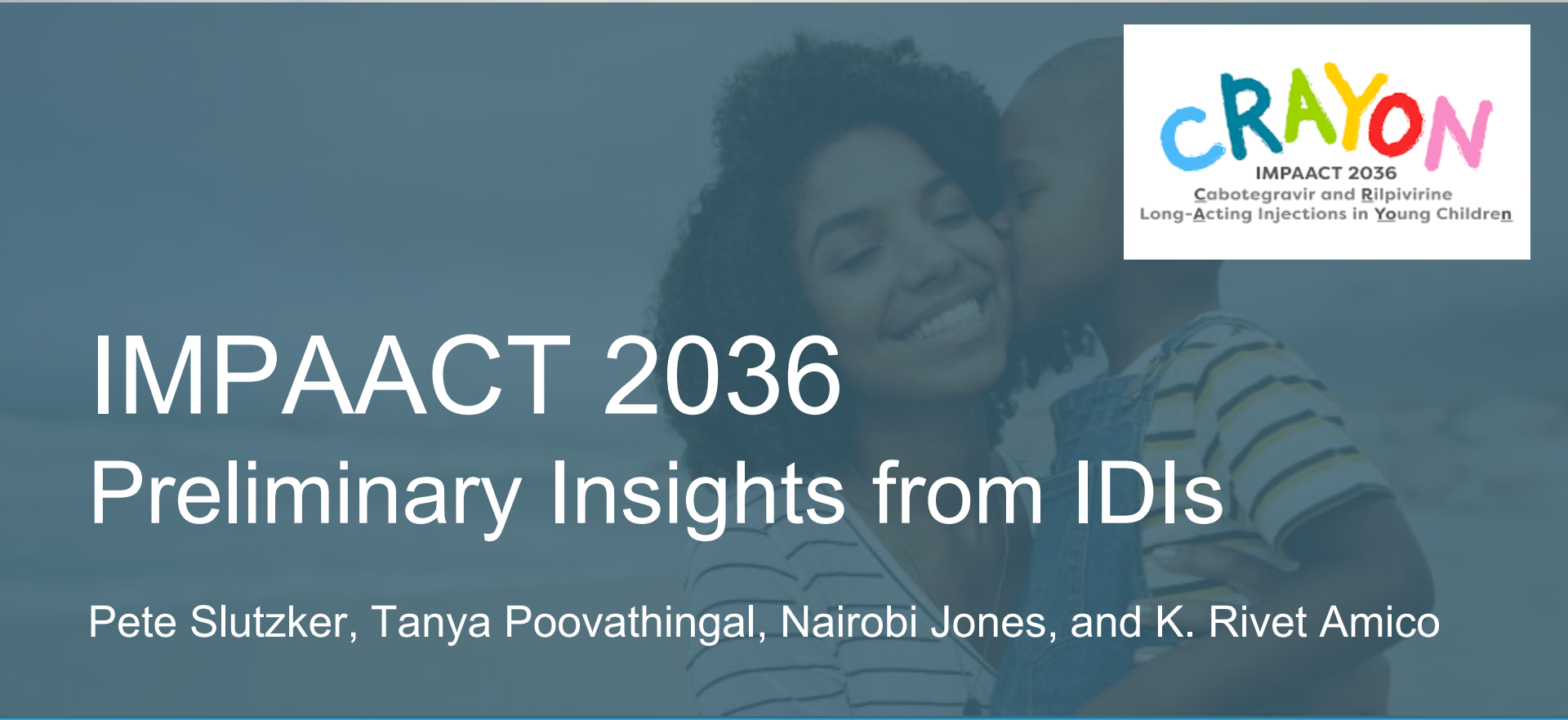

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IMPAACT 2036
Cabotegravir and Rilpivirine
Long-Acting Injections in Young Children

IMPAACT 2036
Preliminary Insights from IDIs

Pete Slutzker, Tanya Poovathingal, Nairobi Jones, and K. Rivet Amico

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Disclaimer:

- The slides and insights presented herein are preliminary – final themes may change

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Overview

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- IMPAACT 2036 Qualitative component
- Sample
- Procedures
- Preliminary insights
  - Stigma reduction
  - Normalcy
  - Pain
  - Preferences/Likes/Dislikes
- Next steps

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- Phase I/II Study of the Safety, Tolerability, Acceptability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed Children Living with HIV-1, Two to Less Than 12 Years of Age
- **Cohort 1** children completed a 4-week oral lead-in followed by IM CAB LA + RPV LA administered every 4 or 8 weeks through 72 weeks of total follow-up
- See study material on IMPAACT website

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Secondary Objective to **evaluate acceptability of injectable CAB LA + RPV LA after an oral lead in**

- Embedded mixed methods exploration of acceptability, feasibility, preferences, and experiences with IM CAB LA + RPV LA
  - In depth interviews (IDI) with 18 caregivers exploring experiences at or around the week 24 study visit
  - Longitudinal survey data from children (ages 7 through 12) and caregivers
    - Injection pain rating both perceived (pre-injection) and experienced (post-injection) for all children ages 3 through 12

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IMPAACT 2036 Qualitative Site Locations

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Thailand
USA
South Africa
Botswana
Brazil

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Interview Sample

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Semi structured IDIs

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- Relationship and Disclosure
- Study Participation and Experiences – Hopes / Expectations
- Likes and Dislikes about Injections as Compared to Oral Medication
- Possible Relationship Effects of Switching from Oral to Injectable Treatment
- Possible Experiences of Stigma
- Final Reflections

Procedures

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- Clinical sites conducting the qualitative portion of the study recruited all caregivers
- Trained interviewers conducted interview in caregiver's language of choice
- Average length: 45 minutes
- Interviews were recorded and transcribed and translated by sites
- Transcripts were then shared with qualitative coding team (University of Michigan)
- A coding team (3 trained coders) implemented thematic analysis and content coding with a hybrid deductive/inductive approach

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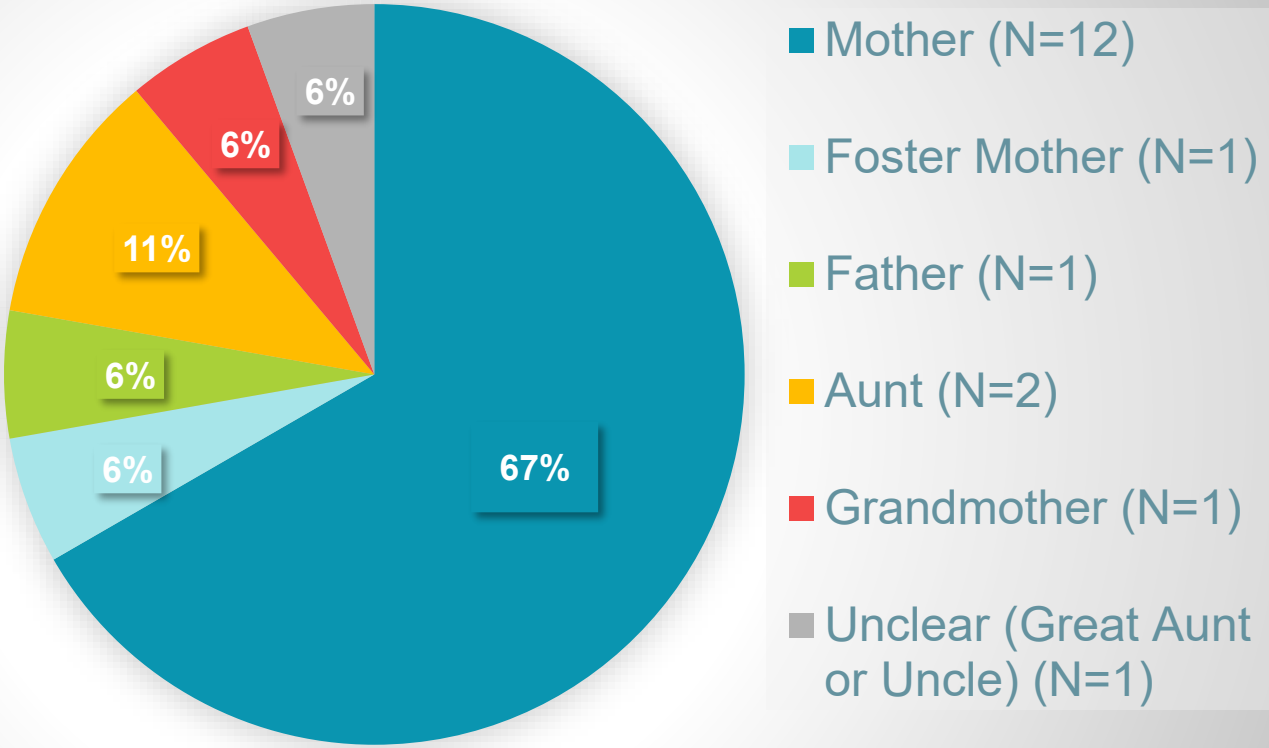
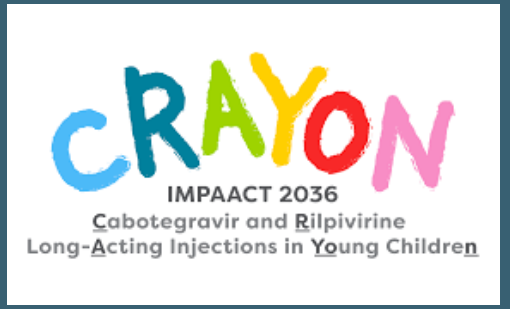
Relationship to Child





Preliminary insights

Stigma, Normalcy, Pain, Preference

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HIV related stigma

- Stigma was explored with caregivers
  Please share with me if you, [child's name], or people living in the household have experienced HIV-related stigma or discrimination? [did injections change those experiences?]
- Stigma also emerged as a theme weaving across experiences with the child's switch to IM CAB LA + RVP LA

Caregivers **expected and experienced HIV Stigma** which they managed through **non-disclosure of child's HIV**

Non-disclosure of child's HIV required substantial investment in hiding medication taking

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Process of hiding medication taking was challenging for caregivers

*Yes, there is a lot of prejudice. A lot, because everyone used to suspect – and still suspects to this day – what his biological mother died from. And I didn't tell anyone…Because of that, everyone kind of fears he might have something, and seeing him taking medication every day just makes people more suspicious…So, if people knew what he has, it would be complicated…I had to hide all the medications, I had to give them to him in secret, call him aside and close the bedroom door so I could give it to him…**I think that part was really exhausting*** -- Foster mother

Switch to injectables offered relief from this

78% **of Caregivers Reported that injections reduced experiences with HIV-stigma**

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Switch to injectables offered relief from managing stigma by hiding child's need for medication

Like, since you take the shot, she can go anywhere that she wants to go ***because I don't have to start explaining****.* ***No, you need to give her this medication at a particular time.*** *And some other people, they know how to use Google. They will start Googling about this medication.*– Biological mother

If it is an injection, he/she ***can also visit*** [with others]***, and feel comfortable without discrimination from others****.*-- Aunt

Even if you leave them with neighbors, ***there is no one who can realize that the child lives with*** *that condition compared to pills as someone can realize and also see what is happening.* -- Biological parent

Switch to injectables offered relief from managing stigma by hiding child's need for medication

Again, this pills thing, ***it is as if it causes discrimination****.* ***People discriminate as you go around with pills.*** *I then saw that; the injection is very important. When you have taken the injection, you* ***become free for the whole month****.*-- Aunt

This freedom from daily dosing allowed children to participate in "normal" social activities for children their age and reduced feelings of "being different"

He likes being able to go a long period without having to take anything, ***having his freedom****, without needing medication.* -- Foster Mother

Injections offered "normalcy"

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94% **of Caregivers reported that injections allowed child to engage in "normal" (social) activities**

Well, I saw it will be more convenient than to take the oral medication every day, you know at least once a month, and then it's finished you do not have to think about it every day, like this child this and that you see. ***So, for the whole month she can just live a normal life of a normal child***.-- Mother

Injections offered "normalcy"

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I'm different to other kids. ***Other kids do not have to take treatments every day****. I'm different. I'm not like them. I do not fit in with them." So, I think, yeah, for other children as well, the* ***way it is benefiting my child, I think it would really benefit other kids in their lifestyle as well****.*-- Mother

"I realized that the child is becoming comfortable, at the time he/she was taking pills, he/she was someone who preferred staying at home, now he/she can go and play with others, having that love, believing in themselves."
-- Aunt

You are going to go to the hospital once a month or whenever they want you to come. But they will give you the injection once a month, and then you do not have to worry about taking your pills every day." And ***he was like "Ah, so then I can go to sleepovers? And I was like "Yeah you will go to sleepovers and not worry about taking any medication. He said "Okay it's fine. Let's go and do it****." He was actually excited. He was the one who was excited more than us.* -- Mother

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Experiences with Injection Pain

- 17 caregivers provided information about the child's experiences with pain
  - Of these
    - 88% reported child experiencing injection pain
    - 24% said it was less than expected
    - 35% said it lasted a few days
  - 29% said pain only experienced at time of injection

I thought it would take 4-5 days, but actually it takes only 2-3 days. -- Mother

The pain lasts for a short period of time, because after the injection, you will see that he is playing like nothing happened. So, it's just during the time when they are injecting him. -- Mother

I think he doesn't like the pain that he feels after getting the shot. But what he does like is that he is no longer taking oral medication. -- Mother

Actually on the left bum, that's the one that he says it's very painful. The first [right bum] *he does not have problem with it.* -- Mother

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Caregiver preference

- 100% of the 18 caregivers preferred the *injections* over oral meds.
  - 17 (94%) noted convenience as deciding factor

    because they reduce the daily need for medication management and make life easier
- 89% believed the child also shared the preference of injections

*I would choose the injection for the child, as I am looking at the fact that the injection **helps them from discrimination** and makes you not take pills accordingly.*
-- Father

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Exploration: Caregiver Dislikes

- 17 caregivers were asked about their dislikes
  - 53% shared that they had no dislikes about IM CAB LA + RPV LA
- Among the 47% discussing aspects of the treatment or related procedures that they disliked…
  - Child experiencing pain
  - Injection schedule (too frequent, disrupts schooling)
  - Travel time

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Caregiver Dislikes/Recommendations

- Longer periods between injections- particularly for children

> *"I wish they would not receive the injections every month. Maybe there could be an option of giving injections like after three months."* --Mother

- Alternative locations to receive the injections

> *"On my side, I don't want to lie, I haven't really thought about the clinic. If it were up to me, I would have chosen the pharmacy."* -- Mother

- Pain

> *"I don't think there is anything she dislikes. I know and believe that she is only scared of the injection because of pain."*-- Mother

Looking forward

- Complete Cohort 2 IDIs
- Analyze all qual data
- Integrate with quant survey data
- Mixed methods recommendations

*“I like it, also because since my child started taking it, my goodness, I see a lot of change. I am not sure if it is due to the injection or what. They are not the same as that time when they were taking pills. There is a lot of difference, the way I see them as the mother. It has even improved their appearance. They are just beautiful, **they are glowing**.”* -- Mother

Acknowledgments

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THANKS!

Any questions?

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