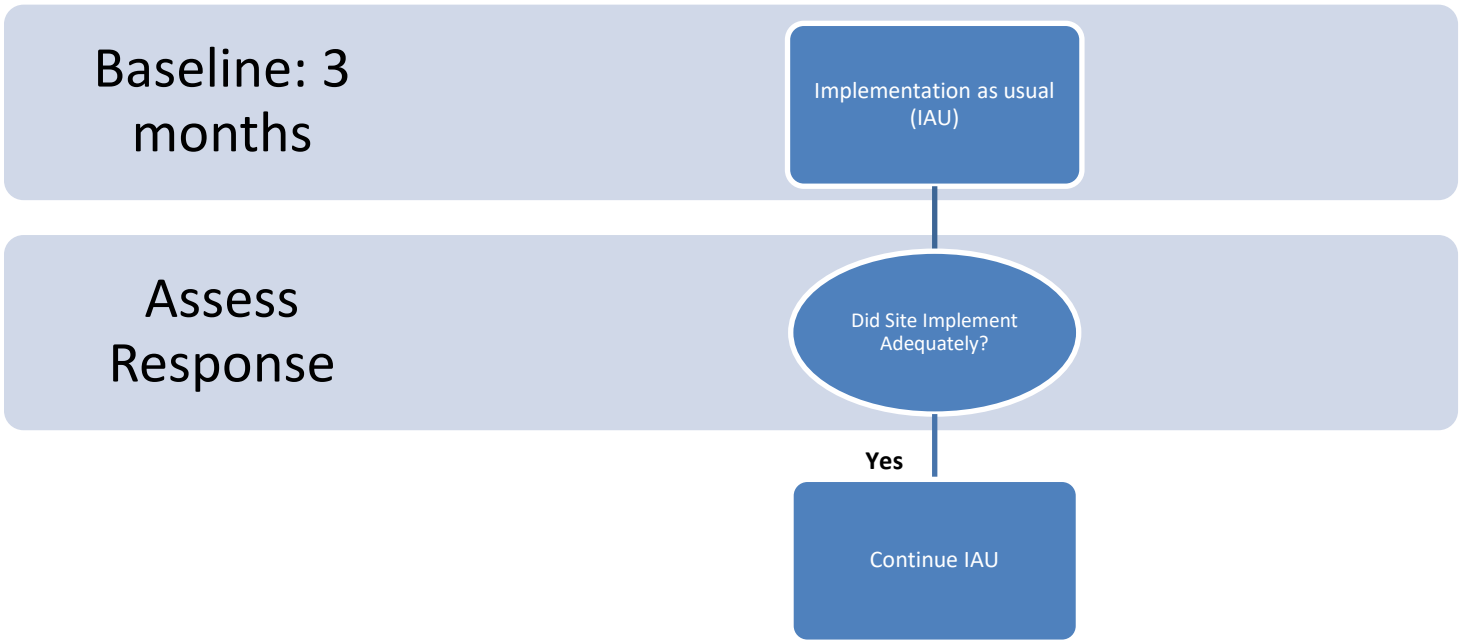
It's All in the Sequence

Run-In/Baseline: Every Facility Receives IAU

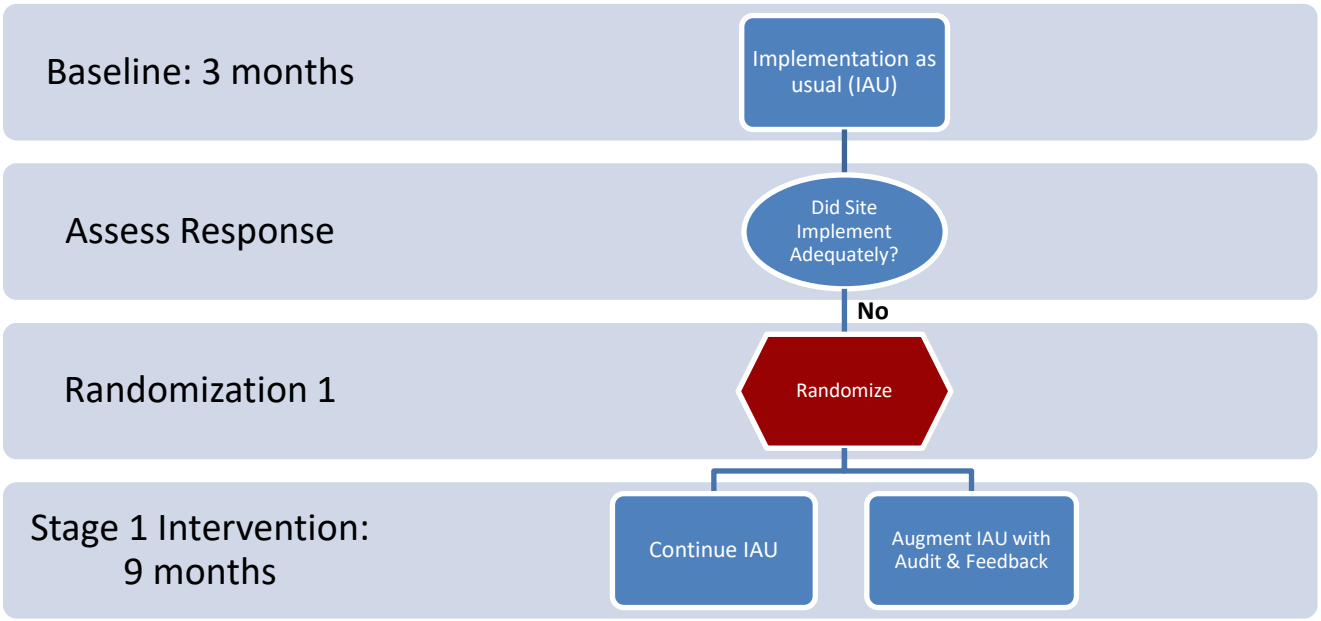
Begin with IAU, and **after three months**, continue IAU if the site meets the pre-determined benchmark for adequate implementation



Stage 1: Add Audit and Feedback

If the site does not meet the benchmark for adequate implementation after 3 months:

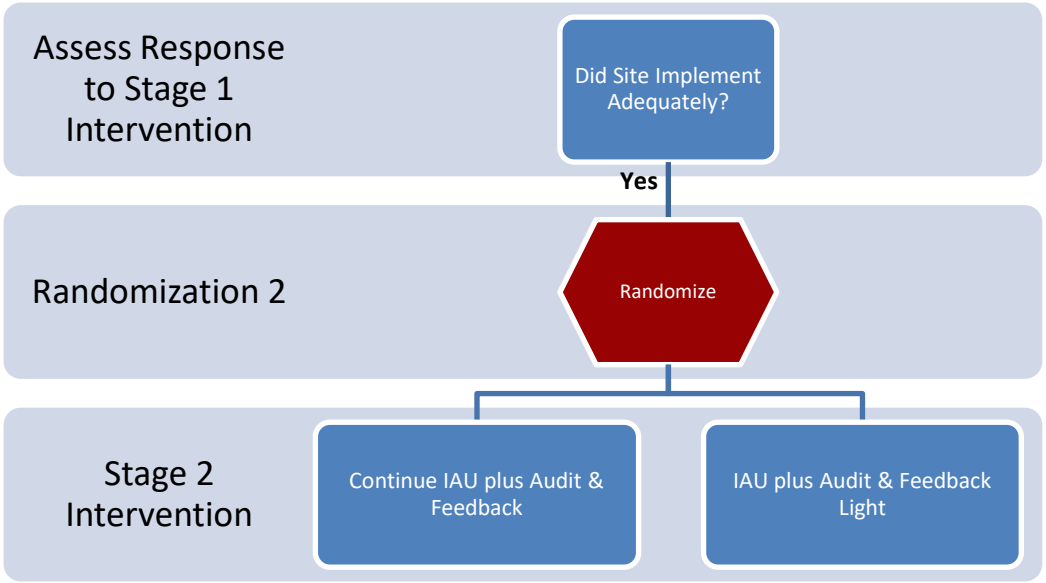
- do nothing and continue to monitor or
- add audit & feedback (A/F) **for 9 months** as a first stage intervention



Stage 2 : IAU plus Audit & Feedback Light

For sites that meet the benchmark for adequate implementation after receiving audit and feedback augmentation:

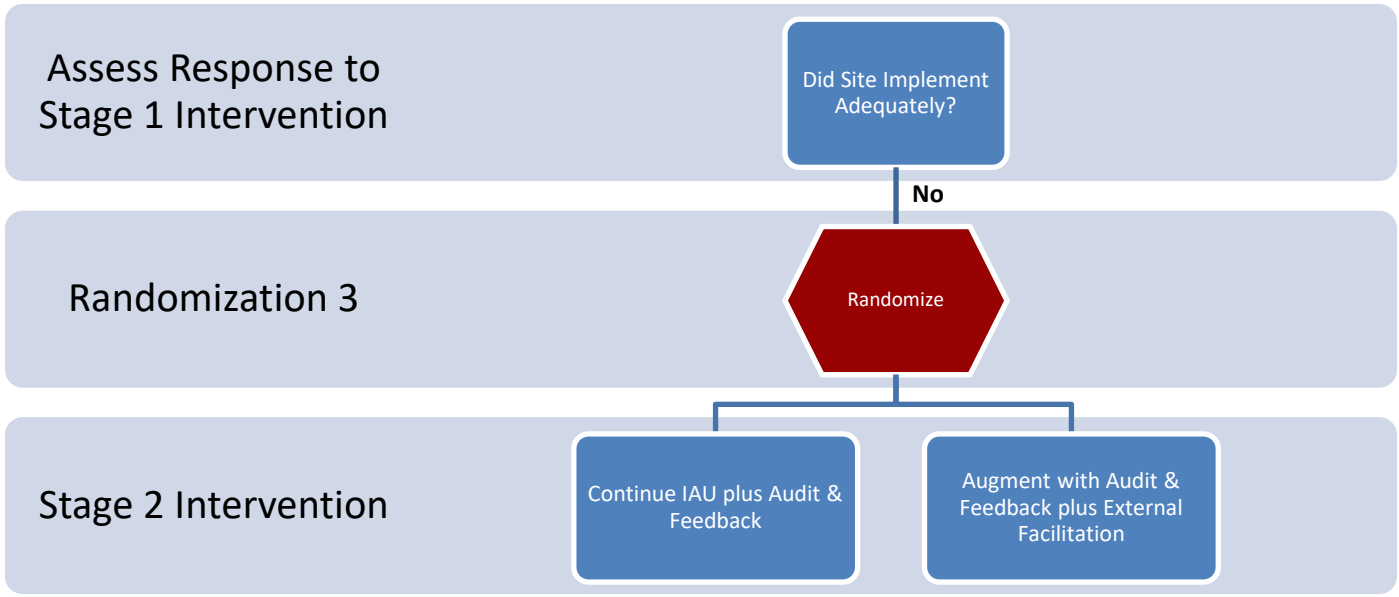
- continue providing audit & feedback
- provide IAU plus audit & feedback light (dashboard access and summary reports without tailored performance insights)



Stage 2: Add External Facilitation

If the site continues to not meet benchmark for adequate implementation after receiving audit & feedback augmentation:

- continue audit & feedback augmentation for **another 9 months** or
- initiate a combination strategy of audit & feedback plus external facilitation



Stage 1 Tailoring Variable

- Performance target of 70% on screening adherence for baseline month
- Based largely on original Risk ID requirements which started with item 9 of PHQ-9 as primary screen
- New universal screening requirements much lower screening adherence (new policy- only three months into implementation)

Randomization 1 (Stage 1)

- March 2021: All sites randomized as no sites met the benchmark for screening adherence
- Randomization stratified on facility complexity and performance (higher vs lower based on the median)
- **69 facilities** randomized to audit and feedback and **69 facilities** to implementation as usual

Randomization 2-3 (Stage 2)

Randomization 2

Audit & Feedback sites whose screening and evaluation adherence were ≥ 70th percentile at end of Stage 1 were randomized to continuation of IAU plus audit & Feedback or back to IAU only

- **12 sites randomized**

Randomization 3

Audit & Feedback sites whose screening and evaluation adherence are ≤ 70th percentile at Audit & Feedback + External Facilitation

- **57 sites randomized**

Also stratified by complexity level (1, 2, 3)

External Facilitation

- 5 waves (5-6 facilities per wave)
- Outreach to VISN PC and MH leads to let them know about opportunity and best way to reach out to facility leadership
- Facilities contacted to schedule a leadership briefing call to learn more about external facilitation and what it entails
- 28 sites randomized to receive external facilitation
  - 11 sites declined
  - 17 sites accepted
    - 11 active sites; 6 completed

SMART Design Considerations

Primary Aim

What is the main effect of first-line intervention?

Among sites that do not meet the benchmark for adequate performance following 3 months of Implementation as Usual (IAU), does the addition of audit & feedback significantly improve scores on Risk ID performance measures compared to IAU alone?

Secondary Aims

Choose secondary aims/questions that further develop the adaptive intervention and take advantage of sequential randomization

1. Among sites that do not meet the benchmark for adequate implementation after 9 months of audit & feedback, does augmentation with external facilitation significantly improve scores on VA Risk ID performance measures compared to A/F alone?

2. Among sites that meet the benchmark following audit & feedback, is performance maintained following discontinuation of audit & feedback?

Gather Additional Data to Explore Potential Moderating Effects and Mechanisms of Change

- Guided by your implementation framework and strategies
- Mixed-Methods
- Include organizational factors
  - Organizational climate, leadership support, staffing levels
  - Implementation Leadership Scale (Aarons, et al., 2014)
  - Implementation Climate Scale (Ehrhart et al., 2019)
  - Organizational Readiness for Change
- Systematically track modifications and adaptations
  - FRAME (Stirman et al., 2019)
  - Risk ID policy change prior to starting Phase 1

Moderating Effects & Mechanisms of Change

Does the effect of audit & feedback augmentation (first stage intervention) vary by baseline information (e.g., leadership support, organizational climate, staffing/resources)?

Is the impact of external facilitation mediated by changes in leadership support?

What are the best tailoring variables and/or decision rules?

- Defining "response" to an implementation strategy
  - Reach, adoption, implementation fidelity
  - Multicomponent interventions/practices
  - Process vs performance metrics
  - Should approximate but not be same as your outcomes
- New practice vs existing practice
  - Ensure adequate baseline data can help inform cut-offs for response
- Explore different options, but keep it practical
  - Performance benchmark, percentiles, percent improvement
  - Binary response status

Final Thoughts

Keep it simple, practical

Choose outcomes that are going to be relevant for real-world practice

Think about different ways to sequence interventions/ implementation strategies (augmentation, dose escalation)

Control what you can, manage the impact of/account for the unexpected, and roll with the rest

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Nazanin.Bahraini@va.gov

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