Applying Implementation Science to Improve Protocols and Enhance Equity: LAI Treatment as a Case Study

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HART Hunter Alliance for Research & Translation

ALAI UP

NATIONAL 2024 RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

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Sarit A. Golub has no relevant financial relationships with ineligible companies to disclose.

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Learning Objectives

At the conclusion of this session, the participant will be able to:

- Summarize the rationale behind implementation-science informed protocol development in practice settings.
- Utilize protocol development worksheets, tools, and templates to address equity goals.
- Apply components of this informed, practice-driven model to a specific practice setting.

THE LEARNING CONTEXT: ALAI UP

Accelerating Implementation of Multilevel-strategies to Advance Long-Acting Injectables for Underserved Populations

This workshop will use long-acting injectable treatment (**LAI Tx**)* as a case study to present an implementation-science informed, practice-driven model for the development or refinement of programmatic protocols with the goal of maximizing equity.

*focusing on injectable cabotegravir/rilpivirine (iCAB/RPV)

Today's Agenda: Why & How

1. **Why** protocols are a critical lever for equity
2. **How** implementation science can help front-line implementers, including program directors, clinicians, and other care providers
3. **Why** psychology is a central (and under-emphasized) component of successful program implementation
4. **How** to use and access the ALAI UP Protocol Development Toolkit
5. **Why** and how the toolkit integrates key lessons from #1-#3 above

#1

Why protocols are a critical lever for equity

There are huge tensions between…

Priorities

- *Which patients would benefit most from LAI Tx*

Guidelines

- *Who is indicated for iCAB/RPV*

Pitfalls

- *Potential for missed injection visits and loss to follow-up*

Resources

- *How much time/effort it takes to get a patient on iCAB/RPV*

Definitions of Health Equity

Equity is the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically. 'Health equity' implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential because of social position or other socially determined circumstances.

World Health Organization (WHO) &
Centers for Disease Control and Prevention (CDC)

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Definitions of Health Equity 3

Health equity is the principle underlying a commitment to reduce — and, ultimately, eliminate — disparities in health and in its determinants, including social determinants. Pursuing health equity means striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Dr. Paula Braverman, *Public Health Reports*

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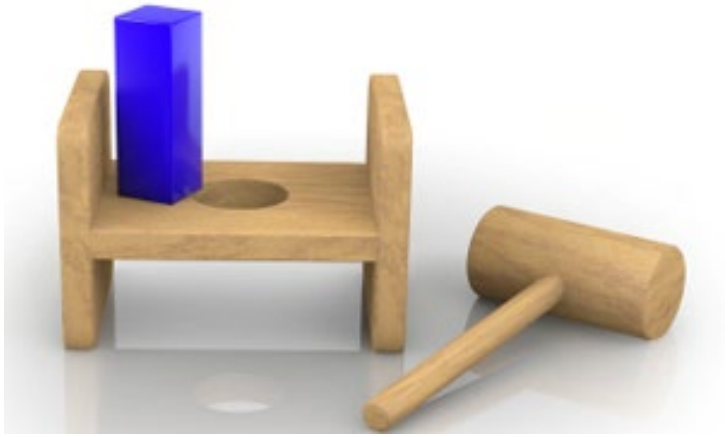
Dr. Paula Braverman, *Public Health Reports*

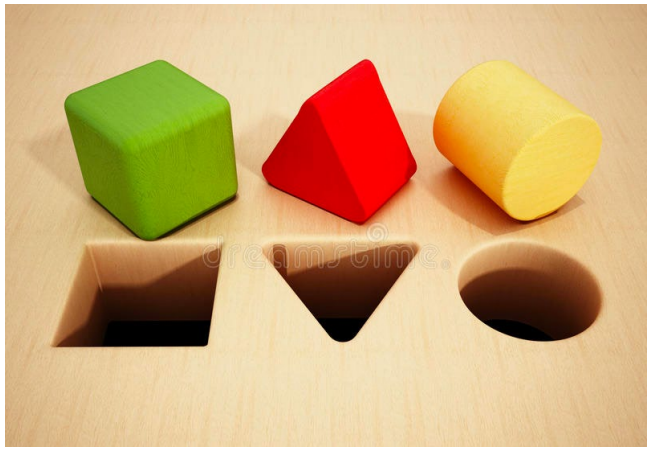
Centering equity

We need to design client-focused systems with **equity as the primary goal**, not the secondary problem to be solved.



How do we reduce disparities in the system?

versus



What system would <u>ensure</u> equity?

Equity Questions for LAI Tx Programs

1. How can the structure and content of our LAI Tx implementation programs increase fair and just opportunities for PWH to be as healthy as possible?

2. How can our LAI Tx protocols and programs reduce disparities in health and its determinants for PWH?

3. What are the potential pitfalls that would cause LAI Tx implementation to disadvantage certain patients because of socially determined circumstances?

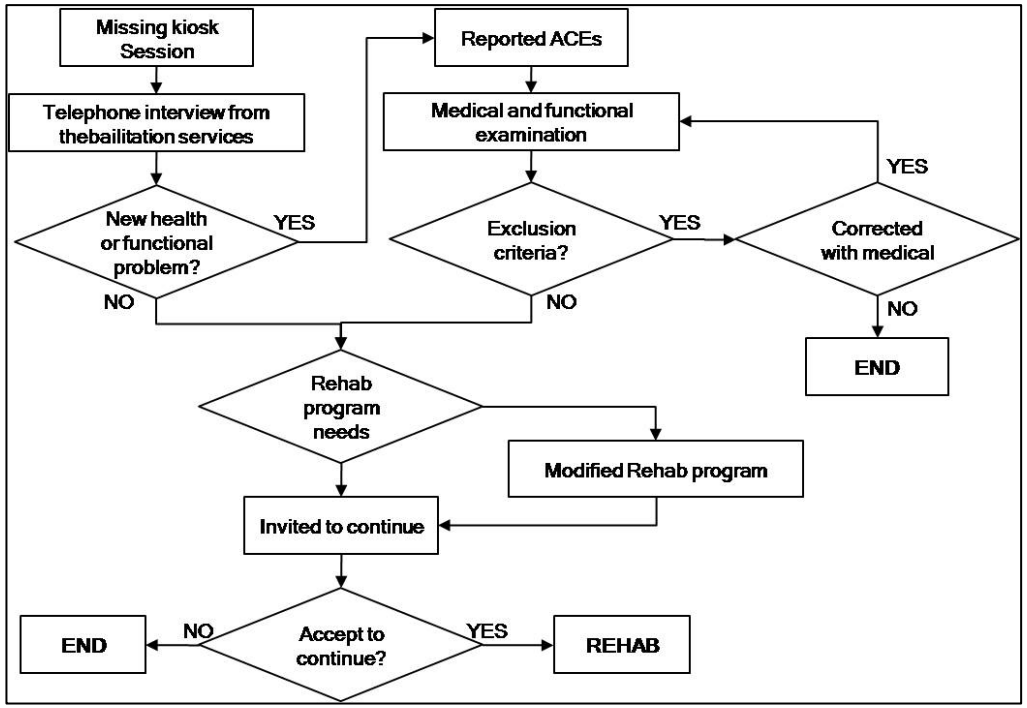
4. What would it mean for LAI Tx programs to be developed with special attention to the PWH at greatest risk of poor health?

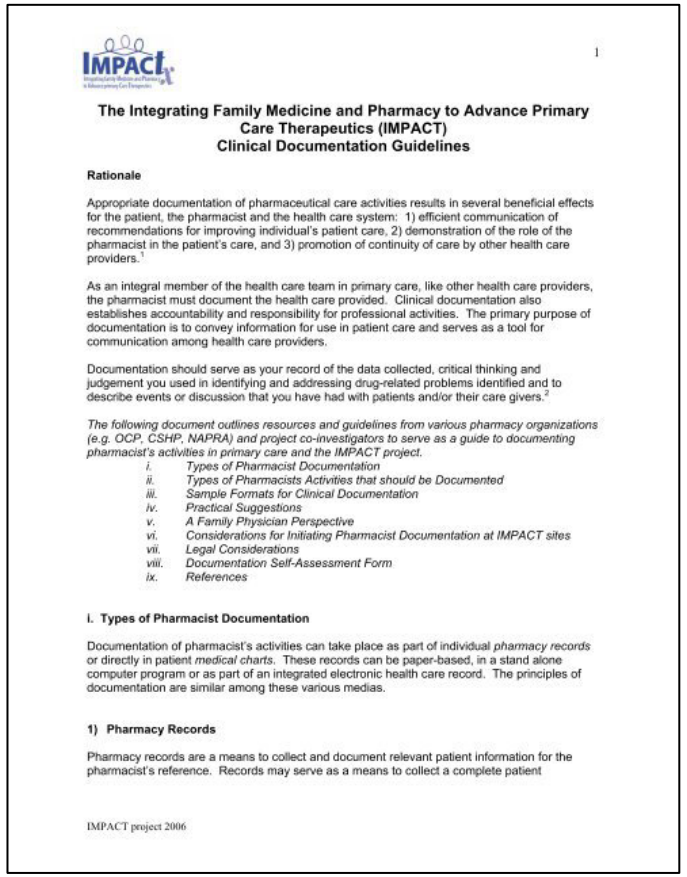
What is a Protocol?

A **formal record of the established procedure** or course of action to be adopted by people working within a particular organization or program.

Clinical protocols are guidelines for **how to proceed in certain situations** and provide health acre practitioners with **parameters in which to operate.**

Types of Protocols





IMPACT

1

The Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT)
Clinical Documentation Guidelines

Rationale

Appropriate documentation of pharmaceutical care activities results in several beneficial effects for the patient, the pharmacist and the health care system: 1) efficient communication of recommendations for improving individual's patient care, 2) demonstration of the role of the pharmacist in the patient's care, and 3) promotion of continuity of care by other health care providers.[1]

As an integral member of the health care team in primary care, like other health care providers, the pharmacist must document the health care provided. Clinical documentation also establishes accountability and responsibility for professional activities. The primary purpose of documentation is to convey information for use in patient care and serves as a tool for communication among health care providers.

Documentation should serve as your record of the data collected, critical thinking and judgement you used in identifying and addressing drug-related problems identified and to describe events or discussion that you have had with patients and/or their care givers.[2]

The following document outlines resources and guidelines from various pharmacy organizations (e.g. OCP, CSHP, NAPRA) and project co-investigators to serve as a guide to documenting pharmacist's activities in primary care and the IMPACT project.

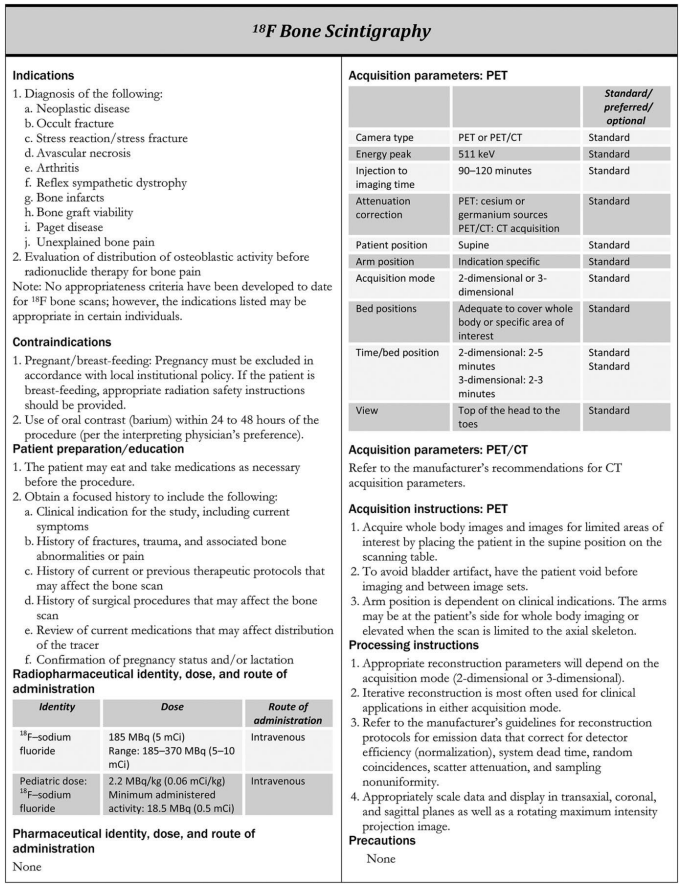
i. Types of Pharmacist Documentation

Documentation of pharmacist's activities can take place as part of individual *pharmacy records* or directly in patient *medical charts*. These records can be paper-based, in a stand alone computer program or as part of an integrated electronic health care record. The principles of documentation are similar among these various medias.

1) Pharmacy Records

Pharmacy records are a means to collect and document relevant patient information for the pharmacist's reference. Records may serve as a means to collect a complete patient

IMPACT project 2006



^{18}F Bone Scintigraphy

Indications

1. Diagnosis of the following:
   a. Neoplastic disease
   b. Occult fracture
   c. Stress reaction/stress fracture
   d. Avascular necrosis
   e. Arthritis
   f. Reflex sympathetic dystrophy
   g. Bone infarcts
   h. Bone graft viability
   i. Paget disease
   j. Unexplained bone pain
2. Evaluation of distribution of osteoblastic activity before radionuclide therapy for bone pain

Note: No appropriateness criteria have been developed to date for ^{18}F bone scans; however, the indications listed may be appropriate in certain individuals.

Contraindications

1. Pregnant/breast-feeding: Pregnancy must be excluded in accordance with local institutional policy. If the patient is breast-feeding, appropriate radiation safety instructions should be provided.
2. Use of oral contrast (barium) within 24 to 48 hours of the procedure (per the interpreting physician's preference).

Patient preparation/education

1. The patient may eat and take medications as necessary before the procedure.
2. Obtain a focused history to include the following:
   a. Clinical indication for the study, including current symptoms
   b. History of fractures, trauma, and associated bone abnormalities or pain
   c. History of current or previous therapeutic protocols that may affect the bone scan
   d. History of surgical procedures that may affect the bone scan
   e. Review of current medications that may affect distribution of the tracer
   f. Confirmation of pregnancy status and/or lactation

Radiopharmaceutical identity, dose, and route of administration

Identity	*Dose*	*Route of administration*
^{18}F–sodium fluoride	185 MBq (5 mCi) Range: 185–370 MBq (5–10 mCi)	Intravenous
Pediatric dose: ^{18}F–sodium fluoride	2.2 MBq/kg (0.06 mCi/kg) Minimum administered activity: 18.5 MBq (0.5 mCi)	Intravenous

Pharmaceutical identity, dose, and route of administration

None

Acquisition parameters: PET

		Standard/ preferred/ optional
Camera type	PET or PET/CT	Standard
Energy peak	511 keV	Standard
Injection to imaging time	90–120 minutes	Standard
Attenuation correction	PET: cesium or germanium sources PET/CT: CT acquisition	Standard
Patient position	Supine	Standard
Arm position	Indication specific	Standard
Acquisition mode	2-dimensional or 3-dimensional	Standard
Bed positions	Adequate to cover whole body or specific area of interest	Standard
Time/bed position	2-dimensional: 2-5 minutes 3-dimensional: 2-3 minutes	Standard Standard
View	Top of the head to the toes	Standard

Acquisition parameters: PET/CT

Refer to the manufacturer's recommendations for CT acquisition parameters.

Acquisition instructions: PET

1. Acquire whole body images and images for limited areas of interest by placing the patient in the supine position on the scanning table.
2. To avoid bladder artifact, have the patient void before imaging and between image sets.
3. Arm position is dependent on clinical indications. The arms may be at the patient's side for whole body imaging or elevated when the scan is limited to the axial skeleton.

Processing instructions

1. Appropriate reconstruction parameters will depend on the acquisition mode (2-dimensional or 3-dimensional).
2. Iterative reconstruction is most often used for clinical applications in either acquisition mode.
3. Refer to the manufacturer's guidelines for reconstruction protocols for emission data that correct for detector efficiency (normalization), system dead time, random coincidences, scatter attenuation, and sampling nonuniformity.
4. Appropriately scale data and display in transaxial, coronal, and sagittal planes as well as a rotating maximum intensity projection image.

Precautions

None

Protocols have four key benefits

1. Provide logistical support to staff

Protocols have four key benefits

1. Provide logistical support to staff

2. **Promote intuitional memory and continuity**

Protocols have four key benefits

1. Provide logistical support to staff

2. Promote intuitional memory and continuity

3. **Ensure an intentional and consistent patient experience**

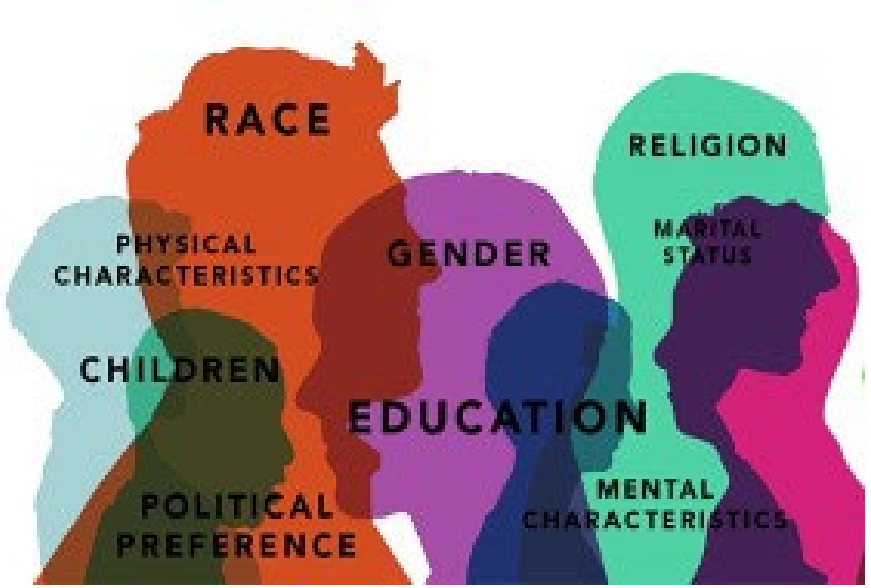
Protocols have four key benefits

1. Provide logistical support to staff

2. Promote intuitional memory and continuity

3. Ensure an intentional and consistent patient experience

4. **Protect individuals and organizations against unconscious bias**



Equity Questions for LAI Tx **PROTOCOLS**

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT 2024

1. How can the structure and content of our LAI Tx implementation programs increase fair and just opportunities for PWH to be as healthy as possible?

2. How can our LAI Tx protocols and programs reduce disparities in health and its determinants for PWH?

3. What are the potential pitfalls that would cause LAI Tx implementation to disadvantage certain patients because of socially determined circumstances?

4. What would it mean for LAI Tx programs to be developed with special attention to the PWH at greatest risk of poor health?

#2

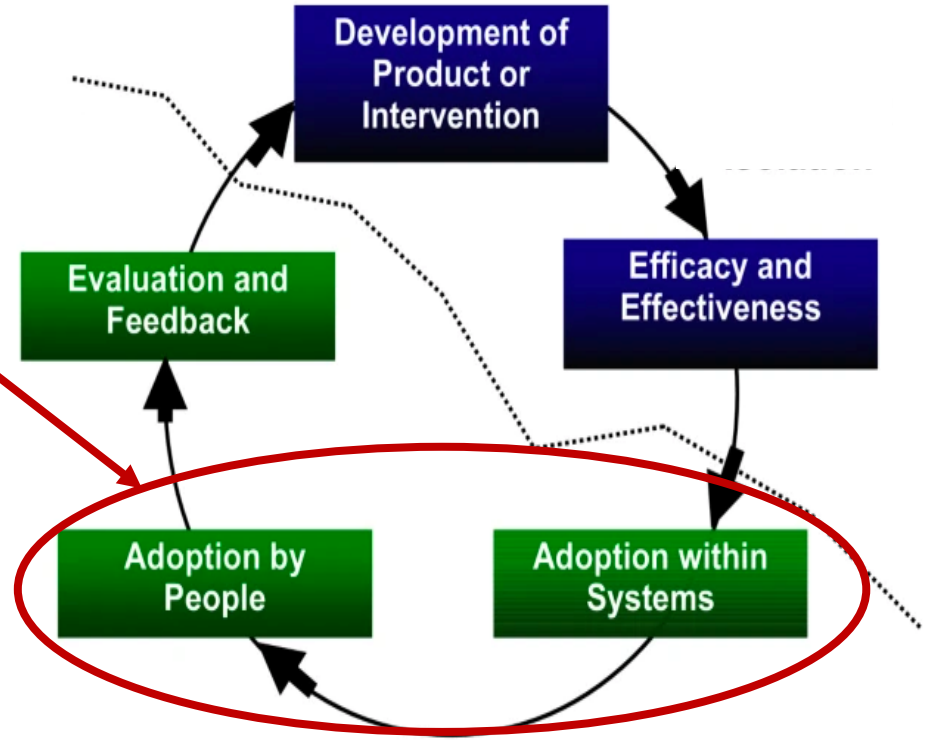
How implementation science can help

Barriers to Protocol Development

- There is nothing worse than staring at a blank screen
- **Time**
- Resources, information, and materials exist…but it's takes time, energy, and effort to find them, evaluate them, and distill them.
- **Time**
- It's hard to know what level of detail to include or what issues to address
- **Time**

Implementation science is the "**application and integration** of research evidence [and methods] **into practice and policy**."

How can we apply research findings and tools to **make this process better**?



Allotey, P., Reidpath, D.D., Ghalib, H. *et al.* Efficacious, effective, and embedded interventions: Implementation research in infectious disease control. *BMC Public Health* **8,** 343 (2008).

4 Key Contributions of IS for Practice

1. Synthesize research on key barriers and facilitators that should be considered when developing protocols

2. Identify best practices from existing (and analogous) programs that prevent sites from having to reinvent the wheel

3. Provide a framework and tools to structure programs and protocols

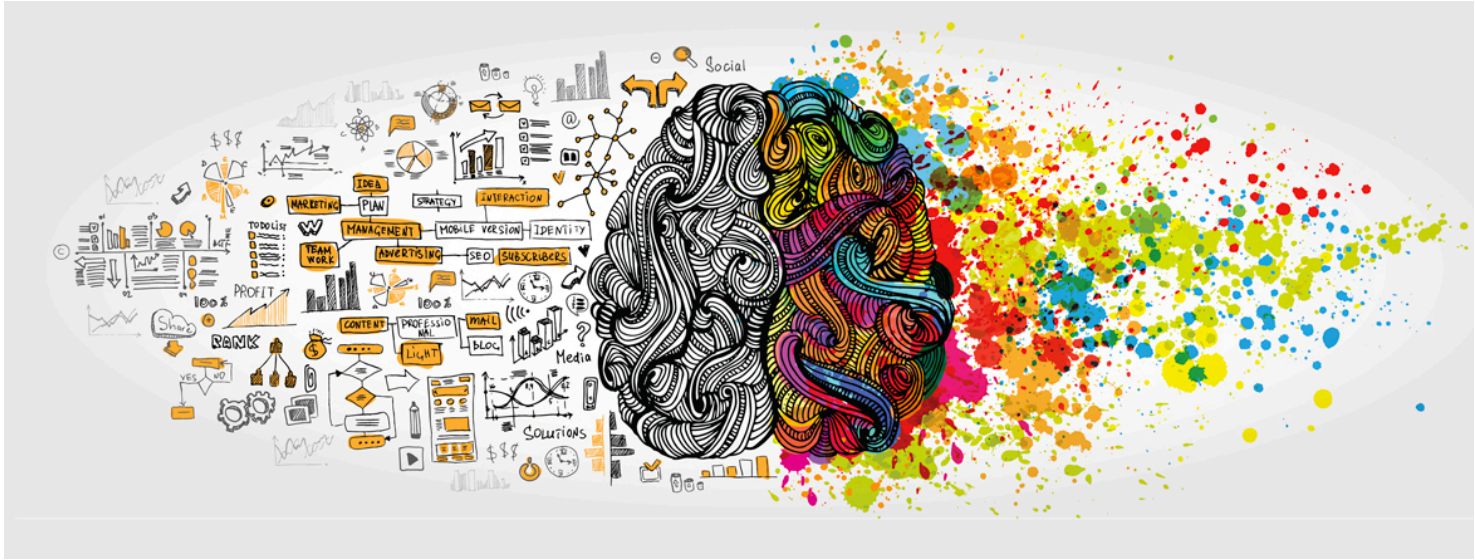
4. Define metrics that can help evaluate whether or not the protocol is working to enhance intervention adoption and promote health equity and why

"Whilst it has been thrilling to anticipate the transition of patients from oral ART to injectable therapies, and ultimately increase adherence and improve outcomes, **what the clinical trial did not prepare providers for** were the piles of denied insurance claims, appeal letters, clinician burnout and **workflow that does not necessarily 'flow'**."

Johnson and Sawkin, 2022

#3

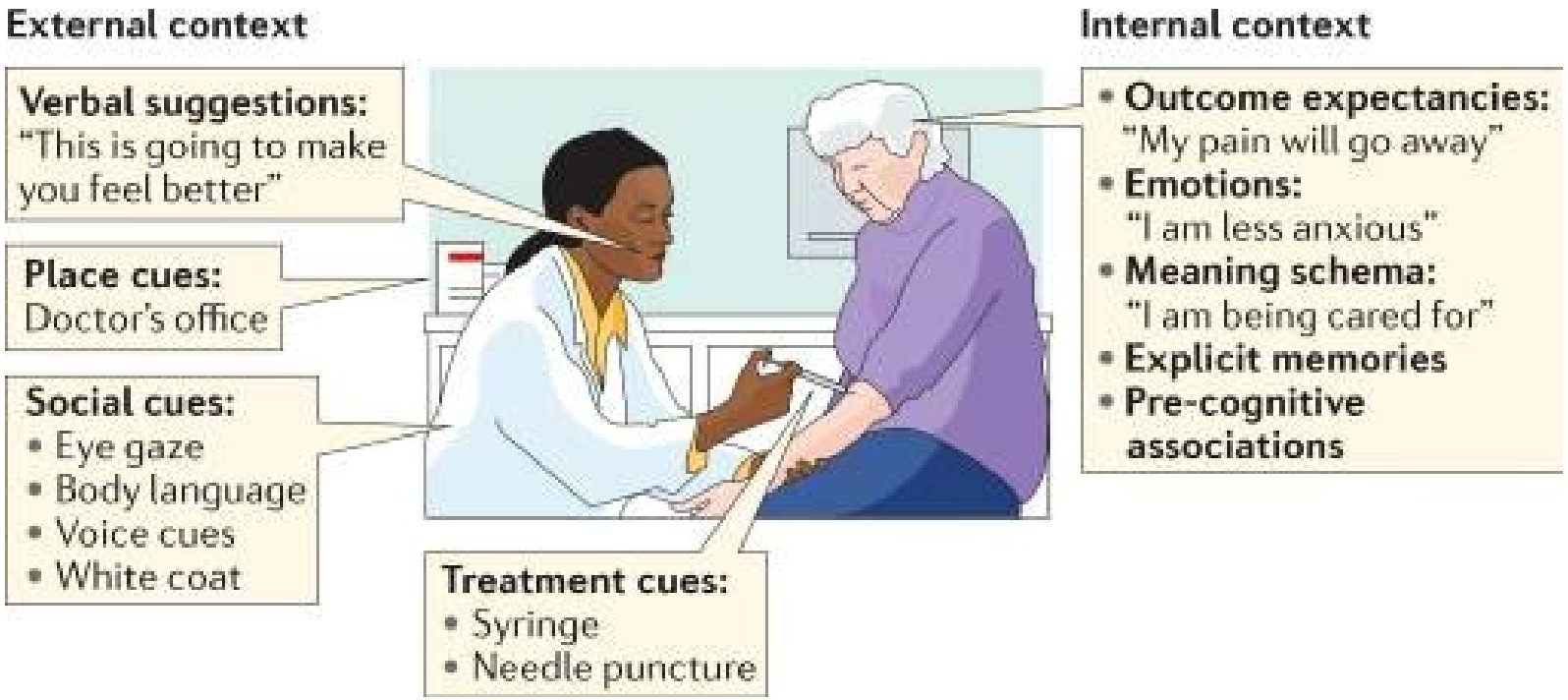
Psychology as a central (and under-emphasized) component of successful program implementation



Program implementation is a **psychological process** that is treated as a logistical one.

Implementation as a psychological process…

- The health care setting, context and “theater” impacts patient expectancies and experience



Implementation as a psychological process… 2

- The health care setting, context and “theater” impacts patient expectancies and experience

- The health care environment impacts staff’s ability to deliver high quality care

ORIGINAL ARTICLE

The Importance of Specific Workplace Environment Characteristics for Maximum Health and Performance

Healthcare Workers’ Perspective

Rana Sagha Zadeh, PhD, MArch, Mardelle M. Shepley, DArch, MA, MArch, BA, Arthur Hamie Owora, MPH, DrPH, Martha C. Dannenbaum, MD, FACOG, Laurie T. Waggener, BSRC, RRT, BID, and Susan Sung Eun Chung, PhD, MID

Implementation as a psychological process… 3

- The health care setting, context and “theater” impacts patient expectancies and experience
- The health care environment impacts staff’s ability to deliver high quality care
- Patient-provider interactions shape engagement

When Your Doctor “Gets It” and “Gets You”: The Critical Role of Competence and Warmth in the Patient–Provider Interaction

Lauren C. Howe[1], Kari A. Leibowitz[2] and Alia J. Crum[2]**

[1] *Department of Business Administration, University of Zurich, Zurich, Switzerland,* [2] *Department of Psychology, Stanford University, Stanford, CA, United States*

Implementation as a psychological process… 4

- The health care setting, context and “theater” impacts patient expectancies and experience
- The health care environment impacts staff’s ability to deliver high quality care
- Patient-provider interactions shape engagement
- Every component of patient interactions communicate WHO and WHAT is **valued** in our health care system and WHO and WHAT is **stigmatized**.

Golub SA and Fikslin RA *Journal of the International AIDS Society* 2022, **25**(S1):e25930
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25930/full | https://doi.org/10.1002/jia2.25930

JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

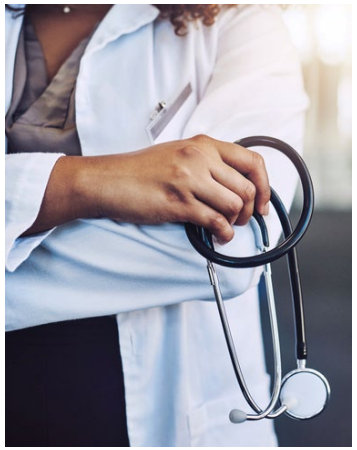
COMMENTARY

Recognizing and disrupting stigma in implementation of HIV prevention and care: a call to research and action

Sarit A. Golub[1,2,3,4,§] and Rachel A. Fikslin[1,2,3]

Stigma occurs in situations in which power is exercised.






Why am I (am I not) being offered LAI Tx?

How many visits do I need to make before the first injection?

What am I asked to sign or “prove” to get access to LAI Tx?

Will my provider judge me or withhold care if I miss an injection appointment?

#4

How to use and access the ALAI UP Protocol Development Toolkit

Protocol Toolkit: Definition

The **ALAI UP Protocol Toolkit** is a set of documents, worksheets, and templates designed to help sites develop and implement an equitable LAI Tx program.

The first generation of ALAI UP resources are specific to iCAB/RPV.

Protocol Toolkit: 5 Guiding principles

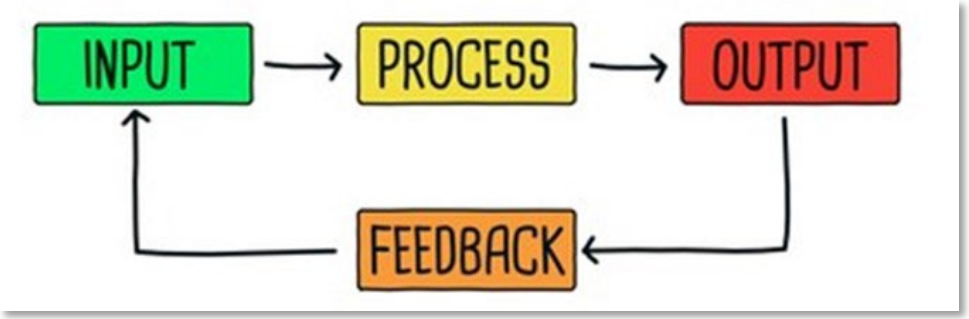
1

It is important for sites to have patient- and provider-facing resources that are **not created by and branded by pharma.**

Protocol Toolkit: 5 Guiding principles

2

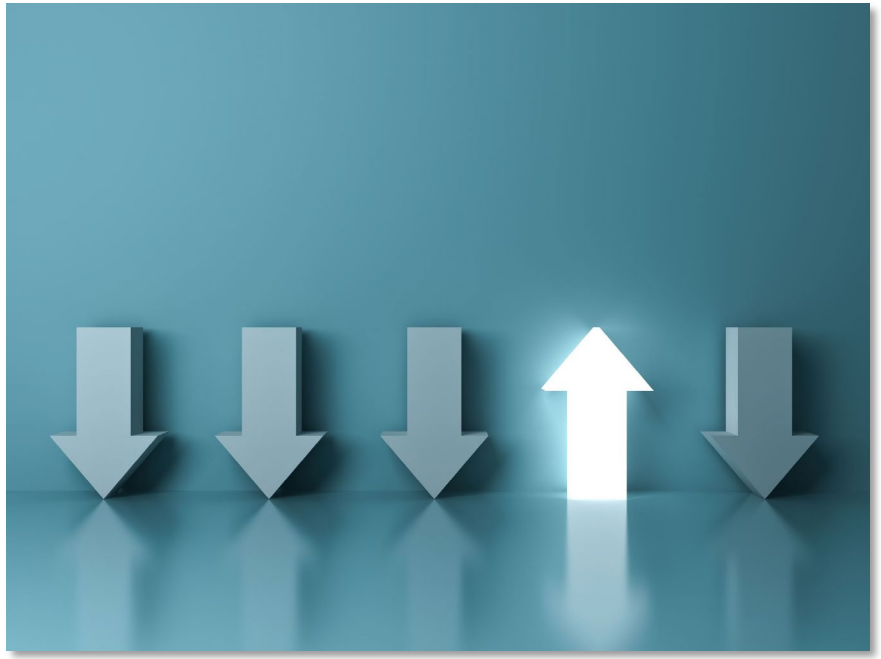
Programs work best when they have **direct and articulated links** between actions and goals.



Protocol Toolkit: 5 Guiding principles

3

Programs benefit from a set of questions that help them **articulate** their **values**, **priorities**, **capacities**, and **constraints**.



Protocol Toolkit: 5 Guiding principles

4

Programs need detailed, **customizable, adaptive resources**.

Protocol Toolkit: 5 Guiding principles

5

Resources should be guided by a framework that **breaks down** the complex process of **LAI Tx implementation** into **manageable** and **coherent chunks**.

Protocol Toolkit: Building Blocks

Engaging Patients

Processes by which a site makes priority patients aware of iCAB/RPV and helps them decide whether or not to take it

Navigating Coverage & Cost

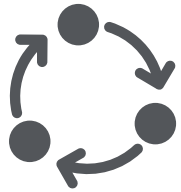
Processes that facilitate coverage of the cost of iCAB/RPV, including: benefits investigation, coverage coordination and navigation, and site-level reimbursement

Procurement & Storage

Logistical tasks related to iCAB/RPV administration, including: medication receipt, storage, temperature monitoring and visit preparation

Prescribing & Administering

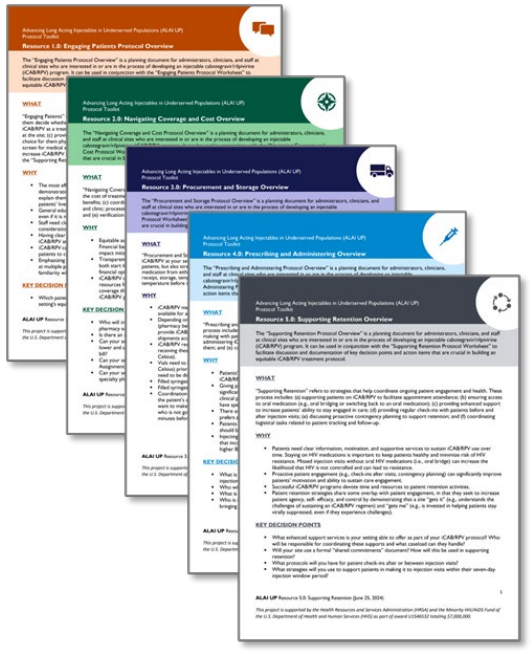
Processes completed by clinical staff to provide iCAB/RPV to patients, including: prescription, injection, monitoring and patient education



Supporting Retention

Strategies (e.g., support services, proactive planning, patient tracking) that increase the likelihood of sustaining patients on iCAB/RPV and/or retaining them in care

Protocol Toolkit: Components



iCAB/RPV Protocol Overview
[Name of Setting]
Last updated: [Insert Date]

SECTION	PAGE
A. ENGAGING PATIENTS	
A1. Priority Populations and Eligibility	2
A2. Strategies for Patient Awareness, Education and Shared Decision Making	3
A3. Components of iCAB/RPV Engagement	4
A4. Health Equity Considerations	5
B. NAVIGATING COVERAGE & COST	
B1. Financial Eligibility Overview	6
B2. Coverage Investigation	6
B3. iCAB/RPV Financial Eligibility Discussion (Before prescription billing)	6
B4. Coordinating Prescription Billing and Determining Cost	7
B5. iCAB/RPV Financial Cost Discussion	8
B6. Coverage Tracking and Follow-Up for Patients on iCAB/RPV	9
B7. Reimbursement & Billing	9
B8. Health Equity Considerations	

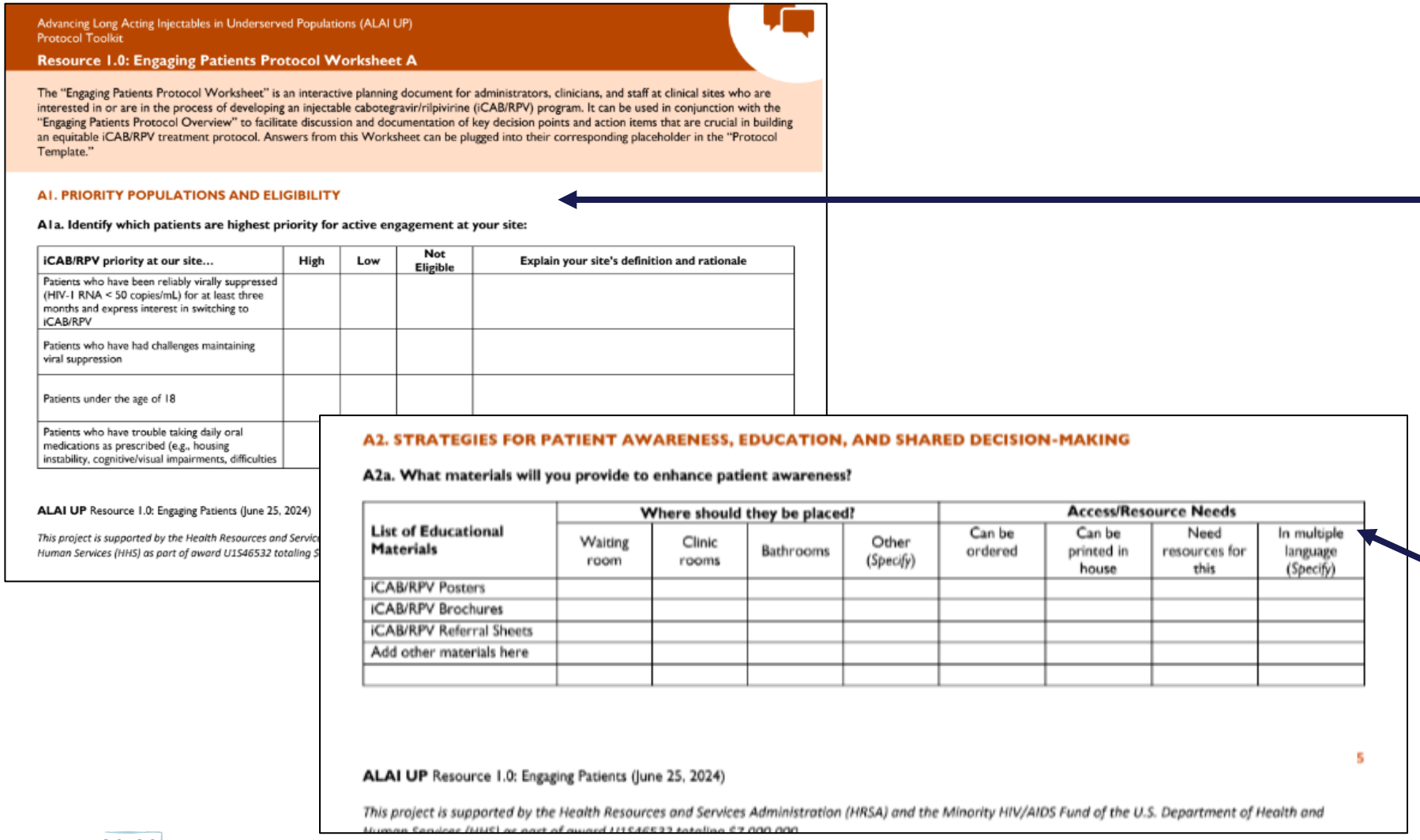
5 Protocol Overviews & Worksheets (1 set per bucket):

Facilitate discussion and documentation of key decision points and action items that are crucial in building an equitable LAI Tx protocol.

Protocol Template

Facilitates codification of decisions into policy. Answers from the worksheets can be “plugged in” to their corresponding placeholder in the Protocol Template.

ALAI UP Worksheets



Advancing Long Acting Injectables in Underserved Populations (ALAI UP)
Protocol Toolkit

Resource 1.0: Engaging Patients Protocol Worksheet A

The "Engaging Patients Protocol Worksheet" is an interactive planning document for administrators, clinicians, and staff at clinical sites who are interested in or are in the process of developing an injectable cabotegravir/rilpivirine (iCAB/RPV) program. It can be used in conjunction with the "Engaging Patients Protocol Overview" to facilitate discussion and documentation of key decision points and action items that are crucial in building an equitable iCAB/RPV treatment protocol. Answers from this Worksheet can be plugged into their corresponding placeholder in the "Protocol Template."

A1. PRIORITY POPULATIONS AND ELIGIBILITY

A1a. Identify which patients are highest priority for active engagement at your site:

iCAB/RPV priority at our site…	High	Low	Not Eligible	Explain your site's definition and rationale
Patients who have been reliably virally suppressed (HIV-1 RNA < 50 copies/mL) for at least three months and express interest in switching to iCAB/RPV				
Patients who have had challenges maintaining viral suppression				
Patients under the age of 18				
Patients who have trouble taking daily oral medications as prescribed (e.g., housing instability, cognitive/visual impairments, difficulties				

ALAI UP Resource 1.0: Engaging Patients (June 25, 2024)

This project is supported by the Health Resources and Servic
Human Services (HHS) as part of award U1S46532 totaling $

A2. STRATEGIES FOR PATIENT AWARENESS, EDUCATION, AND SHARED DECISION-MAKING

A2a. What materials will you provide to enhance patient awareness?

List of Educational Materials	Where should they be placed?				Access/Resource Needs			
	Waiting room	Clinic rooms	Bathrooms	Other (Specify)	Can be ordered	Can be printed in house	Need resources for this	In multiple language (Specify)
iCAB/RPV Posters								
iCAB/RPV Brochures								
iCAB/RPV Referral Sheets								
Add other materials here								

5

ALAI UP Resource 1.0: Engaging Patients (June 25, 2024)

This project is supported by the Health Resources and Services Administration (HRSA) and the Minority HIV/AIDS Fund of the U.S. Department of Health and

Designed to facilitate conversation and decision-making

Correspond directly to components of the Protocol Template

ALAI UP Protocol Template

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT 2024

C. PROCUREMENT AND STORAGE

C1. Overview of Medication Storage and Temperature Monitoring

- iCAB/RPV requires a cold chain shipment and storage process in which vials are maintained at 36-46 degrees Fahrenheit (2-8 degrees Celsius).
- We will use a designated refrigerator in [*location*] to store iCAB/RPV medication.
- [*Staff member*] will monitor the inventory and temperature by [*specify monitoring procedures*].
- If site has both floor stock and pharmacy-supplied medication, [*staff member*] to separate floor stock versus pharmacy supplied if refrigerator size makes this possible.
- [*Staff member*] will alert [*staff member*] immediately of any problem with inventory or refrigeration.
- Any medication that has been at room temperature for more than 6 hours will be destroyed.
- Any medication that has been reconstituted and drawn up must be used within 2 hours or destroyed.

Standard information is already filled in

Common actions are outlined with italic indicators of where to fill in: staff members, locations, or specific procedures

ALAI UP Protocol Template

E. SUPPORTING RETENTION

E1. Check-In Following Initial Injection

- [*Staff member*] will contact patients [*number of days*] after their first injection visit to assess tolerability and side effects.
- [*Staff member*] will log these contacts in [*specify documentation*]
- If patients report any of the following, they will be instructed to discontinue iCAB/RPV and resume their previous oral ART medication:
  - *Specify adverse events that would warrant discontinuation*
- If patients report any of the following, they will be instructed to continue iCAB/RPV, but [*staff member*] will check in with them in one week:
  - *Specify reactions/concerns that would warrant follow-up*

Provides a template for decision-making

Bullets and italics are designed to help concretize policies

Some sections may help you consider new protocol components

ALAI UP Protocol Template

B3. Coverage Investigation

NB: Below we have specifics for coverage investigation for each of the three methods: (1) Coverage Investigation by ViiV; (2) Coverage Investigation by Specialty Pharmacy; (3) Coverage Investigation by on-site staff. Once you have determined the strategy or strategies to be used at your site, delete the sections that are no longer relevant.

Certain sections can be deleted if they don't apply

A2b. Active Engagement and General Education

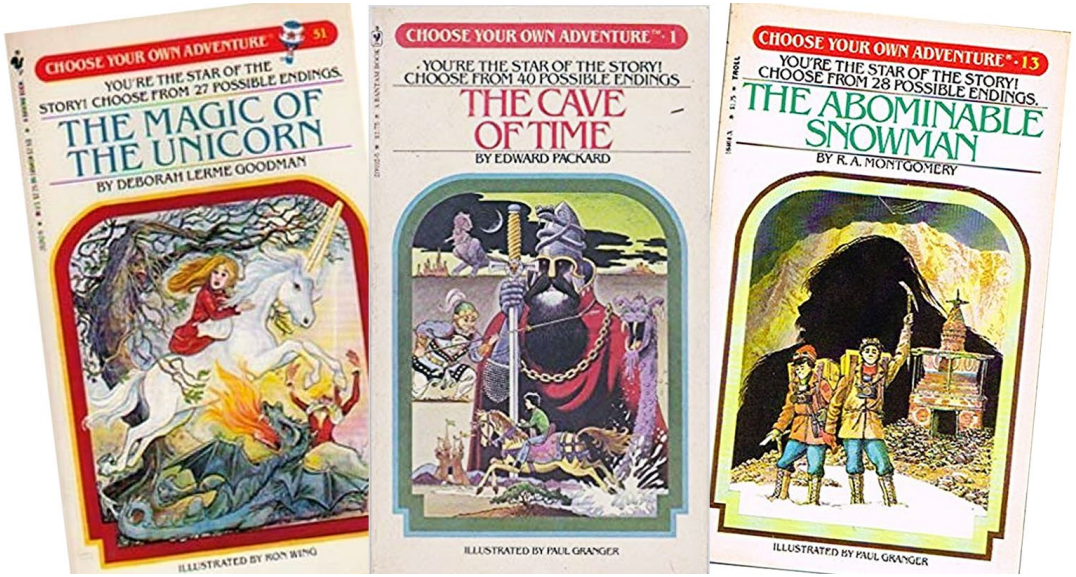
NB: Edit and/or delete the bullets below that are not relevant to your setting.

- Our site tells all patients with HIV about iCAB/RPV [*specify when, by whom, and how often*]
- Our site uses chart review/chart triggers to identify patients who [*enter criteria*]. Chart review is conducted by [*specify staff member]* every [*specify interval*] and patients are flagged for education by [*specify process*].
- Our site identifies patients for iCAB/RPV education through case conferencing, in which [*describe this process*]
- Our site provides information about iCAB/RPV to any patient who asks about it. [*specify by whom*]
- *XXXX [add more strategies here or delete this bullet]*
- General iCAB/RPV at our site includes the components listed in A3 below.

Individual components can be edited, added, or deleted for your particular setting

Choose Your Own Adventure

This process is designed to be helpful for settings at any and all stages of program and protocol development



Example

Block #1: Engaging Patients

ENGAGING PATIENTS

Overview

Engaging Patients refers to the processes by which a site makes patients aware of iCAB/RPV and helps them decide whether or not to take it.

The process includes:

a) ensuring that patients are **aware** of iCAB/RPV as a treatment option;

b) proactively educating priority patients about the availability of iCAB/RPV at the site;

c) providing **decision-making counseling** to help patients decide whether iCAB/RPV is the right choice for them physically, emotionally, socially, and financially;

d) identifying the appropriate staff who will **screen for medical eligibility and/or navigate insurance coverage**; and

e) offering **wrap-around supports** to increase iCAB/RPV access and sustainability

Engaging Patients: **Key Decision Points**

Which patients will be prioritized for education and engagement?

How will they be identified and contacted for patient education?

Which staff will be primarily responsible for the different awareness and education activities?

What logistical and other supports are you able to offer?

Will you use a formal “shared commitments” document?

Example from Worksheet

A1a. Identify which patients are highest priority for active engagement at your site	High	Low	Not Eligible	Rationale
Patients who have been reliably virally suppressed (HIV-1 RNA < 50 copies/mL) for at least three months and express interest in switching to iCAB/RPV				
Patients who have had challenges maintaining viral suppression				
Patients under the age of 18				
Patients who have trouble taking daily oral medications as prescribed				
Patients who have challenges keeping scheduled appointments				
Patients who need supportive services (e.g., case management, housing, food, transportation, etc.)				
Patients who come to your site asking to switch to iCAB/RPV				

Worksheet → Template

A1a. Identify which patients are highest priority for active engagement at your site	High	Low	Not Eligible	Rationale
Patients who have been reliably virall for at least three months and expres				
Patients who have had challenges ma				
Patients under the age of 18				
Patients who have trouble taking dail				
Patients who have challenges keeping				
Patients who need supportive servic transportation, etc.)				
Patients who come to your site askir				

iCAB/RPV Protocol [*Name of Setting*] Last Updated: [*Date*]

A. ENGAGING PATIENTS

A1. Priority Populations and Eligibility

A1a. Priority Populations for [*Name of Setting*]'s iCAB/RPV Program

[*Name of Setting*] provides iCAB/RPV services focused on the following priority populations: [*insert priority populations here*]. Other patients may also receive iCAB/RPV according to the protocol below.

The priority population will be evaluated and revised as needed [*insert time frame, suggested 6 months to 12 months*] utilizing available data and patient/community advisory board input.

A1b. Rationale for Priority Populations and Eligibility

Use this space to explain your site's rationale for the priority populations above. (full eligibility is documented in section D1).

Examples

Sample Content from the Five Building Blocks

Engaging Patients

- Priority Populations and Eligibility Criteria
- Components of iCAB/RPV Engagement
  - General Awareness
  - Targeted Education
  - Shared Decision-making Counseling
- Plans for which patients get which types of engagement, when and how
- Plans for which staff are responsible for each type of engagement strategy

Navigation Cost and Coverage

- Process for coverage investigation
  - Specific methods the apply to investigations done by pharmacy partner, site staff, ViiV connect
- Financial eligibility capacity
  - Sites' capacity to serve patients with pharmacy benefits, medical benefits, ADAP coverage, or uninsured
- Process for financial eligibility discussions with patients
- Processes for coordination prescription billing and determining cost for each benefit type
- Processes for coverage tracking and coordination of billing

Procurement and Storage

- Processes for procurement of medication from pharmacy and/or specialty distributor
- Processes for procurement of oral lead-in and/or oral bridge medication
- Protocols for medication storage and temperature monitoring
- Processes for ordering and stocking additional supplies

Prescribing & Administering

- Medical Eligibility and Contraindications
- Treatment and referral of non-eligible patients
- Shared Commitments discussions
- Recommendations for oral lead in
- Site-preferred dosing schedule (q4 week/q8 week)
- Protocols for scheduling visits in injection window
- Oral bridging and appointment reminder protocols
- Labs and medical monitoring
- Dosing for missed or delayed injections
- Injection logistics and administration

Supporting Retention

- Protocols for communication before and after injection visit
- Protocol for reminder calls before visits
- Protocol for check-in calls post-injection
- Protocols for rescheduling and managing missed appointments
- Provision of Supportive Services to enhance engagement and retention

PLEASE REMEMBER!!!!

We make suggestions. You make decisions.

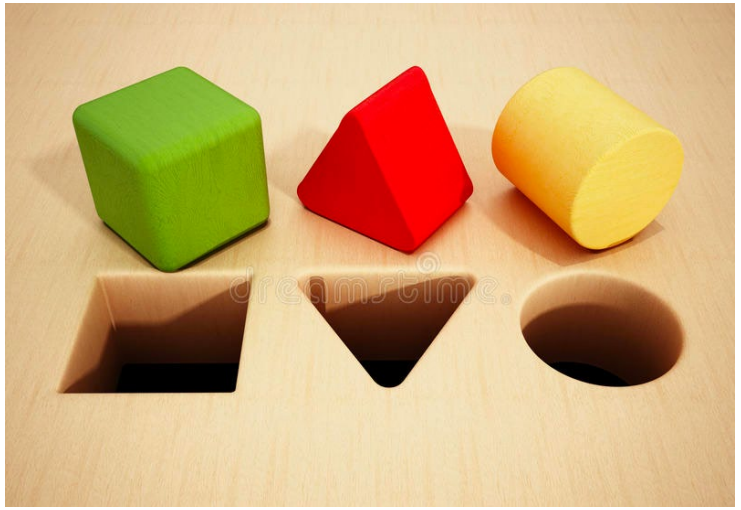

Questions? Comments? Complaints?

#5

Why and how the protocol toolkit integrates key lessons

Equity Example – Wrap-around support

Developing a Protocol for Enhanced Supportive Services for LAI Tx patients



What system would <u>ensure</u> equity?

- We often build materials/resources for the "easiest" or lowest need patients, and then work towards building more comprehensive or high-intensity services.
- What would it mean to design an LAI ART "Cadillac" program as the default, and then remove services not needed by better resourced clients?

Equity Example – Wrap-around support 2

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Developing a Protocol for Enhanced Supportive Services for LAI Tx patients

1. Traditional (existing?) supports

- Mental Health Counseling
- Substance Use Counseling
- Case Management
- Transportation
- Food/Housing Assistance
- Gender Affirming Care

2. Supports specific to the LAI Tx process

- Injection visit care pack
- Post-visit check-ins
- Intensive reminder supports
- Proactive insurance/financial navigation

IS Example – Stakeholder Engagement

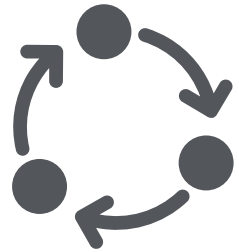
Learning from successes and challenges of past implementation to proactively avoid pitfalls…

- How can you best **balance concerns** of different members of your team?
- How much does the **patients**' desire for iCAB/RPV take precedence over other stakeholders' concerns?
- How do you ensure that stakeholders' concerns are as **devoid of underlying unconscious bias** as possible?
- What is your role for **ambivalent patients**? How much should providers try to "convince" or motivate patients toward iCAB/RPV?

Psych Example -- Patient Experience







Engaging Patients	Navigating Coverage & Cost	Procurement & Storage	Prescribing & Administering	Supporting Retention
Am I being judged for my past treatment outcomes or life circumstances?	Does the health care system care about me?	Is the treatment available to me when I come to the clinic?	How uncomfortable will I be during & after the injections?	Is my provider invested in helping me stay virally suppressed, even if I have challenges?

Common Roadblocks

- Lack of staff time/effort
- Stakeholder resistance
- Lack of infrastructure
- Lack of materials/resources
- Lack of training
- Process is complex & overwhelming

“Detour” Strategies

- Protocol can be a goal or ideal
- Embrace harm reduction
- Make a running list of training, infrastructure and resource needs
- Identify what could be done with the addition of each resource
- Identify program components that are most values aligned

Don’t let perfect be the enemy of the good…

…but don’t “the usual” become the replacement for what’s right.

Continuing Education Credit

If you would like to receive continuing education credit for this activity, please visit:

ryanwhite.cds.affinityced.com

Accessing the ALAI UP Toolkit

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT 2024

You can access the Protocol Toolkit through **TargetHIV**:

https://targethiv.org/spns/alai-up

Questions? Email: elizabeth.furuya@hunter.cuny.edu

ALAI UP PROTOCOL TOOLKIT INSTRUCTIONS

The ALAI UP Protocol Toolkit is an interactive planning tool for administrators, clinicians, and staff at clinical sites who are interested in or are in the process of developing an injectable cabotegravir/rilpivirine (iCAB/RPV) program.

The Toolkit breaks down the complex process of LAI Tx implementation into manageable and coherent "programmatic buckets." It guides users through key decisions and equity considerations in clinical protocol development.

The toolkit consists of:

- **5** Protocol Overviews & Worksheets (1 set per programmatic bucket)
- **1** Protocol Template

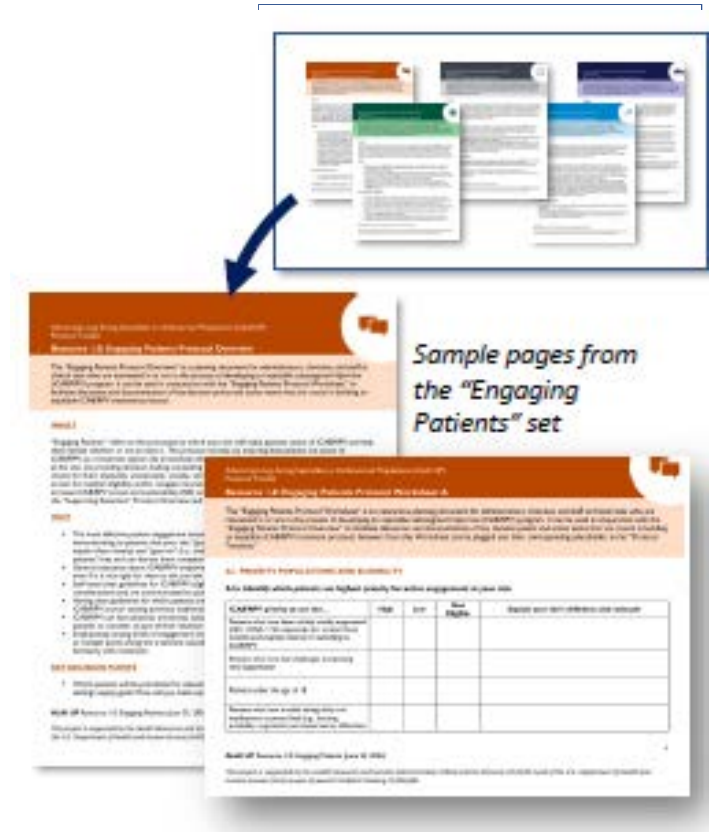
Access the **ALAI UP Protocol Toolkit** through **TargetHIV** or scan the QR code.

Questions? Email elizabeth.furuya@hunter.cuny.edu

STEP 1:

Read through the "Protocol Overview" and complete activities in the "Protocol Worksheet" for each programmatic bucket

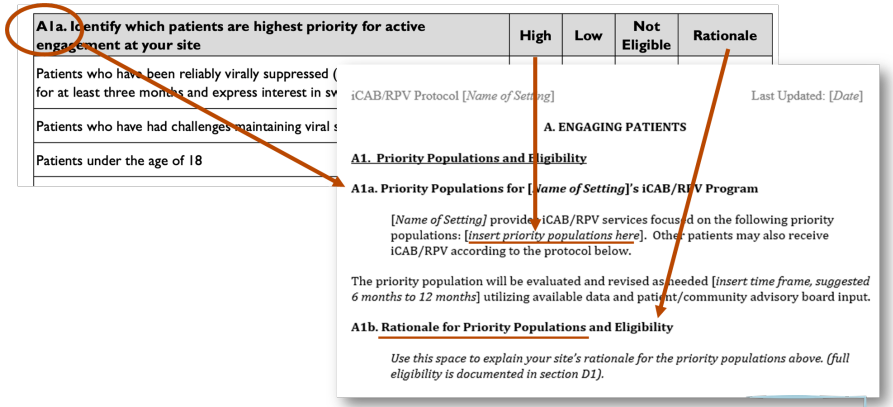
There is one overview and worksheet per programmatic bucket (for a total of 5 documents). Each of these documents aims to facilitate discussion and documentation of key decision points and action items that are crucial in building an equitable LAI Tx protocol



STEP 2:

"Plug-in" worksheet answers to draft a Protocol Template

The protocol template facilitates codification of decisions into policy. Standard information is already filled in and answers from the worksheets can be "plugged in" to their corresponding placeholder. Individual components can be edited, added, or deleted for your particular setting. Furthermore, common actions are outlined with italic indicators of where to fill in: staff members, locations, or specific procedures



This project is supported by the Health Resources and Services Administration (HRSA) and the Minority HIV/AIDS Fund of the U.S. Department of Health and Human Services (HHS) as part of award U1S46532 totaling $7,000,000.

ALAI UP

Other **ALAI UP** Sessions to Attend…

NATIONAL 2024 RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

TA | Motivational Interviewing | Clinical Monitoring | Community Engagement | Resource Development | CE Credit

- ID:25548
- **August 22, 9:45 - 11:15am**
- Accelerating Implementation of Multilevel-strategies to Advance Long-Acting Injectables for Underserved Populations

Implementation Science | Equity | CE Credit | Interactive Workshop

- ID: 25551
- **August 22, 9:45 - 11:15am**
- Specifying implementation strategies to accelerate equitable implementation of long-acting injectable antiretroviral therapy

Real World Experiences | Equity | CE Credit

- ID: 25560
- **August 22, 9:45 - 11:15am**
- Models for Implementing LAI ART with a Lens on Equity

HUNTER The City University of New York

AETC AIDS Education & Training Center Program Southeast

EINSTEIN Albert Einstein College of Medicine

COLUMBIA Columbia University Irving Medical Center

COLUMBIA Columbia University Irving Medical Center

Sinai Chicago

POSITIVE IMPACT HEALTH CENTERS

ap inc. Abounding Prosperity Incorporated

HART ALAI UP

Other sessions by me…

Tomorrow (August 22)
2:45pm – 4:15pm

Other ALAI UP Sessions that have already occured

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT 2024

Patient Education | Equity

- ID:25536
- **August 20, 4:30 - 6:00pm**
- Educational Approaches about Long-Acting Injectable Treatment for HIV that Enhance Equity: Benefits, Challenges, and Strategies

Sinai Chicago | Florida HEALTH Orange County | COLUMBIA Columbia University Irving Medical Center | Coastal Family Health Center

Equity | Protocol Development | Implementation Science

- ID: 25539
- **August 21 – 5:15-6:15pm**
- Applying Implementation Science to Improve Protocols and Enhance Equity: LAI Treatment as a Case Study

HUNTER The City University of New York

Clinical Monitoring | Equity | Data

- ID: 25552
- **August 21, 5:15 - 6:15pm**
- Clinical Monitoring for Real-World Delivery of Long-Acting Injectable Antiretroviral Therapy (LAI ART)

ap inc. Abounding Prosperity Incorporated | Coastal Family Health Center | COLUMBIA Columbia University Irving Medical Center | Sinai Chicago | Mount Sinai Institute for Advanced Medicine

HART | ALAI UP