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Evidence for Contraceptive Options & HIV Outcomes

Report on the ECHO Study Community Dialogues

University of the Witwatersrand WITS RHI

saMRC advancinglife

AVAC Global Advocacy for HIV Prevention

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Abbreviations

AVAC - Aids Vaccine Advocacy Coalition

CAB - Community Advisory Board

CANGO - Coordinating Assembly of Non-Governmental Organizations

COC - Combined Oral Contraceptives

DMPA - Depot Medroxy Progesterone Acetate

DSMB - Data Safety Monitoring Boards

ECCRU - Effective Care Research Unit

ECHO - Evidence for Contraceptive Options and HIV Outcome

FP - Family Planning

GCAG - Global Community Advisory Group

GPP - Good Participatory Practice

HIV - Human Immunodeficiency Virus

ICW - International Community of Women with HIV

IUD - Intrauterine Device

KEMRI - Kenya Medical Research Institute

LARC - Long Acting Reversible Contraceptives

MEC - Medical Eligibility Criteria

MOH - Ministry of Health

MRU - MaTCH Research Unit

NET-EN - Noresthisterone Enanthathe

PrEP - Pre-Exposure Prophylaxis

SAMRC - South African Medical Research Council

SHIMS - Swaziland HIV Incidence Measurement Survey

SRH - Sexual & Reproductive Health

STIs - Sexually Transmitted Infections

UN - United Nations

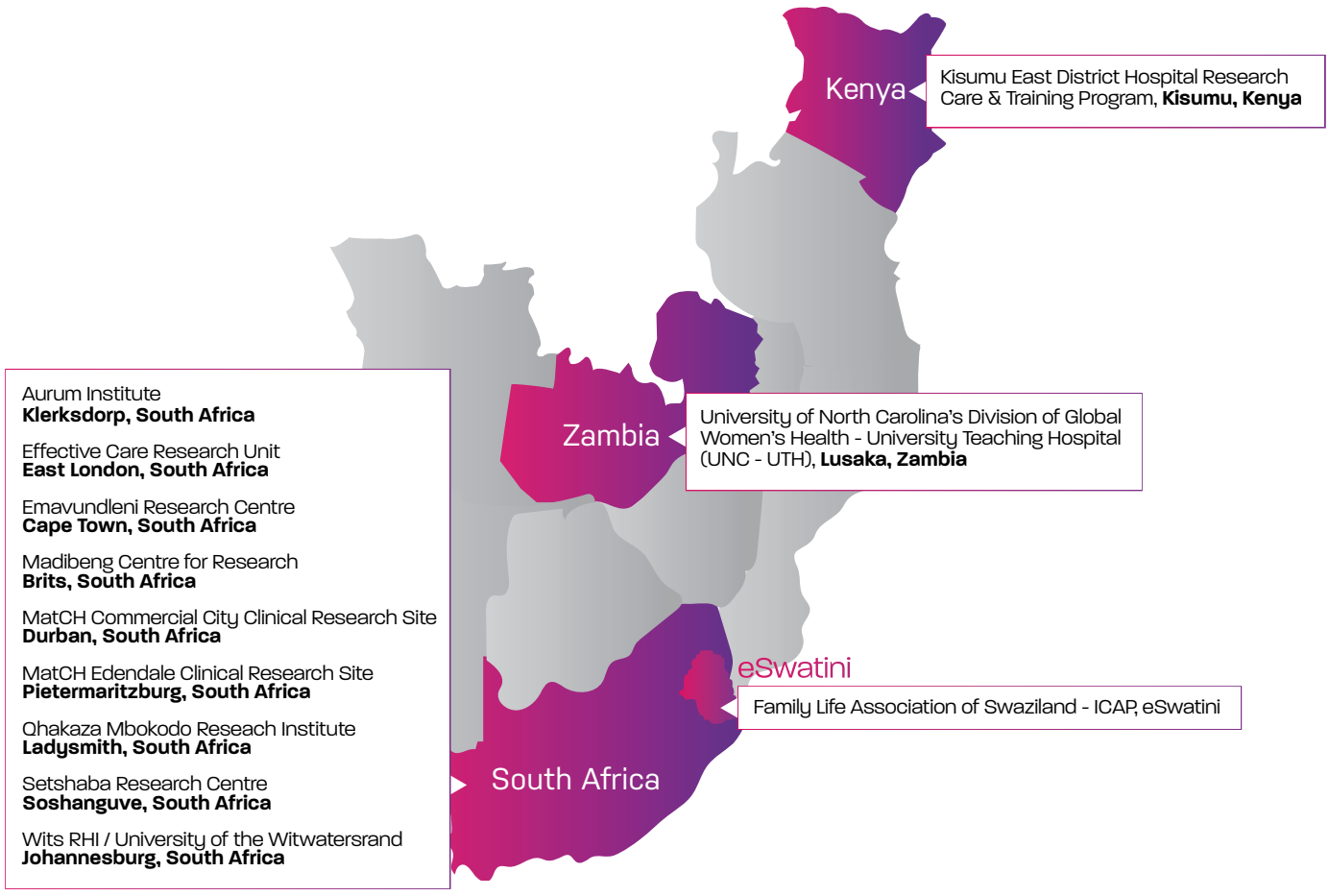
WHO - World Health Organization

Community dialogue objectives

The Contraceptive Options and HIV Outcomes (ECHO) Study held discussions with community representatives in each of its 12 research areas from March to June 2018. These community dialogues took place in the four countries where ECHO is being conducted: Kenya, eSwatini (formerly Swaziland), South Africa and Zambia. The dialogues were a response to the need for ongoing communication and understanding between researchers and community members as part of the ECHO Study's commitment to Good Participatory Practice (GPP). The ECHO team convened the dialogues in collaboration with ECHO's Global Community Advisory Group (GCAG), the International Community of Women with HIV (ICW) and AVAC through funding from the South African Medical Research Council (SAMRC) and AVAC. The purpose of the ECHO community dialogues was to strengthen working relationships between the clinical research sites and community stakeholders in preparation for study results dissemination. The objectives were to:

- Provide an overview of the ECHO Study rationale, design and update to community stakeholders on the progress of the study including emerging issues on hormonal contraceptives and HIV risk acquisition
- Discuss possible outcome scenarios for ECHO and policy and programmatic implications for the field
- Brainstorm and solicit the community's questions, interests and concerns – with the aim of these dialogues informing a responsive and pro-active study result dissemination strategy that takes community input into account in the preparation of message development around study results

Figure 1. ECHO Study sites in four countries (Kenya, eSwatini, South Africa and Zambia)



About this report

This report summarises the ECHO community dialogues convened from March to June 2018. It aims to brief the ECHO team and stakeholders about the discussions and inform the development of the broader strategy for disseminating the study results. The report was developed based on reports received from ECHO research sites and notes collected during the dialogues. It is organised around the objectives of the community dialogues.

Background

ECHO Study

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study is a multi-centre, open-label, randomised clinical trial comparing three highly effective, reversible methods of contraception—the progestogen-only injectable depot medroxyprogesterone acetate (DMPA), the two rod progestogen implant, Jadelle, and the copper IUD—to evaluate whether there is any difference in the risk of HIV acquisition among women using these methods. Now in its third year, ECHO has achieved important milestones, including reaching its recruitment target of 7800 sexually active HIV-negative women ages 16-35 across 12 trial sites in Kenya, eSwatini, South Africa and Zambia. In multiple scheduled reviews, the ECHO Study's independent Data Safety Monitoring Board (DSMB) has evaluated the safety and conduct of the study, commended the team for meeting its high performance standards and recommended that the study continue. Results are expected in 2019.

ECHO Community Dialogues

The ECHO community dialogues focused on fostering collaboration between the researchers and community stakeholders — those who have an interest in the conduct and outcome of the research and may be directly affected by the research. The key purpose of each dialogue was to develop ideas and plans for how best to share and disseminate the ECHO Study results at the community level and nationally. The dialogues covered a range of topics, from study-specific updates and the timing of data release, to an array of issues beyond the study, including the implications for national contraception guidelines and service provision.

About 473 women and men participated in community dialogues across the ECHO sites. The groups represented at the dialogues varied by country and sites, and included advocacy groups, civil society

organisations, health care providers, and members of each site's (See the table below). Some participants had engaged with the ECHO team before and were familiar with the study, but many others were new to the issues raised by the ECHO study.

Table 1. Participation in community dialogues across twelve sites

ECHO Country	Community Stakeholders	Total number of attendees
eSwatini	Ministry of Health Department of education Civil Society Organisations Local CABs Global CABs	52
Kenya	County and Sub-County Health Management Team (CHMT and SCHMT Civil Society Organisations Local CAB members Global CAB members	54
South Africa	Department of Social Development Department of Education Department of Health Ward Councillors Institutions of higher learning Civil Society Organisations Local CABs Global CABs	328
Zambia	Department of Health Zambia Police Force Department of Education Religious organisations Civil society organisations Local Cab members	39
	Total	473

The first community dialogue was convened at Wits RHI on 16 March 2018. This meeting served as a pilot, generating valuable lessons that helped improve the subsequent dialogues. For example, the original discussion did not include the national guidelines on contraceptives or background on the three methods of the study. These topics were added after we learned that attendees needed more information about hormonal contraception and the national guidelines to understand and participate in discussions about the ECHO Study and HC-HIV in general.

In Zambia and eSwatini, advocacy on hormonal contraceptives is at an early stage. In Zambia, community dialogues provided a forum to develop necessary understanding on HC-HIV-related issues and identify issues that advocacy groups can work on. In eSwatini, which is the only ECHO country that has specific communication guidelines on HC-HIV, the dialogue provided a platform for discussions between the ECHO team and Ministry of Health (MOH) officials. In Kenya, the dialogue was used to enhance ECHO Study awareness among sub-country health officials and civil society organisations and to strengthen advocacy on HC-HIV in local communities, in addition to preparing for results dissemination. During all nine dialogues in South Africa, the discussion focused on creating awareness of the ECHO Study and HC-HIV in general, as well as identifying opportunities to strengthen advocacy within local communities. ECHO community dialogues served as empowerment exercises. The feedback the team received from dialogue participants confirms that communities felt empowered on key research concepts and other issues related to the ECHO Study. For example, in eSwatini, community stakeholders realised that proper planning will require additional time and more awareness of the ECHO Study. Accordingly, a task force was established to prepare for results dissemination. In the same dialogue, participants identified platforms for strengthening awareness of the ECHO Study in all communities and especially

in communities where study participants were recruited. This process was beneficial not only to ECHO Study community stakeholders, but also to the ECHO team, because the recommendations will inform the development of a broader strategy for results dissemination.

GCAG involvement in the ECHO Study and Community Dialogues

The ECHO GCAG was established at the beginning of the study in 2015. The GCAG meets regularly to engage with the ECHO Study team about the conduct of the trial, share stakeholders' concerns and discuss how the broader issues related to HC and the possible link to an increased risk of HIV acquisition may affect the study. The GCAG consists of 16 advocates from six countries: Kenya, South Africa, eSwatini, the United States of America, Zambia and Zimbabwe. The achievements associated with the GCAG's involvement in the ECHO Study include:

- Articulating and providing advocates' perspectives on the broader array of questions and issues around HC-HIV that impact but are not directly related to the ECHO trial, including Sayana Press (SP), the World Health Organization (WHO) Medical Eligibility Criteria (MEC) guidance of 2017 (see page 11), and the Mexico City Policy

- Advocating for human rights within the conduct of the trial, including the right to information and access to additional HIV prevention tools such as Pre-Exposure Prophylaxis (PrEP)

The GCAG's involvement in the community dialogues began with the review of the initial proposal and the presentations. In some dialogues, GCAG members actively participated by facilitating the session on 'What we know and what we still need to know about hormonal contraceptives.' This session provided community members with background information on hormonal contraceptives and feedback from the civil society forums on HC-HIV that the GCAG had convened before the community dialogues:

Civil Society Forum, Kenya

Methodology

Approach

The community dialogues were delivered through a participatory approach, which included structured presentations, question & answer sessions, and group discussions on possible scenario planning. The dialogue participants were encouraged to share and draw from their own experiences with study results dissemination. In most of the dialogues, the facilitators were the ECHO community liaison officers (CLOs), who understand the communities, speak the local languages and have gained the trust of community members.

Duration

In Kenya, South Africa and Zambia, each dialogue was held on a single day and comprised of plenary discussions and interactive activities aimed at promoting open discussion. In eSwatini, the dialogue was designed for half a day.

Presentations

Presentations on the following topics were given at each community dialogue:

- What we know and what we still need to know about HC-HIV
- ECHO trial design and community stakeholder engagement
- Stakeholder engagement towards study results dissemination

Discussions and key findings

Although the agenda was standard for all community dialogues, the issues discussed differed by country. For example, the dialogue in eSwatini focused on the trial design, the role of GCAG in the ECHO Study, scenario planning and stakeholder engagement towards study results dissemination. Discussions at the dialogues in Kenya, South Africa and Zambia also addressed the broader contraceptive landscape in those countries.

Summary of opening remarks

Staff at ECHO research sites identified speakers to provide opening remarks and asked them to address specific topics. For example, Prof Justus Hofmeyr, the principal investigator (PI) at the ECRU sites in Mdanstane, East London, presented the historical background on contraceptives in Mdanstane to highlight how clinical research has contributed to improved access to effective contraception. In his opening remarks, Prof Hofmeyr explained that:

> Before 2005, the copper intrauterine device (IUD) was not available in the public health services in East London. Contraceptive uptake was poor, and about 4000 pregnancy terminations were performed each year at Frere and Cecilia Makiwane hospitals. A survey conducted by the ECRU indicated that about two-thirds of births were unintended pregnancies. In 2005, ECRU initiated a program to improve contraceptive uptake ('Expanding Contraceptive Health Options'). The unit motivated for procurement of the copper IUD by the health services and initiated IUD training with

the assistance of Dr PM Shweni. ECRU is one of the nine sites implementing ECHO Study in South Africa.

In eSwatini, Dr. Njabuliso Michael Lukhele of the MOH underscored the significance of quality evidence in his opening remarks:

"It is the first time the country conducts a randomised control trial and looking forward to the findings of this high-quality study. The Ministry of Health values high-quality evidence, which it uses as a tool in achieving its mandate of assuring attainment of the highest possible level of health by all people in eSwatini. Research and the evidence it yields are critical elements for improving global health and health equity, as well as economic development".

What we know and what we still need to know

The presentation on what we know and what we still need to know was delivered by the site PIs or a GCAG member, depending on availability. These presentations provided historical background on hormonal contraceptives and the risk of HIV acquisition, including early and current evidence as well as debates on how to interpret the observational data. They highlighted that we know that some observational studies have shown an association between DMPA use and HIV prevalence that DMPA is the modern method of contraception most widely used by among women in southern and eastern Africa and there is unmet need and limited contraceptive choice in the region. At the policy level, the WHO MEC guidance stipulate that women may use progestogen-only injectables but should be advised about concerns that these methods may increase the risk of HIV acquisition, the uncertainty over whether DMPA use causes increased risk and how to minimise the risk of HIV. It was emphasised that there is uncertainty about the DMPA and HIV link and a lack of data on whether using an IUD or a contraceptive implant affects women's risk of HIV.

In the discussions that followed many of these presentations, participants highlighted the potential for but still fragmented nature of advocacy on HC-HIV and related issues. The ECHO Study was seen as an opportunity to strengthen advocacy on HC-HIV in southern and eastern Africa. Participants noted that advocacy on HC-HIV is currently dominated by scientists and involves few advocates, especially in local communities. It was emphasised that advocates need to be viewed as important partners in disseminating study results, as they serve as a bridge between scientists and civil society. Issues for advocacy were identified and discussed (see Appendix 1).

Summary of dialogue objectives and key issues raised

Objective 1:
Overview of the ECHO Study, including emerging HC-HIV issues

The presentations on the ECHO trial design were delivered by either site principal investigators (PIs) or study coordinators (see Appendix 1, ECHO trial design). The familiarity with the issues varied, however ECHO community stakeholders have been engaged on ECHO trial design since the beginning of the study. The presentations focused on the ECHO Study rationale, objectives, population and current status, including enrolment and retention.

Question and Answer (Q&A) Sessions

Community dialogue participants asked a number of questions based on the presentations on trial design. Some of the most common questions and a summary of the responses are as follows:

Q: Why were males not included in the study design?

A: ECHO was designed for women only, because the study contraceptive methods are women-specific and in most cases, women are the ones who seek family planning services. ECHO respects each woman's right to decide whether to inform her partner about her participation in the trial. Male partners who were informed were included in the study, by participating in activities such as Sexual and Reproductive Health Month events where ECHO sites provided information on Sexual & Reproductive Health (SRH) issues and health testing,

including testing for sexually transmitted infections (STIs). In addition, community engagement activities were conducted for men, especially in July (men's month in South Africa). Participants were invited to sessions and encouraged to bring their male partners.

Q: Do members of the ECHO team encourage participants to use condoms, and are there arrangements to avail oral PrEP to study participants who are willing to use it beyond the study?

A: Study participants are counselled on the use of condoms during each visit and are offered free male or female condoms; however, actual condom use remains an individual choice. They are also offered oral pre-exposure prophylaxis (PrEP) on site or through referrals. ECHO sites have established memoranda of understanding (MOU) with PrEP providers to whom study participants can be referred, where permitted by country guidelines, so they will be able to continue accessing PrEP beyond the ECHO Study.

Q: What were the age-related inclusion criteria?

A: The protocol allowed women ages 16 to 35 to enrol, with some limitations. A woman who was 16 or 17 must have been pregnant at least once in order to enrol in ECHO. In general, women under age 18 were required to have parental consent in order to enrol. However, in Kenya, if a participant was 16 or 17 years of age and had previously been pregnant, she was considered a legally 'emancipated minor' and was able to consent for herself, without her parent's or guardian's consent.

Q: Have there been cases of HIV seroconversion, and what happens if a study participant seroconverts during the study?

A: ECHO researchers do their best to reduce each participant's risk by providing condoms and HIV prevention counselling. Even so, because the rates of HIV are high in their communities, some women are likely to acquire HIV during the study period. If a participant seroconverts, site staff provide counselling and psychological support and refer her to local HIV care providers for ongoing care, including assessment of CD4 cell counts and antiretroviral treatment according to local guidelines. All participants are asked to remain in the study until completion of the follow-up period. This gives HIV-positive participants the opportunity to continue receiving services at the clinical site and allows researchers to continue collecting data relevant to the additional study questions.

Q: Does the study team record side effects, and what is going to happen beyond ECHO to participants who experience side effects related to the study products?

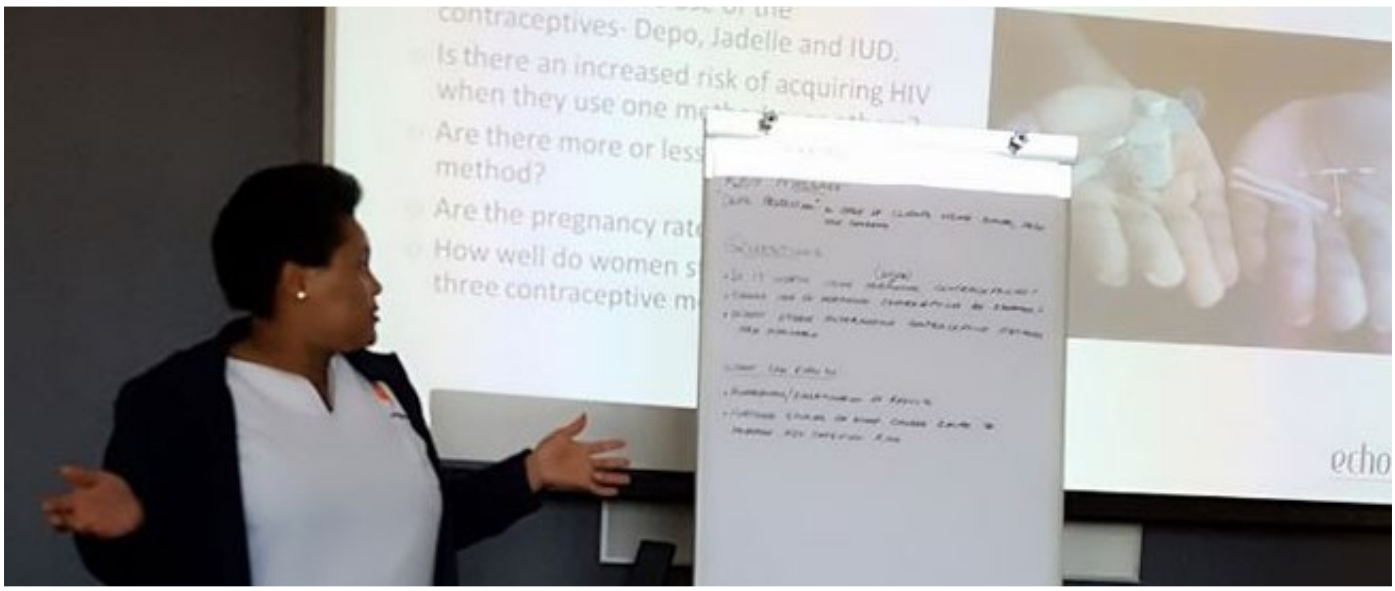
A: When participants come for the visits, they are interviewed and all responses, including any information about side effects, are recorded. Providers have been trained in helping participants manage side effects. After the ECHO Study, referrals to public clinics are arranged.

Q: Are local clinics ready to take over the responsibility of servicing contraceptive users from the ECHO Study?

A: Arrangements are being put in place with local providers to ensure all participants will be able to have Jadelle removed. These are explained to participants on their final study visit. This response led to a lengthy discussion on structural challenges related to removing Jadelle. Participants reported that very few nurses are trained to remove Jadelle, and public health facilities do not have sufficient instruments for inserting and removing Jadelle.

Objective 2:
Discuss possible outcome scenarios for ECHO and their potential policy and programmatic implications.

The scenario planning exercise during the community dialogues was the first step of preparation for study results dissemination at site level. Its purpose was to explore community perspectives on possible ECHO Study results.



Based on two possible results scenarios, participants were divided into two groups and asked to anticipate questions from the community, begin developing key messages and plan the way forward. The feedback from these sessions, captured in each site's community dialogue report, will be used to develop Q&As for community members based on the two scenarios, in preparation for results dissemination in 2019.

The two scenarios discussed were as follows:

- If the study results establish that there is **any difference** in the risk of HIV acquisition among women using any of the three study methods
- If the study results establish that there is **no difference** in the risk of HIV acquisition among women using any of the three study methods

Preparing for a number of possible outcomes reduces the risk that you will be surprised. With good preparation, the members of your communications and management team will have discussed and determined key messages for every scenario. This enhances the likelihood that all team members and partners will have accurate information and will be able to share consistent messages about your results. Some teams even test the messages with groups of participants to assess the effectiveness of the messages. - *Communications Handbook for Clinical Trials (2014)*

Feedback on Scenario 1:
Any difference in HIV acquisition risk in women using one of the three study methods.

The groups that discussed the first scenario generated lists of questions community members might have if one of the methods were shown to have a higher risk of HIV acquisition and brainstormed messages to answer those questions. Many of the questions were about the conduct of the study, including how women were informed of the potential for increased risk of HIV acquisition and the support available to women who acquired HIV during the study period. Other questions were about safe options for contraception and access to safe and effective methods.

These groups also discussed actions that should be taken after results dissemination under Scenario 1. Their recommendations included the following:

- Community engagement focusing on educating women in communities about contraceptives
- Advocacy and counselling on dual protection
- Providing women with access to safe contraceptive options
- Provision of information about the available contraceptive methods

Feedback on Scenario 2:
No difference in HIV acquisition risk in women using one of the three study methods

The questions generated during discussions about Scenario 2 focused on the safety of current methods and how to expand the contraceptive method mix. Participants in several dialogues asked why the study had not been conducted sooner, what had raised concerns about the relationship between hormonal contraception and HIV, and what if the ECHO Study failed to obtain an accurate answer to the main research question. Generally, it was agreed that there would be less to do in this scenario, since the results would indicate no safety concerns. The action plans discussed emphasised community education, male engagement and training health providers to deliver an expanded mix of contraceptive methods and the need for continued dual protection.

Objective 3:
Brainstorm and solicit stakeholders' questions, interests and concerns, with the aim of informing a results dissemination strategy that is responsive to community input.

The stakeholder engagement discussions aimed to identify ways to strengthen partnerships with community stakeholders by highlighting sites' achievements and challenges, soliciting recommendations for addressing those challenges, and mapping implementable actions to prepare for dissemination of the ECHO Study results.

Since its inception, the ECHO Study has followed GPP guidelines, which stipulate that research communities need to be involved in the dissemination of study results. A results dissemination strategy must be designed to improve awareness of study-related issues and community health problems, foster the adoption of health-promoting behaviours and help the public acquire and execute health-related decision-making power. The proposed processes and principles for disseminating ECHO Study results (see page xx) will inform sites' dissemination strategies at the local level as well as the broader results dissemination strategy.

Achievements associated with the partnership with community stakeholders

This section highlights achievements associated with stakeholder engagement, challenges of stakeholder engagement at ECHO site level, opportunities within communities that the ECHO team can tap into during the planning, the dissemination of ECHO Study results and recommendations for strengthening stakeholder engagement and key principles to be considered during planning or actual ECHO Study results dissemination.

At the broader level, all sites agreed that the partnerships with community stakeholders have shifted communities' perceptions of the ECHO research sites, which are now viewed as health development facilities, while creating an enabling environment for recruiting and retaining study participants in the study. Sites' achievements in stakeholder engagement include:

- Increasing recruitment spaces and platforms for creating awareness of the ECHO Study and delivering community education on issues such as HIV prevention, contraception and STIs
- Establishing, maintaining and strengthening community relations
- Building rapport, mutual trust and enhanced research literacy

Challenges associated with the partnership with community stakeholders

Participants in the community dialogues also identified challenges associated with an effective partnership between the ECHO Study and community stakeholders and ways to address those challenges. Common challenges include:

- The CAB functioning in some sites remains weak. They do not report back to their constituencies, as a result, some critical local organisations are not aware of the ECHO Study
- Poor or lack of funding to community-based organisations, as a result, critical local stakeholders shut down
- The functioning of the CABs needs strengthening, including helping CAB members develop strategies for reporting back to their constituencies. At a few sites, CAB members need retraining in other important ECHO issues, such as understanding clinical trials in HIV prevention and the MEC change
- Sustaining relations with various community stakeholders as community-based organisations shut down due to lack of funding is a challenge to some of the sites

Opportunities towards effective ECHO Study results dissemination

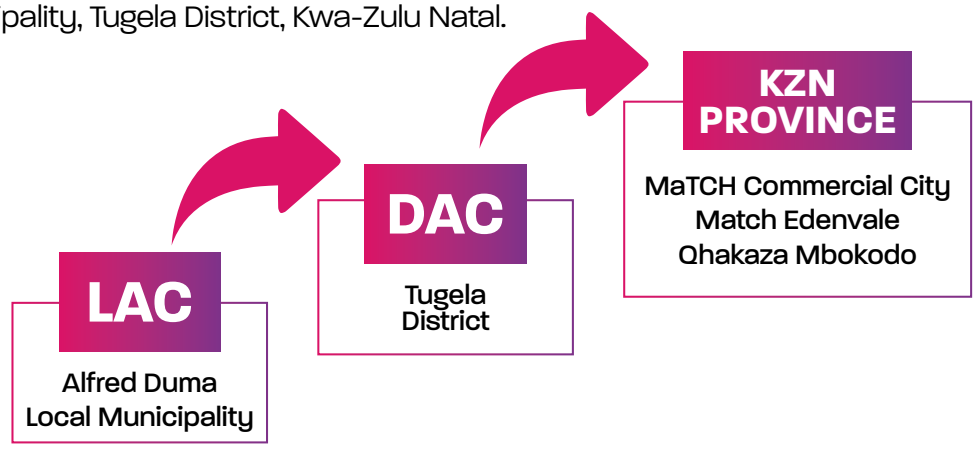
The dialogue participants agreed that since ECHO is a multi-site study, each site will develop its own dissemination plan using the standardised dissemination template within the GPP plan (see Appendix 5). This template is adaptable to respond to local needs and opportunities. The ECHO Community Education Working Group Forum will be utilised to share ideas on strengthening each site's plan. All sites based in South Africa will coordinate their dissemination plan activities at the provincial and national levels to ensure consistency.

Participants also identified community structures that could be used to disseminate ECHO Study results:

- **Municipality and AIDS Council structures within Tugela District, KZN**

  ECHO sites, especially those based in South Africa, already have existing community structures that serve as a communication bridge between community leaders and members. Using these structures to disseminate study results will render ECHO Study results credible in the community, and research sites will be seen to be conforming to community protocols. The following example (Figure 2) of such a structure was discussed during the community dialogue at the Qhazaka Mbokodo research centre in Ladysmith, South Africa:

  Figure 2: Community Structures for ECHO Study Results Dissemination in Alfred Duma Municipality, Tugela District, Kwa-Zulu Natal.

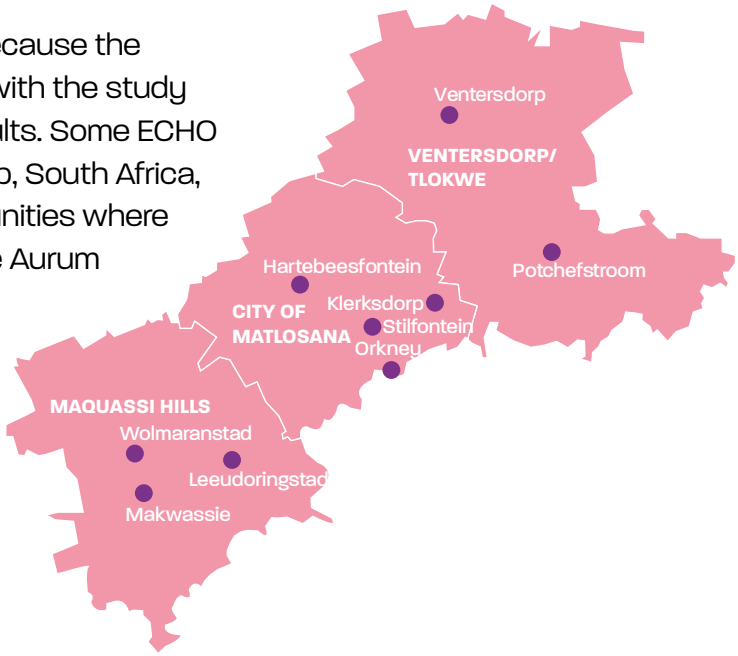


  QM will work with the Local AIDS Council (LAC) to disseminate study results in the Alfred Duma municipality. The LAC will then report to District Aids Council (DAC). Local municipalities establish LACs to develop, implement and monitor a coherent strategy and action plan to address HIV in local communities. DACs are the liaisons between the province and the LACs. All three sites based in Kwazulu-Natal (KZN) will collaborate on dissemination at the provincial level.

- **Communities where study participants were recruited**

  These communities present an opportunity, because the women in these communities may be familiar with the study and may be looking forward to hearing the results. Some ECHO sites, including the Aurum Institute in Klerskdorp, South Africa, intend to disseminate the results in the communities where they recruited study participants. Although the Aurum Institute recruited study participants mainly from Matlosana, some of the participants have moved to Tlokwe. The site's dissemination plan therefore proposes having dissemination events in Potchestroom in Tlokwel as well as Matlosana. However, these activities are subject to the availability of funds.

Figure 3:

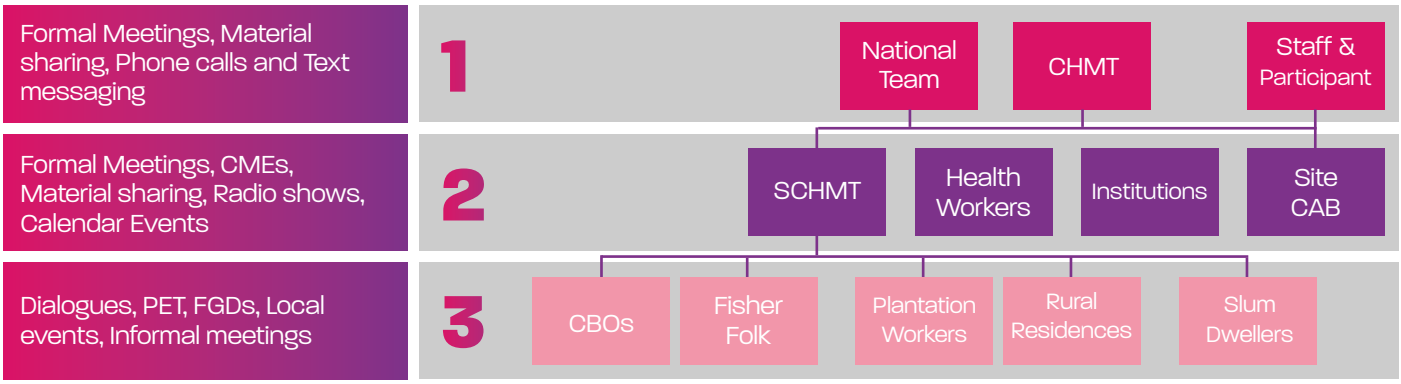


- **Monthly CAB Meetings**
  All ECHO sites convene monthly CAB meeting, amongst others, to discuss study updates. In preparation for results dissemination, CAB meetings should focus on identifying critical stakeholders who are not yet engaged and strengthening the capacity of CAB members in research literacy and other ECHO-related issues. QM, for example, plans to use CAB meetings to retrain CAB members on HIV prevention and the 2017 changes in the MEC guidelines.

ECHO Study results dissemination process

The following diagram illustrates the process for ECHO results dissemination discussed during the community dialogue in Kisumu, Kenya.

Figure 4: Example of a dissemination process from the KEMRI site in Kisumu, Kenya



The approach illustrated in the diagram is divided into three levels:

- Formal dissemination to the national health management teams (NHMTs) (mainly Ministry of Health), County Health Management Teams (CHMTs), staff, CAB members and study participants: This level consists of people involved in the study and the key personnel who will lead public utilisation of the study results.
- Semi-formal dissemination to the Sub-County Health Management Teams (SCHMT), health workers, other research institutions and civil society organisations operating in Kisumu: This level consists mainly of the community stakeholders that KEMRI have been working with since the beginning of the study.
- Informal dissemination through dialogues, focus group discussions (FGDs), local events and meetings.

The task force established in eSwatini to undertake planning for study results dissemination will follow the model developed when ICAP was disseminating the Swaziland Health Information Measurement Survey (SHIMS) results. It consists of eight individuals, including representatives from the MOH, civil society including CANGO, the ECHO team, the UNAIDS CAB members and two ECHO GCAG members.

This group will be responsible for drafting the site's dissemination plan, which will consider:

- How the team will make decisions
- How ECHO Study results will be released
- How study participants will learn about the results
- Required support (including from communication experts or ECHO CORE)

Recommendations for strengthening community stakeholder engagement

The recommendations for ECHO research sites to strenghten their partnerships with community stakeholders include:

- Pre-study results dissemination activities could be designed to create more awareness of the ECHO Study, including printing and widely distributing ECHO pamphlets in local languages to remind people about ECHO and what it seeks to find out. These meetings would also benefit community stakeholders who are new to ECHO
- Community education could be undertaken to help community stakeholders understand the public health implications of the ECHO Study and the research language likely to be used during the dissemination
- Further stakeholder mapping could target critical local stakeholders who have not been involved in ECHO activities, to strengthen the voice of local stakeholders. The suggestion was that, this could be done though face-to-face meetings giving potential stakeholders the opportunity to ask questions
- A workshop could be convened with community stakeholders to discuss their possible role during the study results dissemination
- ECHO research site team could ensure that all meetings are documented and could organise a face-to-face meetings with stakeholders who missed meetings, especially from municipalities to update them on what was discussed

Key Principles to be considered during planning or actual ECHO Study results dissemination

Participants in the community dialogues recommended that the dissemination of ECHO Study results be guided by the following principles:

- **Timing**

  Timing is an important consideration in the results dissemination plans. Each site will develop timelines, which will be updated regularly as the need arises. During the dialogues, it was emphasised that sufficient time must be allocated for study results dissemination, especially for study participants, to allow them time to ask questions. A suggestion from KEMRI was that counsellors need to be on standby to counsel participants. The study results should be released to study participants before or at the same time as the public announcement.

- **Place**

  Consider presenting the results at a central place accessible to local community members.

- **Local languages**

  As with the ECHO recruitment materials, the results should be translated into the 10 local languages spoken in the communities where the ECHO sites are located. In cases where such translation is impossible, the presenter needs to be able to explain the results and answer participants' or community members' questions in their local languages.

- **Creative strategies**

  Consider creative strategies for results dissemination, which might include drama and songs.

- **Tailored messages**

  Messages about the study results need to be tailored to suit different audiences, including young people. With the large numbers of young people using social media, social media will be a useful tool for getting the results to this population. The dialogues in two sites in KZN indicated that young people will need to be trained in research literacy and HC-HIV risk acquisition issues, ensuring that they are equipped to serve as peer educators, to assist with the dissemination to young people.

- **Responsible messaging**

  Based on two possible scenarios (see page 13), ECHO needs to develop responsible messages to ensure that women in communities have accurate information and to avoid unnecessary crises. The team must be prepared to dispel myths and correct misinformation about the study. An example cited was that a responsible message based on a scenario where ECHO Study results finds an association with HIV risk would be: 'This method increases the risk of getting HIV, but it does not cause HIV. Unsafe sex leads to HIV infection.'

- **Media engagement and monitoring**

  Media outlets have already shown interest in the subject of HC-HIV risk in general and in the ECHO Study specifically. Dialogue participants suggested that as part of the preparations for results dissemination, ECHO sites could make contacts with their local media houses and provide them with accurate information. The ECHO team will monitor media globally and locally (and across languages) during the weeks after the release.

Conclusion

Generally, feedback from participants in the community dialogues was positive. Most of the communities where the ECHO study is being conducted are familiar with clinical research; however, the dialogues also gave the study teams an opportunity to engage with stakeholders who were new to ECHO. The dialogues served to reduce mistrust between communities and researchers and strengthen the relationship between them by demonstrating the researchers' respect for the communities where ECHO is being implemented and the social value of the ECHO Study.

The focus of the ECHO Study is critical to women's sexual & reproductive health, especially in eastern and southern Africa, where the rate of HIV among women of reproductive age is high. These dialogues provided a platform for open communication on disparities between national guidelines and practice and improved communities' knowledge of challenges in contraceptive provision at both policy and operational levels.

The dialogues between the ECHO team and community stakeholders will inform the development of a broader strategy for results dissemination. Succinct recommendations were made about pre-study results dissemination activities to be undertaken, study results dissemination processes and principles upon which ECHO Study results dissemination should be based.

Appendix 1: Agenda for ECHO community Dialogues

Date:

Site:

Objectives:

- Review the aims and processes involved in HIV prevention clinical trials
- Provide an update on the ECHO Study, including rationale, design and study progress
- Discuss possible outcomes of the ECHO study, potential next steps following the ECHO Study and depending on the outcome; and brainstorm key issues and questions that stakeholders have about these possible different outcomes
- Discuss ways that trial sites, civil society and local stakeholders can prepare for the ECHO Study results, including any requested resources, possible activities or other key stakeholders to include in these efforts

Facilitator: CLO/ Study Coordinator

Time	Agenda	Responsible Person
08:30 - 09:00	Registration, Tea and Coffee	
09:00 - 09:30	Welcome, Introductions and Objectives of the community dialogues	PI/Coordinator
09:30 - 10:15	Overview of HC and HIV - What we know, What we don't know, What we need to find out	ECHO GPP CORE / or Site Leader (TBC)
10:15 - 10:45	Tea Break	
10:45 - 11:30	ECHO Study: Overview of ECHO trial design and progress to date Q & A with participants	PI/Coordinator
11:30 - 12:30	Preparing for ECHO study results (small group work) - Discuss possible outcome scenarios and implications - Questions for each scenario? - Next steps for ECHO, for the field?	GCAG
12:30 - 13:30	Lunch	
13:30 - 14:30	Report back to main group on each scenario and questions that arose from the small groups	CLO
14:30 - 15:15	Discuss and identify ways to collaborate with and keep local stakeholders engaged and informed about ECHO study progress, and prepare for possible questions from community members	CLO
15:15 - 15:30	Wrap-up. Evaluations and way forward	CLO

Appendix 2: Sexual Reproductive Health Issues for Advocacy

During discussions about advocacy on HC-HIV and related issues, participants in the community dialogues identified the following issues for ongoing advocacy:

The limited range of contraceptive options available at public health facilities in all four countries: Participants in the community dialogues in South Africa noted that the government made positive strides by revising the national contraceptive guidelines in 2012 to promote expanded method mix, dual protection and counselling to inform choice, but widespread disparities between the guidelines and practice persist.

Shortages of nurses trained in family planning, including family planning counselling: Participants in the dialogues in Zambia and in South Africa reported that counselling happens in a haphazard manner due to these shortages and other factors. In South Africa, some participants noted that family planning clients are usually in a hurry and sometimes refuse counselling.

Reproductive health services for youth are less than 'youth-friendly': Youth representatives at most of the dialogues raised concerns about 'youth-friendly corners' in public health facilities, saying that they are viewed as a source of stigma and the waiting periods are too long. Cultural and traditional beliefs about the provision of youth-friendly reproductive health services were cited as a barrier in all 11 dialogues.

Lack of knowledge about WHO's changes in the MEC for DMPA use by women at high risk of HIV: Although local nurses participating in eight of the nine dialogues in South Africa said they had received a communication from the MOH on the WHO MEC reclassification, many did not completely understand it" This lack of knowledge about the MEC change among health workers at the local level was viewed as violating women's right to information and against WHO's recommendations on the change, which centre around human rights principles of ensuring informed decision-making on contraception.

Difficulties with the provision and use of LARCs: When LARCs are available at public health facilities, uptake is often low because of low awareness, poor management of side effects and shortages of health providers trained to insert or remove devices such as Implanon, Jadelle and the copper IUD. Private providers offer a wider range of methods — but at a price that many women cannot afford. Many participants in all 12 dialogues believed that women prefer DMPA to other methods. Reasons cited include that it requires only four clinic visits a year and it offers privacy, so a woman can use it without the knowledge of her partner. Others thought that women do not favour DMPA, but use it because it is what they know and are given at their local clinics.

'When we go to clinics for contraception, we get bullied into DMPA or any other method available. If I request the pill, I get told no, don't go for the pill. You will forget— rather, take the injection."

— Participant in the community dialogue in Madibeng Research Centre"

ECHO Study Community Dialogue

ECHO Study design and progress to date

Outline

- Recalling the rationale for the ECHO Study
- Study objectives
- Study population
- Current status: enrollment and retention.

Recalling the rationale for the ECHO Study

- 25+ years of epidemiologic and biologic studies have tried to determine whether there is truly increased risk of HIV acquisition associated with use of hormonal contraception

Why the ECHO Study?

- There is evidence from observational studies that using of progestogen-only injectable methods — particularly (DMPA) — is linked with an increased risk of acquiring HIV infection
- However, we are still not sure about whether DMPA use actually causes increased risk
- Little research has been done on the use of Jadelle implants or the copper IUD and the risk of HIV.
- ECHO aims to answer this critical public health question of the possible risks (HIV acquisition) and benefits (pregnancy prevention) of three commonly used, effective contraceptive methods among women who desire contraception.

Current evidence

The World Health Organization (WHO) has reviewed the data on hormonal contraception (HC) and HIV in:

- The latest review took place in Dec 2016.
- The group reviewed all the evidence, including a new systematic review that showed a possible link between DMPA use and increased risk of HIV
- All evidence was OBSERVATIONAL – so it is unclear if the link is real or due to other factors.

ECHO Study Objectives

- Among women randomised to DMPA, LNG implants and copper IUDs, compare
  - pregnancy rates
  - rates of method-related serious adverse events
  - rates of method-related adverse events that result in method discontinuation
  - contraceptive method continuation rates.
- Explore
  - whether age modifies the hormonal contraception and HIV acquisition relationship
  - HSV-2 infection status on the relationship between contraception and HIV, and
  - Early HIV disease progression among seroconverters

ECHO Study Design

7,800 women wanting not to conceive and willing to be randomised

Randomise (1:1:1 ratio)

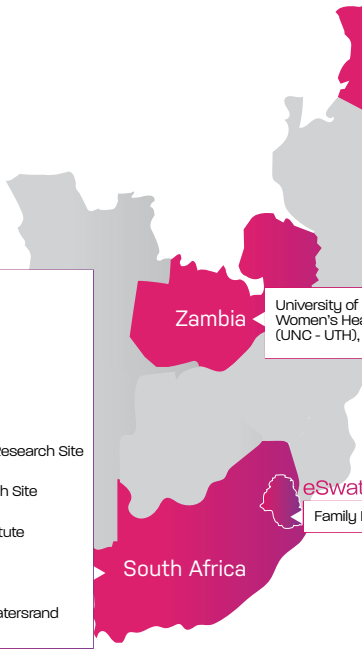
- **DMPA (2,600 women)**
- **LNG implant (2,600 women)**
- **Copper IUD (2,600 women)**

3-monthly visits for up to 18 months

Primary Endpoint: HIV Infection

Secondary Endpoints: Pregnancy, SAEs, Method Continuation

Study Setting



Kisumu East District Hospital Research Care & Training Program, **Kisumu, Kenya**

University of North Carolina's Division of Global Women's Health - University Teaching Hospital (UNC - UTH), **Lusaka, Zambia**

Family Life Association of Swaziland - ICAP, eSwatini

Aurum Institute
Klerksdorp, South Africa

Effective Care Research Unit
East London, South Africa

Emavundleni Research Centre
Cape Town, South Africa

Madibeng Centre for Research
Brits, South Africa

MatCH Commercial City Clinical Research Site
Durban, South Africa

MatCH Edendale Clinical Research Site
Pietermaritzburg, South Africa

Qhakaza Mbokodo Reseach Institute
Ladysmith, South Africa

Setshaba Research Centre
Soshanguve, South Africa

Wits RHI / University of the Witwatersrand
Johannesburg, South Africa

Why a randomized study?

- A randomised trial, if done well, will provide the highest-quality evidence
- High-quality evidence is needed to resolve the uncertainty in the field:
  - Provide clear guidance for policymakers and programs
  - Help formulate clear counselling messages for clinicians
  - Permit women to make fully informed choices

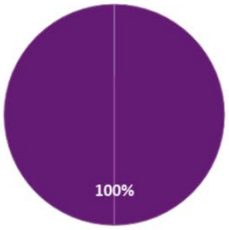
Study Population

The eligibility criteria included women who were:

- Sexually active
- HIV negative
- Seeking effective contraception
- Willing to be randomised to any of the study arms
- Ages 16-35 years old (16-17 if previously pregnant and at sites where adolescent participation in research is allowed by national regulations and ethics review approval)
  - Able and willing to provide written informed consent
  - Not having any medical condition that would make use of the contraceptive methods unsafe

Study progress

7,829
Women enrolled



100%
Enrolment target reached

2019
Study results expected

ECHO Team

ECHO Funders

Contraceptive supplies donated by USAID and the Republic of South Africa

Results Dissemination Plan

Results dissemination upon project completion is an important step in any community-based research. Researchers are also ethically obliged to ensure that the research findings, being either positive, negative or unclear, must be shared and disseminated to research participants, individuals, institutions, stakeholders and other groupings where research was undertaken.

*The (**insert the site name**) ECHO Study results dissemination plan and strategy is outlined below*

Audience	How	When	By Who	Materials	Budget Line Item
Internal					
External					

References

1. FHI360 (2014) Communication Handbook for Clinical Trials. Downloadable at: https://www.fhi360.org/resource/communications-handbook-clinical-trials-strategies-tips-and-tools-manage-controversy-co
2. Ondenge K, McLellan-Lemal E, Awuonda E., et al. Disseminating results: community response and input on Kisumu breastfeeding study. Trans Behav Med 2015;5(2):207-15
3. WHO (2017) Hormonal Contraceptive Eligibility for Women at High Risk of HIV: Downloadable at http://www.who.int/reproductivehealth/topics/family_planning/hormonal-contraception-hiv/en/