



## **Development of a Toolkit to Assist Community Pharmacies Starting Long-Acting ART Administration Programs**

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# Pharmacy-based HIV services

- Much enthusiasm around community pharmacy potential to provide HIV services
  - Increasing state legislation supporting pharmacy testing, HIV PEP, and HIV PrEP
- ↑ use long-acting (LA)-ART/LA-PrEP; diverse real-world implementation experiences
- Potential to leverage pharmacies as alternative administration and care sites
  - Alleviate health system pressures and expand access.
  - Pharmacists unaware of requirements for developing a successful HIV LA-ART program
- Technical assistance A toolkit was drafted and reviewed by key stakeholder groups.
  - Goal: assess content & preliminary usefulness before deploying it to support service development

# Implementing and Designing Effective Administration Strategies for LA-ART

- IDEAS toolkit development
  - *Formative*: Prior study of pharmacy/clinic staff, patients (IAPAC 2023)
  - *Resource review*: PubMed and Internet review of available resources (IAPAC 2024)
  - *Draft*: writing, design, map to ERIC
-  *Stakeholder review process*
  - Three groups: People with HIV, Clinic staff, Pharmacy staff
  - Acceptability of Intervention, Intervention Appropriateness, and Feasibility of Intervention Measures
  - EBP Beliefs and Organizational Culture & Readiness Scales (Short)
  - Focus group soliciting feedback
- *Refinement*: based on feedback, new resources
- *Pilot testing (future)*: with partner pharmacy

STAGE 1: EXPLORATION  
*If you build it, will they come?*

It is an exciting time in development of HIV prevention and treatment therapeutics. New regimens in development are focused on minimizing frequency and increasing patient convenience. Some longer-acting formulations must be administered by injection, by a healthcare provider. These types of treatments offer a unique opportunity for pharmacies to provide these services for their patients.

Pharmacy-administered LA-ART holds many potential benefits. Diversifying locations where these medications can be administered can potentially increase uptake, access, and adherence. It may decrease transportation difficulties for patients, offer opportunities to increase medication literacy, and potentially increase convenience.

Any new service must be carefully thought out prior to launch. Pharmacies that are contemplating whether or not they should offer LA-ART medication administration services might consider the following in their future to help determine overall need.

Exploration: The basics











- Find out how prevalent HIV is in your community
- Assess how much PrEP and PEP your pharmacy is providing
- Identify clinics, community based organizations, and patients in your area who may be interested in LA-ART. Collect preliminary opinions on acceptability, interest, and need.



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  - Medical billing notes
  - Special considerations for discontinuation of LA-ART
  - People who test positive
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Basic Workflow: Pharmacist furnished LA-PrEP

				
Patient expresses interest in LA-PrEP or is referred to pharmacy for services	Pharmacist conducts brief assessment for appropriateness of PrEP and provides initial education. Patient confirms interest. Pharmacist obtains insurance information and begins benefits investigation process.	Pharmacy contacts patient with results of benefit investigation. If pharmacy is able to provide services, conduct medical history including screening for acute HIV. Order labs if necessary and instruct patient to obtain. If pharmacy is not able to provide services, refer patient to another alternative.	Await lab results. If patient is eligible, contact them to schedule injection appointment. Educate patient on manufacturer financial assistance programs and assist with enrollment. Order medication. If patient is not eligible (e.g. HIV positive test), deliver results and refer patient to care.	Provide reminder call in advance of appointment.
				
Pt arrives. Staff or technician checks in for appointment, escorts patient to injection area, and alerts pharmacist that patient has arrived.	Pharmacist prepares medication and initial documentation	Pharmacist performs patient assessment and provides counseling. Pharmacist exits briefly if patient needs to disrobe. Pharmacist administers medication.	Pharmacist exits to complete any pharmacy documentation and submits notes to patient's primary care provider. Patient waits 10 minutes for observation.	Technician comes in to schedule next visit and alerts patient it is ok to leave.

## Workflows, protocols, and checklists

While visual outlines of workflows can be helpful, many pharmacists are used to operating under specific protocols and prefer guidance from a checklist. In many cases a workflow outlines “how” while the protocol describes more of the “how to”. Some LA-ART manufacturers have created

# Stakeholder Demographics (Staff)

	<u>Clinic staff (n=4)</u>	<u>Pharmacy staff (n=4)</u>
<b>Age (years, mean)</b>	37	38.8
<b>Female sex at birth, n (%)</b>	3 (75)	2 (50)
<b>Gender identity, n (%)</b>		
Man	1 (25)	2 (50)
Woman	3 (75)	2 (50)
Non-binary	0 (0)	0 (0)
<b>Self-reported race, n (%)</b>		
White	2 (50)	2 (50)
Black	1 (25)	1 (25)
Asian	0 (0)	0 (0)
Other	0 (0)	1 (25)
Declined	1 (25)	0 (0)
<b>Role</b>		
Clinic pharmacist	3 (75)	
Behavioral health or social work	1 (25)	
Pharmacy manager		1 (25)
Pharmacist		3 (75)



# Stakeholder Demographics (Patients)

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	<b><u>Patients (n=8)</u></b>
<b>Age (years, mean)</b>	30.1
<b>Female sex at birth, n (%)</b>	0 (0)
<b>Gender identity, n (%)</b>	
Man	7 (87.5)
Woman	0 (0)
Non-binary	1 (12.5)
<b>Self-reported race, n (%)</b>	
White	2 (25)
Black	0 (0)
Asian	1 (12.5)
Other	2 (25)
Declined	3 (37.5)
<b>HIV status</b>	
HIV on treatment	3 (37.5)
At risk on PrEP	5 (62.5)
<b>How often you visit a pharmacy, n (%)</b>	
2-3 times/month	2 (25)
Once a month	4 (50)
Once every 2 months	1 (12.5)
Less than once every three months	1 (12.5)

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# EBP Beliefs & Org Culture/Readiness

<u>Evidence Based Practice Beliefs Scale (Short)</u>	Clinic Staff	Patients	Pharmacy Staff	P value*
I believe that having pharmacies administer long-acting injectable HIV medicines results in the best clinical care for patients	3.75	3.88	4.5	-
I am sure that pharmacies can implement administering long-acting injectable HIV medicines.	4.25	4.375	4.75	-
I am sure that having pharmacies administer long-acting injectable HIV medicines will improve the care delivered to patients.	3.75	3.875	4.75	-
<b>EBP Beliefs (Short) Total</b>	11.75	12.125	14	0.14
<u>Organizational Culture and Readiness Scale (Short)</u>				
Pharmacies have a culture that supports administering long-acting injectable HIV medicines.	2.5	3.375	4	-
Pharmacies have readily available resources to start administering long-acting injectable HIV medicines	2.25	3.375	2.75	-
Pharmacies have mentors to assist them in administering long-acting injectable HIV medicines.	3	3.125	2.5	-
<b>EBP - OCR (Short) Total</b>	7.75	9.875	9.25	0.46

\*Kruskal-Wallis H test for differences in mean ranks

Melnik, et al. Worldview Evid Based Nurs 2021; 18(4): 243-50

# Acceptability, Appropriateness, Feasibility

	Clinic Staff	Patients	Pharmacy Staff	p-value
<b>Acceptability of Intervention Measure</b>				
Having patients get long-acting HIV medications injected by their pharmacy meets my approval	3.75	4.25	4.75	-
Having patients get long-acting HIV medications injected by their pharmacy is appealing to me	4	3.875	4.25	-
I like the idea of patients getting long-acting HIV medications injected at their pharmacy	4.25	4.375	4.5	-
I welcome long-acting HIV medications being injected by pharmacies	4	4.625	4.25	-
<b>AIM Total</b>	16	17.125	17.75	0.39
<b>Intervention Appropriateness Measure</b>				
Having patients get long-acting HIV medications injected by a pharmacy seems fitting	4.25	4.375	4.75	-
Having patients get long-acting HIV medications injected by a pharmacy seems suitable	3.5	4.25	4.75	-
Having patients get long-acting HIV medications injected by a pharmacy seems applicable	3.75	4.125	4.75	-
Having patients get long-acting HIV medications injected by a pharmacy seems like a good idea	3.75	4.25	4.75	-
<b>IAM Total</b>	15.25	17	19	0.11
<b>Feasibility of Intervention Measure</b>				
Having patients get long-acting HIV medications injected by a pharmacy seems implementable	3.5	4.25	4	-
Having patients get long-acting HIV medications injected by a pharmacy seems possible	4	4.5	4.75	-
Having patients get long-acting HIV medications injected by a pharmacy seems doable	3.75	4.375	4.25	-
Having patients get long-acting HIV medications injected by a pharmacy seems easy	1.75	3.75	3	-
<b>FIM Total</b>	13	16.875	16	0.16



# Feedback: Clinic Staff



- **Coordination**

- *“It’s the aftercare that I would want to know a bit more about, you know —can a patient be able to reach a pharmacist if they’re having any pain or if they have any specific questions about the injection after they left the pharmacy.” – Clinic pharmacist*
- *“...just really thinking about all the staff that’s there, so there’s the front desk. It’s like would they have any involvement in calling patients and appointment reminders?” – Social worker*
- *“Could it be that people who are trying to do this in pharmacies are also unaware of what the processes are in clinics, and do you think it would be helpful for them to understand what happens in clinics so that they can design successful programs?” – Clinic pharmacist*

- **Billing**

- *“Most insurance plans pay for these injections through medical benefits, so figuring out how the pharmacy would be able to administer and build the medical benefits is definitely a big challenge.” – Clinic pharmacist*
- *“Going based off my own experience in starting this at my practice sites, one of the biggest areas that I was just completely lost in is medical billing.” – Clinic pharmacist*

# Feedback: Patients



## Clinical information for pharmacists

- *“The one thing I always like to see is like the side effects of anything.” – Person with HIV*
- *“Pharmacy knowledge of like what will interact well with what I’m already taking or not, you know, and if the injectable would be a problem with other drugs and stuff.” – Person with HIV*

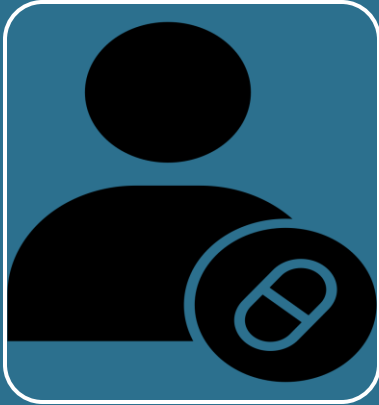
## • Ways for pharmacists to support patients

- *“Not using certain words that can frighten them, because I know there’s a lot of different words, like something like ‘positive’ or, you know, some words can trigger people into like having bad thinking towards it.” – Person with HIV*
- *“Maybe having like resources for support groups or... So that way, it can go from like testing at your pharmacy to know the area around it, its community.” – Person with HIV*

## • Considerations for moderating pharmacy environment

- *“I would probably be frustrated that there would be a long line and the pharmacist would be having to consult with all the people in the line, and then they would get mad at me for wanting to take up the one pharmacist’s time to administer this prep.” – Person from affected community*
- *“There’s no private room that you can go into. If I went to it right now, it’s like an open floor plan.” – Person with HIV*

# Feedback: Pharmacy Staff



## **Clinical information for pharmacists**

- *“A section on follow up, on what to do when things go wrong would be useful for a pharmacist to thumb through and find quickly.”– Pharmacist*
- *“Maybe giving a little more guidance to providers, directing them towards some organization (beyond them contacting the drug manufacturer) to get trained on a gluteal or dorsogluteal injection.” - Pharmacist*
- *“...examples or links to patient education around the disease state or around what it’s for and the drugs...” - Pharmacist*

## **Billing**

- *“Is there a section on medical billing? Because that’s definitely one thing to expand a lot.” - Pharmacist*

## **Potential partnerships**

- *“I find that you need to partner with local providers, but also things like the AMA. It’s a huge voice.”– Pharmacist*
- *“The biggest collaboration is the manufacturer, is access. Because this drug is a certain class of Class of Trade, many pharmacies can’t even access the drug.” – Pharmacy manager*

# Exercise: Mapping to ERIC Strategies

- Toolkit = strategy of strategies
- Color code to ERIC implementation strategies
  - 4 Pink
  - 40 Yellow
  - 29 Green
- Opportunity for reflection in combination with focus group feedback

## A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project

Powell et al. *Implementation Science* (2015) 10:21

Pink = not observed

Yellow = can be improved

Green = addressed in Toolkit or implementation

Table 3 ERIC discrete implementation strategy compilation (n = 73)

Strategy	Definitions
<b>Access new funding</b> not discussed. no funding to facilitate implementation—paragraph about grants?	Access new or existing money to facilitate the implementation
<b>Alter incentive/allowance structures</b> not discussed	Work to incentivize the adoption and implementation of the clinical innovation
<b>Alter patient/consumer fees</b> Same fees in pharmacy & clinic	Create fee structures where patients/consumers pay less for preferred treatments (the clinical innovation) and more for less-preferred treatments
<b>Assess for readiness and identify barriers and facilitators</b> Maybe this is where Betty's work can partner? Checklist for readiness?	Assess various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort
<b>Audit and provide feedback</b> We could do interviews with individuals once it's been implemented? Pg. 21 sustainability section	Collect and summarize clinical performance data over a specified time period and give it to clinicians and administrators to monitor, evaluate, and modify provider behavior
<b>Build a coalition</b> UCSF pharmacists? Others?	Recruit and cultivate relationships with partners in the implementation effort
<b>Capture and share local knowledge</b> Interviews	Capture local knowledge from implementation sites on how implementers and clinicians made something work in their setting and then share it with other sites
<b>Centralize technical assistance</b> Entire toolkit	Develop and use a centralized system to deliver technical assistance focused on implementation issues
<b>Change accreditation or membership requirements</b> This would be addressed by talking about advocacy—not within scope of toolkit —sustainability p. 21	Strive to alter accreditation standards so that they require or encourage use of the clinical innovation. Work to alter membership organization requirements so that those who want to affiliate with the organization are encouraged or required to use the clinical innovation
<b>Change liability laws</b> Are we doing this?	Participate in liability reform efforts that make clinicians more willing to deliver the clinical innovation
<b>Change physical structure and equipment</b> Discussed on pg. 12	Evaluate current configurations and adapt, as needed, the physical structure and/or equipment (e.g., changing the layout of a room, adding equipment) to best accommodate the targeted innovation
<b>Change record systems</b> pg. 20	Change records systems to allow better assessment of implementation or clinical outcomes

# Lessons learned

- Stakeholders provide perspectives on LA-ART most relevant to their scope
  - General positive support, parties recognize there's a long way to go
- Challenge: difficult to be everything to everyone
- Moving target
  - Resources rapidly evolving (ALAI-up toolkit; Rx EACH initiative, Pharmacist Virtual COP)
  - Determine reasonable scope of technical assistance
- Reflection: “Instruction manual (101)” vs. “Toolbox”
  - *What* versus *how*: both are needed
  - Instruction manual, toolbox...*then consultant*

# Next steps

- Trial the toolkit ... in one (maybe two) pharmacies
  - Novice pharmacies versus experienced pharmacies
  - Feedback on utility versus just content
- Post it ... and welcome additional feedback
  - Living document, constantly learning new things/new needs
- Future state
  - More interactive (than static PDF, e.g. app)
  - More examples (build the toolbox)

*“If everyone is moving forward together, then success takes care of itself.”*

*- Henry Ford*



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