

# Implementing Long-Acting Studies in Adolescents: lessons from the field



**ANNUAL MEETING**  
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# Overview

- ▶ Operational lessons learned)
- ▶ **What the patients and their families are telling us**

# RATIONALE & APPROACH.

For this study we utilized a mixed-methods approach to collect acceptability and tolerability data



# METHODS.

- ▶ **Staff-administered questionnaires** completed by all adolescents at study entry and after receipt of 3 injectable doses (***quantitative data***)
  - ▶ Reasons for choosing the LA ARV
  - ▶ Perceptions of injections
  - ▶ Health-related quality of life (PedsQL™)
  
- ▶ **In-depth phone interviews** of selected adolescent participants and selected parents/ caregivers (***qualitative data***)

# METHODS. Analysis Framework: Consolidated Framework for Advancing Implementation Research (CFIR)

WITH NEW TREATMENT APPROACHES, IT IS CRITICAL TO TRY TO ANTICIPATE FUTURE IMPLEMENTATION CHALLENGES.

- ▶ Comprehensive framework composed of **constructs associated with effective implementation**
  - ▶ Allows for **systematic coding/analysis** of the interview data according to 5 domains
  - ▶ Used to **inform later implementation**
- ▶ **Intervention characteristics**
  - ▶ **Outer setting**  
(e.g. patient needs and resources, barriers and facilitators to meeting those needs)
  - ▶ **Inner setting**  
(e.g. structural characteristics, communications, tension for change)
  - ▶ **Characteristics of individuals**
  - ▶ **Process of Implementation**

# RESULTS. Characteristics of Cohort

Characteristic	All Adolescent Participants	Interviewed Adolescents
	N=23*	N=11
Age	Median: 16 Range: 12-17	Median: 15 Range: 12-17
Female Sex	10 (43.5%)	5 (45.5%)
Cohort		
CAB	8 (34.8%)	6 (54.5%)
RPV	15 (65.2%)	5 (45.5%)
Study Site		
Emory	8 (34.8%)	3 (27.3%)
Johns Hopkins	5 (21.7%)	3 (27.3%)
Lurie Children's	1 (4.3%)	1 (9.1%)
St. Jude	1 (4.3%)	0
Texas Children's	2 (8.7%)	0
U. Colorado	5 (21.7%)	3 (27.3%)
USC	1 (4.3%)	1 (9.1%)

## RESULTS.

- ▶ Overall, perceptions of injections were favorable
- ▶ Health-related QoL was similar before vs. after initiation of LA
- ▶ Of 21\* adolescents who received 3 study injections, 90.5% (19/21) reported wanting to receive LA ARV even after the study ended
  - ▶ Definitely (15/21 (71.4%))
  - ▶ Probably (4/21 (19.1%))

\*1 discontinued study drug after the entry visit due to hypersensitivity reaction to the first oral dose. 1 participant declined injections after needle insertion but prior to receiving the first IM dose. Both were in the RPV group

\*\*Participants indicated all that were applicable to them



# RESULTS. In-depth phone interviews of selected adolescent participants and selected parents/ caregivers (qualitative data)





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CFIR DOMAIN	EXAMPLE CODES	SUMMARY OF REPRESENTATION OF CODES IN DATA
CHARACTERISTICS OF INJECTION	RELATIVE ADVANTAGE	Perception of advantage of implementing LA ART vs. pill-based treatment
	ADAPTABILITY	Degree to which LA ART can be adapted or refined to meet the needs of adolescents
	COMPLEXITY	Perceived difficulty of adolescents accessing and maintaining LA ART
INNER SETTING	COMPATIBILITY	Degree of fit of LA ART with stakeholders' norms, values and systems
	TENSION FOR CHANGE	Degree to which stakeholders consider current situation in need of change
OUTER SETTING	PATIENT NEEDS & RESOURCES	Extent to which adolescent patients' needs, barriers and facilitators are known and prioritized by implementer
	COSMOPOLITANISM	Degree to which implementer is networked with complementary organizations
INDIVIDUAL CHARACTERISTICS	SELF-EFFICACY	Individual belief in own/adolescent's capacity to execute course of action to achieve implementation goals
	INDIVIDUAL STAGE OF CHANGE	Characterization of phase an individual is in towards accepting and maintaining LA ART
PROCESS	PLANNING & ENGAGING	Development of plan and involvement of appropriate individuals in intervention
	EXECUTING	Ability to carry out the implementation according to plan
	REFLECTING & EVALUATING	Feedback about adolescents' experience of receiving LA ART

# Representative Quotes. Characteristics of Injection

Parents and adolescents agreed that adaptability is a distinct advantage of injectables:

## CONSTRUCTS

### Relative Advantage

*"I liked how after I got the shot, I could just forget about it."*  
-17-year-old male

### Adaptability

Parents and adolescents said that not having to remember daily pills once on an all-injectable regimen would simplify their lives. But some had concerns about sourcing injections close to home:

### Complexity

*"We thought it was a good idea because she's getting ready to graduate from high school and she's gonna be going to college and it would be a better way for her to get her medicine rather than trying to get a pill every day. I felt more comfortable because people have to remind her."*  
-mother of 17-year-old female

# Representative Quotes. Individual Characteristics

## CONSTRUCTS

Knowledge  
and  
Beliefs

Several participants discussed having been waiting for the opportunity to try long-acting injectables:

*“We have (multiple) children who are HIV positive and so we’ve been looking forward to the possibility of getting injections for years, as long as we’ve known about it.”*

*-mother of 12-year-old male*

Self-Efficacy

Individual  
Stage of  
Change

**Lack of self-efficacy regarding pill-taking was a driving force for many:**

*“Parents are trying to give them more independence, but we don’t know for sure if they’re actually taking their meds or when they are skipping them.”*

*-mother of 12-year-old male*

Capacity

# Representative Quotes. Inner Setting

## CONSTRUCTS

Network  
and  
Communication

Culture

Tension  
for  
Change

Compatibility

Long-acting formulations overall were seen as compatible with adolescent priorities:

*“When I go to college it’s going to be worse because I’m going to be in college, and I’m not going to be thinking about taking my medicine and stuff. If I have a shot, then it’s going to be easy.” -17-year-old female*

*“You’re partying and stuff. You’re probably going to be coming in late, probably sleeping in late. You’re going to end up forgetting stuff. If you were already taking a shot and you already got your shot, you don’t have to worry about it, you can just live your life.” -17-year-old female*

# Representative Quotes. Inner Setting (continued)

## CONSTRUCTS

Network  
and  
Communication

For these virologically suppressed adolescents, the adolescents overall had stronger desire to try injections (tension for change) than their parents:

*"I was wondering if there was a way to not take medicine, but just get shots or something. So, when the shots came up, I was excited to do that." -15-year-old female*

Culture

*"She said, 'Mommy, for real. I really want to do it.' I said, 'But I can't. I don't know what's gonna happen.' She said, 'mommy, I'll be fine, don't you worry.' I said, 'I cannot stop worrying.'" -mother of 16-year-old female*

Tension  
for  
Change

Compatibility

*"He's not scared. He was the one that said he want it... ..when I was panicking, he was one telling me, 'mommy, please stop, stop.' I was like, 'okay, he's not scared.'" -mother of 14-year-old male*

# Representative Quotes. Outer Setting

Adolescent-friendly services were seen as important for delivery of injections:

## CONSTRUCTS

Patient Needs  
and  
Resources

*“I think they’d rather have it where they usually go to. So, it’ll feel more comforting than a new environment...My doctor usually talks to me without my parents, so I can feel more comfort and I can tell him my problems.”*

*-15-year-old female*

Cosmopolitanism

*“I think if they have a professional team, a caring team – a team that’s gonna be patient with the adolescent children that take the shot, I think that’ll work.”*

*-grandmother of adolescent*

# Representative Quotes. Process

## CONSTRUCTS

Planning  
and  
Engaging

Parents expressed having more initial fears about the process of ensuring safety and practical follow-up needs:

*“To be honest, I was scared... ..I started asking them series of questions... ..If they give it to him now and it started reacting on him, how are they going to flush it out from his system?” - mother of 14-year-old male*

Executing

However, all interviewed parents reported being reassured after experiencing the process:

Reflecting  
and  
Evaluating

*“I really was scared that he won’t be able to go to school, but he went to school the next day.”*

*“My advice to other parents is that – I think, on my own part, that the injection is better (than daily pills).” -mother of 14-year-old male*



# Representative Quotes. Process (continued)

Adolescents expressed ongoing concern about the location of the injection:

## CONSTRUCTS

Planning  
and  
Engaging

*"When I first heard that it would be on the butt, I was a little self-conscious about it. And weirded out."*

*-15-year-old female*

Executing

*"some people might not like taking shots in their butt cheek...that's the only thing I would change."*

*-14-year-old male*

Reflecting  
and  
Evaluating

*"having it on your butt is just really inconvenient for anybody—especially younger people...If they could put it somewhere else other than on the butt, I would love it."*

*-17-year-old female*

**Nevertheless, all interviewed adolescents said they would recommend injections to peers:**

*"Take the shot once a month, be over with it and you can actually live a normal life instead of taking pills on front of people every day or looking at yourself like you're not a real human or something. It's better."* -12-year-old female

## CONCLUSIONS.

The first adolescents to access LA ARV through the MOCHA Study and their parents found the formulation to be acceptable.

Adolescent-specific concerns such as differences of opinion between adolescents and their consenting parent regarding whether or not they should initiate LA ARV arose. However, most dyads indicated that the relative advantage of avoiding pill-taking for long-term therapy would outweigh potential disadvantages of making the switch.

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