

## BACKGROUND

- The ongoing More Options for Children and Adolescents Study (MOCHA; Clinicaltrials.gov NCT03497676) is a phase I/II study, the first to examine use of long-acting injectable (LAI) antiretrovirals (cabotegravir (CAB) and rilpivirine (RPV)) in adolescents living with HIV (age 12-<18 years)
- MOCHA participants were the first virologically suppressed adolescents to access LAI antiretrovirals (ARV)
- Little is known about the acceptability of LAI treatment for adolescents, including whether it changes over time

## METHODS

To assess LA acceptability issues of importance to adolescents, we used a mixed-methods approach among participants in Cohort 2 of this Phase I/II multi-center study including:

- Querying all Cohort 2 adolescents about their preferred choice of treatment at 8, 24 and 48 weeks:
  - LAI versus daily oral
  - Reasons for this preference
- Reasons for the preferred regimen were recorded verbatim and coded thematically
- In-depth telephone interviews (IDI) with U.S.-based English-speaking adolescents (N=8) and their parents/caregivers ("parents"; N=4) after at least 24 weeks on study
- Coding and thematic analysis of IDIs using the consolidated framework for implementation research (CFIR)

## RESULTS

**TABLE 1. Characteristics of Cohort**

	All Adolescent Participants (N=144)	Interviewed Adolescents (N=8)
Age	Median: 15 Range: 12-17	Median: 16 Range: 12-17
Female Sex	74 (51.4%)	3 (37.5%)
Race		
Asian	36 (25%)	0
Black/African	106 (73.6%)	8 (100%)
White	2 (1.4%)	0
Mode of Infection		
Perinatal	132 (91.7%)	8 (100%)
Not Perinatal	12 (8.3%)	0
Site		
Botswana	25 (17.4%)	0
South Africa	43 (29.9%)	0
Thailand	36 (25.0%)	0
Uganda	20 (13.9%)	0
USA	20 (13.9%)	8 (100%)

\*2 adolescents did not complete week 8 (2 withdrew during oral lead-in); a third did not complete week 24 (pregnancy); a 4<sup>th</sup> did not complete week 48 (lost to follow-up)

The two most prominent perceived reducers of treatment burden with injectable treatment were:  
**1) Having the medical team's support and monitoring for adherence to each injection, and 2) Freedom from the daily reminder of HIV diagnosis seen as inherent to oral treatment.**

## RESULTS

- Week 8: All but 4/142 (2.8%) participants stated preference for LAI**
- Week 24: All but 2/141 (1.4%) participants stated preference for LAI**
- Week 48: All (N=140) participants stated preference for LAI**
- All participants who preferred pills noted injection pain as the reason
- Reasons for preferring LAI fell into the broad categories of "Convenience" and "Burden Reduction" and were coded accordingly. More specific reasons for thinking LAI was more convenient or reduced burden were sub-coded as outlined in Table 2.
- Overall, parental interviews confirmed what we heard in adolescent interviews, providing some helpful context and developmental insights (e.g., pre-treatment counseling was sometimes misunderstood or discounted by adolescents)**

### Example Coded Data from Preferences Questionnaire:

"It's convenient!" (Convenience without subcode)  
 "Because I don't have to remember to take my tablets anymore at soccer." (Convenience, uninterrupted lifestyle)  
 "I don't have to wake up early to take my medicine." (Convenience, uninterrupted lifestyle)  
 "Because I do not have to take tablets every day." (Convenience, no daily treatment)  
 "The injection treatment is not so stressful" (Burden Reduction, anxiety reduction)  
 "I was tired of tablets" (Burden Reduction, treatment fatigue)  
 "I hate pills and I would forget to take them" (Burden Reduction, adherence)  
 "The injection is more private" (Burden Reduction, Privacy)  
 "People won't ask me about the medicine if I get the injection" (Burden Reduction, Privacy)

**TABLE 2. Reasons for Preferring Injectable Medicines**

	Week 8 (N=138)	Week 24 (N=139)	Week 48 (N=140)
<b>Convenience</b>	<b>73 (53%)*</b>	<b>89 (64%)</b>	<b>96 (69%)</b>
Uninterrupted lifestyle	4 (3%)	8 (6%)	15 (11%)
No daily treatment	39 (28%)	49 (35%)	47 (34%)
<b>Burden Reduction</b>	<b>73 (53%)</b>	<b>64 (46%)</b>	<b>65 (46%)</b>
Anxiety reduction	28 (20%)	21 (15%)	12 (9%)
Treatment fatigue	6 (4%)	2 (2%)	8 (6%)
Adherence	12 (9%)	17 (12%)	19 (14%)
Privacy	7 (5%)	7 (5%)	4 (3%)

\*totals add up to >100% because some participants mentioned multiple reasons for preferring injectable medicines

**TABLE 3. Coding Structure for In-Depth Interviews to Inform Implementation**

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

### IDI's revealed that adolescents did not always understand or internalize pre-injection instructions:

"I'm like, where?!... I thought I was getting it in my arm."  
 -14-year-old female  
 "I thought I wasn't going to feel it at all."  
 -14-year-old male  
 "I was really excited about taking the shots, and then like I did zone out a little bit for the debriefing and all of that."  
 -17-year-old male  
 "They did explain it to her, but she was not hearing it."  
 -parent of 15-year-old female

## CONCLUSIONS

- Feedback from adolescents receiving LAI ARVs for 48 weeks in the MOCHA Study was favorable
- In this cohort of adolescents who chose to be among the first to receive LAI, preference for this formulation remained high through week 48
- IDI data suggest that structured and developmentally tailored counseling administered by trained clinic staff may be essential to successful LAI implementation for adolescents

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