Civil Society Forum on 
Hormonal Contraception and HIV 
9 May 2018 
Ngong Hills Hotel, Nairobi, Kenya 

Report
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1. **Introduction**

Over 50 participants drawn from various organizations and comprising advocates, researchers, lawyers, young women, hormonal contraception users, representatives from the ECHO trial centers, health professionals and CAB members, attended the Kenya Civil Society Forum on Hormonal Contraception and HIV, on 9 May 2018.

The meeting’s primary objective was to engage stakeholders on issues related to hormonal contraception and HIV, including the ECHO trial, whose results are expected in 2019. Other objectives were to develop perspectives to share at the ECHO site-level dialogue, which took place in Kisumu on 11 May, and to identify next steps and needs for continued advocacy.

Agenda, Speakers’ presentations, and participants list are attached to this report.

Ms Inviolata Inviolata Mwali Mmbwavi of ICW-Kenya gave opening remarks. Prof. Peter Gichangi (Associate Professor, University of Nairobi, Visiting Professor, Ghent University, and Executive Director of ICRHK) then gave the Keynote address dealing with global perspectives on issue of HC and HIV, after which Ms Imeldah Wakhungu, Study Coordinator of the ECHO Kisumu site, updated the meeting on the study, with a site-level perspective.

In a recent meta-analysis (Polis et al., AIDS 2016), the injectable Depot Medroxyprogesterone Acetate (DMPA) was associated with a 40% increased likelihood of HIV acquisition, and ECHO study will shed light on whether the risk is real.

The ECHO study is comparing relative risks (HIV acquisition) and benefits (pregnancy prevention) of three common, effective contraceptive methods: DMPA, Levonorgestrel (LNG) implant, and the non-hormonal copper intrauterine device (IUD).
The randomized trial study started in December 2015 and will be concluded in October 2018. Currently 7830 women ages 15-35 are enrolled in 12 sites in Kenya, South Africa, Swaziland and Zambia. Performance metrics are excellent and the study has been well received by participants and the trial communities. The study is no longer enrolling new participants. Final results of the study are expected in 2019.

Prof Gichangi said the proportion of women using DMPA has increased, and there is limited data available for hormonal implants and IUDs with respect to HIV. Furthermore, African countries with high HIV rates also have high rates of women using hormonal contraception, especially DMPA which some people call Depo.

In Kenya, the ECHO study was reviewed and approved by the ethics review boards of FHI 360 (leading the study), KEMRI Ethics Review Committee and Kenya’s Pharmacy and Poisons Board.

Ms Wakhungu and Prof Gichangi emphasized the importance of the trial: By providing evidence, its findings will help clarify messaging for health care providers, policymakers, and women, as far as HC-HIV is concerned.

Ms Wakhungu said without the trial:
-If the HC-HIV risk actually exists, unnecessary infections will continue to occur.
-If the HC-HIV risk does not exist, policies and/or individual women’s choices may alter based on fear, with potentially serious negative consequences for maternal morbidity/mortality.

The ECHO consortium has a website where it posts updates for the public: [http://echo-consortium.com/](http://echo-consortium.com/)

2. **Popcorn Game: “What do we know/ think we know about hormonal contraception?”**

Participants were taken through the popcorn game, where they anonymously wrote their views. See Annex III for full responses, and a WordCloud representation on the image below.
3. Overall Recommendations and Comments from participants

All stakeholders need to be prepared for the results of the study which are expected in 2019. If the HC-HIV risk is found to be real, the results announcement may cause panic. The best approach for the results announcement would be:

- Feedback to the community
- Official statement to advocates and CSOs
- News to be publicized on mainstream and social media.
- Results announced at a site in one of the African countries which were involved in the study, at the same time as they are announced internationally.
- WHO to examine the data and evaluate results and implication of MEC changes if the HC-HIV risk is found. Countries will then decide the way forward.
- Guide researchers to do more research on other causes of HIV (more study sites)
- The research will make women make informed choices about contraception
- Disseminate it the facts to all relevant stakeholders, including women
- Use actual products of hormonal contraception when informing women in the community – ‘see and touch’ principle
- Dispel the myths and share the information with the community
- Develop a National-level dissemination matrix before the end of the study to educate people on how to prioritize, how to say, and where to say the results and develop key messages. Use examples from the VMMC study.
- Factor in the uniqueness of the countries and breakdown to the communities accordingly.
- Simplify the science for ease of understanding
- Support sensitization
- Carry out mobilization
- CHWs to give health talks in clinics e.g. as the media which has done well

In order to transition this information from this meeting, CSOs in this meeting can share information through their respective organizations.
4. **Key messages - who should disseminate?**

The CSO Forum recommended that the ECHO Study team should disseminate the findings through the research team to the National, County and Community level. The following should also pass on Key Messages about the ECHO study:

- Global Level – WHO
- Regional Level – African Union
- National Level – MOH (Duty bearers)
- County Level - MOH at the country level to sub-county level (Director of Health).
- Community level – opinion leaders (Churches, CHWs, CSOs, NGOs and Extension workers), as well as Community Health Volunteers (CHVs).

The media will cross-cut, and communication strategy should include social media.

Even if ECHO finds that none of the 3 methods increase the risk of HIV, the study needs to follow all the processes and the MOH needs to give policy direction. WHO will also need to give its direction guidelines.

**ECHO Scenario Outcomes**

<table>
<thead>
<tr>
<th>If ECHO finds that any of the methods increase the risk HIV</th>
<th>If ECHO finds that none of methods increases the risk of HIV</th>
<th>If ECHO has unclear findings on the risk of HIV?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the better methods women can use?</td>
<td>Continue with use of hormonal contraception – Around 60 percent of women in Kenya use Depo.</td>
<td>Fund research to continue the work further</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>What happens to women who become HIV Positive during the study?</td>
<td>These women will receive counselling. They will be referred to local HIV care providers for on-going care according to the National guidelines. And they will be advised to remain in the study until completion and continue receiving services and for collection of data relevant to the additional study questions.</td>
<td></td>
</tr>
<tr>
<td>What happens to women who become pregnant during the study?</td>
<td>The Participant will receive care or be referred for further care. She will be discontinued from her assigned method. She will remain in the study until completion for Collection of data on HIV acquisition. If the pregnancy ends before completion of study, the woman will be encouraged to resume her allocated method or any other method available at the clinic. It is also the participant’s choice to carry the pregnancy to term or terminate it, although they are told on the risks of abortion.</td>
<td></td>
</tr>
<tr>
<td>According to WHO, a HIV+ woman at an advanced stage should not use an IUD (Late stage HIV vs IUD), Why?</td>
<td>According to the WHO, a HIV woman at an advanced stage should not use an IUD; instead the person can use DMPA because infection easily finds its way to the uterus through the strings.</td>
<td></td>
</tr>
<tr>
<td>How will you interpret neutral results of the study?</td>
<td>If Neutral results are received, the team will go back to the data collected and do further analysis.</td>
<td></td>
</tr>
<tr>
<td>How was selection of the sites done?</td>
<td>Selection of the sites was done in relation to the incidence of HIV in the country</td>
<td></td>
</tr>
<tr>
<td>How will the results of the study be communicated?</td>
<td>The results of the study will be communicated by partners through a special dissemination model</td>
<td></td>
</tr>
<tr>
<td>If DMPA is withdrawn, how many pregnancies and infections will be expected?</td>
<td>Many unplanned pregnancies</td>
<td></td>
</tr>
<tr>
<td>Why did Kenya get only one site for the trial?</td>
<td>Kenya got only 1 site for the trial because funds allocated to research depend on research opportunities and HIV burden</td>
<td></td>
</tr>
</tbody>
</table>
| Supposing the results come out to 3, what next?                         | If the results come out to 3:  
  - The study needs to follow all the process  
  The MOH needs to give policy direction and WHO will also have its direction guidelines                                                                                                                                                                                                 |
<p>| Is there any other available contraceptive for women?                   | Yes - Copper IUD, Jadelle Implant, condoms, pills, and others                                                                                                                                                                                                                                                                               |
| Are there arrangements for dissemination of the results?               | In the Process                                                                                                                                                                                                                                                                                                                           |
| Why the number on trial enrolled?                                       | The size used (7800 women i.e. 2600 per study group) was in order to give the trial power to answer the research question.                                                                                                                                                                                                           |
| What microbicides are used at the site?                                 | -                                                                                                                                                                                                                                                                                                                                         |
| How will the findings in all sites be comparable, whereas socio-demographics are different? | All the countries and CSOs will be notified of the overall results                                                                                                                                                                                                                                                                       |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switching methods – how is it going to affect data/results</td>
<td>Clients may change methods of contraception at any given time during the study. Some participants may switch to another method after receiving counseling and treatment of any side effects. Women who switch methods will remain in the study and will be seen accordingly. Switching can affect the results by not getting clear data. But study cannot disclose the switching trends at the moment.</td>
</tr>
<tr>
<td>Misinformation about switching</td>
<td>There is misinformation/myths by both the church and community about side effects caused by contraceptives e.g. causes cervical cancer; this may affect women and cause them to switch</td>
</tr>
<tr>
<td>How does one qualify to join the study?</td>
<td>Women are assessed before enrollment if they have been using any contraception. They do not qualify for enrollment if they had been using PrEP for the last six months. Clients are given the right and proper information in order to embrace family planning.</td>
</tr>
<tr>
<td>Is PrEP part of the package or voluntary?</td>
<td>PrEP is being introduced as a package, women are assessed if they are fit to take PrEP and they can also choose when to take it.</td>
</tr>
<tr>
<td>Do participants below 18 years old need parental consent?</td>
<td>Clients 16-17 years who have had a pregnancy before are eligible and clients below 18 years who have not had pregnancy do not qualify.</td>
</tr>
<tr>
<td>Number on the study has risen. Why?</td>
<td>Enrolment in the study crossed the 7,800 intended enrolment number. Enrolment closed in September 2017. This in essence means clients/women have embraced family planning.</td>
</tr>
<tr>
<td>When are results going to be announced?</td>
<td>The results are going to be announced in 2019</td>
</tr>
<tr>
<td>Do you involve partners/men?</td>
<td>Partners are not involved but those clients living with partners are given time to discuss with their partners and come back with their final decision</td>
</tr>
<tr>
<td>From your observations, when do women get DMPA injections?</td>
<td>During Church days (Sundays) and Market days, because they are free on those days.</td>
</tr>
</tbody>
</table>
6. Afternoon Session

In the afternoon, the ECHO Scenarios presentation was made, and participants gathered in three groups, to discuss the scenarios, focus areas until the ECHO Results are released in 2019, and next steps. The below matrix captures those discussions.

### Group Discussion Key messages

<table>
<thead>
<tr>
<th>Key Messages we would like to have from ECHO study team</th>
<th>Who would we like to hear the messages from?</th>
<th>Who needs to take what action?</th>
<th>Support needed from ECHO Site and Trial Team</th>
<th>What we will offer the ECHO site and Trial Team</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group I: Civil Society reps</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
| By what percentage did the method increase the HIV incidence among women, in what age bracket and geographical area? | Globally from WHO, Regionally from the duty bearers, and at the National level from the MOH (Director of Health, NASCOP, NACC, county and community level). The community level will involve the NGOs, CSOs CHWs. | • Ministry of Health – to give policy direction or memo  
• WHO to give policy guidelines  
• CSOs (dealing with HIV and Family Planning to be charged with advocacy) | There must be consistent dissemination plan. Hold more of information meetings, decentralized dissemination meetings to break down the process of “science”. | Give inputs and facilitate meetings, mobilize stakeholders and develop key messages. |
<table>
<thead>
<tr>
<th>Key Messages we would like to have from ECHO study team</th>
<th>Who would we like to hear the messages from?</th>
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<th>What we will offer the ECHO site and Trial Team</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group II: Young People</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Best methods that are there</td>
<td>– Person from the community (fellow YOYO).</td>
<td>– To remove what is not working</td>
<td>– The research should improve the products</td>
<td>– Meaningful involvement of young people in</td>
</tr>
<tr>
<td>– It is optional, and women have the right to choose method</td>
<td>– Someone who has been involved in the research.</td>
<td>– Clear simple language and not</td>
<td>and bring a viable result to advocate for</td>
<td>disseminating results from the word go.</td>
</tr>
<tr>
<td>– Pros and cons of the contraceptives</td>
<td>– A peer who has used the method (testimonials)</td>
<td>a booklet; it should be</td>
<td>more improved contraception</td>
<td>– Advocate for male contraceptives and shift</td>
</tr>
<tr>
<td>– To give credible results that are relied on</td>
<td>– A peer who understands the language</td>
<td>colorful; inviting</td>
<td>Packaging of information should be</td>
<td>the research to male contraceptives</td>
</tr>
<tr>
<td>– Dual protection options (to prevent pregnancy and HIV)</td>
<td>– Someone who is not judgmental -- it will be more engaging to discuss it with the peer</td>
<td>Channels to be used e.g.</td>
<td>simple, clear</td>
<td>– Young people to develop an interest and</td>
</tr>
<tr>
<td>– Side effects of the contraceptives</td>
<td></td>
<td>whatsapp, twitter, broadcasting (media)</td>
<td>depending on where it is coming from (rural, urban)</td>
<td>participate in science research</td>
</tr>
<tr>
<td>– The information given should be definite</td>
<td></td>
<td>The IEC materials should be everywhere like billboards on the streets</td>
<td>– To mentor young people to conduct small research within their community that can inform the larger research</td>
<td>– Advocate for short term periods of research for other contraceptives that were not used in the ECHO study</td>
</tr>
<tr>
<td>Key Messages we would like to have from ECHO study team</td>
<td>Who would we like to hear the messages from?</td>
<td>Who needs to take what action?</td>
<td>Support needed from ECHO Site and Trial Team</td>
<td>What we will offer the ECHO site and Trial Team</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>--------------------------------------------</td>
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<td>---------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Group III: Scientists/Researchers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Discuss the objectives, methods and all protocols of the study</td>
<td>– Participants and stakeholders (from the National level to community level)</td>
<td>– Enhance the method of dual protection (condoms)</td>
<td>– The main challenge of disseminating the scientific findings is complex because of the inability to sustain the authenticity of information.</td>
<td>– Researchers should have a team to oversee how the findings are disseminated and how they are interpreted.</td>
</tr>
<tr>
<td>– Discuss how the risk came about; what was tested, site distribution, etc</td>
<td>– Who should be given information?</td>
<td>– Give clients other options</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– If the above was in order then the products will be reviewed</td>
<td>– In Scenario 1, assure that the study looked at all the scenarios</td>
<td>– In Scenario 1, Analyze country by country.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Need for seeking other options</td>
<td>– Disseminate information whether positive or negative</td>
<td>– Disseminate information whether positive or negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– The study ruled out all possibilities apart from behavior</td>
<td></td>
<td></td>
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</tbody>
</table>
# Annexes

## Annex I: Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.00 am - 8.30 am</td>
<td>Arrival and Registration</td>
<td>Petronilla Khamusali</td>
</tr>
<tr>
<td>8.30 am – 8.45 am</td>
<td>Opening and Welcome</td>
<td>Inviolata Mmbwavi</td>
</tr>
<tr>
<td>8.45 am – 9.00 am</td>
<td>Who’s in the room</td>
<td>Jacktone Hamisi</td>
</tr>
<tr>
<td>9.00 am - 10.00 am</td>
<td>Hormonal Contraception and HIV</td>
<td>Prof. Peter Gichangi, Director, ICRHK</td>
</tr>
<tr>
<td></td>
<td>Global Perspectives Discussion</td>
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</tr>
<tr>
<td>10.00 am – 11.00 am</td>
<td>Hormonal Contraception and HIV:</td>
<td>Jacque Wambui</td>
</tr>
<tr>
<td></td>
<td>Civil Society Perspectives Popcorn Activity</td>
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<tr>
<td></td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>11.00 am – 11.30 am</td>
<td>Tea/coffee/Health Break</td>
<td></td>
</tr>
<tr>
<td>11.30 am – 12.00 am</td>
<td>The ECHO Trial</td>
<td>Imelda Wakhungu, ECHO Study Coordinator (Kenya)</td>
</tr>
<tr>
<td></td>
<td>(With special reference to Kenya)</td>
<td></td>
</tr>
<tr>
<td>12.00 – 1.00 pm</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>1.00 pm – 2.00 pm</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>2.00 pm – 4.00 pm</td>
<td>Scenarios Presentation</td>
<td>Consolata Opiyo, Jacque, Team</td>
</tr>
<tr>
<td></td>
<td>What have we heard</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What are our focus areas until the ECHO Results are released in 2019?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Next Steps</td>
<td></td>
</tr>
<tr>
<td>4.00 pm – 4.30 pm</td>
<td>Tea/Coffee/Health Break</td>
<td></td>
</tr>
</tbody>
</table>
# Annex II: List of Participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Organization</th>
<th>Email</th>
<th>mobile</th>
<th>Home Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Agneta Adero</td>
<td>AGYW Ambassador</td>
<td>Learn Ambassador</td>
<td><a href="mailto:akothagneta92@email.com">akothagneta92@email.com</a></td>
<td>070315419</td>
<td>Homabay</td>
</tr>
<tr>
<td>Mr Aghan Daniel</td>
<td>Secretary</td>
<td>MESHA</td>
<td><a href="mailto:aghan@meshakenya.org">aghan@meshakenya.org</a></td>
<td>0728279966</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Anastasia Kendi</td>
<td>AGYW Advocate</td>
<td>Sauti Skika</td>
<td><a href="mailto:annastaciakendi@email.com">annastaciakendi@email.com</a></td>
<td>072492450</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Angeline Olou</td>
<td>Advocacy Officer</td>
<td>ITPC EA</td>
<td><a href="mailto:ochieng.aochieng.anjeline837@email.com">ochieng.aochieng.anjeline837@email.com</a></td>
<td>073346726</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Belianne Onyango</td>
<td>AGYW Ambassador</td>
<td>Learn Ambassador</td>
<td><a href="mailto:belianauma@email.com">belianauma@email.com</a></td>
<td>070139322</td>
<td>Homabay</td>
</tr>
<tr>
<td>Ms Carol Nyadat</td>
<td>Executive Director</td>
<td>KMET (Kisumu Medical and Education Trust)</td>
<td><a href="mailto:carol@kmet.co.ke">carol@kmet.co.ke</a></td>
<td>072182526</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Ms Caroline Njoroge</td>
<td>Program coordinator</td>
<td>KESWA</td>
<td><a href="mailto:caroln170@email.com">caroln170@email.com</a></td>
<td>072998787</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Dr Charles Muga</td>
<td>Behavioral Scientist</td>
<td>KEMRI-RCTP</td>
<td><a href="mailto:ctmuga2002@yahoo.com">ctmuga2002@yahoo.com</a></td>
<td>072215696</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Consolata Opiyo</td>
<td>AVAC Fellow 2018</td>
<td>ICW-Kenya</td>
<td><a href="mailto:o_consolata@yahoo.com">o_consolata@yahoo.com</a></td>
<td>071865123</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Daisy Ouya</td>
<td>Communications Advisor</td>
<td>AVAC</td>
<td><a href="mailto:douya@avac.org">douya@avac.org</a></td>
<td>708159934</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Dalphine Kemunto</td>
<td>Regional Coordinator</td>
<td>Marie Stopes Kenya</td>
<td><a href="mailto:daphokioms@gmail.com">daphokioms@gmail.com</a></td>
<td>072947712</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Ms Diana Ondato</td>
<td>Member</td>
<td>Lean on Me Foundation</td>
<td><a href="mailto:ondatodiana@yahoo.com">ondatodiana@yahoo.com</a></td>
<td>071650144</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Elizabeth Magero</td>
<td>Health Care worker</td>
<td>Nyarami VCT</td>
<td><a href="mailto:lizbena2010@gmail.com">lizbena2010@gmail.com</a></td>
<td>070362822</td>
<td>Migori</td>
</tr>
<tr>
<td>Ms Elizabeth Nasimiyu</td>
<td>Community Health Volunteer</td>
<td>Jitete Hope Givers Support Group</td>
<td><a href="mailto:nasimiyu73@yahoo.com">nasimiyu73@yahoo.com</a></td>
<td>070033282</td>
<td>Bungoma</td>
</tr>
<tr>
<td>Mr Eric Ayiera</td>
<td>Training Manager</td>
<td>Marie Stopes Kenya</td>
<td><a href="mailto:Eric.Ayiera@mariestopes.or.ke">Eric.Ayiera@mariestopes.or.ke</a></td>
<td>072890350</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Mr Ethel Makila</td>
<td>Director</td>
<td>IAVI</td>
<td><a href="mailto:emakila@iavi.org">emakila@iavi.org</a></td>
<td>070736795</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Mr Festo Owino</td>
<td>ECHO CAB</td>
<td>KEMRI</td>
<td><a href="mailto:festoowino@gmail.com">festoowino@gmail.com</a></td>
<td>072028413</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Name</td>
<td>Designation</td>
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<td>Ms Florence Awuor Okumu</td>
<td>Board Member</td>
<td>COPFAM</td>
<td><a href="mailto:floapina@gmail.com">floapina@gmail.com</a></td>
<td>0725968688</td>
<td>Migori</td>
</tr>
<tr>
<td>Mr Geoffrey Gumba Ochieng</td>
<td>Advocate</td>
<td>Lean on Me Foundation</td>
<td><a href="mailto:geoleanonme@gmail.com">geoleanonme@gmail.com</a></td>
<td>0724307471</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Mr Godfrey Okumu</td>
<td>Coordinator</td>
<td>NIGEE</td>
<td><a href="mailto:gokumu@nigee.org">gokumu@nigee.org</a></td>
<td>0723247287</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Ms Grace Muthoni Njuki</td>
<td>Coordinator</td>
<td>AYARHEP</td>
<td><a href="mailto:grace@ayarhep.or.ke">grace@ayarhep.or.ke</a></td>
<td>0722390635</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Grace Wanjiku Kamaa</td>
<td>Member</td>
<td>Sauti Skika</td>
<td><a href="mailto:graceykamau44@gmail.com">graceykamau44@gmail.com</a></td>
<td>708165897</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Imeldah Wakhungu</td>
<td>ECHO Study Coordinator</td>
<td>KEMRI</td>
<td><a href="mailto:iwakhungu@gmail.com">iwakhungu@gmail.com</a></td>
<td>0726605720</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Ms Inviolata Mmbwavi</td>
<td>National Coordinator</td>
<td>ICW-Kenya</td>
<td><a href="mailto:involom@yahoo.com">involom@yahoo.com</a></td>
<td>0722749603</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Irene Choge</td>
<td>Communications Officer</td>
<td>Jhpiego</td>
<td><a href="mailto:irene.choge@jhpiego.org">irene.choge@jhpiego.org</a></td>
<td>713765488</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Irene Wanjiru</td>
<td>Member</td>
<td>ICW-K</td>
<td><a href="mailto:mwangiirenawanjiru@gmail.com">mwangiirenawanjiru@gmail.com</a></td>
<td>726981354</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Mr Jacktone Hamisi</td>
<td>Community Liaison Officer</td>
<td>KEMRI</td>
<td><a href="mailto:jacktonehamisi@gmail.com">jacktonehamisi@gmail.com</a></td>
<td>0721830412</td>
<td>Kisumu</td>
</tr>
<tr>
<td>Ms Jacque Wambui</td>
<td>ECHO GCAG Member</td>
<td>NEPHAK</td>
<td><a href="mailto:jcqwambui@gmail.com">jcqwambui@gmail.com</a></td>
<td>0734668809</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Mrs Joan Ongere</td>
<td>ECHO Study Nurse</td>
<td>KEMRI</td>
<td><a href="mailto:auwojoan@yahoo.com">auwojoan@yahoo.com</a></td>
<td>0720416131</td>
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</tr>
<tr>
<td>Dr Johnstone Kuya</td>
<td>Coordinator</td>
<td>SRH Alliance</td>
<td><a href="mailto:Kuya@srhralliance.or.ke">Kuya@srhralliance.or.ke</a></td>
<td>0710630635</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Josephine Odoyo</td>
<td>Prep Implementor</td>
<td>KEMRI-Partner scale up</td>
<td><a href="mailto:orajosse@kemri.ucsf.org">orajosse@kemri.ucsf.org</a></td>
<td>0733276275</td>
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</tr>
<tr>
<td>Ms Juliet Akumu</td>
<td>ECHO GCAG/AGYW</td>
<td>Sauti Skika</td>
<td><a href="mailto:juliet.akumu09@gmail.com">juliet.akumu09@gmail.com</a></td>
<td>0717550345</td>
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<tr>
<td>Prof Kawango Agot</td>
<td>Director</td>
<td>Impact-RDO and NIGEE</td>
<td><a href="mailto:mamagifto@yahoo.com">mamagifto@yahoo.com</a></td>
<td>0736505046</td>
<td>Kisumu</td>
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<tr>
<td>Ms Laura Thuo</td>
<td>AGYW Advocate</td>
<td>ICW-Chapter of AGYW</td>
<td><a href="mailto:laurawangechi@gmail.com">laurawangechi@gmail.com</a></td>
<td>0715420956</td>
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<td>Ms Lucy Atela</td>
<td>Community Health Volunteer</td>
<td>Harambee Health centre</td>
<td><a href="mailto:atelalucy@gmail.com">atelalucy@gmail.com</a></td>
<td>070781733</td>
<td>Homabay (Ringa)</td>
</tr>
<tr>
<td>Ms Lucy Wanjiku Njenga</td>
<td>AGYW Advocate</td>
<td>PYWV(Positive young women voices)</td>
<td><a href="mailto:akirulucia@gmail.com">akirulucia@gmail.com</a></td>
<td>071985851</td>
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<tr>
<td>Ms Nelly Omwando</td>
<td>AGYW Advocate</td>
<td>ICW-Kenya</td>
<td><a href="mailto:nellyomwando@yahoo.com">nellyomwando@yahoo.com</a></td>
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<tr>
<td>Dr Nomthandazo Mbando</td>
<td>Project Manager</td>
<td>WITS-RHI</td>
<td><a href="mailto:Nmbandazayo@wrhi.ac.za">Nmbandazayo@wrhi.ac.za</a></td>
<td>+27113585</td>
<td>Johannesberg</td>
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<tr>
<td>Ms Patricia Asero</td>
<td>Vice Chair</td>
<td>ICW -Kenya</td>
<td><a href="mailto:dacasa2001@yahoo.com">dacasa2001@yahoo.com</a></td>
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<tr>
<td>Prof. Peter Gichangi</td>
<td>Executive Director</td>
<td>ICRHK</td>
<td><a href="mailto:gichangip@yahoo.com">gichangip@yahoo.com</a></td>
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<td>Ms Petronilla Khamusali</td>
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<td>ICW -Kenya</td>
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<td>Ms Rennah Anyango</td>
<td>Assistant CLO</td>
<td>KEMRI</td>
<td><a href="mailto:anyangorennah@gmail.com">anyangorennah@gmail.com</a></td>
<td>072793600</td>
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<tr>
<td>Ms Sandra Mhishi</td>
<td>Fellow</td>
<td>Waci Health</td>
<td><a href="mailto:sandra@wacihealth.org">sandra@wacihealth.org</a></td>
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<td>Ms Sharon Maurine</td>
<td>Student Leader - KIM College</td>
<td>Student</td>
<td><a href="mailto:shabanjisharon3@gmail.com">shabanjisharon3@gmail.com</a></td>
<td>079120274</td>
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<tr>
<td>Mr Stephen Anguva</td>
<td>Coordinator</td>
<td>Pamoja TB</td>
<td><a href="mailto:steveanguva@gmail.com">steveanguva@gmail.com</a></td>
<td>071419917</td>
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<tr>
<td>Ms Swinter Akumu</td>
<td>Member</td>
<td>ICW-K</td>
<td><a href="mailto:swinterokumu@gmail.com">swinterokumu@gmail.com</a></td>
<td>726022393</td>
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<tr>
<td>Ms Tabitha Saoyo</td>
<td>Deputy Executive Director</td>
<td>KELIN</td>
<td><a href="mailto:tsaoyo@kelinkea.org">tsaoyo@kelinkea.org</a></td>
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<tr>
<td>Ms Wambui Waithaka</td>
<td>Regional Technical Advisor:</td>
<td>JSI</td>
<td>wambui <a href="mailto:waithaka@ke.jsi.com">waithaka@ke.jsi.com</a></td>
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<td>INERELA-Kenya</td>
<td><a href="mailto:mawaiw@inerelakenya.org">mawaiw@inerelakenya.org</a></td>
<td>710599565</td>
<td>Nairobi</td>
</tr>
<tr>
<td>Ms Winnie Wadera</td>
<td>Community and Media Partnership Coordinator</td>
<td>Alice Visionary Foundation</td>
<td><a href="mailto:Winnie@alicevisionary.org">Winnie@alicevisionary.org</a></td>
<td>0727267340</td>
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### Annex III: Popcorn Game Results

**Responses to “What do we know/think we know about hormonal contraception”**

| Some studies showed that they expose women to HIV Risk | Hormonal contraceptives use forms of our bodies norms to prevent one from getting pregnant |
| Hormonal Contraception regulates different process in the body. | Prevent pregnancies |
| Hormonal contraceptives contribute a lot to spread of HIV/AIDS | Others have risks |
| IUD is not recommended for women/ladies with several partners | Improves fertility |
| What is hormonal contraception?: Changing the hormones of the body that regulates fertility to stop fertility | Breaks families because of side effects/misconception |
| Hormonal contraceptive are believed to deform women bodies | I think they should be used only to married people |
| Use of contraceptives for family planning | I know that hormonal contraceptives are family planning methods I need as sexually active wife that I really wish I did not need due to the grave consequences |
| Hormonal contraception | Contraceptives are great |
| Are among FP methods | They lead to infertility, Delayed conception, Hormonal imbalance |
| Regulate body hormones to control pregnancy | Can be complicated to women living with HIV especially those on second line |
| Hormonal contraceptives have positively affected our communities, but also a complain is raised that due to the influence of FP women have become promiscuous | The make ladies to expose themselves to me since they won’t get pregnant |
| Hormonal contraceptives are always perceived as methods that women use to prevent pregnancy, they may affect the overall emotions and weight of women | They can be effective to everyone (women) apart from coil, which cannot be used by women who have multiple partners |
| The trial in place is good for women. How I wish we consider those girls between ages 12-15, they give birth as well in their early ages. Some even have more than 2 kids and still under the care of their parents or guardians | Contraceptives are good. They have controlled the population; help us manage our family hence less stress |
| Hormonal contraceptives are methods to prevent contraception | Contraceptives save lives – prevent backstreet abortions |
| | Hormonal contraceptives are highly misunderstood by the community |
| | Hormonal contraception reduces maternal mortality |
| | Myth: They stop fertility, |
Empower women

Have Side effects

Come in the form of different methods

Hormonal contraception leads to higher rate of sexual exposure especially in youth or participants – 15-25 years of age. It leads to high spread of HIV because the participants only fear pregnancy but not HIV

Hormonal contraceptive is fit for all women except those who are positive and on Ritonavir (Haart)

If used for long, can cause infertility

They lead to infertility

One bleeds after putting them everyday

May lead to hormonal imbalance

They are substances that use initiated/taken, they change body hormone

Some of them can delay fertility – DMPA

You can get pregnant while on the hormonal contraceptives

I know is that they can cause high blood pressure

Increase weight

Safe family planning

What you know;

That there are several myths and misconceptions on hormonal contraceptives that need to be debunked:

Can cause cancer

Can make a woman give birth to abnormal child after use

Causes stretch marks

Used by women

There are different types

The IUD are not safe. They can easily come out of the uterus

If used for long, one can get a deformed baby/miscarry (this is about IUD)

There are lots of studies being carried out about the relationship between hormonal contraceptives to HIV

Main role is prevent pregnancy

Different kinds: Injectables, Pills, Implants

Have link to HIV infections

Influences user’s mood

Synthetic version of actual hormones, used to prevent contraception

Hormonal contraceptives are usually out of stock in Kenyan facilities

Hormonal contraception is good for birth control and very effective

They prevent pregnancy

They are irreversible

They cause amenorrhea

Irregular monthly periods

The do not prevent one from getting infected with HIV ad STIs

They are several i.e. IUD, DMPA, implants

Hormonal contraceptives refers to birth control methods that act on endocrine system

Almost all methods are composed of steroid hormones

Myth: They stop fertility
Annex IV Presentations
Hormonal contraception and HIV: What do we know, what do we need to find out

Session goals

• To share knowledge and opinions – this is a safe space – what do we know, hear, believe about hormonal contraception and its risks and benefits?
• To acquire, update and refresh knowledge – this is a learning space -- what does the current research say about hormonal contraception and HIV and what might we learn—and how?

What is hormonal contraception?

• Hormones are substances in our body that regulate and affect many, many different processes: growth, fertility, hunger, emotions – and much more.
• Hormonal contraceptives use synthetic forms of our bodies’ hormones to prevent us from falling pregnant
• There are many different kinds of synthetic hormones used in contraception these include: progestins, estrogins and others

What do we know or think we know about hormonal contraception

• Popcorn activity
What do we know about hormonal contraception and HIV risk

- For many years, there has been a question about whether some hormonal contraceptives affect women’s risk of getting HIV
- The greatest concern has been about contraceptives that contain a specific progestin (a synthetic form of progesterone). This progestin is found in the injectable known as DMPA or “Depo” or sometimes just “the shot”
- The evidence is mixed – some studies suggest that women who use DMPA are at higher risk of getting HIV than women who use other methods – but other studies do not

Why is the evidence mixed? In part because of where it comes from

We can choose our beliefs, not our facts

- The World Health Organization has, since 2016, classified DMPA and another progestin-only contraceptive, NET-EN, as having a “theoretical or possible risk” of increasing women’s risk of HIV
- There is no clear answer – right now, we do not know for sure.
- We may know soon, because of an ongoing trial called ECHO
- The goal of the rest of today is to talk about what we might do, depending on what ECHO shows
Update on the Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial

A Multi-Center, Open-Label, Randomised Clinical Trial Comparing HIV Incidence and Contraceptive Benefits in Women using Depot Medroxyprogesterone Acetate (DMPA), Levonorgestrel (LNG) Implant, and Copper Intrauterine Devices (IUD)

Prof Peter Gichangi
AVAC CSO meeting
Ngong Hills Hotel, Nairobi
May 9, 2018
ECHO Team

fhi360
UNIVERSITY of WASHINGTON

Selshaba Research Centre

In Search of Better Health

Global Women's Health

THE AURUM INSTITUTE

ICAP

MRU

Match Research Unit

University of the Witwatersrand

WITS RHI

UNIVERSITY OF THE WITWATERSRAND

University of the Witwatersrand


Mallman School of Public Health

Effective Care Research Unit

ICRH

Ohakaza Mbokodo Research Clinic

Ladysmith, KwaZulu Natal, RSA

Evidence for Contraceptive Options & HIV Outcomes
Overview

- Review of ECHO rationale, context, and design
- Status of ECHO
- Review of recommendations from November 2017 meeting
ECHO rationale, context, design
ECHO: overarching goal

To answer the pressing public health question of the relative risks (HIV acquisition) and benefits (pregnancy prevention) of three commonly-used, effective contraceptive methods among women who desire contraception.
Safe and effective contraception is essential to health and development of women, children, and families worldwide.
ECHO context and rationale

- Observational studies suggest that some contraceptive methods (particularly injectable methods, particularly DMPA) could increase HIV susceptibility in women. However,
  - data are not definitive,
  - policy has not changed,
  - alternative methods may/may not be better.

- 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
ECHO context and rationale

• In a recent meta-analysis (Polis et al., AIDS 2016), the injectable progestin depot medroxyprogesterone acetate (DMPA) was associated with a 40% (95% CI 1.23-1.59) increased likelihood of HIV acquisition

➢ In 2017, the WHO changed its guidance regarding use of injectable progestins for women at risk of HIV from a MEC category “1” to a “2” (condition for which the advantages of using the method generally outweigh the theoretical or proven risks)

• Norethisterone enanthate (NET-EN) is another injectable that might be similar or distinct from DMPA with respect to HIV; data to disentangle are being weighed

• Oral contraceptive pills appear not to increase HIV risk

• Limited data are available for hormonal implants and hormonal and non-hormonal IUDs with respect to HIV
# ECHO overview

**Design**  
Multi-center, open-label randomized trial

**Arms**  
Random allocation to: DMPA, levonorgestrel (LNG) implant, or copper IUD

**Population**  
Sexually active HIV-uninfected women, ages 16-35 years seeking highly effective contraception, willing to be randomized to any study arm

**Sample size**  
7,800 women (~2,600 per study group)

**Outcomes**  
Primary = HIV  
Secondary = pregnancy, SAEs, method continuation

**Follow-up**  
Up to 18 months per woman; M1 then quarterly visits; HIV prevention, contraception, and counseling

**Sites**  
12 sites in Kenya, South Africa (9), Swaziland, Zambia
ECHO: design power

- ECHO is designed with 80% power to rule out a 50% difference in incident HIV across each of the three potential comparisons:
  - DMPA vs. IUD  |  Implant vs. IUD  |  DMPA vs. Implant
    * Including adjustment for multiple comparisons

- The 50% difference was decided upon after extensive consultation with policymakers, researchers, community members, and other stakeholders – addressing an important effect, a doable trial, and a reliable answer.
ECHO design

7,800 women ages 16-35 wanting to prevent pregnancy and willing to be randomized

Randomize (1:1:1 ratio)

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

- **Ethical review** of protocol conducted prior to study start and annually IRBs/ECs at FHI 360, WHO, and each study site.

- The study is done to international **quality control and assurance standards**, and being reviewed by qualified **independent clinical monitors**.

- A **safety oversight committee** reviews safety data from all sites monthly and has 24/7 availability for clinical advice.

- A **Global Community Advisory Group** and **CABs** at each site meet regularly. Each site has an active **Good Participatory Practice** plan.

- An **independent DSMB** reviews data on participant safety, study conduct, and scientific validity and integrity of the trial approximately every 6 months.
Study visits

Study visits are at Month 1 and quarterly for up to 18 months:

- HIV testing (quarterly) and contraceptive counseling
- Brief questionnaires on behavior, symptoms, and related factors

All participants are provided a comprehensive contraceptive, HIV prevention, and HIV care package:

- Risk-reduction counselling, condoms, offer of partner testing
- STI screening and treatment
- Other prevention options (like PrEP and microbicides), as they become part of regular care
- HIV care plans for seroconverters
- Linkage to contraceptive services at the end of follow-up
ECHO status
ECHO current status in brief

- **Started** December 2015, **today’s data** are for visits through 30 January 2018
- **Open** at 12 of 12 sites
- **Enrollment** complete
- **Performance Standards** on track
Operational Metric #1: Accrual

• GOAL: Rate sufficient to achieve the target sample size within approximately 18 months of the first enrolment

• Where are we now?
  
  • ECHO enrolment is closed
    • Crossed 7800 on 29 August 2017
    • Closed to final enrolments on 12 September 2017
  • 7830 participants enrolled (7829 are followed)
Timelines
Timelines

- The trial SAP plans that all participants will have a minimum of 12 months of follow-up

- 7800 Aug ‘17
- DSMB Nov ‘17
- DSMB Mar ‘18
- Staged exits Q3 or Q4 ’18?
- Results late ‘18 / more likely early-mid ‘19
ECHO in summary

• The ECHO Study has completed enrollment at 12 sites in Kenya, South Africa, Swaziland and Zambia
• Follow-up is continuing and is on schedule.
• Performance metrics are excellent; the study has been well received by participants and in the trial communities
• Results from the trial will be highest quality evidence, and as a result:
  • Women will have highest quality information to make informed choices
  • Providers will have highest quality information for contraceptive counseling
  • Policymakers will have highest quality information about contraceptive risks and benefits for family planning programs
Contraceptive supplies donated by USAID and the Republic of South Africa.
THANK YOU

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study

More than 150 million women worldwide use modern methods of contraception for family planning. By enabling women to avoid high-risk pregnancies, these contraceptive methods help prevent hundreds of thousands of maternal and infant deaths every year.

There is evidence from observational studies that use of progestogen-only injectable methods — particularly depo-medroxyprogesterone acetate (DMPA) — is associated with an increased risk of acquiring HIV infection, but uncertainty remains about whether DMPA use actually causes increased risk.

The World Health Organization has determined that women at high risk of HIV infection may use DMPA because the benefits outweigh the possible risks, but that more research is needed. Data on whether use of contraceptive implants or IUDs affects HIV risk are also limited.

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study is designed to address this critical knowledge gap. Read more.

http://echo-consortium.com/
The Evidence for Contraceptive options and HIV Outcomes (ECHO) Study
KEMRI – RCTP Study centre, KISUMU
By Imeldah Wakhungu, ECHO Study coordinator

What is the ECHO Study?

The Evidence for Contraceptive options and HIV Outcomes is an open-label randomised clinical trial that will compare three highly effective, reversible methods of contraception to evaluate whether there is a link between use of any of these methods and increased risk of acquiring HIV infection.

Study approvals

- The study has been reviewed and approved by the ethics review boards of FHI 360 and KEMRI Ethics Review committee
- In addition, national regulatory authorities, including the Kenya’s Pharmacy and Poison Board, have been notified and have approved the study.

Kenyan Site Investigators

Investigators
Prof. Elizabeth Bukusi
Dr. Maricianah Onono
Dr. Stella Njuguna

Role
Principal Investigator
Co-Principal investigator
Co-Investigator

Sponsor
Bill and Melinda gates Foundation.

Coordinated by FHI 360
Background

- Women worldwide need family planning, and in Africa, the use of hormonal contraception, and especially Depo, provide women with a long-acting, reversible and safe option for birth control.
- More than 150 million women around the world use hormonal contraceptives.
- African women are at high risk of HIV.
  - 16 million women aged 15 years and older are living with HIV; 80% live in sub-Saharan Africa
  - Young women 15–24 years old in sub-Saharan Africa are twice as likely as young men to be living with HIV.

African countries with HIV prevalence also have high rates of women using hormonal contraception

- The reasons for this are unclear.
- There is confusing data about whether there is a link between using some contraceptives and an increased risk of contracting HIV.

Trends in the Use of Contraception-Kenya

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<td>3.5</td>
<td>2.8</td>
</tr>
<tr>
<td>IUD</td>
<td>7.3</td>
<td>7.2</td>
<td>6.0</td>
</tr>
<tr>
<td>Depo</td>
<td>2.9</td>
<td>2.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Ovulation inhibitors</td>
<td>2.4</td>
<td>2.1</td>
<td>2.0</td>
</tr>
<tr>
<td>Condoms</td>
<td>14.3</td>
<td>19.5</td>
<td>30.4</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>12.0</td>
<td>13.8</td>
<td>16.6</td>
</tr>
<tr>
<td>Other modern method</td>
<td>1.3</td>
<td>0.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Any traditional method</td>
<td>7.2</td>
<td>5.3</td>
<td>4.0</td>
</tr>
<tr>
<td>Abortion</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Oral medication</td>
<td>1.0</td>
<td>0.7</td>
<td>0.1</td>
</tr>
<tr>
<td>Male condom</td>
<td>1.9</td>
<td>1.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Not currently using</td>
<td>85.7</td>
<td>54.9</td>
<td>48.0</td>
</tr>
<tr>
<td>Total</td>
<td>198.3</td>
<td>165.3</td>
<td>165.0</td>
</tr>
<tr>
<td>Number of women</td>
<td>4,338</td>
<td>4,508</td>
<td>4,540</td>
</tr>
</tbody>
</table>

* The question did not specify male condom.

Current Use of Contraception Across Age Groups
Objectives

Primary objective
- To compare the risks of HIV acquisition between women randomised to DMPA, levonorgestrel (LNG) implants, and copper IUDs

Secondary and tertiary objectives
- Pregnancy, safety, contraceptive continuation

Why do we need the ECHO Study?

- For over 25 years, the world has lived with the uncertainty about whether or not use of hormonal contraceptives increases HIV risk.
- ECHO aims to answer this critical public health question of the possible risks (HIV acquisition) and benefits (pregnancy prevention) of the three commonly-used, effective contraceptive methods among women who desire contraception.

Purpose of the ECHO Study

When comparing women’s use of the contraceptives—Depo, Jadelle and IUD:

- Is there an increased risk of acquiring HIV when they use one method over the others?
- Are there more or less side effects of each method?
- Are the pregnancy rates the same?
- How well do women stay on each of the three contraceptive methods?

ECHO Study Schema

- Design: Multi-center, open-label randomized clinical trial
- Study arms: Random allocation to one of three study arms: DMPA, levonorgestrel (LNG) implant, copper IUD
- Population: Sexually active HIV-uninfected women, ages 16-35 years seeking highly effective contraception, willing to be randomized to any study arm
- Sample size: 7800 women (~2600 per study group), approximately 1000 women were to be enrolled at Kisumu site
- Study Sites: 12 sites in East and southern Africa
- Recruitment sources: Family planning clinics, post-partum and post-abortion, clinics, primary care clinics within Kisumu county and its environs
- Study Duration: Follow-up: 18 months per woman
  Total study duration of ~36 months
ECHO Sites
The study will take place at 12 sites across Eastern and Southern Africa, including sites in:
- Kenya - Kisumu
- South Africa
- Swaziland
- Zambia

Who can participate in the ECHO study
- Sexually active women 16-35 years old
- HIV negative and willing to be tested
- Seeking effective contraception
- Do not want to become pregnant for the duration of study participation
- Willing to be randomised to any of the three contraceptives being tested
- Willing to give consent to participate

Voluntary and confidential
- All information shared with trial staff will kept confidential.
- Women are asked to be honest at all times in their answers to staff.
- Participation is voluntary and women may leave the study at any time they wish.

Study products
- DMMA or Depo Provera
  - Most widely used progestin-only injectable
  - Given every 3 months as injection in arm
  - Return of fertility is often delayed, by a minimum of four months
- Jadelle Implant
  - Consists of two thin, flexible rods filled with synthetic progestin that are inserted just under the skin of a woman’s upper arm
  - Once inserted, lasts up to 5 years, although one can have it removed at any time
  - Rapid return to fertility once removed
- Copper IUD (Cu-IUD)
  - The copper-bearing intrauterine device (Cu-IUD) is a small, flexible plastic frame with copper sleeves or wire around it that is inserted in the uterus (womb)
  - Once inserted, lasts up to 10 years, although one can have it removed at any time
  - Return to fertility is immediate
How the study works

Recruitment and Enrolling in the Study

Potential participants have been invited to the trial site to learn about the study.

During initial visit, they learnt about the risks and benefits, and also about what is included in the visits (known as informed consent).

Women learnt about the 3 contraceptives being tested and asked if they were willing to use any of the 3 products.

Study groups

- When a woman enrols in ECHO, she will be randomly placed in 1 of 3 groups:

  (DMPA) Depo Provera
  Jadelle Implant
  Copper IUD (Cu-IUD)

- OR

- OR

Participants in all groups will be given the same standard prevention package (condoms, HCT, STI treatment)

The study groups, continued

- All women have an equal chance of being placed into each group.
- Neither she nor the staff can choose which product each participant will receive.
- Selection into a group is random, like rolling a dice.
- Once a participant is in a group, she will be encouraged to remain on her assigned method for the duration of the study.
Participant study visits schedule

- Screening visit
- Enrolment visit
- One-month follow-up visit
- Quarterly follow-up visits (at Month 3, 6, 9, 12, and 15 months)

What happens during study visits?

- Provide contraceptive counselling
- Provide HIV counselling and testing
- Ask questions about sexual behaviour
- Do a pregnancy test if needed
- Check health – for STIs and side effects to products
- Update contact information
- Schedule next appointment
- Give reimbursement for transport

What happens to women during the study who:

- Receive counselling
- Referred to local HIV care providers for on-going care according to the National guidelines
- Remain in the study until completion and continue receiving services
- Collection of data relevant to the additional study questions

Became HIV-positive

- Receive care or referred for further care
- Discontinue her assigned method
- Remain in the study until completion
- Collection of data on HIV acquisition
- If pregnancy ends before completion of study, the woman will be encouraged to resume her allocated method or offered a choice of any method available at the clinic

Become pregnant
What happens to women during the study who:

- Advised to come to the clinic to discuss her concerns and experience with the method
- Some women may wish to switch to another method after receiving counselling and treatment for any side effects
- Participants may change methods at any time during the study
- Women who switch methods will remain in the study and will be seen accordingly

Want to switch or stop contraception

Participants safety and monitoring

- An independent Data Safety Monitoring Board (DSMB), comprised of global experts in reproductive health and HIV will meet regularly (six monthly) to oversee the well being of participants.
- DSMB will review the data regularly (six monthly) to ensure the safety of participants and to determine if the study should continue.
- The study site investigators (PI) are responsible for continuous safety monitoring of all participants.

KEMRI-RCTP ECHO Current Status

- Completed Recruitment phase - Met target
- Participant follow up phase ongoing:
  - Active follow up
  - Study exit (at month 18)
- Data cleaning
- Stakeholder engagement for trial results

What If No Trial

- The observational evidence base is unlikely to improve
- Without a trial, messaging will continue to be challenging for providers, policymakers, and patients. Essentially:
  - If HIV risk exists in truth, unnecessary infections will continue to occur.
  - If HIV risk does not exist in truth, policies and/or individual women’s choices may alter, with potentially serious negative consequences for maternal morbidity/mortality
- **Women need accurate information to exercise informed contraceptive choices**
What role can you play?

- Continue to learn and ask questions about the ECHO Study whenever needed.
- Support women who choose to participate in the study.
- Dispel misinformation about the ECHO Study and research in general.
- Invite site team to talk in your community.

On-going Communication

- For more information about joining the ECHO study, please contact: Dr. Maricianah Onono at 0732390992
- For regular updates on the ECHO study progress and information related to hormonal contraceptives and HIV, please visit our website and sign up for our newsletter at: www.echo-consortium.com