



BOSTON MEDICAL CENTER

Stakeholder- engaged adaptation and implementation of Brief STAIR for PTSD in safety net integrated primary care

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Why engage stakeholders in research?

- Help researchers understand complex systems, areas of need or strength, and differences in organization, provider, and patient culture.¹⁻³
- Early, multiphasic engagement with stakeholders may promote community investment in the success of the intervention and lead to improved effectiveness and implementation outcomes.⁴⁻⁶
- Collaborating across all stages of research, including planning, data collection, and dissemination of results, allows for provisions to be built at each step that mutually benefit both researchers and stakeholders in the process.⁷

Why engage stakeholders in research?

MOST IMPORTANTLY...

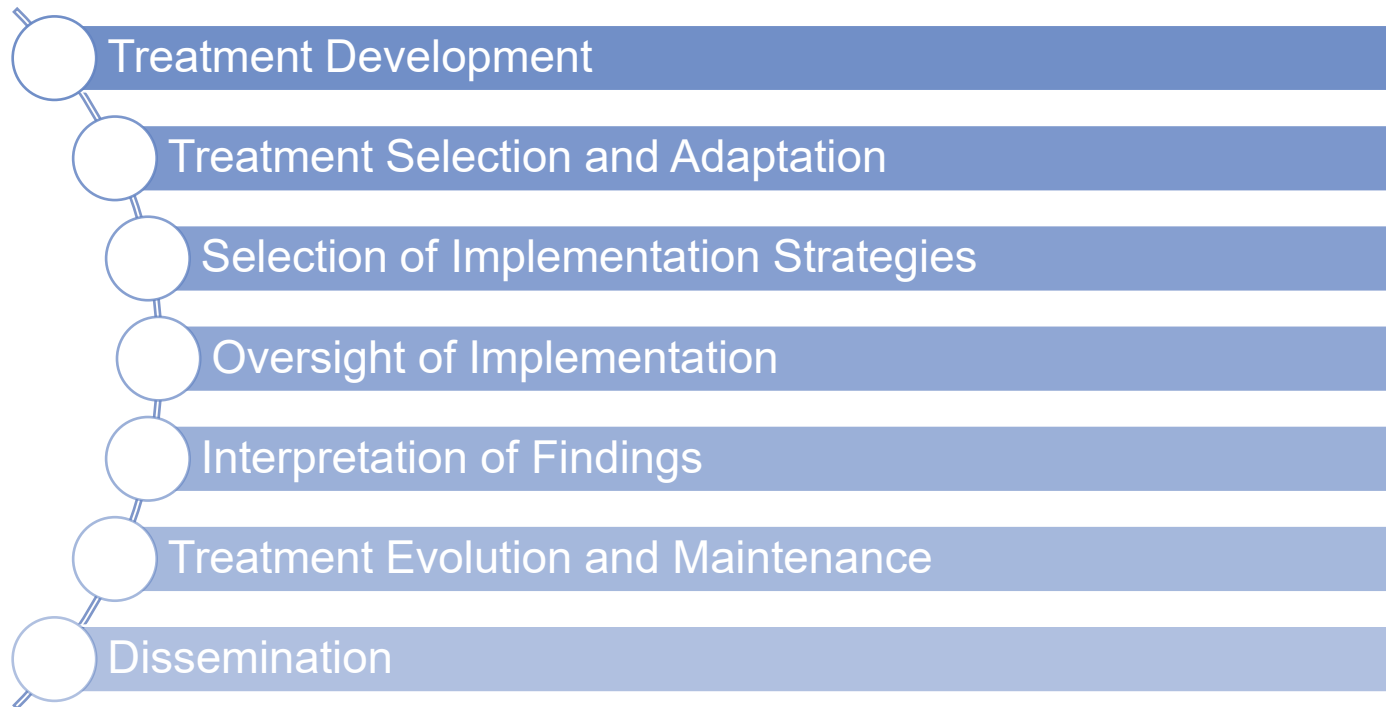
- Researchers who fail to foster healthy partnerships can erode trust in the research process and EBTs
 - May reinforce mistrust based on historical exploitation of minoritized groups by researchers and the medical system.^{8,9}
- Despite the significant time and effort required to engineer meaningful stakeholder engagement,¹⁰ this work is essential to the conduct of ethical clinical research that produces mutual benefit.

Planning for Stakeholder Engagement

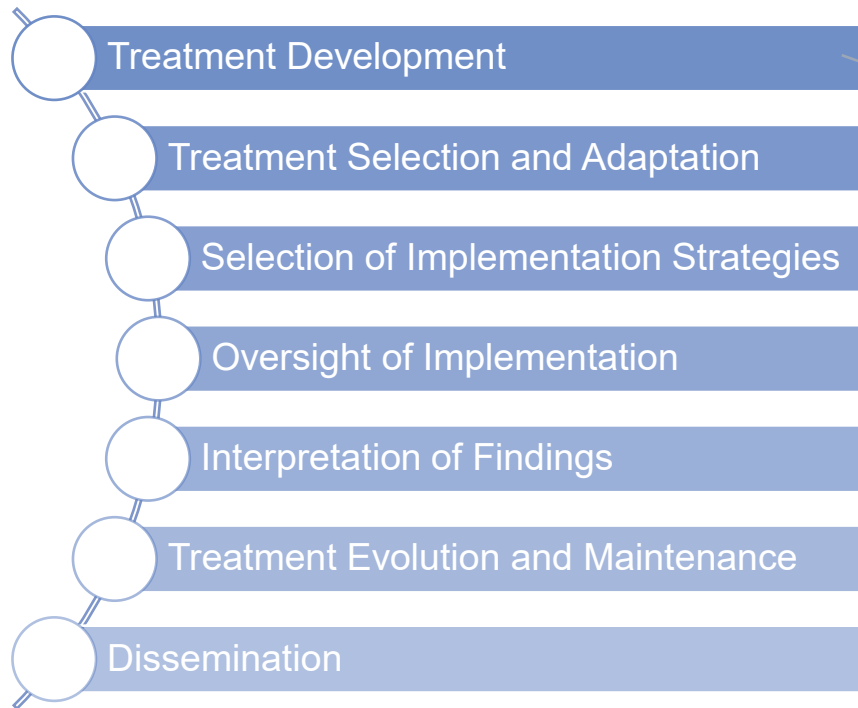
- **Identify perspectives needed to ensure implementation success**
 - Patients
 - Providers
 - Interventionists
 - Other providers involved with patients in the local setting
 - Organizational Leadership
 - “Champions”
 - “Gatekeepers”

- **Determine best format of engagement**
 - Study participants (surveys and interviews)
 - As Community Advisory Board members
 - Train-the-trainer or apprenticeship engagement
 - Co-Investigators

Stakeholder Roles



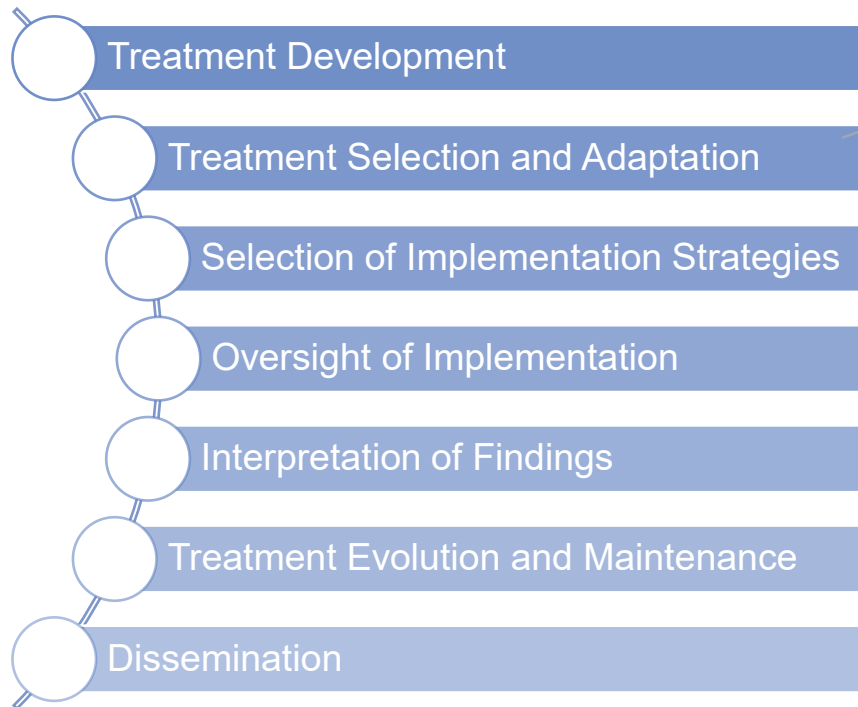
Stakeholder Roles



Mixed-methods investigation
to inform conceptual
treatment models and
hypothesize mechanisms

Engage stakeholders in
“workshopping” intervention

Stakeholder Roles

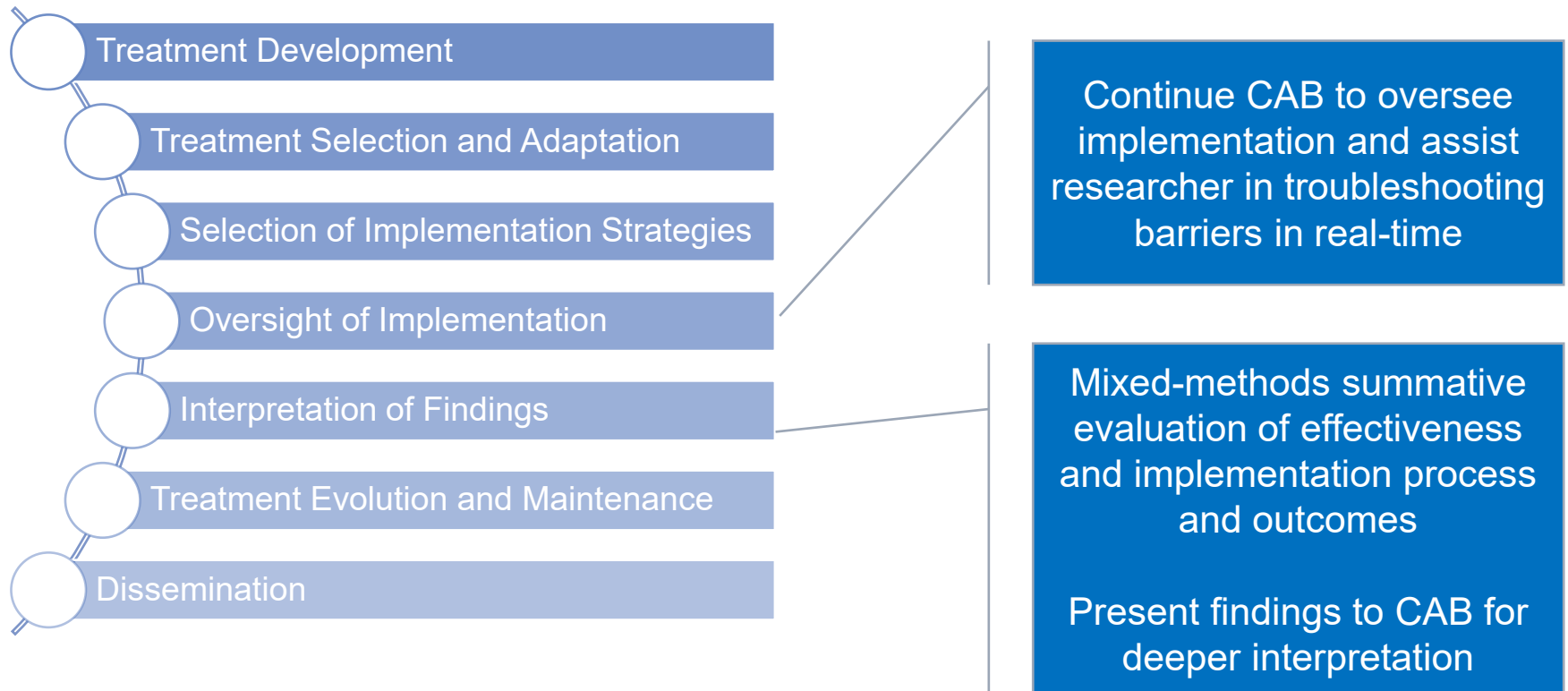


Engage stakeholders in the local context when selecting interventions, and when applying for funding

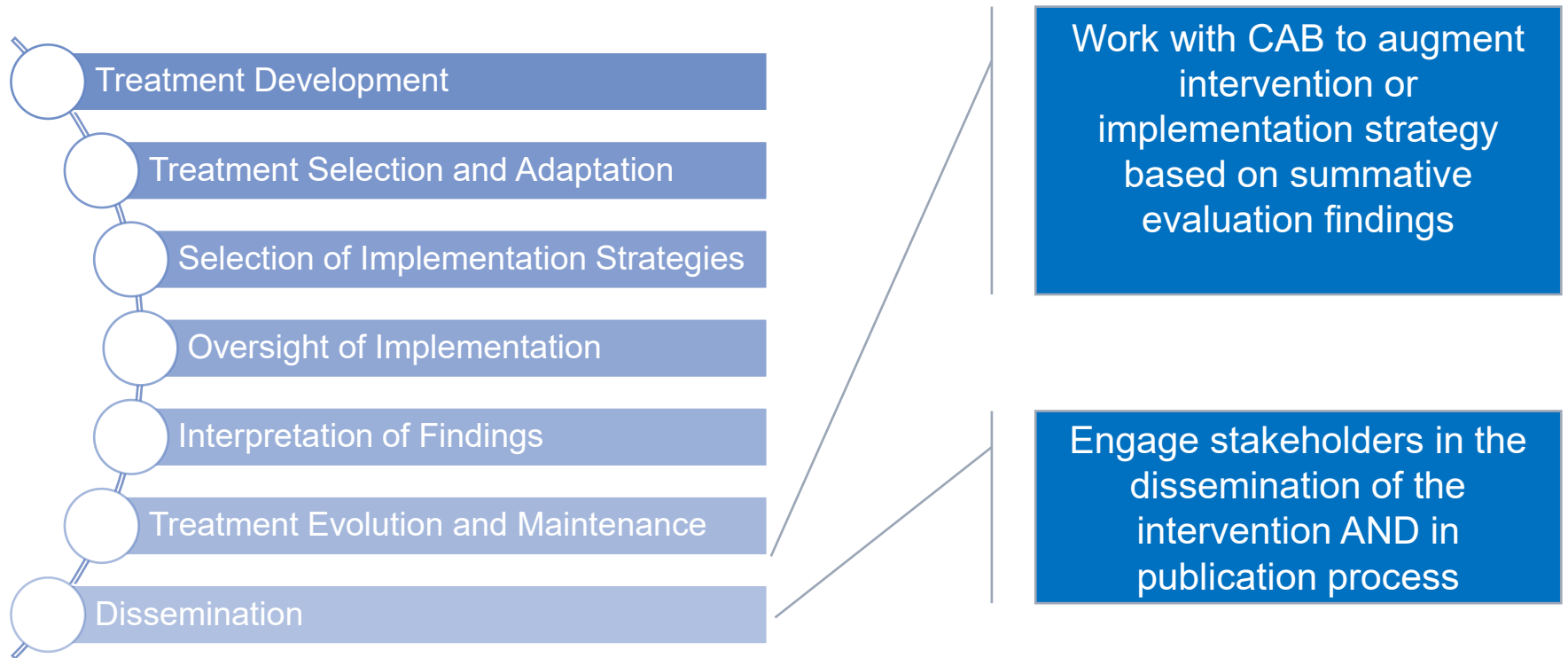
Conduct mixed-methods formative evaluation to identify need for augmentation and barrier/facilitators to implementation

Assemble community advisory boards to “workshop” the intervention and select implementation strategies to overcome barriers to implementation

Stakeholder Roles



Stakeholder Roles



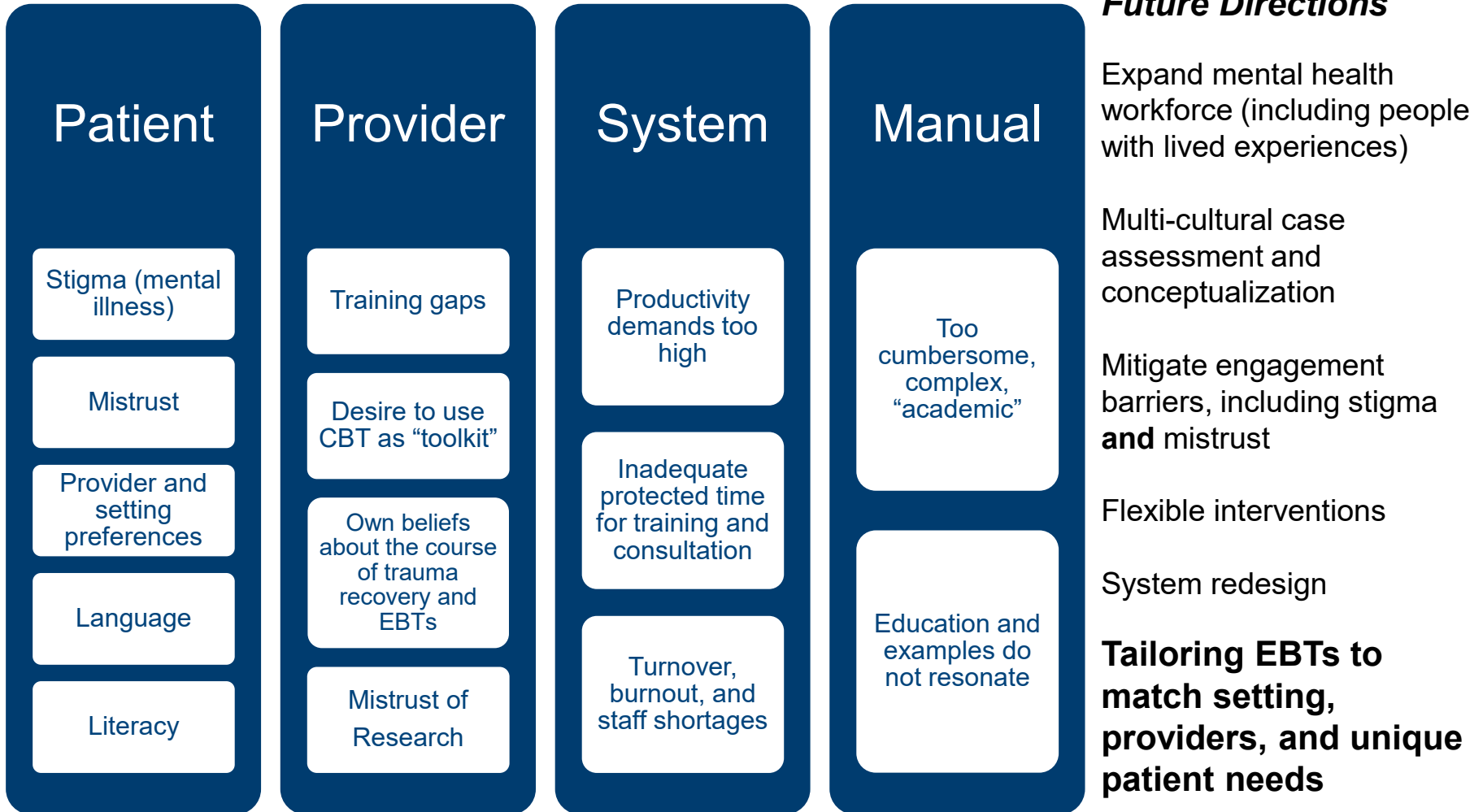
An implementation science approach to optimizing evidence-based treatments for posttraumatic stress disorder (PTSD) for non-specialty settings

NIMH K23 Project (PI: Valentine)

Background

- An estimated 33-46% of clients seen in safety net hospital primary care have posttraumatic stress disorder (PTSD),¹¹⁻¹³ yet only 13% receive any treatment.¹¹
 - Only 33% of those who access PTSD treatment receive a minimally adequate dose of therapy¹⁴
- Poor access and low quality of PTSD treatment
 - Shortage of trained specialists¹⁵⁻¹⁸
 - Low adoption of EBTs (even when training is made available)¹⁹
 - Stigma associated with seeking specialty mental health care²⁰
 - Patient preferences for care in primary care or community settings²¹
 - First line EBTs (CPT and PE) can be burdensome to implement in safety net settings

Overview: Barriers to Implementation of EBTs for PTSD^{22,23}



Stepped Care Service Delivery

(spanning non-specialty and specialty care)

- Stepped care models usually begin with interventions that are convenient and acceptable to clients (Step 1), and, if indicated, progress to more intensive care (Step 2).
- Stepped care approaches may improve access by accommodating client preferences²⁴⁻²⁶ and increasing the availability of evidence-based treatments (EBTs).
- Yet, stepped care models have not been developed for adults with PTSD seen in safety net hospital settings.
- This study will inform the development of a stepped care approach to PTSD treatment that bridges integrated behavioral health (IBH) and outpatient mental health settings (future R01)

Local Setting

- Boston Medical Center, the largest safety net hospital in New England
 - One third of patients do not speak English as their primary language and more than half represent underserved populations.
- Primary care practice spanning two departments (General Internal Medicine and Family Medicine) serve approximately 50,000
 - The majority of primary care patients are insured through Medicaid (70%)
 - 56% of Medicaid-insured patients have a behavioral health diagnosis
- Integrated behavioral health (IBH) model
 - Collaboration, coordination, and colocation of primary care and behavioral health
 - A population-based, stepped care approach

Step 1 Intervention for PTSD



- Skills Training in Affective and Interpersonal Regulation (STAIR) for PTSD
 - Effective,²⁷⁻³⁰ even in community-based settings³⁰ and by non-specialists³¹
- **STAIR-PC**: abbreviated, 5-session version of STAIR adapted for delivery in primary care (PC)³²
 - Does not involve memory reprocessing or exposures
 - Functional improvement, emotion management, social engagement, and interpersonal communication skills
 - Selected during trial planning in collaboration with primary care leadership
- **WebSTAIR** is a web-based version of STAIR³²
 - Includes the same content as STAIR-PC, divided into ten online, self-guided modules
 - Added as comparator during Aim 2b

K23 Study Overview

Aims to accomplish over 5 years (2018 – 2023):

Aim 1

- Gather feedback on setting and STAIR-PC
- Formative evaluation based on surveys and interviews with key informants

Aim 2

- Refine STAIR-PC, develop plan for implementation
- In collaboration with community advisory boards (CABs)

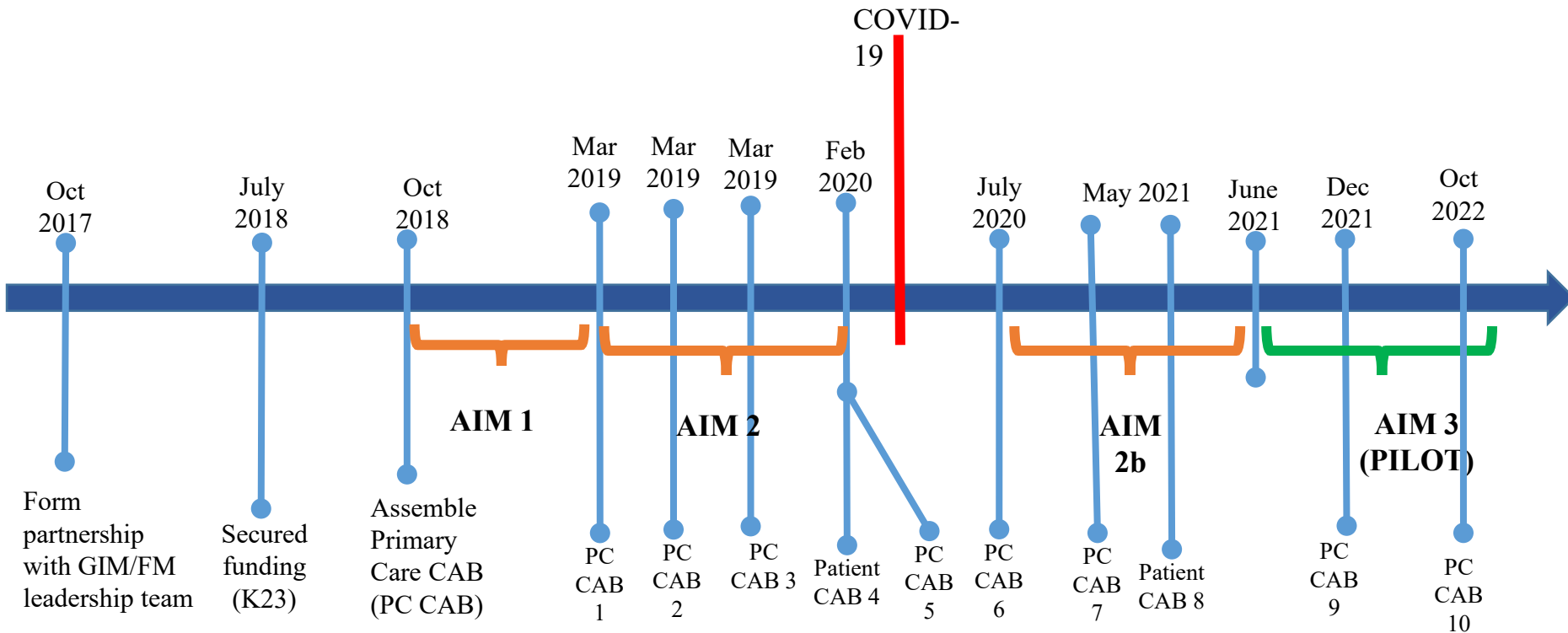
Aim 2b

- Re-characterize the setting: COVID-19, racism, racial trauma
- Further refine STAIR and implementation plan

Aim 3

- Pilot RCT of STAIR-PC v. webSTAIR in hybrid 1 effectiveness-implementation trial
- Post-trial: surveys and interviews with key informants, further refine intervention in collaboration with CABs

Study Timeline



Stakeholders in the Clinical-Research Partnership

- **Stakeholder Group: Key Informants (N=25)**
 - Primary care stakeholders (n=15): hospital employees in integrated primary care (e.g., PCPs, leadership)
 - Interventionists (n=10): behavioral health specialists in IBH primary care
- Key informants complete surveys and semi-structured interviews during Aims 1, 2b
 - Also Aim 3 (post-trial) to contextualize the setting and gather recommendations for adaptations

Stakeholders in the Clinical-Research Partnership

- **Stakeholder Group: Community advisory boards (CABs)**
 - Primary Care CAB (n=10) = Employees in IBH or specialty behavioral health with highly relevant expertise and/or decision-making authority in the practice
 - Patient CAB (n=6) = Patients with history of PTSD and/or experience with various mental health services at the hospital, nominated by PC CAB members
- The CABs directly inform all phases of the study
 - **Aims 1,2, 2b:** Intervention selection and adaptation, development of implementation blueprint, ensure system alignment prior to trial start
 - **Aim 3:** Trial oversight
 - Meet every 9 months to receive update on study progress and respond to real-time implementation challenges
 - **Post-trial:** effectiveness and implementation findings from the trial will be presented to CABs to operationalize adaptations to promote sustainability and uptake in the setting

REP Framework³³

- This current study applies the Replicating Effective Programs Framework to guide the refinement and pre-implementation of a “Step 1” evidence-based treatment (EBT) for PTSD in primary care.
- The REP framework is a multiphasic approach for implementing EBTs in real-world settings.
- The REP specifies steps needed to maximize fidelity to EBT core components while allowing for local tailoring and adaptations to treatment delivery in order to maximize intervention uptake and sustainability

Stakeholder engagement and research activities by REP Phase

Table 1
Stakeholder engagement and research activities by REP Phase

	Pre-Conditions (Oct 2018 - Feb 2019)	Pre-Implementation (A) (Feb 2018 - Feb 2020)	Pre-Implementation (B) (Feb 2020-Present)	Implementation (Next Steps)	Maintenance and Evolution (Next Steps)
Stakeholder Engagement	Key Informants			Key Informants	
		Primary Care CAB	Patient CAB		
Primary Research Activities	Identify barriers to implementation (organizational needs assessment, usual care; i.e. integrated primary care context)	Refine package, Core elements and menu options (refined based on CAB input, adjudicated by intervention developers)	Finalize package based on Patient CAB input, prepare for trial start	Ongoing Training	Organizational, financial changes
	Distinguish core elements, menu options	Refine training, technical assistance, approach strategies per CAB input	Operationalize implementation strategies and finalize blueprint	Technical Assistance	National dissemination
	Assemble Primary Care Community Advisory Board (CAB)	Select expert recommended implementation strategies	Pilot implementation package (intervention and implementation strategies) in primary care	Full scale evaluation	Re-customize delivery as needed
		Assemble Patient CAB			

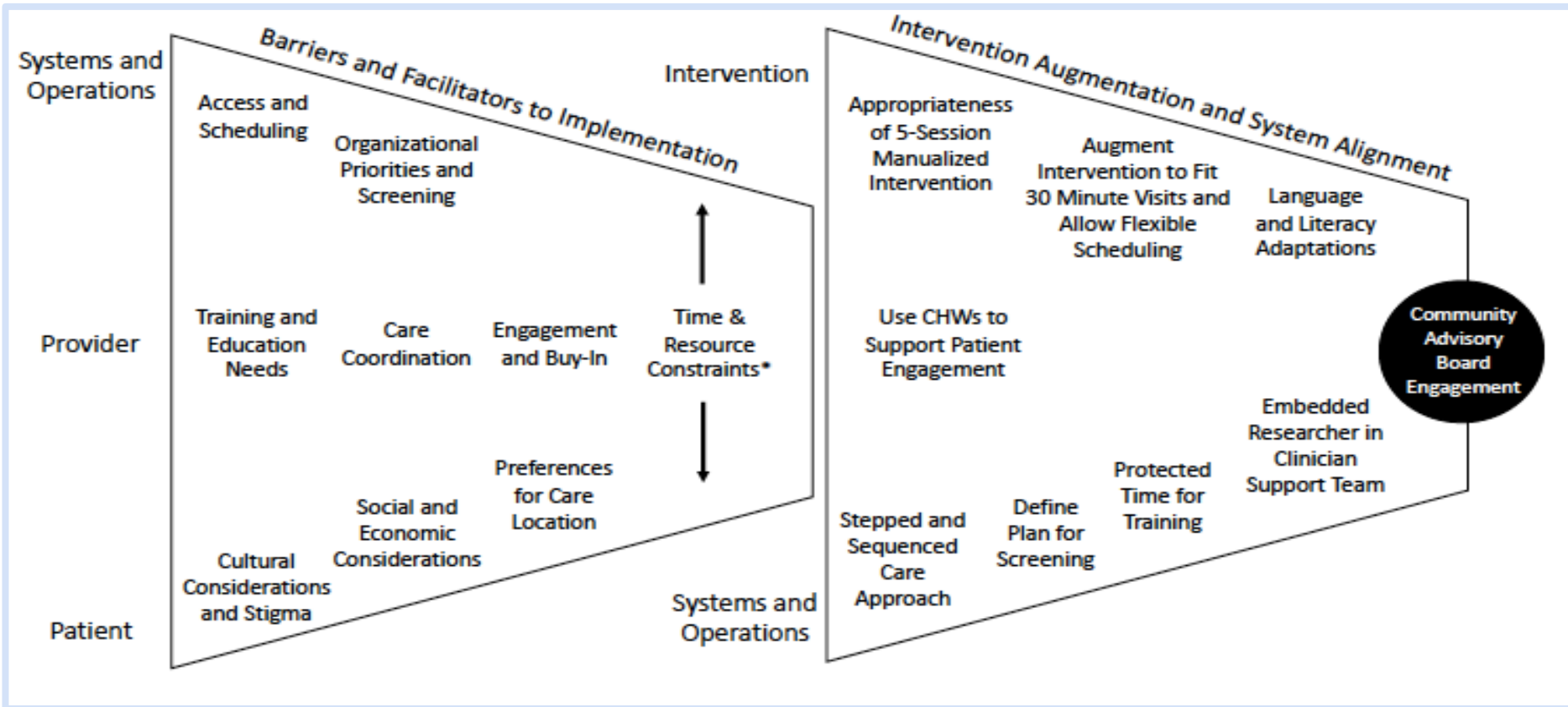
Aim 1 (Pre-conditions)

Gather feedback on the integrated primary care setting and STAIR-PC prior to trial start

Aim 1 Formative Evaluation

- We conducted a mixed methods formative evaluation to contextualize the integrated primary care setting, identify barriers/facilitators to implementation, and gather suggestions to refine the implementation plan
- Participants (N=22): key informants in primary care (PC)
 - Potential interventionists (n=11) : 6 clinical social workers in IBH, 2 psychologists, 3 community wellness advocates
 - PC stakeholders (n=11): 6 primary care physicians (PCPs), 5 primary care leadership
- Guided by the Consolidated Framework for Implementation Research (CFIR)³⁴
 - Surveys assessed implementation climate and attitudes towards EBTs and behavioral health integration
 - Semi-structured interviews identified barriers and facilitators to implementation, need for augmentation

Key Findings from Aim 1 Formative Evaluation



Stakeholder Buy-In for STAIR-PC

- Utilizing skills across patients, transdiagnostic application, toolkit
- Raised awareness across primary care providers of trauma exposure, PTSD, and effective treatments
 - Importance of detecting and addressing PTSD in primary care
 - Feasible to address PTSD symptoms in primary care through brief interventions
- Increased confidence and comfort with this level of training and consultation among therapists
 - Ongoing consultation to apply to our patients is essential (staying the course while being patient-centered)



Aim 2 (Pre-implementation)

Refine study design, intervention, and implementation blueprint based on Aim 1 findings in collaboration with Community Advisory Boards (CABs)

Aim 2

- We presented Aim 1 findings to our CABs who assisted in operationalizing adaptations to our implementation blueprint
- We selected expert-recommended implementation strategies detailed by Powell and colleagues (“The Expert Recommendations for Implementing Change [ERIC] Project”)³⁵

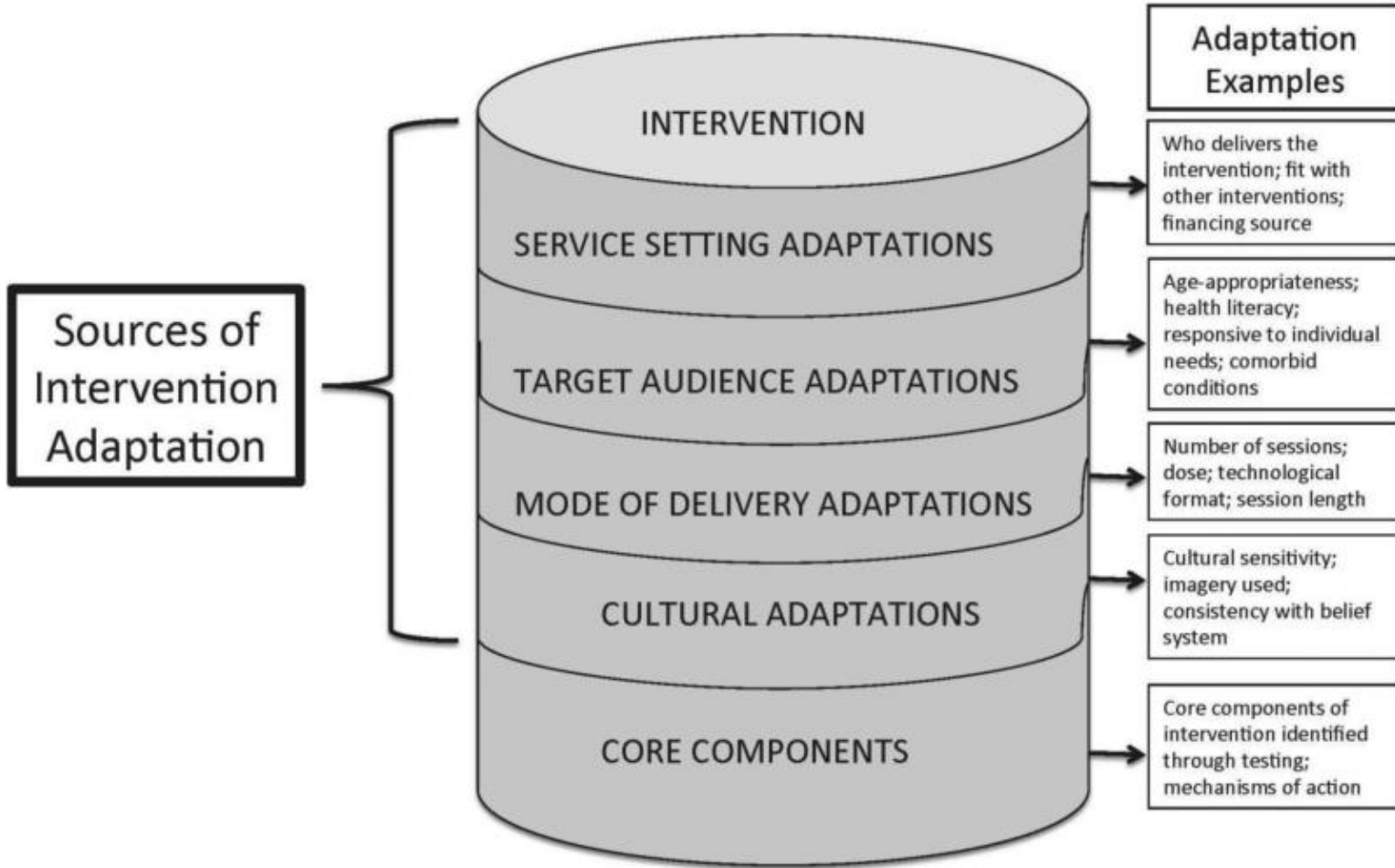
Evolution of Implementation Blueprint

Meeting	Focus
1. PC CAB	<ul style="list-style-type: none">• Present Aim 1 findings• Identify system, provider, patient barriers to prioritize
2. PC CAB	<ul style="list-style-type: none">• Plan for selecting and training interventionists, technological supports for screening, documentation, and care coordination to ease therapist burden
3. PC CAB	<ul style="list-style-type: none">• Finalize manual, training and consultation plan, and prepare for Patient CAB meeting
4. Patient CAB	<ul style="list-style-type: none">• Present implementation blueprint and intervention for feedback <p><u>Important factors raised by Patient CAB:</u></p> <ul style="list-style-type: none">• Reducing discrimination and stigma in patient experiences• Misdiagnosis of PTSD resulting from biased screening practices• The lack of access to non-pharmaceutical treatment• Perceived lower quality of care for minoritized groups
5. PC CAB	Present Patient CAB feedback, finalize intervention and implementation blueprint

Key Aim 2 Findings³⁶

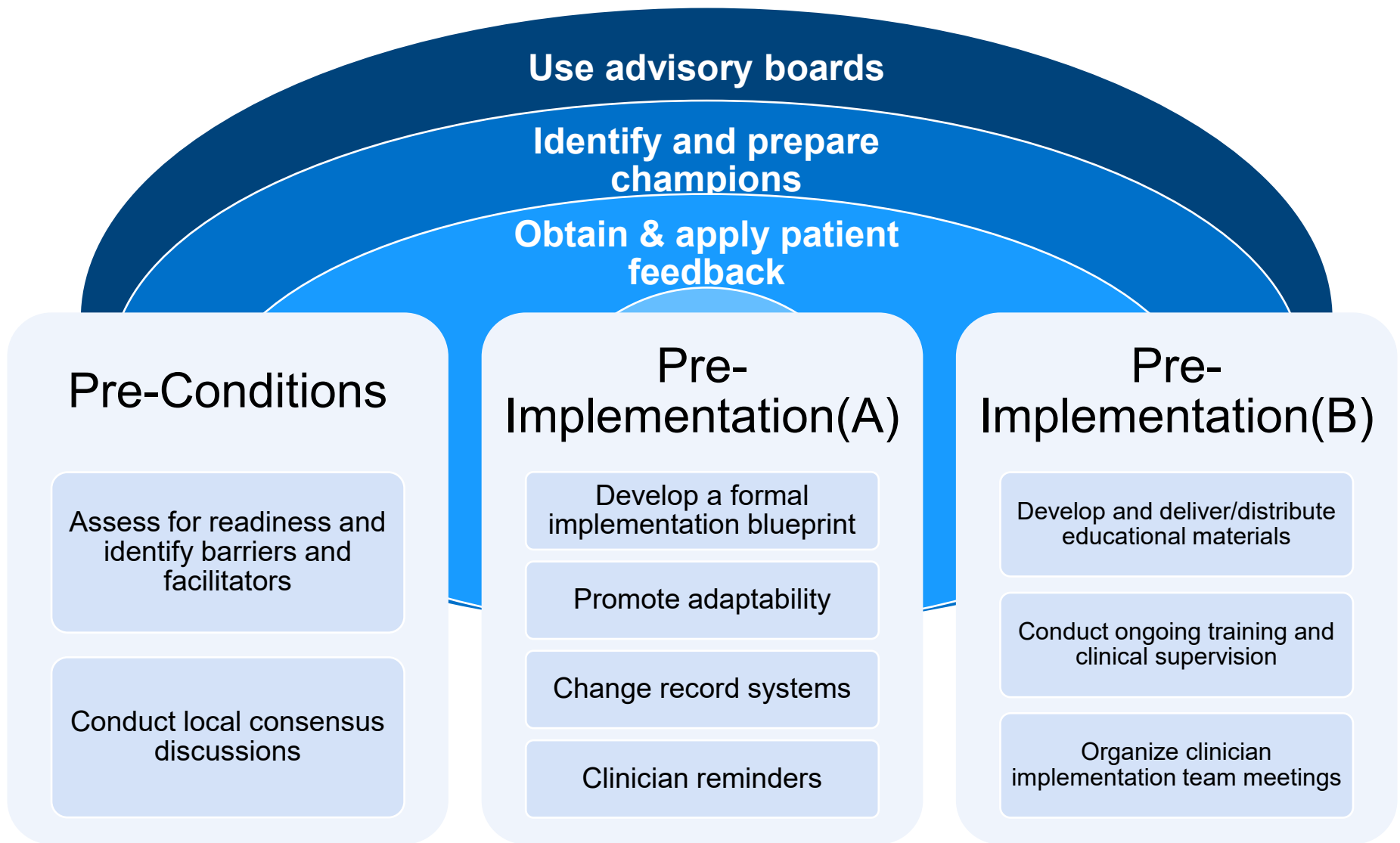
- Both PC and Patient CABs affirmed the research question and proposed intervention are appropriate and relevant based on provider and patient needs
- Staff turnover is high in this setting, both due to the highly stressful clinical environment as well as the nature of teaching hospitals
- Prioritization of PTSD screening was not feasible at this time, but a worthy long-term goal for the practice
- Adaptations to support implementation included service setting adaptations (e.g., shorten length, designate some modules as optional, fit 30-min session scheduling demands) and target audience adaptations (e.g., reading level, remove pathologizing terms)

Aim 2 Adaptations



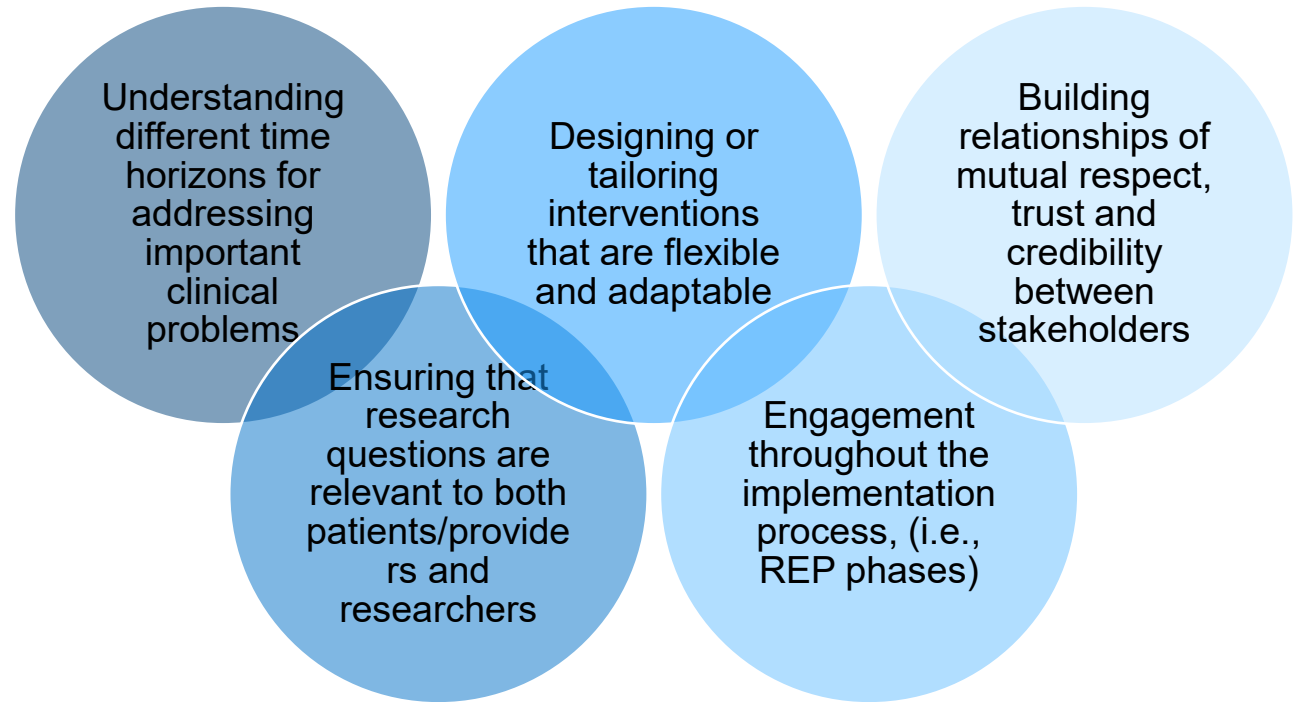
Chambers' Adaptome³⁷

Selected Implementation Strategies³⁵



Aim 2 Conclusion

Engaging stakeholders in the development of an implementation blueprint to guide implementation of STAIR-PC involved:





Aim 2b (in response to COVID-19)

Re-characterize the setting in light of COVID-19, racism, racial trauma and further refine the implementation blueprint.

Aim 2b

- Planned trial start (March 2020) halted due to COVID-19
- We conducted an additional formative evaluation based on surveys and semi-structured interviews with our key informants
 - Research questions and interview guides driven by CABs
 - Explicit focus on COVID-19-related changes to the setting, experiences of racism and racial trauma as implementation factors
- Findings were presented to the CABs to operationalize further adaptations to our implementation blueprint prior to new trial start date (June 2021)

Interview Guide

- **COVID-19 (to fit practice)**

- How has COVID-19 led to changes in patient behavioral health needs?
- How are patients' mental health needs being identified and prioritized in light of COVID?
- How has the COVID-19 pandemic shifted your practice?
- Are there any suggestions you have about the need to further adapt the intervention, in light of COVID-19?

- **Anti-Racist Clinical Practice (to fit patients and identify training needs)**

- In what ways do you think racial identity or racism is related to PTSD for your patients?
- What is the common way that you learn about your patient's racial identities and experiences of racism? Does telehealth affect this process?
- How is racism usually talked about with your patients? In your practice?
- How do you identify your own race? What differences do you notice in your approach or comfort in providing therapy to someone of your own race versus another race?
- How would you define anti-racist clinical practice?
- What suggestions do you have for integrating anti-racist principles into therapy?

Aim 2b Key Findings

COVID-19³⁸

- Increase in patient volume and acuity in the setting led to increased provider burden and burnout
- Need to offer flexible treatment delivery options

Racism, racial trauma³⁹

- Providers acknowledged the impact of racism, racial stress and trauma on patient engagement
- Characterized the harms of experiences of racism at the patient and provider level, and offered recommendations:
 - Staff/hiring practices
 - Examination of racist policies
 - Increases in support for providers of color
 - Potential need to adapt PTSD treatments

Study Responses:

- Addition of webSTAIR as comparator (expand patient access, minimize provider burden)
- Increased administrative support from study team (e.g., scheduling, medical record documentation)
- Addition of post-trial patient interviews and revisions to post-trial provider interview guides to assess for potential need for cultural adaptations to the intervention

Aim 3: Implementing a Skills Training Evidence-based Treatment for PTSD in primary care (I-STEP) Study

Hybrid type 1 effectiveness-implementation trial⁴⁰ of therapist-delivered STAIR-PC vs. webSTAIR

I-STEP Study Trial Design

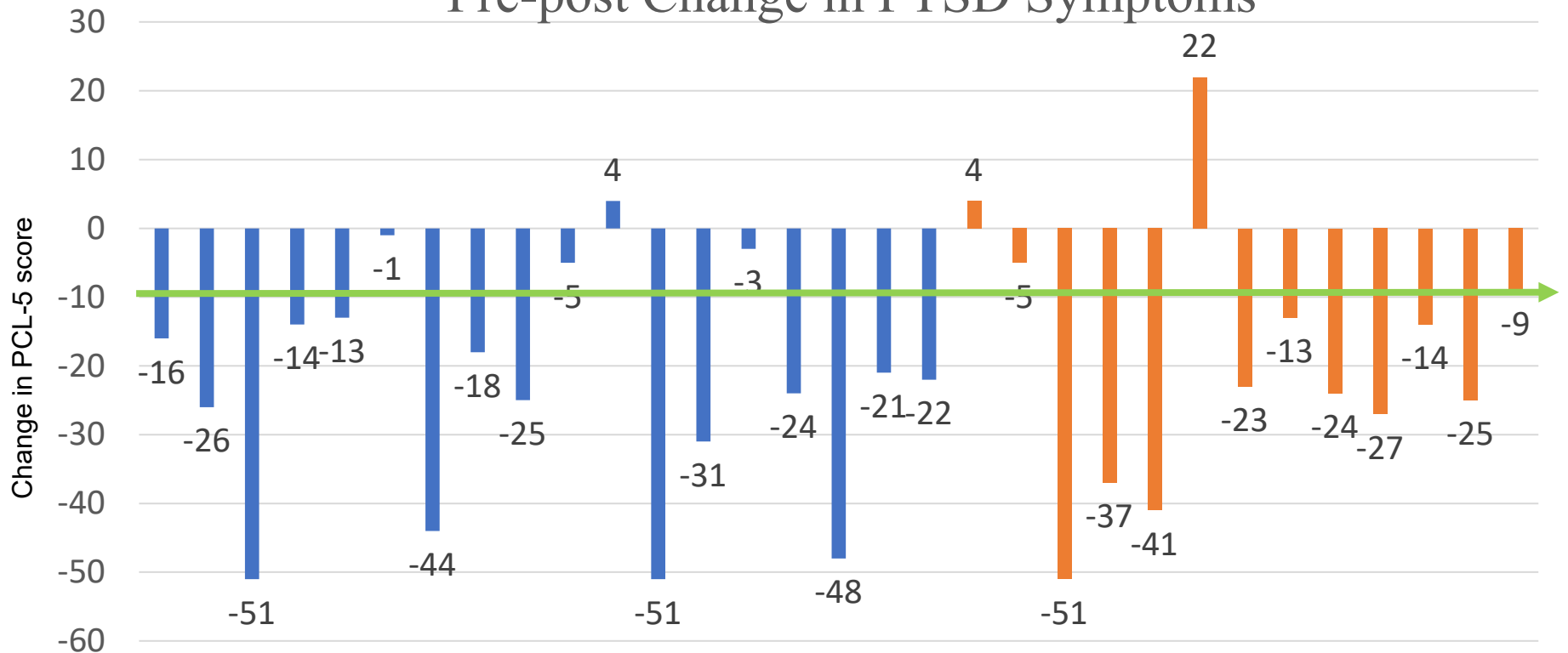
- Randomized Control Trial (N=60, over 18 months)
- Participants will complete therapist-delivered STAIR-PC or online, self-administered webSTAIR over a 15-week treatment period
- Study visits: Baseline, 15 weeks (post-treatment), 9 months

STAIR-PC In-person/telehealth	WebSTAIR
<ul style="list-style-type: none">• Synchronous, in-person or telehealth (phone/video)• Meet with clinician every other week• RA check-ins every 2 weeks for 15 weeks<ul style="list-style-type: none">• Collect PCL• Encourage engagement with material	<ul style="list-style-type: none">• Self-paced, asynchronous• Clinician schedule as usual• RA check-ins every 2 weeks for 15 weeks<ul style="list-style-type: none">• Collect PCL• Encourage engagement with material

Preliminary Data (N=31)

- Average Baseline PCL-5 = 61
- Average post-treatment PCL-5 = 39

Pre-post Change in PTSD Symptoms



Blue = telehealth/in-person STAIR-PC **Orange** = webSTAIR

Next Steps

- Post-trial (or upon completion of participation in the trial in case of therapist turnover), key informants will complete surveys and a semi-structured interview to assess the need for additional refinement to promote sustainability in the setting
- We will conduct a summative evaluation based on effectiveness and implementation findings and present to our CAB to operationalize adaptations

Discussion

- Knowing which implementation strategies to apply, when to apply them, and at what level requires careful coordination across managerial levels and often negotiation with various stakeholders.
- In this project, some implementation strategies discussed with the CABs were tabled, but may be applied in the future.
 - For example, expanding interventionist provider type, offering via telehealth, implementing universal PTSD screening
- CAB members showed appreciation for the structure and transparency of the meetings (i.e., the research team presented exactly *how* stakeholder feedback was incorporated into revisions).
 - This approach was respectful of the CAB members' limited time and helped to minimize CAB member work between meetings.

Discussion

- It is important to consider that healthcare organizations are often not centered around the implementation of EBTs for behavioral health, and that these interventions may need to be adapted to fit organizational context and need.
- There is also a case to be made that healthcare systems could benefit from reorganization around behavioral health concerns, especially in safety net hospitals where behavioral health needs are high.
 - Even in hospitals that have embraced IBH models, the implementation of PTSD treatment can pose additional challenges, given that first line treatments for PTSD often place high burden on patients, therapist time, and systems.
 - Thus, intervention adaptation and implementation strategies for PTSD should focus centrally at reducing time and resource burdens associated with these treatments.

Conclusion

- Repeated and ongoing engagement of patients and providers throughout the implementation process is needed to
 - Ensure research questions are relevant to both patients and clinical providers
 - Build relationships of mutual respect, trust, credibility between research team, providers, patients
- Leads to interventions that are flexible and adaptable, and takes into account the needs of the local setting [sustainability]
- Acknowledges that there may be different timelines for addressing clinical problems for the research team and clinicians

K23 Publications

- Valentine, S.E., Fuchs, C., Sarkisova, N., Olesinski, E.A., Elwy, A.R. Formative evaluation prior to implementation of a brief treatment for PTSD in primary care. (*Under revision at Implementation Science Communications*)
- Valentine, S. E., Fuchs, C., Carlson, M., & Elwy, A. R. (2022). Leveraging multistakeholder engagement to develop an implementation blueprint for a brief trauma-focused cognitive behavioral therapy in primary care. *Psychological trauma : theory, research, practice and policy*, 14(6), 914–923. <https://doi.org/10.1037/tra0001145>
- Valentine, S. E., Fuchs, C., Godfrey, L., & Elwy, A. R. (2022). Redesign of a brief PTSD treatment in safety net integrated primary care: Supporting implementation in the context of the COVID-19 pandemic. *General hospital psychiatry*, 74, 94–101. <https://doi.org/10.1016/j.genhosppsy.2021.12.004>
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Questions or Comments?

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