



Preparing for pharmacy-based delivery of long-acting injectable antiretroviral therapy

Jennifer Cocohoba, PharmD; Yvette Cuca, PhD; Elizabeth Sherman PharmD; George Udeani, PharmD; Kelly Hester PharmD; Michael Bryan Sigua, BSA; Parya Saberi, PharmD

Adherence 2023 • June 11-13 • Puerto Rico



Background

- Long-acting injectable antiretroviral therapy (LA-ART) facilitates patients avoiding/minimizing daily oral therapy
- Studies demonstrate feasibility of implementing LA-ART in clinics
 - If increasing desire for LA-ART consider differentiated care models to expand access and delivery
- Community pharmacists play an important role on HIV care teams
 - 90% of persons in the United States live within 5 miles of a pharmacy
 - Little known about patient/clinic staff/pharmacists attitudes about getting LA-ART in pharmacies



Research aims

- To evaluate pharmacy staff, clinic staff, and patient attitudes towards administration of LA-ART in community pharmacies
- To identify barriers and facilitators for LA-ART implementation in community pharmacies
- To develop guidance to assist pharmacies in implementing LA-ART administration in their setting



Methods

- Convergent parallel mixed methods design
- Inclusion
 - Age \geq 18 years
 - Location: California SF Bay Area, Texas, Alabama, South Florida
 - Clinic/pharmacy staff: Population with HIV served \geq 5% total
 - Persons with HIV: on or eligible for ART
- Recruitment and sampling strategy
 - Pharmacies/HIV Clinics: Flyers and emails
 - Patients: recruited locally through word of mouth or flyers (if allowed)
 - Purposive sampling plus snowball sampling
 - Screening and consent performed electronically



Methods

Data collection

- Survey
 - Conducted via REDCap
- Interview
 - Semi-structured based on Consolidated Framework for Implementation Research (CFIR)
 - Audio-only, recorded via Zoom
 - Transcribed & loaded into Dedoose

Data analysis

- Survey
 - Descriptive statistics for counts, means, medians
- Interview
 - Thematic analysis



	Pharmacy Staff (n=14)	Clinic Staff (n=19)	People with HIV (n=20)
Location, n(%)			
San Francisco	3 (21)	5 (26)	10 (50)
Texas	2 (14)	5 (26)	0 (0)
Alabama	5 (36)	3 (16)	4 (20)
Florida	4 (29)	6 (32)	6 (30)
Age, years, mean (SD)	44 (10)	42 (10)	52 (12)
Female sex at birth, n(%)	10 (71)	13 (68)	11 (55)
Gender n(%)			
Man	4 (29)	5 (26)	8 (40)
Woman	10 (71)	12 (63)	11 (55)
Trans	0 (0)	1 (5)	1 (5)
Other/prefer not to state	0 (0)	1 (5)	0 (0)
Race, n(%)			
White	5 (36)	10 (53)	6 (30)
Black	2 (14)	4 (21)	9 (45)
Other	7 (50)	5 (26)	3 (15)
Education, n(%)			
High school diploma/lower grade	0 (0)	0 (0)	6 (30)
Some college	0 (0)	2 (11)	9 (45)
Four year college or Grad degree	14 (100)	17 (89)	5 (25)

Results: Overall Demographics



	People with HIV (n=20)
Years since diagnosis, n(%)	
1-5 years	1 (2)
6-10 years	3 (5)
> 10 years	16 (30)
Currently on ART, n(%)	20 (100)
Pharmacy type used to obtain ART?	
Retail/chain	9 (45)
Independent	1 (5)
Clinic-associated	2 (10)
Mail-order	5 (25)
Hospital	2 (10)
Other	1 (5)
How do you usually get medicines from the pharmacy?, n(%)	
Pick up at pharmacy	5 (25)
Pharmacy delivery or mail	11 (55)
Both	1 (5)
Other	3 (15)
Self-reported # meds currently taking, mean(SD)	5.35 (4)
Average # visits to pharmacy, n(%)	
1 or more times/month	11 (55)
every 2 months	4 (20)
every 3 months	1 (5)
Hardly ever	4 (20)

Results: Demographics (People with HIV)



	Pharmacy staff (n=14)	Clinic Staff (n=19)
Time employed by organization, n(%)		
> 5 years	6 (43)	7 (37)
6-10 years	2 (14)	6 (32)
> 10 years	6 (43)	6 (32)
How long been serving persons with HIV?, n(%)		
> 5 years	5 (36)	6 (32)
6-10 years	2 (14)	3 (16)
> 10 years	7 (50)	10 (53)
Persons with HIV cared for per week		
<50 persons	9 (64)	15 (79)
51-100 persons	3 (21)	2 (11)
> 100 persons	2 (14)	2 (11)
Prescriptions filled per day (pharmacy) OR HIV patients per year (clinic), n(%)		
< 100 prescriptions daily or patients/year	0 (0)	1 (5)
100-300 prescriptions daily or patients/year	7 (50)	2 (11)
301-500 prescriptions daily or patients/year	5 (36)	5 (26)
> 500 prescriptions daily or patients/year	2 (14)	11 (58)
Pharmacy Role, n(%)		
Manager	7 (50)	N/A
Pharmacist	7 (50)	N/A
Type of pharmacy, n(%)		
Independent	2 (14)	N/A
Retail/chain	7 (50)	N/A
Clinic-associated pharmacy	5 (36)	N/A

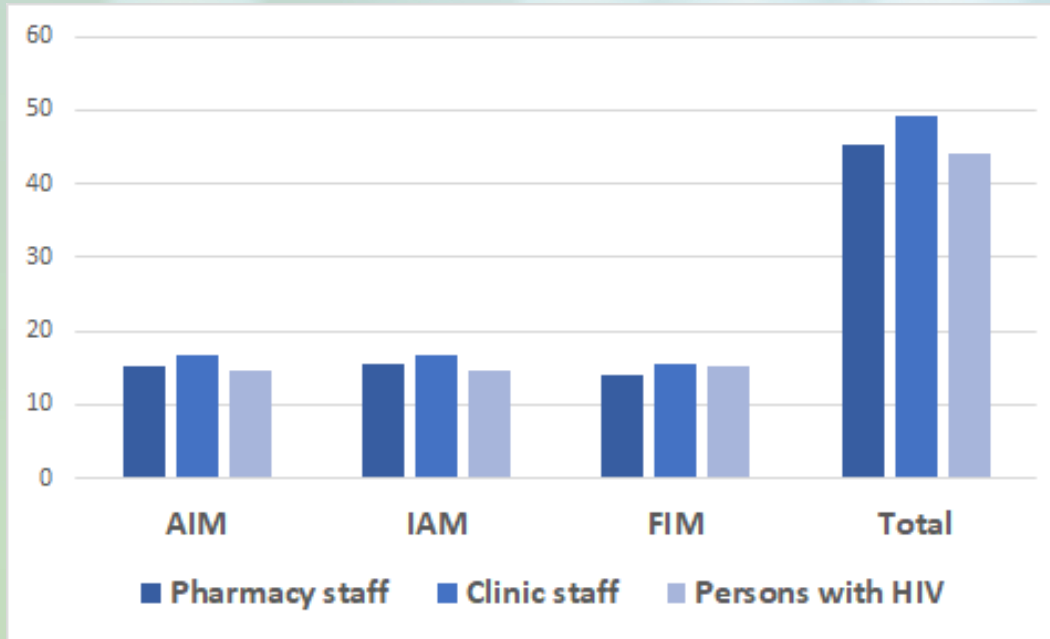
Results: Demographics (Clinic and Pharmacy Staff)



	<u>Pharmacy Staff</u> <u>(n=14)</u>	<u>Clinic Staff</u> <u>(n=19)</u>	<u>People with HIV</u> <u>(n=20)</u>
Self-rated knowledgeable about LA-ART?, n(%)			
Not knowledgeable	2 (14)	0 (0)	--
Slight/moderate	8 (57)	11 (58)	--
Very/extremely	4 (28)	8 (42)	--
Role in LA-ART?			
Working directly with patients on eligibility	2 (14)	14 (74)	--
Setting up clinic or pharmacy programs	1 (7)	3 (16)	--
Dispensing or ordering medication	11 (79)	1 (5)	--
Other type of support	0 (0)	1 (5)	--
# persons getting LA-ART injected by your org			
1-10 persons		7 (37)	--
11- 25 persons		7 (37)	--
26-50 persons		0 (0)	--
> 50 persons		5 (26)	--
Currently on LA-ART, n(%)			7 (35)
Not on LA-ART, doctor has mentioned it, n(%)			6 (46)
Definitely will not try it in the future, n(%)	--	--	1 (8)
Might or might not try it in the future, n(%)	--	--	3 (23)
Probably will try it in the future, n(%)	--	--	1 (8)
Definitely will try it in the future, n(%)	--	--	8 (62)



Acceptability, Appropriateness, Feasibility



- Three scales
 - Acceptability of intervention Measure (AIM)
 - Appropriateness of intervention Measure (IAM)
 - Feasibility of intervention measure (FIM)

Attitudes

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"I mean, if the pharmacist is qualified to give me a shot yeah, give me a shot". – Patient, CA

"Anything that helps patients receive appropriate care & appropriate medications, anything that makes that easier for the patient as long as it's done in a safe way, I am 100% in favor of." – Clinician, AL

"I am concerned about pharmacies administering them. Not so much dispensing, but more administration. When I say pharmacy, I mean like chain pharmacies." – Pharmacist, AL

"I think it'll be a good idea. I really do. For the people that want to take the shot, that could be real convenient to a lot of people." – Patient, AL

"I'm hesitant just because of where community pharmacy is, for the most part, right now." – Clinician, FL

"I think from an adherence perspective, I love this." – Pharmacist, TX



Good in theory – The "Pros"

Outer setting (External views)

Access: *"pharmacies available on every corner, patients can choose where to get their shot"*

Convenience: *"Pharmacies open later hours and on weekends"*

Costs: *"No copay needed at a pharmacy – cheaper for patients"*

Inner setting (Pharmacy)

Access: *"Specialty pharmacies would be better suited, not all pharmacies can"*

Convenience: *"Would work best with an appointment based system"*

Costs: *"Pharmacists don't get reimbursed for clinical services, it's not sustainable"*

Facilitators for LA-ART

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General positive regard for pharmacists

"I think patients feel comfortable with those community pharmacists. They are trusted providers." - Clinician, TX

I'm assuming the pharmacist is administering it or is involved, so because of their knowledge about medications, they would be able to better assess when issues arise, like missed doses—they kind of know how to triage it. – Clinician, TX

They got some good pharmacies there with good attitudes, everybody's friendly. – Patient, SF

Experience with COVID-19 and immunizations

Like I said, they have people who give shots. What's the difference of a HIV shot than a COVID or a Monkeypox or a flu shot? ...I mean they're trained to give you a shot. –Patient, SF

I have full confidence. I mean, pharmacies do all kinds of injections all the time. You know, flu shots, COVID vaccines, all the regular vaccines that people get, whooping cough (pertussis) and all that. I have full confidence that they'd be able to do that. – Clinician, TX

It [wouldn't] interrupt me anymore than a vaccine would. I take a vaccine out—or in this case, an injectable—I would sit it. I continue to do my workflow as I'm making sure it's sitting there for 15 minutes. I go back to it, then draw it up. It's not like I just stand there and stare at it. It's not any different than a COVID booster, as far as timeline. – Pharmacist, AL

Facilitators for LA-ART

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Relationships	<p><i>[O]ur physicians have a very good relationship with the pharmacy across the street, but we've had a lot of difficulties with certain pharmacies. [It] would be important to see if that relationship was there because they would have to kind of be trusting that the monitoring is occurring, the follow-ups ...are occurring when you prescribe it in that setting vs. having the patient come see me. – Clinician, FL</i></p> <p><i>I have to have a bond with them. I have to learn to understand them. They have to understand me too. That's why I do everything through XXX Pharmacy, that team is great...I'm just afraid to go to any neighborhood drugstore pharmacy. – Patient, FL</i></p> <p><i>I think pharmacists do have a kind of trusted relationship with ...patients that feeds into a culture that can potentially be successful. I think patients are more likely to talk to those pharmacists about things like side effects, adherence issues, challenges with staying in care than they will their provider. Often they're gonna see their pharmacist more than they see their doctor. I think that there is that kind of closeness that happens with the pharmacist and with the pharmacy team that doesn't necessarily happen with clinical staff. – Clinician, TX</i></p>
Clinic overwhelm	<p><i>I have a list of 50 patients that are waiting to start Cabenuva that we can't because we don't have the capacity in our clinic. Yeah, so that would alleviate it and would allow us to provide that service for them. – Clinician, FL</i></p> <p><i>As a clinic, we struggle with capacity and provider availability even for something like walk-in, just injections or scheduled injections. Pharmacies have capacity to have later hours, weekends, nights. – Clinician, TX</i></p>

Barriers to LA-ART

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Space/ privacy	<i>I think the biggest challenge would be privacy, right? Because it has to be done on the gluteus muscles compared to someone just sitting in the waiting area or having a little privacy screen that some of the retail locations have when they administer vaccines. You would definitely need more privacy. You would have to have a little room, a consultation area where you can do it behind a closed door. - Pharmacist, FL</i>
Staffing	<i>Pharmacies, we are always experiencing staffing issues. That's also taking a toll on us. Our team right now is aware of that. They are working a little bit extra. I would say a little bit stressful, yes. - Pharmacist, TX</i>
Reimbursement	<p><i>I only know my profits and loss for the whole—it's not really fully broken down. It's a brand medication, so I know that our reimbursement on it is not that great at the beginning. – Pharmacist, FL</i></p> <p><i>Our business model ...you sometimes will get sideways with the wholesaler if you order too many expensive brands because they want you to hit a certain percentage with the generics. So now you have a challenge because, again, you're disincentivized to order brand name medications because you have a contract or an agreement in place with your wholesaler. So if you are a pharmacy that does a lot of HIV medications and you spent \$100,000 a month just on these injectables, I mean that's going to be very difficult to achieve your generic compliance rate. – Pharmacist, AL</i></p>
Training	<i>It has to be administered on the gluteus muscle. It can't be done in any other location, so it does need a little more training than injecting a vaccine and an IM on the deltoid. We definitely will need more training in that field. – Pharmacist, FL</i>



Intervention complexity

Division of responsibility

**Lack of integration of
EMR between
pharmacy/clinics**

**Tracking patients and
supporting adherence**

**Uncoupling clinic follow
up from injections**



Discussion: Moving the needle

- Positive support around *idea* of pharmacy-administered LA-ART with much trepidation about implementation *details*
 - Facilitators & barriers not surprising
 - Some challenging to modify quickly for scale-up (EMR, space)
 - Others reasonably overcome (training)
- Optimal use of pharmacies to support LA-ART depends on local context
 - Consider needs of local clinics
 - Stratify pharmacies for continuum of responsibility from dispensing to administration to follow-up
 - Similar consideration for LA-PrEP
- Support needed for success: integrated tracking, reimbursement streams

Conclusion

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- Generalized openness to pharmacy-administered LA-ART
- No “one size fits all” model for pharmacy
 - Ideal pharmacy for administration services: community need, strong relationships, adequate staffing, private spaces, facile communication streams, and methods to ensure financial stability
- Need to develop methods to better integrate clinic/community pharmacy communication and workflows to share responsibilities and tasks associated with LA-ART