FLAS/ICAP ECHO Clinical Trial Site

Community Civil Society Forum on Hormonal Contraception and HIV

DATE: Thursday 21st June 2018
VENUE: Happy Valley – Swaziland

1. **Welcoming Remarks – Ministry of Health Representative -** *One key lesson from eSwatini for the ECHO trial is the strong links to government and their involvement in every step of the study.*

Dr Lukhele on behalf of Director of Health Services who was attending another meeting at same venue dealing with sector wide approaches to health systems. He is the Senior Manager for Public Health.
This is the first time for Swaziland to run a randomised control study. Looking forward to the results and implementation of recommendations. The results will be used as a tool to ensure attainment of highest possible health care and will help improve service delivery in health care. Also hopes it improves effectiveness of systems – as RCT is most reliable and high-quality evidence.
Government is excited, it is a milestone. Stressed the interdependence between researchers and community. Inclusive participation, authentic narratives, requires academic members to become part of community, unique learning environment before, during, after the trial. Community engagement remains imperative. Findings must be communicated well, **requested** that findings are packaged to suit different audiences.

2. **ICAP: On behalf of Dr Ruben Sahabo – Director of ICAP Swaziland**

Strongly believe study will contribute to safer outcomes and safer options for women. ICAP/ FLAS been implement ECHO since September 2016. Government of eSwatini and MOH research unit have been central and involved in the partnership particularly the SRH/ Technical working groups and Pharmacy. Research capacity development has been undertaken and ICAP is committed to continuing the fight against HIV.
ECHO has built capacity in research which can be used in upcoming HPTN study.
Gratitude to AVAC and funders of ECHO trial.

3. **ECHO STUDY OVERVIEW Implementation and Dissemination Plans - Dr Harriet - ICAP**

Dr Harriet stressed that planning for dissemination of research is best practice and the research team and partners are grateful to AVAC for giving the opportunity to strategize for any possible eventuality/ scenario.

What was necessity of the ECHO trial?

- A Randomised Control Trial was needed as the only existing data on hormonal contraception and HIV acquisition risk is from observational studies which are not definitive.
- Observational studies signaled increased HIV acquisition among women on DMPA
- Policy hadn't changed on the use of hormonal contraception

- Needed clear counselling guidelines for clients

A randomized trial, if done well, provides the highest-quality evidence:

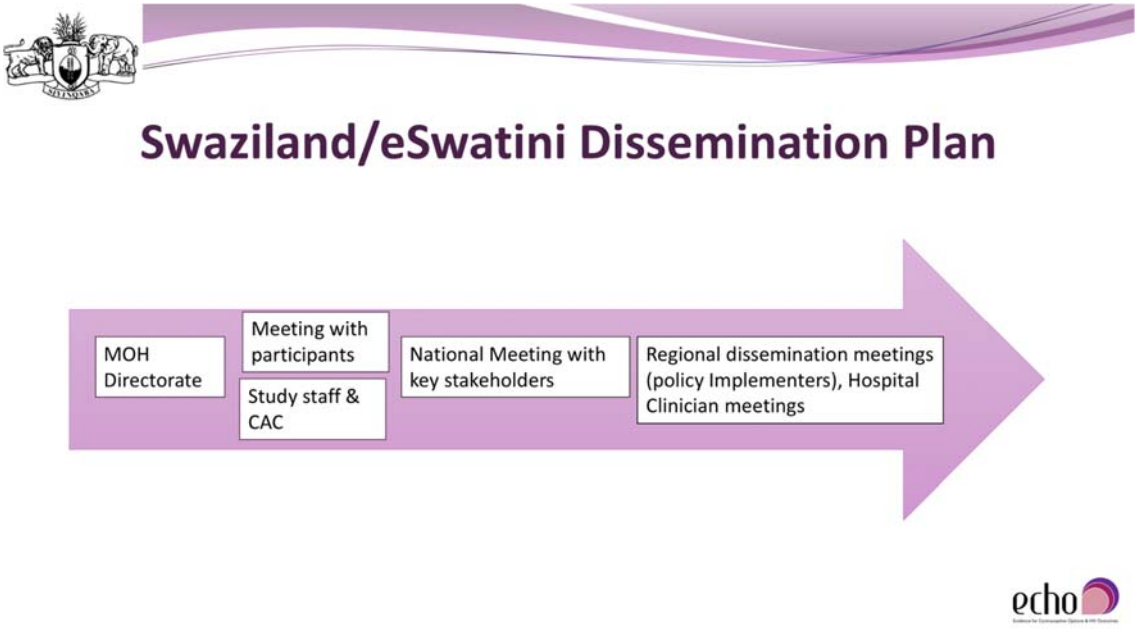
- Providing clear guidance for policymakers and programs
- Helping to formulate clear counselling messages for clinicians
- Permitting women to make fully informed choices

The research seeks primary findings concerned with HIV acquisition risk and Secondary findings will include: pregnancy, severe adverse events, method continuation and other results that will give additional information.

Involvement in the ECHO trial was by competitive selection and Swaziland was one of countries selected along with Kenya, Zambia and South Africa. An ethical review of protocol conducted prior to study start and annually Institutional Review Boards/Ethical Committees at FHI 360, WHO, and each study site.

Implementation in Swaziland began in September 2016 and in total 621 women were screened and 502 who were HIV negative and between ages of 16 - 35 enrolled.
The last visits will be in October 2018 then there will be data cleaning and analysis with results expected in the first half of 2019.

4. **<u>eSwatini Dissemination Plan:</u>**



PLANNING:

- What is the message for each audience depending on scenario?
- Who develops it? How is it packaged?

PRE-ACTIVITY:

- No one knows what ECHO is. Tell people about importance of ECHO trial before the results come out.
- All levels are involved in each step of the dissemination so that there is ownership and accountability.
- CAG – Start sensitisation at HIV consortium meetings – Quarterly and when there are urgent matters
- Meetings with specific stakeholders/ journal- meetings/

DISSEMINATION

When and to whom?

- First known in country or simultaneous dissemination?
- How does local link into global launch? Per country? Simultaneously?
- We must communicate with ECHO Management – global plan is recommended for dissemination

Stakeholders/ Audiences for Dissemination:

- Media - Media is key so that they don't sensationalise or publish incorrect information
- Country directors of civil society organisations/ MOH/
- Technocrats: Communication technical working group/ Clinicians / Civil Society – Activists (advocacy in Swaziland is in infancy – advocates should know issues and how to take them forward)
- CAB members and community

Communication:

- Transparent/ fair/ communicating consistent and clear messages.
- Communications teams should be key/ health workers as well to assist with packaging.
- Prioritise health care workers as they will need to communicate to client
- even most illiterate person should understand outcomes of the trial.

5. **<u>GCAC Presentation – Sibongile Maseko</u>**

GCAC are the Link between researchers and community. There are two such in eSwatini. They communicate with their counterparts across the site countries.
Their role is to:

- Enforce human rights within conduct of research
- Provide input from global perspective recommend and share opportunities
- Participate in community meetings

Challenges:

Lack of funding for face to face meetings

6. **Lindiwe Malaza – Family Planning Focal Person – MOH – Discussions and Way Forward**

FORMATION OF ECHO ACTION TEAM:

Research - Zandi
SRH – MOH –Linda
HPU -
CANGO – Nqobile
UN – Dr Bongani
GCAG –Sibongile/ Siphiwe
ICAP/FLAS –Samkelo / Rita
CAC member

FLAS/ICAP ECHO Clinical Trial Site

Community Dialogue summary notes

DATE: Friday 22nd June 2018

7.

Questions:

Question: Why did ECHO have age limit of up to >35 years because in Swaziland most of our reproductive age is 35-40 years?

RITA - The age group 18-35 years was chosen because that's mostly reproductive age.

Question: What is the mechanism of risk / how are there women exposed to HIV?

Dr. HARRIET - The mechanism of risk is unknown because most of observational studies have been unclear but it's mostly through sexual behaviour

Question: Why is focus mainly on HIV negative women only?

RITA - The primary objective of the study is to look at HIV acquisition so for that reason we were enrolling HIV negative women.

Question: How did the study ensure that they enrolled HIV negative women only because you may find that some participants may have been on window period when they were screened?

RITA - HIV test is done at every visit when the participant comes for their visit and we also conduct RNA test.

Question: How is study linked to sexual behaviour?

Don't forget to discuss high risk sexual behaviour – how do we ensure they are not exposing themselves during the study?

RITA - ECHO: We are collecting data related to sexual behaviour – Dual protection is encouraged

Lindiwe: Preventative package – condoms were emphasised

8. SCENARIO PLANNING:

GREEN	AMBER	RED

HIV incidence is similar for all 3 methods **Implications/ No extra HIV risk from DMPA**	**Results are unclear / murky or inconclusive. Implications – more data needed?**	**HIV incidence is significantly higher for DMPA than other two methods. Or higher for implant? Or IUD? Implications? Changes un FO policies and guidelines.**
	<u>Stakeholders to inform</u> • Research Body • Policy Makers • Implementers • Public	<u>Stakeholders to inform</u> • Ministry of Health • Donors • ECHO participants • WHO • UN • Pharmaceuticals
<u>Implications</u> No implication Reassure people through strengthening counselling Communicate with participants and put emphasis on dual protection Explain why the study was being conducted	<u>Implications</u> • Research Body – more to be done to clarify (False panic) • Need to revisit SRH Policy and Guidelines • There is a need to talk to health workers as they are there primary implementers • Family Planning should be extensively marketed and also put emphasis on dual protection.	<u>Implications</u> • There would be lost trust in Family Planning • Participants may feel betrayed and want to sue or compensation • There will be increased in unwanted pregnancies which may lead to abortions • We would need to change SRH program and education • Use study results to send out positives messaged with emphasis on dual protection and encourage HIV testing and disclosure
	<u>Implementers</u> • Provide rationale of study • Share all study results and be transparent • They should put emphasis on dual protection • Importance of Family Planning counselling • Introspection – services provider should look	<u>Implications</u> • Civil society needs to come with litigation plan which should minimize any negative that may arise this should show the value of research • If there results came in the red it will give us a base to promote dual protection • Implementers will lose faith in Family Planning

	back into what went wrong • Emphasis on why client needs to know when they come for Family Planning	• Another member suggested that this shouldn't impact other programs as we can emphasis on advocacy and education as we need to keep educating • We need to ensure people are informed and should create awareness

9.

10. <u>Way Forward</u>

<u>More civil society Stakeholders to be included in task team</u>

- Open Society Initiative for Southern Africa (OSISA)
- Media Institute of Southern Africa (MISA)
- Coordinating Assembly for NGO's (CANGO)

Task team/steering committee should make the best of last 12 months of trial.

- They need to do pre-results dissemination and post activities
- We need sensitize and to plan early and look at the various scenarios
- The chairperson highlighted that there will be simultaneous dissemination of results both internationally and locally

11. Closing Remarks – MOH

Miss Make Bonsile on behalf of Director of Health Services. Thanked everyone for attending such an important meeting. She highlighted that ECHO is a milestone for the country as it's the first clinical trial. Looking forward to the evidence-ECHO will provide us with that is unique and country based and it will help us in our programming. The three scenarios presented will help us greatly as health workers. We still need your support to come up with inclusive plan for our stakeholders. I would like to take this opportunity to thank our sponsor who made it possible for this gathering AVAC, FLAS, ICAP and Ministry of Health officials who made time to be with us. Lastly, I would like to thank GCAC and CAC members for the wonderful work they have done with ECHO trial.