

WHO IMPAACT Non-Clinical Workgroup Call #2

31st of March 2021

What do patients want and need to know in order to make a decision to stay on study drug or participate in a trial while pregnant?

Community Perspective

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Presentation Outline

- Background
- Who truly represents the Patient (Community) Perspective?
- Information patients need - Emerging themes
- Further information.

Background

- Personal experience of pregnancy after HIV diagnosis
- Personal experience of being a clinical trial participant - [PIVOT](#)
- Advocate for the **Meaningful Involvement** of Women Living with HIV in Clinical Trials – including pregnant women
- Understand the importance of provision of information to enable women to make informed choices about participation

We need to remember that...pregnant & breastfeeding women are also doctors, nurses, researchers, teachers & active community members...

- Important to move from active exclusion to safer Inclusion.

What do you as a patient want and need to know to make a decision to stay on study drug while pregnant or participate in trial while pregnant?

What information is necessary/useful and how should it be presented in a comprehensive way?

Who truly represents the Patient (Community) Perspective?



Long standing patient representatives can lose their independent perspective as they become embedded into formal committees and organizational norms.

Several European patient organizations have become concerned about the number of committees where one or two firmly established patients are there to represent all cancer patients... even in discussions where type and stage of cancer does not relate to their own.....

- I therefore asked members of the [4M Network of Mentor Mothers](#) for their views in order to inform this presentation
- **10 MMs responded** (Had children either before or after HIV diagnosis or diagnosed during pregnancy).

Demographics

Age: Late 30s to mid 50s

Ethnicity: White British (3)

Black British Caribbean (1)

Black British African (6)

African Countries of origin (Botswana, Gambia, Kenya, Malawi, Nigeria & Zambia)

Question 1.

What do you as a patient want and need to know to make a decision to stay on study drug while pregnant or participate in trial while pregnant?

Information needed - Emerging themes (Questions)

General Information / safety & effectiveness

- What is the aim/purpose of the trial?
- Have the drugs been tested before, i.e. on men, women, children, animals?
- How safe and effective is/are the trial drug/s?
- What are the potential pros & cons?
- How long will the trial last?
- What form will the trial drug take – will it be pills, injections or implants?
- What will the dosage be and how much time in - between doses?
- Are there any food/drink restrictions?
- What advantages might there be over my current meds? Is this a better newer drug?

Side Effects, Follow-up & Monitoring

- What are the known side effects?
- What are the potential side effects, both for me or my unborn child?
- Will I and/or my baby need extra tests? How often will I be monitored?
- Will my baby be followed up after the trial?
- If yes, for how long after?

Information needed - Emerging themes (Questions)

Drug drug interactions

- What are the possible interactions with other medications I am taking, eg for diabetes?
- Will the drugs interact with vitamins and others I am taking whilst pregnant eg folic acid?

Long term effects

- What are the potential long term effects of the drug in terms of osteoporosis, kidney & liver problems?

Infant feeding and delivery options

- Will I be able to breastfeed?
- Will I be able to deliver vaginally?

Benefits of participating

What's in it for me and my baby? Why should I participate in the trial?

Information needed - Emerging themes (Questions)

Other practical questions

- Are women living with HIV on the project team for the trial
- Will I have access to emotional support whilst on the trial?
- Can I withdraw at any point?
- Can I speak to other trial participants?
- Where will I have to go to take part in the trial?
- Will I receive remuneration? (beyond the usual £20!)
- Will my transport and childcare costs be met (to enable me to attend monitoring etc appointments)

After the trial

- Will there be an opportunity for me to be followed up after the trial to make sure there are no ongoing effects
- Will the results be available in patient friendly language, including translations?
- Will trial results be made available directly to participants?
- Will there be support available for me to share my experience with my peers?

Question 2.

What information is necessary/useful and how should it be presented in a comprehensive way?

- Information about how this trial will help/benefit other pregnant women
- Information about how this can support other women living with HIV in the future, to make better choices
- Information should be presented in a supportive, encouraging way, with an opportunity to talk it through, rather than just a leaflet.
- To have the information explained by a woman living with HIV
- Information should be presented in simple, clear, patient friendly language (no jargon or jargon explained clearly)
- Information should be presented in a variety of formats that are easily available in order to enable accessibility for diverse groups of women, taking into account their diverse literacy levels (both language and treatment literacy levels)

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Aicha **Alice**

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Further information

Interview with Lucy, a young woman living with HIV, in Kenya on women's thoughts on the Dolutegravir restrictions.

<https://salamandertrust.net/podcast/podcast-episode-1/>

Follow-up interview with Lucy a year later, where she talks about how women came together to overcome the restrictions (select episode 9).

<https://salamandertrust.net/project/podcasts/>

Consolidated Guideline on SRHR of Women living with HIV (A checklist for community engagement to implement the *WHO Consolidated guideline on sexual and reproductive health and rights of women living with HIV*)

https://www.who.int/reproductivehealth/publications/gender_rights/srhr-women-hiv/en/