WHO Technical Consultation on Hormonal Contraception and HIV: Where should we be with Policy, Programmes, and Research, on Family Planning/Contraception and - HIV Prevention and Care Services

Lusaka, Zambia

26 – 28 February 2019

Contents

Acronyms 3

Executive Summary 4

Background 8

Day 1: Tuesday 26 February 2019 8

Session 1: Welcome, introductions, Objectives 8

Session 2: Review progress and status of family planning research regarding hormonal contraception and HIV to explore strategies to address the gaps identified in research including implementation research. 9

Session 3: Progress and status of Family Planning policy and programmes regarding hormonal contraception and HIV. 11

Session 4: Review progress and status of family planning policy and programmes regarding hormonal contraception and HIV to explore strategies to address the gaps identified in programmes and policies including implementation research. 13

Sessions 5 and 6: To explore strategies to address gaps identified in programmes, policies and research, including implementation research. 16

Day 2: Wednesday, 27 February 2019 19

Session 7: Communication and counselling messages on HC and HIV 19

Session 8: Specific communication strategies for ECHO results 21

Session 9: Review and update on country readiness for ECHO trial results 23

Session 10: To identify priority actions on communication required in anticipation of the ECHO study results 24

Day 3: Thursday, 28 February 2019 26

Session 11: To develop country specific priority actions in anticipation of the ECHO study results 26

Session 12: Summary and conclusions 27

Annex I: Agenda 31

Annex II: Gaps identified in programmes, policies and research 35

Annex III: List of resources promoted at the Hormonal Contraception / HIV Consultation 42

Annex IV: Follow-up support offered at the Hormonal Contraception / HIV Technical Consultation . 44

Acronyms

AIDS	acquired immune deficiency syndrome
APHA	Advocates for Prevention of HIV and AIDS
ART	antiretroviral therapy
AVAC	AIDS Vaccine Advocacy Coalition
BMGF	Bill and Melinda Gates Foundation
COC	combined oral contraceptive pill
CSO	Civil Society Organisation
DMPA	depot medroxyprogesterone acetate
DMPA-IM	intramuscular depo medroxyprogesterone acetate
DMPA-SC	subcutaneous depo medroxyprogesterone acetate
DTG	dolutegravir
ECHO	Evidence for Contraceptive Options and HIV Outcomes
FP	family planning
HC	hormonal contraception
HIV	human immunodeficiency virus
IPPF	International Planned Parenthood Federation
IUD	intrauterine device
KEMRI	Kenya Medical Research Institute
LARCs	long acting reversible methods
LNG	levonorgestrel
MEC	medical eligibility criteria for contraceptive use
MoH	ministry of health
MSI	Marie Stopes International
Net-EN	norethisterone enanthate
NTDs	neural tube defects
PEPFAR	President's Emergency Plan for AIDS Relief
SIDA	Swedish International Development Cooperation Agency
SRHR	sexual and reproductive health and rights
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UPA	ulipristal acetate
USAID	United States Agency for International Development
WHO	World Health Organisation
WHO/AFRO	World Health Organisation Africa Regional Office
WHO/HIV/HQ	World Health Organisation HIV Department, Headquarters
WHO/RHR/HQ	World Health Organisation Reproductive Health and Research Department, Headquarters
WLHIV	women living with HIV

Executive Summary

Background

Providing clarity about the safety of hormonal contraceptive (HC) methods for women at risk of HIV and for women living with HIV is a public health priority. The World Health Organization (WHO) publishes the Medical eligibility criteria for contraceptive use (MEC), an evidence-based guideline informed by a continuous review of evidence, that provides recommendations on the safety of contraceptive methods for women with various medical conditions or personal characteristics, including recommendations for use of various contraceptive methods by women at high risk of HIV, women living with HIV, and women using antiretroviral therapy (ART).

The Evidence for Contraceptive options and HIV Outcomes (ECHO) Trial ECHO-trial compares the risks of HIV acquisition between women randomised to DMPA- IM, levonorgestrel (LNG) implant, and copper IUDs. Results from this study are expected in mid- July 2019, after which WHO will review the evidence and, if warranted, revise the MEC. To prepare for the release of the results, WHO convened a technical consultation to review progress, policies and programmes, and identify priority actions and communication messages. Representatives from countries and technical agencies were joined by experts to recommend actions for country and global stakeholders to undertake during three phases: prior to the release of the trial results (March-July); during the period while WHO Guideline Development Group reviews the body of evidence and evaluates to impact on its current recommendations (July-September); and following any revised recommendations (September onwards).

The participants affirmed several principles for action. First, policies, programmes and communications must keep women, and their priorities and rights, at the centre. Second, programmes should re- commit to informed choice through offering multiple contraceptive methods and clear information so women can choose and use a method based on their preferences. This commitment should emphasize integration of dual protection against unintended pregnancy and HIV. Finally, programmes and policies should continue to focus on safeguarding the health and rights of contraceptive users.

ECHO study

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study is an open-label randomised clinical trial that aims to compare three highly effective, reversible methods of contraception to evaluate whether there is any difference in the risk of HIV acquisition among women using these three methods. The study is also comparing side effects, pregnancy rates and women's patterns of use for the three contraceptive methods: the progestogen-only injectable depot medroxyprogesterone acetate (DMPA), a levonorgestrel (LNG) implant, and the copper intrauterine device (IUD). The study's overarching goal is to answer the pressing public health question of the relative risks (HIV acquisition) and benefits (pregnancy prevention) of these three commonly-used, effective contraceptive methods among women who desire contraception. ECHO enrolled 7,832 HIV-negative women aged 16-35 years in twelve sites in Kenya (1), South Africa (9), Swaziland (1) and Zambia (1). More information on the sites, implementation, oversight, community participation and other aspects of the study can be found at http://echoconsortium.com/echostudy-3/.

It is expected that ECHO will provide more robust evidence to support and guide individual, policy and programmatic decision-making on contraception for women at risk of acquiring HIV infection. WHO will incorporate the ECHO results into its review of the relevant MEC recommendations in the context of existing evidence. Given existing patterns of contraceptive use and HIV risk, any new guidance may have implications for country programs, especially in the sub-Saharan African region. Countries may also need to plan how best to differentiate actions and messages for individuals, populations and locations with distinct patterns of contraceptive use and HIV risk.

Country priority actions

There was consensus that specific actions will vary by country, however overarching areas within which countries should plan and respond to the ECHO study were identified as outlined below.

March – June 2019: Prepare for ECHO results release

i) Establish or strengthen a Task Team

Actions should be coordinated through an inclusive yet nimble country structure that can take initiative and act quickly. This 'Task Team' should use or build upon existing structures where feasible – for example a Technical Working Group – whilst ensuring membership includes a broad range of stakeholders such as the Ministry of Health, WHO, UNFPA, UNAIDS, FP2020, civil society organisations and research agencies. The membership should also include stakeholders with communications expertise.

ii) Develop and implement a roadmap

The Task Team will rapidly develop a roadmap that charts the key activities for preparing for the ECHO results release as well as what should happen once the findings have been released and after the WHO guidance has been updated. Whilst every roadmap will depend on the specific country context, it will be likely to include the following activities:

- Sensitizing policy makers and providers in preparation for release of the study findings
- Developing sub-national/regional plans for dissemination of the findings
- Scenario planning so can take a swift response if the findings show an increased risk of HIV acquisition for one or more contraceptive methods. This could include identifying who would be considered as high risk, what extra interventions are required, and what the associated programmatic implications would be.

iii) Prepare messaging and a communications plan

It is very important to ensure there is a timely, accurate, cohesive and coordinated dissemination of the ECHO study results that put women at the centre, and are framed within the broader context of FP and HIV prevention needs for women. In order to achieve this, the following actions should be taken:

- Develop communication messages which are clear, tested and tailored to different audiences. Beware of jargon when developing these messages. The key messages prior to the findings release could include: whatever the results of the trial, women's priorities and rights will be upmost; contraceptives do not prevent HIV; the government is committed to increasing method mix as no one method is suitable for everyone.

- Develop a plan for communicating these messages to different target audiences including healthcare providers, users and other constituencies.
- Prepare the media through giving trusted media outlets time and access just prior to the finding release, for example through a Media Cafe. If the first stories are correct, others will pick up on these stories, greatly increasing the chance of the right messages being promoted.
- Identify a focal person or persons on the 'Task Team' who can become the spokesperson/s for the ECHO trial at the country level. Ensure they are well versed in the ECHO trial itself and given media training if required. Also provide support and training to the official government spokespeople if necessary.

July – August 2019: Once ECHO results have been released

iv) Plan for actions in the period between the ECHO results and updated WHO recommendations

When the ECHO findings are released, WHO will issue a statement which provides recommendations for what countries should do in the interim before the updated WHO guidance is released. Actions will include:

- Promoting the actual findings and messages agreed above, responding swiftly to any misinformation that is circulating.
- Share the message (especially among colleagues in government) that updated WHO guidelines are forthcoming and the process to update national policy will be started once these guidelines have been released.
- Develop communications based on the WHO statement

September 2019 onwards: Once the updated WHO guideline released

v) If required, and if the recommendations are updated, incorporate updated recommendations into national policies and guidelines

Based on the ECHO findings and the updated WHO guideline and if the WHO MEC category change, and if relevant decision makers in a country feel a change is needed to existing policy, they should undertake the relevant process for reviewing and updating national policies/guidelines. Once updated, clear plans should be made to implement the policy including training and tool updates as required.

Ongoing actions

Regardless of the findings of the ECHO study, there are two important ongoing actions that all countries should undertake:

1. Improve family planning education and provision:

Family planning programmes in every country need continual investment and strengthening. The key areas where this strengthening can be focused include: expanding the method mix available at all primary healthcare points including long acting reversible methods such as the copper IUD and implant; training of providers in the provision of a broad range of modern methods – including improving the counselling provided; and eliminating commodity stock outs.

2. Improve the integration of HIV services within contraception services

Within any primary healthcare facility, a broad range of contraception and HIV services should be available from the same provider in the same consultation. A client should not have to queue twice

to receive these services. This includes HIV prevention services, condom provision, counselling on dual protection, and contraception services for women living with HIV.

Next steps

Action	Who leads	When
Share executive summary of the Lusaka meeting	WHO	8 March 2019
Brief supervisors and stakeholders on Lusaka consultation outcomes	Meeting participants	By 15 March
Convene working group to develop action plan	MoH, WHO	By 29 March
Implementation of action plan (1st phase – pre-results)	Working group	April – July
Webinar to follow-up on progress	WHO	By 25 April
Release of ECHO study results	ECHO research team	Mid-July
Implement action plan (2nd phase – post results and pre-guidelines)	MoH, WHO, CSO	July – Sept
WHO guideline review process	WHO	July – Sept
Implement action plan (3rd phase – post guidelines)	MoH, UNFPA, WHO	Oct onwards

Background

Providing clarity about the safety of hormonal contraceptive (HC) methods for women at risk of HIV and for women living with HIV (WLHIV) is a public health priority. The World Health Organization (WHO) publishes the medical eligibility criteria for contraceptive use (MEC). The MEC is an evidence-based guideline informed by a continuous review of evidence that provides recommendations on the safety of contraceptive methods for women with various medical conditions or personal characteristics. These include recommendations for use of different contraceptive methods by women at high risk of HIV, women living with HIV, and women using antiretroviral therapy (ART).

The Evidence for Contraceptive options and HIV Outcomes (ECHO) Trial compares the risks of HIV acquisition between women randomised to intramuscular depo-medroxyprogesterone acetate (DMPA-IM), levonorgestrel (LNG) implant, and copper intrauterine device (IUD). It is expected that ECHO will provide more robust evidence to support and guide individual, policy and programmatic decision-making on contraception for women at risk of HIV acquisition. WHO will incorporate the ECHO results into its review of the relevant MEC recommendations in the context of existing evidence. Given existing patterns of contraceptive use and HIV risk, any new guidance may have implications for country programmes, especially in the sub-Saharan African region. Countries may also need to determine how best to differentiate actions and messages for individuals, populations and locations with distinct patterns of contraceptive use and HIV risk.

Results from this trial are expected in mid-July 2019, after which WHO will review the evidence and, if indicated, revise the MEC. To prepare for the release of the results, WHO convened a technical consultation with representatives from countries, technical agencies and civil society, and experts to:

- Review progress and status of family planning policy, programmes and research regarding hormonal contraception and HIV
- Explore strategies to address the gaps identified in programmes, policies and research including implementation research
- Review communication and counselling messages based on WHO guidance on hormonal contraception and HIV its implications for research, programme and policy
- Identify priority actions and communication messages required in anticipation of the ECHO trial results

This report summarizes the key points and actions identified during presentations, discussions and group work.

Day 1: Tuesday 26 February 2019

Session 1: Welcome, introductions, Objectives

Representatives of WHO and the Ministry of Health Zambia welcomed participants including representatives from ministries of health in countries where HC use and HIV patterns are a concern; WHO representatives from headquarters, the African Regional Office (AFRO) and country offices; UNFPA; key organizations supporting family planning implementation and funding; ECHO trial investigators; experts on the science of HC and HIV; and civil society. Participants were charged with taking advantage of the expertise and perspectives available in the room to prepare for the ECHO results and any implications they may have for policies, programmes and people. They were also

reminded this consultation is one in a series of recent meetings on HC and HIV to review different aspects of science, research, policy and programmes.[1]

Session 2: Review progress and status of family planning research regarding hormonal contraception and HIV to explore strategies to address the gaps identified in research including implementation research.

In introductory remarks, session chair Helen Rees of the Wits Reproductive Health and HIV Institute noted that observational data has generated concern around the relationship between hormonal contraceptive use and HIV acquisition for some 25 years. Despite this concern the global health community was slow to develop – and fund – a randomised trial that could provide more definitive evidence. She attributed this in part to complacency around family planning and contraceptive technologies. Though they are the most common health technologies used by women, contraception attracts little private investment and relies on public funding to advance products and scientific understanding. She cautioned that similar complacency with respect to HIV will hamper any reduction in HIV incidence. ECHO provides an opportunity to address both HIV and contraceptive access and the critical relationship between them through the lens of women's rights.

Charles Morrison from FHI360 **reviewed the current progress and status of research on epidemiologic associations and biologic determinants of hormonal contraception and HIV acquisition**. Scientists have continued to analyse observational data on HC/HIV associations from individual studies and meta-analyses. Two recent large meta-analyses suggest that use of DMPA is associated with an increased risk of HIV acquisition of 40-50%, with this effect estimate consistent among studies. These meta-analyses do not show an increased risk of HIV acquisition among women using combined oral contraception or norethisterone enanthate (Net-EN). All of the data analysed are observational and as such have possible selection and confounding biases which meta-analysis cannot correct for. While the exact mechanism(s) of HIV acquisition in the female genital tract is unknown, evidence is increasing for potential pathways and the effects that contraceptive steroids may have on these pathways. Building this evidence base has been hampered by much of the evidence coming from secondary analyses of studies with diverse designs, though more studies are being designed with understanding biological mechanisms as the primary objective. Possible mechanisms of HIV infection, and known association to contraceptive hormones include: alteration of inflammation; alteration of cellular targets; alteration of the vaginal microbiome; and disruption of the cervico-vaginal epithelial barrier. There is little or no evidence for key questions on the potential implications for clinical recommendations, including comparative data on biologic determinants of HIV risk between DMPA delivered intramuscularly and subcutaneously. Many scientists believe that data supports disaggregating DMPA and Net-EN in contraceptive guidelines. Higher quality clinical studies are needed to disentangle the biologic determinants of risk among different progestins.

Andy Gray from the University of Kwazulu Natal provided an **update on pharmacokinetics and drug interactions** between anti-retrovirals and hormonal contraceptives. A 2015 review underscored the many unanswered questions on this topic, among them the time dependent interaction between efavirenz and sub-dermal implants containing LNG or etonogestrel, interactions with Net-EN and sub-cutaneous DMPA, and the effect of low-dose efavirenz on contraceptive efficacy. WHO's 2018 recommendation on first-line ART that shifted to a dolutegravir (DTG)-based regimen was

[1] For a summary of the outcomes from the meetings see Riley, H. et al (2017) Hormonal contraceptive methods and HIV: research gaps and programmatic priorities. *Contraception Volume 96, Issue 2, Pages 67–71.* Available from https://doi.org/10.1016/j.contraception.2017.05.015

complicated by evidence of increased risk of neural tube defects, raising practical concerns about which contraceptives to advise for women using DTG. A small study indicated that effectiveness of contraceptive implants may be lower for women taking efavirenz-based ART, while a more recent study suggests that use of the dapivirine ring for HIV prevention does not reduce the effectiveness of hormonal contraceptives for pregnancy prevention. The US Food and Drug Administration underscored the importance of this topic by convening a public meeting in 2018 on drug interactions with hormonal contraceptives, and a number of researchers have proposed a multidisciplinary framework for establishing a collaborative open-source mechanism to study drug-drug interactions of HC.

An **expert panel** comprised of Sharon Achilles, University of Pittsburgh, and Nelly Mugo and Elizabeth Bukusi both of KEMRI, provided additional insights:

- Understanding the biological mechanisms of HIV acquisition in women and the effect of HC is critical to building safe and effective contraception and multi-purpose prevention technologies. This understanding is still in its infancy and is hampered by the lack of clear biomarkers for HIV acquisition, and the complexity and heterogeneity of contraceptive hormones and modes of delivery.
- Advancing this field requires studies designed to look specifically at these biological mechanisms within the complexity women's biology. Most existing data are from convenience samples from studies designed for other purposes and are difficult to interpret.
- Family planning and HIV policymakers and healthcare providers need to deliver comprehensive integrated services to meet the needs and preferences of individual women, including HIV testing, contraception, pre-exposure prophylaxis (PrEP), counselling and other services. ECHO provides an opportunity to reconsider how to provide integrated services, and it is critical to ensure that programmes and services are informed by new and existing evidence.
- Understanding and application of the lessons from ECHO will vary in different epidemiological contexts. Programme managers, providers and individual women will need to understand the implications for weighing "risk" for individuals and populations. The implications may differ in different populations and geographic settings, between and within countries. Defining "elevated risk" of HIV acquisition will vary significantly in settings with different underlying HIV prevalence and incidence rates.
- Health systems will need to grapple with whether and under which circumstances it may be appropriate to consider replacing one or more contraceptive methods. This may require significant shifts in training, procurement, financing, information provision and so forth.

Participants and panellists **echoed some of these observations, and raised several related topics** in questions and comments:

- ECHO is examining the relative risk of three different contraceptives on HIV acquisition, but is not designed to answer questions about the associated biological mechanisms.
- ECHO should also provide important information about women's willingness to use implants and IUDs. In many settings in Africa, high uptake and provision of DMPA has skewed the "method mix", and ECHO may provide evidence of acceptability that can leverage increased access to a wider range of contraceptive options.
- Any WHO recommendations that result from ECHO will centre around women at "high risk" of HIV. Programmes and providers will need to consider how to operationalize these recommendations in the context of family planning services, and other on-going programming around HIV, such as scaling up PrEP and Undetectable=Untransmittable. PrEP programme experience with women's risk self-assessment may be helpful.

Session 3: Progress and status of Family Planning policy and programmes regarding hormonal contraception and HIV.

Petrus Steyn, WHO/RHR/HQ reviewed the **progress and status of family planning policy and programmes regarding hormonal contraception and HIV**.[2] WHO works to expedite the process through which major research findings influence practice norms by translating research into guidelines that can be systematically disseminated. WHO regularly produces family planning/contraception guidelines and tools to provide global standards for developing or updating national guidelines on contraceptive use. Following a 2016 systematic review, technical consultation and working group, the medical eligibility criteria for progestogen-only injectables for women at high risk of HIV changed from category 1 to category 2. This change was reflected in the March 2017 *WHO guidance statement on Hormonal contraceptive eligibility for women at high risk of HIV* and disseminated through stakeholder meetings and webinars. The statement emphasized counselling and information for women, and WHO worked to bridge the gap between guidelines and practice through additional tools and documents, webinars, and follow up with countries, including country visits. WHO can build on these tools and experience to disseminate any changes in the MEC based on the ECHO trial and priorities identified during the consultation.

Manjulaa Narasimhan, WHO/RHR/HQ, stressed that specific attention is needed to ensure that biomedical research findings are expressed **in integrated, woman-centred family planning and HIV services**. Woman-centred health services are those that consciously, proactively and purposefully adopt the perspectives of women and girls. Putting these principles into practice, WHO undertook a major consultative process to place women living with HIV (WLHIV) and their priorities at the centre of updating guidelines on the SRHR for WLHIV. They underscored that grounding SRH interventions in principles of gender equality and human rights can have a positive impact on quality of life, and that respect and an enabling environment are as important as the quality of medical care. The model they developed emphasized meaningful community engagement and placed health care in the broader context of their lives and communities. This consultative approach and the principles and priorities that emerged can inform services for women and girls at risk of HIV. Services can also build on the experience and seven key principles that are the foundation of FP/HIV linkages: address structural determinants; focus on human rights and gender; promote a coordinated and coherent response; meaningfully involve people living with HIV; foster community participation; reduce stigma and discrimination; and recognize the centrality of sexuality. Country specific data that include more than 150 indicators covering the full scope of HIV and sexual and reproductive health and rights (SRHR) linkages can be found at http://bit.ly/LinkagesSnapshot. Figure 1 identifies complementary WHO guidance on best supporting and strengthening FP and HIV linkages, and underscores the importance of human rights, gender equality and sexual health.

[2] For further information see Han, L. et al (2017) From Research to Policy: The WHO Experience With Developing Guidelines on the Potential Risk of HIV Acquisition and Progestogen-Only Contraception Use. *Global Health: Science and Practice* 5(4):540-546; https://doi.org/10.9745/GHSP-D-17-00278

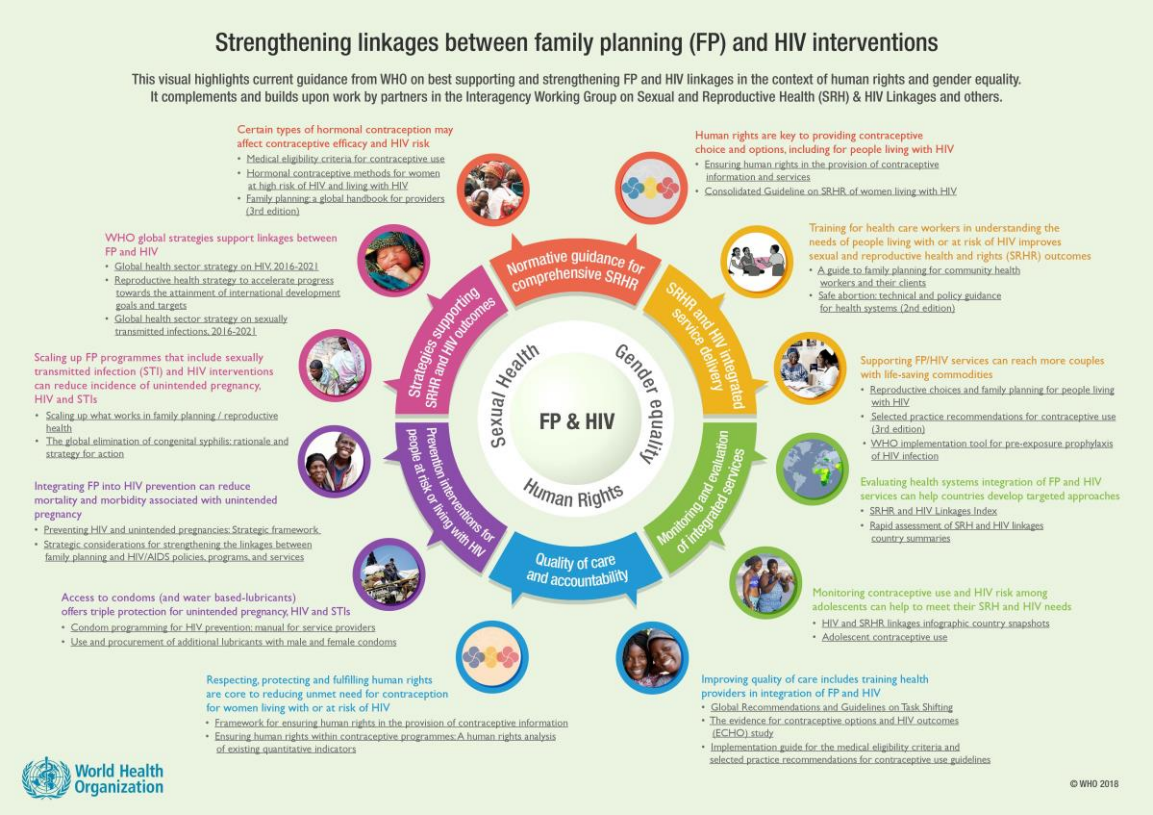

Figure 1: Strengthening linkages between family planning and HIV interventions

Caitlin Kennedy, Johns Hopkins University, presented the systematic review of **values and preferences** undertaken as part of WHO's guideline development process. This review includes the perspectives of end-users, or the individuals and populations affected by an intervention, in WHO guidelines and recommendations. Applying the values and preferences review to the MEC guidelines is unusually complex given that they involve multiple contraceptive methods used by multiple sub-populations. Distinct from other WHO guidelines, choice is fundamental to family planning, and the recommendations consider who is medically eligible for each method but does not recommend one method over another. The 373 studies that met the search criteria[3] evidenced wide variability in values and preferences within and across studies, and that values and preferences are shaped by the context and the available options. Across studies, the values and preferences centred on themes of:

- **Choice:** Women wanted a range of options; different women preferred different methods
- **Ease of use:** Easy to use, reversible, long-acting, hard to forget, doesn't interfere with sex
- **Side effects:** Few side effects/bleeding; some desire for "natural"/non-hormonal method
- **Efficacy:** Effective pregnancy prevention, interest in dual protection against HIV/STIs
- **Secondary issues:** Cost, availability, partner preference/covert use
- **Providers:** Support women's choice and counsel, but some lack of knowledge
- **Specific method preferences varied** by study, setting, and options that were considered or available. Women generally reported satisfaction with methods they were using. Method choice is a personal decision, but can be influenced through provider counselling
- **Women using DMPA generally like it**: it is discreet, long-acting, and reversible

[3] Data published in a peer-reviewed journal between January 1, 2005 and December 31, 2017 were included with no restriction placed on language of publication, setting or study design.

The few small, unpublished studies **related to HC and HIV risk** suggest that clients and providers appreciate being told important information to help make an informed choice and there is some evidence that women may choose to switch to other methods after counselling. However, client and provider misunderstandings may be a challenge given discomfort with the nuanced messages and technical terms needed to convey the implications of the guidance. Finally, known barriers to condom use may make this part of the recommendation difficult or impractical.

Panellists Zanele Mabaso, Sonke Gender Justice and Manala Makua, Department of Health, both in South Africa, and Placid Mihayo, Ministry of Health, Uganda, reflected on their **experience with programme integration and implementing the guidelines** and meeting participants provided additional comments.

- FP programmes must do a better job at responding to the needs of "women at high risk", and defining this still somewhat nebulous concept.
- Young people still struggle to get information they need on FP and SRHR services. Programmes need to promote these services, and encourage combination prevention through scaling up availability of PrEP and innovative delivery approaches for using PrEP and contraception together. Young peoples' voices and perspectives are key any such effort, and they need more opportunities and resources to participate in program design and implementation.
- The stated commitment to integration is belied by guidelines, which are generally developed in silos. Some, like the SRHR guideline with 13 components, are very complex. While HIV is intended to be a component of SRHR, it is often "chased" from SRH programmes.
- Counselling with the end user is central to implementing the guideline, and communication needs to be consistent, reliable, and continuous. If ECHO does show an elevated risk of HIV acquisition, it may be very complex to convey a nuanced message about choice within a service setting where some women can continue with their method and others should switch.
- If HIV risk reduction is predicated on contraceptive choice in official guidelines, other contraceptive options must be available. In reality, availability of commodities is very limited in some settings and "informed choice" may not be feasible. Just four months before the ECHO trial results are expected we are not prepared to answer the most urgent question for women: if HC increases the risk of HIV, what are we going to do?

Session 4: Review progress and status of family planning policy and programmes regarding hormonal contraception and HIV to explore strategies to address the gaps identified in programmes and policies including implementation research.

Morkor Newman, WHO/HIV/HQ reviewed the **FP needs of women and adolescent girls when implementing ART programs, including use of Dolutegravir (DTG).** Following publication of WHO interim recommendations on first-line and second-line ARV regimens in 2018 recommending DTG as the preferred first line regimen, a signal emerged of a possible higher rate of neural tube defects (NTDs) in babies whose mothers became pregnant while taking DTG. WHO continues to recommend the DTG-containing regimen as the preferred first line for adults and adolescents including those of child-bearing potential who are advised to also use consistent and effective contraception. WHO maintains its respect for a woman's autonomy in decision-making and views this as an opportunity to ensure all WLHIV have access to contraception, and ensuring access and choice for WLHIV to recommended ART regimens and contraceptive methods. With appropriate information and access, it is expected that women will choose the best method for their individual situation. Special attention will likely be required to provide access to: adolescents (tailoring to individual needs and expanding the method mix, including long acting reversible methods – LARCs); post-partum contraception depending on future fertility goals; and women with tuberculosis co-infection due to

drug-drug interaction. WHO has developed and is testing an implementation tool for countries to better provide access to contraception for women and adolescents living with HIV.

Michelle Rodolph, WHO/HIV/HQ outlined **considerations of the family planning needs of women when developing pre-exposure prophylaxis (PrEP) programmes**. WHO's 2015 recommendation that oral PrEP (tenofovir) be made available as an additional prevention choice for people at substantial risk of HIV was not population-specific. Rather, it was defined as areas, locations or populations with incidence higher than 3/100 per person-years. WHO has always seen PrEP as part of comprehensive prevention, which should include contraception and RH services, and so any woman seeking PrEP should be referred for FP services. If ECHO shows that any of the contraceptive methods increase HIV risk, PrEP could potentially help mitigate that risk. While PrEP has been delivered primarily in HIV services, some programs have experience with PrEP delivery within FP services, and this approach can be considered more widely. Providing HIV testing in the same location, rather than as a referral, would be an important first step. In sum, PrEP is here, and is an important tool, and it is the job of the public health community to make it safe, effective and available.

Beth Mallalieu, Johns Hopkins School of Public Health, presented results of a pilot project in Tanzania to assess the outcome for women of providing **counselling and communication on HC and HIV** based on the messages in MEC guidance. With training support and materials, providers counselled women who were using, or interested in using, DMPA. The project addressed two main questions: does the information in the MEC translate to women; and what happens when you deliver the associated messages? Following counselling, of 471 women tested, 1 decided to stop using a modern contraceptive method, and 4 decided to switch to a different method. Overall both women (67.5%) and providers (81%) answered correctly that using DMPA may increase a woman's risk of acquiring HIV, with fewer than 4% of reporting an incorrect understanding. Providers' understanding and recall of the information was high on using other measures as well, and most felt confident communicating messages to clients. Providers were not clear about whether other methods increased the risk of HIV, especially the combined oral contraceptive pill (COC). Clients were concerned that DMPA may contain HIV, and wanted to know the exact mechanism that may lead to increased risk of HIV. Overall the pilot project suggested that providers can be trained to convey the MEC messages about DMPA and HIV risk, and that most clients can repeat the information. Client questions highlight areas where additional information or attention may be needed.

Tim Mastro, FHI360 presented on planning for FP programmes in the context of HIV by introducing **the Preparing for Outcomes Model**, an interactive model that would show how changes in the proportion of injectable contraceptives in the method mix could affect HIV and maternal and child health indicators. Injectable contraceptives comprise a large proportion of modern family planning methods, and the vast majority are DMPA. The model calculates the expected change per year in key HIV and maternal and child health indicators, along with select other indicators: contraceptive prevalence rate and number of contraceptive users before and after change; HIV infections before and after change; unintended live births per each HIV infection averted in women; additional maternal and neonatal health costs/year; and previous DMPA users who must be reallocated to balance pregnancy outcomes. This interactive spreadsheet model includes data for 22 countries and is available from https://planning4outcomes.ctiexchange.org/.

Three key areas were raised during the discussion that followed the presentations:

- Consultations have repeatedly stressed that the trade-off between HIV and FP not be expressed in deaths, and the Preparing for Outcomes Model presented seems to contradict that value as well as the stated commitment to keep women at the centre. It does not, for example, prompt governments to consider other actions such as structural interventions, and takes the discussion back to a "bottom-line" approach to measuring impact primarily in mortality that does not consider women's preferences. The speaker responded that it is not a dynamic model and so does not include all the approaches that may be needed to slow down the HIV epidemic.
- Governments have taken different policy approaches to DTG and contraception, with regulators in South Africa taking a conservative approach that condom-only is not a contraceptive option for women using DTG, while in Botswana women are given individual choice within the constraints of access.
- Women-centred approaches that are working need to be prioritised, and rather than simply noting that there will be higher levels of HIV infections, policy and programmatic preparations should reflect the same urgency brought to voluntary medical male circumcision programmes. If the ECHO results mirror the observational data on HC/HIV, it is not acceptable to continue with "business as usual". Programs and policy decisions need to be driven by a clear understanding of the options available to women.

Yvette Raphael**,** Advocates for Prevention of HIV and AIDS, read a **statement from a civil society meeting held on 24-25 February 2019** that reflects broader consultation with nearly 250 women. The statement stressed key principles for taking forward the ECHO findings that included:

- "Women centred" means that every woman matters, and rejects the distinction and trade-offs between HIV and maternal mortality. Women's values and preferences in the most affected countries must be included in the process of developing guidelines, which should reflect a woman-centred approach guided by science.
- Deliberations from this meeting should be framed as a strong commitment to method mix, and reinforce that African women will use a range of methods, and governments and donors have the information to act on making more contraceptive methods available now.
- At least two African women should be included on the WHO Guideline Steering Committee when the MEC guidelines are updated following the release of the ECHO trail results.
- Women-led civil society organizations, including those led by young women, must be supported and funded to undertake advocacy and take information to communities before and after the ECHO results are released.
- Governments should develop concrete, costed plans for action steps guided by the ECHO results and all key actors (e.g. FP2020, MSI, PATH, others) should use their national, regional and global networks to support this, raise awareness and to disseminate clear information with the ECHO results.

The full statement is available from https://resultsforinformedchoice.org/material/every-woman-matters-statement-from-civil-society-meeting-on-hc-hiv-24-25-february-2019/

Jared Baeten, University of Washington, summarized the **ECHO trial's design, key outcomes, and significance.** ECHO is an open-label randomised clinical trial that aims to compare three highly effective, reversible methods of contraception to evaluate whether there is any difference in the risk of HIV acquisition among women using these three methods. The study is also comparing side effects, pregnancy rates and women's patterns of use for the three contraceptive methods: DMPA, a LNG implant, and the copper IUD. The study's overarching goal is to answer the pressing public health question of the relative risks (HIV acquisition) and benefits (pregnancy prevention) of these three commonly-used, effective contraceptive methods among women who desire contraception. ECHO enrolled 7,832 HIV-negative women aged 16-35 years in twelve sites in Kenya (1), South Africa

(9), Swaziland (1) and Zambia (1). Women in the study receive a comprehensive contraceptive and HIV prevention package: counselling, condoms, offer of partner HIV testing, STI screening and treatment, and offer of oral PrEP, which was introduced during the study as national policies allowed. Women in the study were able to get a method, change methods during the study and at the end, and to change after the trial if they wish. The ECHO team is working to ensure capacity to remove IUDs and implants at or near each site following the trial. More information on the sites, implementation, oversight, community participation and other aspects of the trial can be found at http://echo-consortium.com/echo- study-3/

ECHO will provide evidence – not prescriptions – for policy, programme and individual decision-making. It will provide evidence in important areas: comparative HIV incidence among women in each group (injectable, implant, IUD); comparison of how many women decided to stop using the contraceptive method they were assigned at the beginning of the trial; comparison of how many women became pregnant in each contraceptive group; and possible biologic mechanisms from ancillary studies. On the other hand ECHO cannot provide information about other important questions: HIV risk compared to no contraception, or for methods that were not tested (e.g. combined oral contraceptives, Net-EN, DMPA-sub cutaneous, etonogestrel implant, progestin intrauterine system), or increase in HIV risk smaller than an approximately 35%.

Sessions 5 and 6: To explore strategies to address gaps identified in programmes, policies and research, including implementation research.

Participants were divided into six working groups and charged with identifying and proposing solutions to key current gaps. Each group was provided with a template to complete; these can be found in Annex II. The following key gaps were shared during the feedback session:

Working Group	Gaps
1: Family Planning policies and programmes relevant to HC and HIV	• Standardised definition of high risk for HIV in various policies • No female controlled method for HIV prevention that is easily available, such as PrEP • Separate FP and HIV policies • No policy that provides a clear enabling environment for woman to take decision and consent to contraception • Age of consent barriers not allowing access to services (either contraception or HIV testing). • Comprehensive Sexuality Education (CSE) not allowed to be given to young people
2: Basic research relevant to HC and HIV	• Data on HIV risk and newer contraceptives (Net-EN, low dose DMPA, DMPA-SC, ulipristal acetate (UPA)) • Standardized methods and endpoints/outcomes for many aspects of studies: specimens, timing, lab methods, exposure measurement • Basic research/in vitro mechanistic studies to explain results of clinical studies and inform new studies • Indirect effects of bleeding, vaginal washing, behaviour and standardized methods to measure • Funding to preserve and catalogue specimens from large studies/trials • Agreed study designs to use samples in a strategic way to answer questions about biologic mechanisms
3. Epidemiology and	• How is “high risk” defined? • Can risk or high risk be assessed?

implementation research relevant to HC and HIV	• Are women who use PrEP different than those who don't use PrEP? • Are there factors that modify the association between DMPA and HIV acquisition? • How will the implementation of recommendations from ECHO results impact stock-outs? • Practical options to address any changes in FP practice or policy that may result from new recommendations (i.e. if DMPA is shown to increase risk of HIV acquisition?) • Poor understanding of the drivers of provider bias. For example, how does provider bias influence programme and policy makers' perceptions and vice versa. • Implementation research: How do women/men/couples weigh the trade-offs in different risks?

4. Intersection between Family Planning and HIV, including PrEP, DTG, HIV testing and referral	• Missed opportunities. SRH officer in MoH pushing uptake of FP options without offering HIV prevention options. Similarly, HIV officer pushing HIV prevention / treatment without offering FP
	• Limited number of healthcare workers unable to provide all needed care
	• Provider-initiated family planning in HIV clinics for people living with HIV. (In some, providers push for shorter-term methods (DMPA/COC). LARC referred to FP clinics in same or other facility)
	• Access to DTG
	  ○ Access to DTG by women of reproductive potential
	  ○ Access to LARC to make DTG feasible
	  ○ DTG/LARC access impeded in settings where faith based providers (especially Catholic) will provide ART but not FP.
	  ○ Women's knowledge of LARC
	• Counselling capacity
	  ○ FP and HIV both require intensive counselling. System needed to combine counselling: FP, PrEP, ART, DTG, HIV self-testing
	  ○ Insufficient healthcare worker time for counselling

5. Counselling and Communication	• Lack of objective and judgment-free counselling • Lack of trained counsellors (specifically trained to counsel) • Lack of specific counselling resources (including easy-to-use tools) • Lack of accommodation of language, vision, hearing difficulties • Lack of clarity and consensus around trusted sources of information. • Lack of effective, non-stigmatizing communication to 'women-at-risk' • Guidance for moment ECHO results are released
6. Integration of FP and HIV services	• Opportunities missed at service delivery level • Confidentiality at multiple levels: i.e. information, data-protection and physical space • Failure to integrate stigma and discrimination, gender-based violence, within SRHR/HIV services • Provider capacity to address a number of SRH and HIV issues • Empowering communities and meaningful community engagement • Multi-sectoral integration • Measuring impact of SRHR/HIV • Confining integration to services in the absence of policy and programmes • Vertical funding • Too many vertical tools

	• Brain drain, turnover, challenges with skills retention

Helen Rees, the session chair, synthesized issues from the day's presentations and discussions around ten key themes:

1. **Legislation and policy:** Legislation and policy can powerfully influence the capacity of systems to prepare and respond to evidence and for people to realize their rights to information and services. Policies relevant to the context for the ECHO findings include those related to stigmatizing or criminalizing key populations, age of consent, women's rights and status and other social policies, procurement, regulatory, and health policies on access to contraception and HIV care.
2. **Ethics and rights**: Ethics and rights are also key, including stigma, confidentiality, and practical and realistic informed consent within services so that women can make informed choices about contraception, DTG, and other interventions critical to their health and autonomy.
3. **Political leadership**: Political leaders need to understand the ECHO results, the issues around them, and the implications for policy, programmes, public health, individual choice, and ensuring women have access to contraceptive methods of their choice. Governments need to consider how they can drive the discussion and decision-making within the realities of international funding for contraception and HIV services.
4. **Health Services:** Health services have a unique opportunity to take advantage of the spotlight that ECHO will focus on the interface of SRH, FP and HIV. Integrating services require integrated policy, and practical approaches to budgeting, staffing, supply chain and other areas. Training and counselling are consistent themes necessary to work toward service integration. At the same time, services face real constraints: space, staffing levels, job definitions, burnout, provider bias, and ever growing responsibilities.
5. **Beyond the health sector**: Efforts to educate, innovate, and reach people should extend beyond the health sector, by, for example, working with the education sector to champion and support comprehensive sexuality education, and school- and community-based services to reach adolescents.
6. **Engaging communities:** Community activists and community leaders are trusted links that can bridge health systems, communities and clients. They can present and convey information, and help surface and respond to concerns. They can be effective messengers – in both directions, and the various actors – researchers, funders, ministries, policymakers, providers – should heed their insights and advice.
7. **Technologies:** Health and related systems should strive to make better use of existing technologies and support development and implementation of new innovations. We can begin now to expand access to existing interventions like PrEP and LARCs, while supporting development and testing of new HIV prevention products, multi-purpose prevention technologies, and other health products. This process should be extended to other arenas including digital solutions to conveying information, and supporting health education, medication adherence, clinic attendance, and so forth.
8. **Epidemiology, monitoring and evaluation**: Programme success and emphasis often rests on effective targeting and monitoring. Identifying "high risk" individuals and communities can be especially challenging, and may be central to delivering information and services that respond to new knowledge from ECHO. Programmes need to continually ask whether data is being collected for indicators that measure what is trying to be achieved.
9. **Research:** It is a critical time to capitalize on growing evidence from basic research around HIV acquisition, the role of hormonal contraception, and related topics. This will require intellectual and financial investment in a wide range of areas: standardizing methods and measurements

within and between studies, examining new contraceptive agents, and collaboration to ensure a strategic approach to studying and preserving existing samples.

10. **Funding**: the ECHO results will have implications for a range of actors in the health sector and beyond: Ministries of Health, partner agencies, donors, researchers and others. ECHO and other interactions such as women living with HIV of reproductive age using DTG underscore the clear links between SRHR and HIV. These may compel agencies to consider and reframe their work in more integrated ways, for example prompting PEPFAR to take a more vigorous and systematic approach to SRHR/HIV integration.

Day 2: Wednesday, 27 February 2019

Session 7: Communication and counselling messages on HC and HIV

Joanne Skinner from Johns Hopkins Center for Communication Programs gave a presentation on **engaging diverse stakeholders** in which she outlined the different stakeholders to be included in a communications plan and how to engage them, keeping in mind that women need to be at the centre. A mapping should be conducted first to identify the key stakeholders and then a national communications strategy created to help Ministries plan and prepare for the ECHO study results. This strategy should include an audience analysis to answer the following questions for each stakeholder group: what they already know, what they need to know, when they need to know it and who do they trust receiving messages from. One key stakeholder group is women of reproductive age who need to be reached with clear communications and counselling around FP methods and HIV risk. While it will be important to clearly convey risk, DMPA (or one of the other contraceptives in the ECHO study) is still very likely to be a good contraceptive option for women not at high risk of HIV. Two useful resources mentioned were:

- Strategic Communication Framework for Hormonal Contraceptive Methods and Potential HIV-Related Risks: http://healthcommcapacity.org/wp-content/uploads/2017/05/HC-HIV-strategy_May2017_final.pdf Provides a useful framework and step-by-step approach for ministries and other partners to think through the process of situation analysis and audience segmentation.
- Results 4 Informed Choice: http://resultsforinformedchoice.org A collection of tools, resources and data to help HIV and family planning programme implementers, government representatives, advocates and journalists prepare for and respond to the ECHO trial results so that women have the required information to make an informed choice in adopting and using a contraceptive method.

Yvette Raphael from Advocates for Prevention of HIV and AIDS presented on **Community Engagement** within the ECHO trial. She started with a metaphor to illustrate the importance of meaningfully including women, stating that if women are not fully involved in decisions and able to provide their perspective on the ECHO trial results, "it would be like making lamb curry without the lamb". Civil Society have been engaged during the ECHO trial through the Global Community Advisory Group which consists of 16 members from six countries. This group has been involved in Civil Society forums and community dialogues, and will be engaged in results dissemination – including at each of the trial sites. If ECHO finds that any methods increase the risk of HIV acquisition the advocates are prepared to take the necessary action, whilst considering both the short and long term effects.

Natasha Salifyani Kaoma from Copper Rose presented on **Youth and Populations at High Risk** where she highlighted many problems with traditional communication approaches when communicating with young people aged 18-24. Communication requires both a speaker and a listener yet often this does not happen, for example, with the healthcare provider doing all the talking, too much information given at once, or incorrect or inappropriate information provided. Terminology is also important – for example, "family planning" often is not relevant to young people who want to avoid an unintended pregnancy and are not thinking of planning a family. Some approaches for successful communication include:

- *Develop more than one set of messages* to reach different groups of young people as they are not a heterogeneous group. Ensure the research messages are broken down into a form that young people can understand and apply to make an informed choice.
- *Use different communication channels* - this includes radio, TV and social media – and be creative in the way the information is disseminated on these channels, for example, one minute videos, short interviews and visual tools.
- *Ensure health services and commodities are available, accessible and acceptable* for young people as communication alone is not enough. This requires putting aside religion and culture to see and meet the sexual and reproductive health needs that young people are currently facing.

Panellists were asked to share some thoughts and experiences on **Media Engagement**. Yvette highlighted that AVAC runs media cafes annually to educate journalists on SRHR and HIV related topics. APHA also uses twitter to share the latest findings and information. Joanna explained that the Results 4 Informed Choice website has a section specifically for journalists which presents key information they will need to communicate the ECHO study results. Natasha mentioned that the Ministry of Health in Zambia are working on a reproductive, maternal, newborn, child and adolescent health communication strategy for different groups. Young people should be seen as an asset in any communication strategy – for example, supporting information dissemination, including through social media.

In the discussion following the presentations, five main topics were covered:

i) *How the ECHO trial results will be released and WHO's communication plans:* the current plans and proposed timelines were shared in Session 8 (see below). WHO's role is to share the evidence and the possible implications with the Ministry of Health in each country. Help will be needed from many actors to disseminate the correct messages, especially to the community level.

ii) *Ensure messages are tested* so they are understood and do no harm, including in local languages. For example, Natasha mentioned that there is no clear translation of 'risk' in her local language. Careful consideration is needed to convey key concepts such as this and the implications that translation may have for crafting effective and accurate messages for programmes and individuals.

iii) *Plan clearly for how the specific messages will be communicated* as they will play into both the users' reactions and the government response. For example, a result showing that one method increases risk of HIV acquisition could create a situation where contraceptive use across methods declines, or lead to a government withdrawing a particular method without the capacity to scale up the provision of alternative methods. Messages need to be clear that no contraceptive method prevents HIV, and each woman needs to make an informed choice as to the contraceptive method that will serve her best in balancing preventing unintended pregnancy

and reducing her risk of acquiring HIV. Leaders and communicators need to be aware of how opposition groups plan to use the ECHO trial results, how this could potentially damage the FP programme, and devise approaches to counter specific opposition strategies. One of the best ways to deal with opposition is to have a cadre of credible voices who can speak with authority who are the "go-to" people to be interviewed. In many countries these spokespeople will be from Ministry of Health staff so they need to be fully briefed and comfortable with the ECHO trial results and implications.

iv) *Bolster communications expertise within Ministries of Health* to ensure that the messages that come from WHO are not given straight to journalists or communities to interpret. It was recommended that ministries bring on partners with expertise in strategic communications and who can craft clear yet nuanced messages for the different stakeholders. The Ministries also need to appoint and train spokes people who are credible and knowledgeable.

v) *Use a number of different methods to prepare journalists in advance* such as media training through Internews or AVAC media cafes to train health and science journalists so they are aware of the study, understand it, and can quickly release a clear and accurate story once the results are disseminated. Preparatory work with journalists is taking place in 14 countries (including all those involved in the consultation) to ensure that the initial reporting is accurate. This is important as later stories often refer back to the first stories published. Journalists also need tools such as factsheets that minimise or explain jargon like 'open label' or 'randomised trial' as these terms may not be widely understood.

Session 8: Specific communication strategies for ECHO results

Cath Hamill from WHO/RHR/HQ presented the **WHO communication strategy** for the ECHO trial results which will involve a four phase communication approach.

1. *Communications prior to the release of results (March to July 2019)* includes: engaging with international and national communications groups; mapping stakeholders; and supporting the development, testing and refining of messages. Information about the ECHO trial will be published on the WHO website starting in May with frequent updates when something new can be shared with the public, including a pre-release press alert to engage journalists and highlight when the findings are due.
2. *Communications at the release (July 2019):* A press conference will be held at WHO to disseminate the results, implications and a statement of WHO follow-up actions. Information will also be shared directly with WHO regional and country offices, UN Partners and via the WHO website, social media and newsletters. Each WHO country office will reach out to the Ministry of Health in that country; ideally they will have partnered on preparing for the ECHO results.
3. *Communications between results release and revised guidance release (July – September 2019):* WHO will continue to provide information and messages to diverse stakeholders through existing networks, webinars, and promoting the results at conferences. Additional messages will be developed as needed and media enquiries will be responded to.
4. *Communications at and after the revised guidance released (October 2019 onwards):* The updated guidance will be shared through a number of channels including the press briefings, the WHO website, social media, the downloadable MEC App, webinars and existing networks. WHO regional and country offices will be briefed on the updated guidance with supporting material for communication with Ministries of Health.

Nomthandazo Mbandazayo from WITS RHI presented the **ECHO Communication Strategy** on behalf of the ECHO consortium. The ECHO trial communications plan and dissemination strategy aims to ensure timely, accurate, cohesive and coordinated dissemination of the ECHO trial results. To communicate the findings, the ECHO team are committed to releasing the results via a scientific peer review publication. Results will be simultaneously released to participants, trial sites, and local and global stakeholders. The findings will be released transparently with a thorough presentation of the data. Since the beginning, ECHO has been and remains committed to implementing good participatory practice, putting women at the centre and ensuring strong community engagement. For example, the trial has worked with a Community Engagement Working Group with a Community Liaison Representative at each study site. The trial staff have worked with coalitions and civil society networks, including FP2020 and AVAC, and partnered with AVAC to run Community Dialogues and Civil Society Forums that brought diverse stakeholders together last year to begin discussing possible outcome scenarios and brainstorm key questions and messages.

Mary-Lyn Gaffield from WHO/RHR/HQ presented on **Provider-client communications: Messaging from the 2017 guidance** and highlighted a number of key WHO resources available (see Annex III) in particular the updated 2018 Global Family Planning Handbook. This handbook for providers consolidates all the guidance regarding contraceptive use, including the 2017 updated guidance on hormonal contraception. Each chapter covers a different contraceptive method and includes counselling tips for providers as well as frequently asked questions to help women make an informed decision regarding their contraceptive choice. For more information see www.fphandbook.org

Lindiwe Malaza from the Ministry of Health presented the **eSwatini country experience** implementing the ECHO trial. The study took place in a private facility – Family Life Association of Swaziland – in collaboration with the Ministry of Health between September 2016 and September 2017. A strong emphasis was put on dual protection with each client being asked at each visit whether they were using condoms and with additional counselling for clients experiencing contraceptive side effects. Clients who opted to change from their randomised method of contraception were allowed to do so. In preparation for the findings release, a steering committee has been formed by the Ministry of Health and partners with a team tasked with developing messages to prepare for dissemination of the ECHO results.

Dr Edward Serem from the Ministry of Health presented the **Kenya country experience** strengthening family planning programmes. He highlighted the current unmet need for contraception (18%). With 70% of adolescents sexually active, they need to have access to information and services to prevent unintended pregnancies and HIV acquisition. To expand contraceptive use, the Ministry of Health are currently training pharmacists to provide injectable contraceptives to increase access, especially for young people. The ministry is also seeking to change to the national health insurance fund to include all family planning services, and to employ bulk procurement within the East African Community of family planning commodities to reduce the cost per unit for each country.

Angel Mwiche from the Ministry of Health presented the **Zambia country experience** implementing the ECHO trial and preparing for results. If the results are in line with existing evidence regarding the effect of progestogens on HIV acquisition, then the changes in programmes will likely not be substantial. However, the presenter did express a fear of the unknown if the risk of HIV acquisition

from any method is much higher than expected. In this case, the reaction of communities to the findings will need to be carefully monitored. To develop a communication strategy, the Ministry of Health plans to use the existing communications team in the health promotion unit. If national policy and guidance needs to change as a result of the findings, the necessary processes will be undertaken, once the updated guidance is released by WHO.

The discussion following the presentations highlighted that very nuanced messaging may be needed on the findings, for example, if risk of HIV acquisition depends on age. This has been done before in WHO guidelines so it was not seen to be of particular concern. Professional organisations, such as the International Council of Midwives, the International Council of Nurses and FIGO can play an important role in disseminating information through their networks.

The release of the ECHO trial findings will also be a good opportunity to push positive messages for improved contraceptive method choice and better counselling for women accessing contraception. When creating communications plans it is important to consider the positive and negative influence of actions that one country may have on other countries in the region – especially larger countries such as South Africa.

Finally, the discussion underscored the importance of pre-evaluating messages and testing how they are being received once released. There is always a risk of messages being misunderstood. Therefore, it is important to monitor how they are picked up and used, especially on social media, and being available to quickly step in and correct them if necessary.

Session 9: Review and update on country readiness for ECHO trial results

Mary-Lyn Gaffield from WHO/RHR/HQ opened the session by introducing the process for **Guideline development in response to the ECHO study**. The 2017 guidance statement is the starting point for how WHO will respond to the ECHO trial results. In March 2017 a guideline development group met and – using the GRADE approach – reviewed the evidence, including values and preferences of individual users on progestogen-only contraceptives. Based on the evidence presented, they advised that for women at high risk of HIV, DMPA / Net-EN contraceptives should be changed from a MEC category 1 where there are no restrictions for use, to a MEC category 2 where the advantages of using the method generally outweigh the risks. This GRADE process will be followed again when the ECHO findings are released to determine whether the recommendation needs a further update. The Guideline Development Group is currently being convened and will meet at the end of July. It is expected that the updated guideline will be available from September 2019.

Dr Leopold Ouedraogo from WHO/AFRO presented a **Country preparedness overview** highlighting what it means for WHO/AFRO to be prepared for the ECHO results. He outlined several criteria:

1. 2017 WHO statement on HC/HIV has been disseminated to in-country FP/HIV stakeholders
2. Updated categorization for DMPA in women at high risk of HIV is reflected in the national FP guidelines and tools. The current designation is a MEC category 2, with emphasis on providing appropriate information and counselling.
3. Key counselling messages are included in national tools and used in FP counselling
4. Dual contraception, especially for women at high risk of HIV acquisition, already being promoted
5. FP/HIV stakeholders are aware of the ECHO trial, understand the study design, objectives and implications, and are prepared for the release of the results.

A survey has been conducted by AFRO to assess the extent to which countries are prepared based on the above criteria.

Zuhuru Mbuguni from the Ministry of Health shared **Tanzania's preparedness for the ECHO trial results** by highlighting work undertaken by University College London, with support from USAID, to use modelling to evaluate the impacts of changes in the method mix. This is especially important given the heavy reliance on DMPA use in Tanzania and will help to inform policy and programmatic responses to the findings from the ECHO study.

Florence Kakanou from the HIV, STI and Tuberculosis control programme shared **Cameroon's preparedness on the ECHO trial results**, emphasising the need to focus on challenges and best practices to improve FP and HIV service provision. This includes improving communication and coordination between the government departments responsible for family planning and HIV, and engaging with civil society, in order to collectively address the ECHO study results.

During the discussion that followed it was noted that family planning providers often have little or no time for counselling on contraceptive options, a situation that will be made more difficult if the messaging around different contraceptive options becomes more nuanced and complex. It was agreed that, whatever the findings of ECHO, this provides a good opportunity to strengthen family planning programmes.

The importance of looking beyond DMPA and planning for different possible scenarios – for example if the copper IUD or implant has an impact on HIV acquisition – was also raised as an important consideration for countries preparing for the ECHO results.

Session 10: To identify priority actions on communication required in anticipation of the ECHO study results

The meeting participants split into four groups to identify the critical components of readiness, how the results should be delivered to countries, and what actions need to be taken to ensure that clear, consistent and accurate messages are given and received by policy makers, healthcare providers and users. There was consensus that while specific actions will vary by country, overarching areas within which countries should plan and respond to the ECHO study were identified.

March – June 2019: Prepare for ECHO results release	
i) Establish or strengthen a Task Team	Actions should be coordinated through an inclusive yet nimble country structure that can take initiative and act quickly. This 'Task Team' should use or build upon existing structures where feasible – for example a Technical Working Group – whilst ensuring membership includes a broad range of stakeholders such as the Ministry of Health, WHO, UNFPA, UNAIDS, FP2020, civil society organisations and research agencies. The membership should also include stakeholders with communications expertise.
ii) Develop and implement a roadmap	The Task Team will rapidly develop a roadmap that charts the key activities for preparing for the ECHO results release as well as what should happen once the findings have been released and after the WHO guidance has been updated. Whilst every roadmap will depend on the specific country context, it will be likely to include the following activities:

	• Sensitizing policy makers and providers in preparation for release of the study findings • Developing sub-national/regional plans for dissemination of the findings • Scenario planning so a swift response can be implemented if the findings show an increased risk of HIV acquisition for one or more contraceptive methods. This could include identifying who would be considered high risk, what extra interventions are required, and what the associated programmatic implications would be.
iii) Prepare messaging and a communications plan	It is very important to ensure there is a timely, accurate, cohesive and coordinated dissemination of the ECHO study results that put women at the centre, and are framed within the broader context of FP and HIV prevention needs for women. In order to achieve this, the following actions should be taken: • Develop communication messages that are clear, tested and tailored to different audiences. Beware of jargon when developing these messages. The key messages prior to the findings release could include: whatever the results of the trial, women's priorities and rights are central; contraceptives do not prevent HIV; the government is committed to increasing contraceptive method mix as no one method is suitable for everyone. • Develop a plan for communicating these messages to different target audiences including healthcare providers, users and other constituencies. • Prepare the media through giving trusted media outlets time and access just prior to the ECHO findings release, for example through a Media Cafe. If the first stories are correct, others will pick up on these stories, greatly increasing the chance of the right messages being promoted. • Identify a focal person or persons on the 'Task Team' who can become the spokesperson/s for the ECHO trial at the country level. Ensure they are well versed in the ECHO trial itself and given media training if required. Provide support and training to the official government spokespeople if necessary.
July – August 2019: Once ECHO results have been released	
iv) Plan for actions in the period between the ECHO results and updated WHO recommendations	When the ECHO findings are released, WHO will issue a statement which provides recommendations for what countries should do in the interim before the updated WHO guidance is released. Actions will include: • Promoting the actual findings and messages agreed above, responding swiftly to any misinformation that is circulating. • Share the message (especially among colleagues in government) that updated WHO guidelines are forthcoming and the process to update national policy will be started once these guidelines have been released. • Develop communications based on the WHO statement
September 2019 onwards: Once the updated WHO guideline released	
v) If required, and if the	If relevant decision makers in a country feel a change is needed to existing policy based on the ECHO findings and any updated WHO guideline or change

recommendations are updated, incorporate updated recommendations into national policies and guidelines	in WHO MEC categorisation, they should undertake the relevant process for reviewing and updating national policies and guidelines. Once updated, clear plans should be made to implement the policy including revised training and tools as required.

Ongoing actions:

Regardless of the findings of the ECHO study, two important ongoing actions were identified that all countries should undertake:

1. Improve family planning education and provision:

Family planning programmes in every country need continual investment and strengthening. The key areas where this strengthening can be focused include: expanding the method mix available at all primary healthcare points including long acting reversible methods such as the copper IUD and implant; training providers in the provision of a broad range of modern methods – including improving the counselling provided; and minimising commodity stock outs.

2. Improve the integration of HIV services within contraception services and vice versa

Within any primary healthcare facility, a broad range of contraception and HIV services should be available from the same provider in the same consultation. A client should not have to queue twice or return to the service delivery point to receive these services. HIV prevention services, condom provision, counselling on dual protection, STI and HIV testing, and contraception services should be available for all women, including those living with HIV.

Day 3: Thursday, 28 February 2019

Session 11: To develop country specific priority actions in anticipation of the ECHO study results

After a summary recap of the discussions from day two, participants split into country groups to develop a priority action plan based on a template which included the priority actions outlined during the group work on day 2. The following completed action plans are available from the WHO SharePoint site: Botswana; Democratic Republic of Congo; eSwatini; Kenya; Lesotho; Republic of Tanzania; South Africa; and Uganda

Rather than each country presenting its action plan, the meeting participants were asked in plenary to respond to two topics:

i) Priority actions that had not been included in the suggested list that countries had identified as important

- **To share standard background information about the ECHO trial** – it was suggested that the ECHO fact sheet and ECHO FAQs would be shared as part of this as well as the slides Jared Baeten presented on day one.
- I**nclude an activity on sensitising policy makers and regional and sub-regional actors** – for example, as the implementation of any changes in procedure will be the responsibility of the District Health Offices, they need to be included in the communications plan.

- **Need to include consideration of commodity forecasting and quantification** – Procurement and Supply Chain Officers and the Ministry of Finance need to be included, especially as the long lead time for procurement, and procurement cycles, mean that any sudden changes in commodity requirements (e.g. due to a change in method mix) will have implications in commodity supply needs. It may be difficult to meet such changes through existing mechanisms.

ii) Priority actions included in the template that were problematic

- **When and how to conduct media training** based on concern that conducting media training too early could lead to journalists putting out a story before the results are available with sensational or inaccurate reporting to "make news".
    - Whilst it was noted that working with media is complex, knowledgeable participants suggested that a longer term 'low dose' consistent approach can build relationships with trusted media and may help reporters to understand issues better than a one-day training. To avoid inaccurate or sensationalistic reporting, include a formal agreement within the training session that the information provided is not for publication at the current time.
    - Achieving accurate reporting in the early stories published makes the communication of messages easier as these early stories are often picked up by other media outlets.
    - BMGF and AVAC will expand media training work to all 14 countries closer to when the results are released.
    - South Africa shared the Ministry of Health communication plans developed after two articles were published in the country on the possible link between HC and HIV acquisition. The current strategy is to emphasise key messages that are agnostic to the specific results such as: whatever the results, women are at the centre; contraceptives do not prevent HIV; and the government is committed to increasing method mix as no one method is suitable for everyone. Before the findings are released, government media spokespeople will be educated on the ECHO trial and given clear messages to use. After the results are released, the focus will be on getting these messages to healthcare providers and contraceptive users.
- **What should countries do after the results are released and before the updated WHO guidelines are issued?** The initial WHO statement will not issue guidelines for providers (i.e. a MEC categorisation) but they will interpret the results and explain what countries can to do in the interim. It will be up to countries to decide whether to take action based on the findings and if so, what action to take if they must act before the WHO recommendations are released.

Session 12: Summary and conclusions

James Kiarie from WHO/RHR/HQ invited representatives of different agencies to speak about their plans and perspectives on the consultation and technical support that is available in preparing for, disseminating and addressing the ECHO trial results. A summary is available in Annex IV.

WHO/AFRO: Leopold Ouedraogo highlighted that the WHO regional office is available to provide technical support to countries, and to work with WHO/RHR/HQ to provide harmonised support. This support can include capacity building and assistance with developing and updating tools and guidelines. AFRO is also currently considering one or two regional dissemination meetings once the ECHO findings are released to ensure the results and their implications are clearly understood.

WHO/RHR/HQ: James Kiarie highlighted the technical support that will be provided to WHO Country Offices. The country offices will support convening national working groups in each country ensuring that the process gets started. If challenges arise with communicating the study findings in a

country, then HQ staff can link up with country staff to discuss how to help improve communication. Cath Hamill from WHO/RHR/HQ added that she establish a communications group to connect and keep informed people involved in communications for their organisations. This group will help country teams identify timelines for messaging, developing materials, engaging the media etc. WHO will support the development of global messages, which will be shared and can be used or adapted by each country.

UNFPA HQ: Gifty Addico highlighted that they are the operational partner for family planning and engage closely with countries in capacity building, advocacy work and providing funding to country programmes for these activities. UNFPA has some additional resources for specific countries and expects that UNFPA country offices will work with the country teams from this meeting. Feedback will be provided by UNFPA HQ to the country officers who were not able to attend the consultation. Commodity security is a key area for UNFPA and support will be provided to supply chain managers to consider the implications of ECHO for pipelines and procurement of contraceptive commodities including strategic demand forecasting. UNFPA also works with NGOs that provide contraceptives and FP services such as IPPF and MSI, whose work will also be key to implementing any changes or follow up based on ECHO.

AVAC: Emily Bass highlighted that AVAC works across a number of arenas and have materials on many issues key to ECHO including informed choice, research and communications. AVAC is planning media cafes during which researchers, civil society and other experts talk informally with trusted experienced journalists. These cafes are planned for every ECHO trial country and are available from AVAC on demand. AVAC works closely in coalition with civil society, including women's SRH justice activists and advocates. Hard copies of the statement developed by SRH justice activists and advocates before the meeting were shared including a readiness checklist which underscores the importance of working within the context of existing Civil Society engagement (see Annex II).

FP2020: Beth Schlachter noted that FP202 works with many of the country teams already and will be a part of the partnership to support the response to the ECHO results before and after the updated WHO guidance is released. The FP2020 reference group will meet in Washington DC in April and the ECHO trial is prominent on the agenda, as it is at an FP2020 convened 17 country workshop in Addis Ababa in May. FP2020 can support country plans and other activities at the country level. The FP2020 focus is ultimately on healthy outcomes for women and that women must be provided with information and access to a range of contraceptive options so they can make an informed "good" choice to meet their needs.

SIDA: James Kiarie noted that SIDA is supporting WHO's participation in the ECHO study and had provided funding for the meeting. Two SIDA representatives had participated in the consultation by skype.

Bill and Melinda Gates Foundation (BMGF): Ryan Cherlin shared that the Foundation is willing to offer support in a number of ways. They will work with WHO to support setting up country level working groups, and will explore how the communications and messaging activities of these groups could possibly be funded via existing country partners. BMGF will continue to work with AVAC to support media training and media preparedness. In terms of community engagement, BMGF are

open to ideas from each of the countries as to what this might look like and what resources are needed so key information and messages reach the contraceptive users.

USAID: Abdulmumin Saad highlighted that USAID has been working on a number of activities and ECHO presents a big opportunity to further FP/HIV integration work. Resources include an ECHO scenario planning template to help countries think through the different programmatic implications for 8 different scenarios which is available on the SharePoint site. USAID has also supported a strategic communications framework for HC / HIV communications available here. Research on counselling and implementation underway in Tanzania was presented at the consultation, and results will be made available when it is completed. Work is also ongoing on modelling that can support policy makers to make informed programmatic choices when the findings are released and an additional webinar will be convened to share this. USAID is in a good position to support country led activities and can consider additional support if needed, such as convening regular phone calls with the chair or lead of country working groups to provide information, support and advice as needed.

Summary of the meeting and discussion on outputs

Ian Askew from WHO/RHR/HQ summarised the work achieved and presented the key next steps to be taken following the meeting. Participants were reminded that the ECHO trial will provide evidence but not prescriptions for policy, programme and individual decision making on contraceptive options. The ECHO trial results will prompt a review of the current MEC guidelines. This may have implications in countries across the region and each country will need to examine the results and guidelines to assess implications for their own policy and programmes. Regardless of the findings, contraceptive options, information and services need to be improved to reduce high levels of unmet need for contraception among women, and there needs to be improved bi-directional FP and HIV integration – improving HIV prevention for women accessing family planning and offering contraceptive services for women living with HIV. Moving ahead will require clear messages that are tested and tailored to different policy settings, epidemics, and individuals.

The relatively short timeline until the ECHO results are released means that the next steps need to be undertaken with a sense of urgency and commitment. The group agreed on the following key next steps and timeline:

Action	Who leads	When
Share executive summary of the Lusaka meeting	WHO	8 March 2019
Brief supervisors and stakeholders on Lusaka consultation outcomes	Meeting participants	By 15 March
Convene working group to develop action plan	MoH, WHO	By 29 March
Implementation of action plan (1st phase – pre-results)	Working group	April – July
Webinar to follow-up on progress	WHO	By 25 April

Release of ECHO study results	ECHO research team	Mid-July
Implement action plan (2nd phase – post results and pre-guidelines)	MoH, WHO, CSO	July – Sept
WHO guideline review process	WHO	July – Sept
Implement action plan (3rd phase – post guidelines)	MoH, UNFPA, WHO	Oct onwards

Sarai Malumo from WHO Zambia closed the meeting noting that it had been an important opportunity to develop priority action plans. Now these plans need to be implemented so countries are prepared for the ECHO trial results to ensure there is minimum disruption to FP and HIV service delivery and strengthened integration between the two programmes.

Annex I: Agenda

Day 1: Tuesday, 26 February 2019

Session 1: Welcome, introductions, DOI, objectives.

Time	Topic	Participants
Session 1	Welcome and objectives	Chair: James Kiarie
08:00 – 08:	Introductions and summary of declarations of interest	James Kiarie
08:10 – 08:30	Welcome remarks	Ian Askew Chilufya Kasanda Sarah Vulani
08:30 – 08:45	Summary and outcomes of previous meeting Objectives of the meeting	Petrus Steyn

Session 2: To review progress and status of family planning research regarding hormonal contraception and HIV to explore strategies to address the gaps identified in research including implementation research.

08:45 -10:05	Progress and status of Family Planning research regarding hormonal contraception and HIV.	Chair: Helen Rees
Presentation 08:45 -09:00	Progress and status of Family Planning research regarding hormonal contraception and HIV, including inter-disciplinary collaboration and dialogue between basic, clinical, and epidemiological scientists	Charlie Morrison
Presentation 09:00 -09:10	Progress and status, including the most important gaps in the understanding of pharmacokinetic findings and potential drug interactions of clinical importance	Andy Gray
Panel 09:10 -09:25		Sharon Achilles, Nellie Mugo and Elizabeth Bukusi
09:30- 10:10	**Questions and answers**	
10:10 -10:40	***Tea***	

Session 3: To review progress and status of family planning policy and programmes regarding hormonal contraception and HIV to explore strategies to address the gaps identified in programmes and policies including implementation research.

10:40 -12:00	Progress and status of Family Planning policy and programmes regarding hormonal contraception and HIV	Chair: Ian Askew
Presentation 10:40 – 10:55	Progress and status of Family Planning policy and programmes regarding hormonal contraception and HIV	Petrus Steyn
Presentation 10:55 – 11:05	Integration of woman-centred family planning and HIV services	Manjulaa Narasimhan

Presentation 11:05 – 11:15	Values and preferences	Caitlin Kennedy
Panel 11:15 – 11:20		Zanele Mabaso, Manala Makua and Placid Mihayo
11:30 – 12:00	**Questions and answers**	
12:00 -13:30	***Lunch***	

Session 4: To review progress and status of family planning policy and programmes regarding hormonal contraception and HIV to explore strategies to address the gaps identified in programmes and policies including implementation research.

13:30 -14:30	**Flash presentations**: Intersection of Family Planning and HIV	Chair: Sifelani Malima
13:30 – 13:38	Consideration of FP needs for women and adolescent girls when implementing ART programs including the use of DTG	Morkor Newman
13:38 – 13:46	Consideration of the FP needs of women when developing pre-exposure prophylaxis (PrEP) programmes	Michelle Rodolph
13:46 – 13:54	Counselling and communication on HC and HIV	Beth Mallalieu
13:54 – 14:04	Planning for FP programmes in the context of HIV	Tim Mastro
14:04 – 14:30	**Questions and answers**	
14:30-14:45	Statement from Civil Society Meeting	Yvette Raphael
14:40-15:00	The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial	Jared Baeten

Session 5: To explore strategies to address the gaps identified in programmes, policies and research including implementation research

15:00 -16:15	***Working groups:*** Addressing the gaps identified	Chairs:
	Identify and propose solutions to key current gaps in: **Working group 1:** Family Planning policies and programmes that are relevant to HC and HIV **Working group 2:** Basic research that are relevant to HC and HIV **Working group 3:** Epidemiology and implementation research that are relevant to HC and HIV **Working group 4:** Intersection between Family Planning and HIV, including PReP, DTG, HIV testing and referral. **Working group 5:** Counselling and communication	Agnes Chidanyika Sharon Cameron Phil Hannaford Emily Bass Lebogang Ramafoko Mike Mbizvo

	Working group 6: Integration of FP and HIV services	
16:15 - 16:30	***Tea***	

Session 6: Group feedback:

16:30 -17:50	***Feedback of Working groups:*** Addressing the gaps identified	Chair: Helen Rees
17:50 – 18:00	***Synthesis***	Helen Rees

Day 2: Wednesday, 27 February 2019

Session 7: To present a summary of previous day and to review communication and counselling messages on hormonal contraception and HIV its implications for research, programme and policy – in this session some general principles on whom to involve in communication will be explored.

08:30 – 09:00	Feedback on previous day	Chair: Limpho Maile
09:00 -10:00	**Flash presentations**: Communication – engaging stakeholders	
09:00 -09:08	Engaging diverse stakeholders	Joanna Skinner
09:08 -09:16	Community engagement.	Yvette Raphael
09:16 -09:25	Youth and populations at high risk	Natasha Salifyani Kaoma
09:25 -10:00	**Discussion**	
10:00 -10:30	***Coffee***	

Session 8: To review communication and counselling messages on hormonal contraception and HIV its implications for research, programme and policy – in this session some specific communication strategies for the ECHO-results will be presented.

10:30 -12:00	**Short presentations (8 minutes each):** Specific communication strategies	Chair: Mary Mulombe Phiri
10:30 – 10:38	WHO communication strategy	Cath Hamill
10:38 – 10:46	ECHO communication strategy	Nomthandazo Mbandazayo
10:46 – 10:54	Provider-client Communication messaging from the February 2017 WHO guidance	Mary-Lyn Gaffield
10:54 – 11:04	Country experiences - Kenya	Edward K. Serem
11:04 – 11:12	Country experiences - eSwatini	Lindiwe Malaza
11:12 – 11:20	Country experiences - Zambia	Angel Mwiche
40 minutes	**Discussion**	
12:00 -13:30	***Lunch***	

Session 9: Aim: To get an update on the status of the ECHO-trial and to review country readiness for the results for the ECHO-results that will be presented.

13:30 -14:30	***Presentations on***: Anticipating ECHO results	Chair: Foibe Moses
13:30 – 13:50	Update on WHO guideline development process	Mary-Lyn Gaffield
13:50 – 14:00	Country preparedness - overview	Leopold Ouedraogo
14:00 – 14:10	Country preparedness – Tanzania Cameroon	 Zuhuru Mbuguni Florence Zeh Kakanou
14:10 – 14:30	Discussion	

Session 10: To identify priority actions on communication required in anticipation of the ECHO study results

14:30 -16:00	***Working groups:*** a. What are the critical components of readiness? b. How should the results be delivered to countries? c. What action should be taken to prevent inappropriate reactions by policy makers and programme managers? d. What action should be taken to prevent inappropriate reactions by providers and users?	Chairs: Fatim Tall Sanni Saliyou Sarai Malumo Sitembile Dlamini-Nqekto
16:00 -16:30	***Tea***	
16:30 -18:00	***Feedback on working groups***	Noela Chicuecue

Day 3: Thursday, 28 February 2019

Session 11: To develop country specific priority actions in anticipation of the ECHO study results

09:00 -12:00	***Working groups:*** Priority actions for countries	
12:00 -13:30	***Lunch***	
13:30 -15:30	***Feedback Working groups:*** Priority actions for countries and the way forward	Chair: Mtumwa Ibrahim Kombo

Session 12: Summary and concluding results

15:30 – 15:50	Summary of the meeting and discussion on output of the meeting	Petrus Steyn
15:50 – 16:00	Concluding remarks	Ian Askew

Annex II: Gaps identified in programmes, policies and research

Group 1: Family Planning policies and programmes relevant to HC and HIV

Gaps identified	Current situation (why a gap)	Proposed solution(s)
Standardised definition of high risk for HIV in various policies	Service providers unclear about what counts as high risk.	Include definition in policies
No female controlled method for HIV prevention that is easily available	In many countries no access to PrEP or female condoms	• Ensure relevant policies changed to allow PrEP • Strengthen provision of PrEP and demand creation • Conduct and deploy Implementation science on adolescent girls' use of PrEP
Separate FP and HIV policies	Sectors don't talk to each other	Integrated policies and ensure joint planning
No policy that provides a clear enabling environment for woman to take decision and consent to contraception	Lack of women's empowerment	Allow better method mix
Age of consent barriers not allowing access to services (either contraception or HIV testing).	Countries differ in experience. Different age group limits for each of the different groups. A barrier to accessing services	Align [and revise] laws and policies where possible.
Comprehensive Sexuality Education (CSE) not allowed to be given to young people	Young people and adolescents don't have the information and education they need to make informed choice about contraception or HIV prevention	Work with Ministry of Education to implement at least the parts that are acceptable culturally or religiously as a starting point

Group 2: Basic research relevant to HC and HIV

Gaps identified	Current situation (why a gap)	Proposed Solutions
Data on HIV risk and newer contraceptives (Net-EN, low dose DMPA, DMPA-SC, UPA)	Has not been studied in a clinical trial	Determine possible study design following ECHO results
Standardized methods and endpoints/outcomes for many aspects of studies: specimens, timing, lab methods, exposure measurement		Update research gaps Identify new and better norms for doing studies
Basic research/in vitro mechanistic studies to explain results of clinical studies and inform new studies		In vitro and mechanistic studies
Indirect effects of bleeding, vaginal washing, behaviour and standardized methods to measure		Standardize measurement of confounders and effect modifiers
Funding to preserve specimens from large studies/trials and to catalogue specimens Agreed study designs to use samples in a strategic way to answer questions about biologic mechanisms	Insufficient coordination and incentives among research networks Inadequate funding	Funding support to catalogue biologic samples we have and determine how to use in a strategic way to answer questions about biologic mechanisms

Group 3: Epidemiology and implementation research relevant to HC and HIV

Gaps identified	Current situation (why a gap)
How is “high risk” defined? Can risk or high risk be assessed?	Suggested that definition of “high risk” can vary by geography, individual, behaviour, location, co-morbidities
Are women who use PrEP different than those who don’t use PrEP?	Background differences between women PrEP users and non-users may be an important confounder for future studies
Are there factors that modify the association between DMPA and HIV acquisition?	Does the association between DMPA and HIV acquisition vary by age, co-morbidities, co-medication, behaviours, PrEP use, other factors?
Implementation: how will any new recommendations from ECHO results impact stockouts? Practical options to address any changes in FP practice or policy that may result from new recommendations (i.e. if DMPA is shown to increase risk of HIV acquisition?)	
Poor understanding of the drivers of provider bias. For example, how does provider bias influence programme and policy makers’ perceptions and vice versa.	Provider biases defined by age, cost, stock-outs, training, availability, personal biases and regulatory issues
Implementation research: How do women/men/couples weigh the trade-offs in different risks?	

Group 4: Intersection between Family Planning and HIV, including PrEP, DTG, HIV testing and referral

Gaps identified	Current situation (why a gap)	Proposed solution(s)
Missed opportunities • SRH officer from MoH pushing uptake of FP options without taking advantage of offering HIV prevention options • HIV officer pushing HIV prevention/treatment without offering FP	Desire to have more women on more family planning options Increase uptake to HIV prevention services	A tool to merge these two approaches (FP and HIV) Integration of training modules for facility (on site) training Integrated planning Develop referral system between FP and HIV services; mapping of all providers offering these services
Limited number of HCWs unable to provide all needed care Provider initiated FP in HIV clinics for people living with HIV. In some, providers push for shorter-term methods (DMPA/COC). LARC referred to FP clinics in same or other facility Provider initiated testing and counselling for HIV introduced in FP clinics, initiated in 2013	Need for health systems strengthening Limited cross-function training Most structures have only a single room to provide ART services.	Integrated facility based trainings to allow for training more people in FP/Reproductive Health/HIV. Expansion of investment of staff and other cadres Innovative response and tools e.g. increased use of the phone. PEPFAR COP 2019: pushing for more staff.
Access to DTG • Access to DTG by women of reproductive potential • Access to LARC to make DTG feasible • DTG/LARC access impeded in settings where faith based providers (especially Catholic) will provide ARV but not FP. • Women's knowledge of LARC	Need to clarify how to deliver DTG Policies and provider bias	Develop a clear consent form re: offering DTG and possible side effects. Ensure DTG offered routinely; people informed it is an option (some reports people have to ask for DTG and/or women not able to access DTG) Informed choice for women on ARV; choices is also important
Capacity for Counselling • FP and HIV both require intensive counselling. System needed to combine counselling: FP, PrEP, ARV, DTG, HIV self-testing • Healthcare worker time for counselling.		Build capacity of HIV counsellors to work across topic areas

Group 5: Counselling and Communication

Gaps identified	Current situation (why a gap)	Proposed solution(s)
Lack of objective and judgment-free counselling	• Lack of time/resources for wide-ranging, contextualized counselling discussion with time for questions • Power imbalances • Cultural factors (clients as passive recipients of information) • Provider biases	• More feedback (requires more time, resources, training of counsellors, including around unconscious biases) • Stronger assurance of confidentiality • Use existing HIV lay counsellors and infrastructure, with updated skills and tools. • Broaden counsellor base beyond people with bio-medical background.
Lack of trained counsellors (specifically trained to counsel)	• Limited resources	• More investment and speed training counsellors • Use existing HIV lay counsellors and infrastructure, with updated skills and tools. • Broaden counsellor base beyond people with bio-medical background.
Lack of specific counselling resources (including easy-to-use tools) Lack of accommodation of language, vision, hearing difficulties	• Limited resources	• Leverage HIV experience of improving treatment literacy. • Myths v Facts tools • Definitional and language tools • Risk assessment tools • Interactive tools and exercises
Lack of clarity and consensus around trusted sources of information. Lack of effective, non-stigmatizing communication to 'women-at-risk'	• Higher illiteracy rates among women • Complexity of issues • Lack of distinction between information-sharing and counselling • Political/cultural forces proscribing some language/concepts	• Leverage HIV experience of improving treatment literacy. • Myths v Facts tools • Definitional and language tools • Move to human rights / gender equality framework
Guidance for moment of ECHO results are released	• Protocols	• Focus on available channels and tools in interim • Landscape analysis

Group 6: Integration of FP and HIV services[4]

Gaps identified	Current situation (why a gap)	Proposed solution(s)
Opportunities missed at service delivery level	Multiple benefits (provider, client, policy makers) not clearly known Incomplete integration of services Vertical services	Clearly articulate benefits of integration at multiple levels in terms of why it is important to integrate. Communication and advocacy, educate on integration to bring resources back to a comprehensive approach to SRHR.
Confidentiality at multiple levels: i.e. information, data-protection and physical space	Lack of safe supportive environment for vulnerable populations Lack of privacy during counselling	Accountability framework
Failure to integrate stigma and discrimination, GBV, within SRHR/HIV services	Stigma and discrimination, coercion, violence faced by vulnerable populations Can lead to lack of informed choice	Supportive attitudes, safe and supportive enabling environments particularly for vulnerable populations Tools for providers to identify and respond to stigma and discrimination, GBV and related needs.
Provider capacity to address a number of SRH and HIV issues	Not enough health care providers, inadequate training	Better distribution of tasks Better training and organization Integrated standard operating procedures for healthcare workers Incentives
Empowering communities and meaningful community engagement	Adolescents, PLHIV, key populations do not have access to quality services Harmful laws and policies	Demand generation for integration at community level and with civil society Identifying support systems available within communities. Build capacity for communities. People-centred care across the life course
Multi-sectoral integration	Inadequate planning across sectors Inadequate joint solutions	Joint planning across sectors Absorbing innovative approaches (digital platforms, self-care,

[4] For more information see: WHO and UNFPA 2018 *Call to Action to attain universal health coverage through linked sexual and reproductive health and rights and HIV interventions* https://apps.who.int/iris/bitstream/handle/10665/273148/WHO-RHR-18.13-eng.pdf?ua=1

	Lack of broad-based political will, with accountable leadership and governance	multipurpose technologies) into SRHR/HIV
Measuring impact of SRHR/HIV	Need for indicators. What gets measured gets done because need to report on indicators.	Integrated combination indicators
Confining integration to services in the absence of policy and programmes	Without integration at policy level, service providers are overwhelmed.	Policies harmonized. Clearly articulated benefits at policy levels
Vertical funding	Successful integration requires resources Bringing attention to difficulties is a benefit in itself. Short-term donor funding that does not build upon successful policies and programmes. Use of funding for specific programmes for other areas. Commodity insecurity	Resource mobilization for integrated approaches and interventions Commodity security at service delivery point
Too many vertical tools		Integrated tools, integrated package of services; and integrated guidance
Brain drain, turnover, challenges with skills retention		Motivation for HCWs, results based financing

Annex III: List of resources promoted at the Hormonal Contraception / HIV Consultation

Hormonal Contraception and HIV

- ECHO fact sheet and ECHO FAQs http://echo-consortium.com/about-echo/
  - http://echo-consortium.com/echo-study-factsheet/
  - http://echo-consortium.com/echo-study-qa-november-2017/
- Hormonal contraception eligibility for women at high risk of HIV: Guidance statement - https://www.who.int/reproductivehealth/publications/family_planning/HC-and-HIV-2017/en/. This is a summary of the March 2017 decision to change DMPA from a category 1 to a category 2 in the MEC guidelines and the reasons why.
- http://resultsforinformedchoice.org – a collection of all available resources gathered in one place. It's searchable. Includes country snapshots of key FP and HIV data and a timeline. It is intended to be a community resource so not duplicating efforts.
- Preparing for Outcomes Model, FHI360 https://planning4outcomes.ctiexchange.org/
- ECHO Scenario Planning Template that helps countries to think through the different programmatic implications for 8 different scenarios (available from the WHO SharePoint site)
- AVAC materials on informed choice, policy and programs, e.g. MEC, DSMB, partial protection.
  - https://www.avac.org/trial/evidence-contraceptive-options-and-hiv-outcomes-trial-echo
  - https://www.avac.org/hc/basics
  - https://www.avac.org/resource/what-dmpa-and-grades-family-planning
  - https://www.avac.org/data-safety-monitoring-boards
- Every Woman Matters: Statement from Civil Society Meeting on HC-HIV, 24-25 February, 2019: https://resultsforinformedchoice.org/material/every-woman-matters-statement-from-civil-society-meeting-on-hc-hiv-24-25-february-2019/

Contraception

- Medical eligibility criteria for contraceptive use, 5th edition https://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/
- Selected practice recommendations for contraceptive use, 3rd edition https://www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/
- 2018 Global Family Planning Handbook: www.fphandbook.org A handbook for providers that consolidates all the guidance regarding FP and contraceptive use in one place. The latest edition is February 2018 and includes updated 2017 guidance.
- Medical Eligibility Criteria (MEC) App - https://www.who.int/reproductivehealth/mec-app/en/

SRHR and HIV integration

- HIV and SRHR linkages infographic snapshots - bring together the key indicators for the full scope of SRHR and HIV linkages one place and are available for 25 countries. https://www.who.int/reproductivehealth/hiv-srhr-linkages-infographic-snapshots/en/
- Call to Action to attain universal health coverage through linked sexual and reproductive health and rights and HIV interventions https://apps.who.int/iris/bitstream/handle/10665/273148/WHO-RHR-18.13-eng.pdf?ua=1
- FP and HIV integration wheel (hard copies were available at the meeting) – this infographic highlights the current guidance from WHO relating to FP and HIV integration. https://www.who.int/entity/reproductivehealth/test/Linkages-FP-HIV.pdf?ua=1
- WHO portal to SRHR and HIV integration tools and resources - https://www.who.int/reproductivehealth/topics/linkages/en/

Media training and communication

- Media landscape mapping JHU CCP have conducted https://resultsforinformedchoice.org/material/assessing-communication-and-advocacy-needs-around-the-evidence-for-contraceptive-option-and-hiv-outcomes-echo-trial-results-a-landscape-assessment/
- AVAC resources on research, communications and other related topics: https://www.avac.org/resources
- Strategic Communication Framework for Hormonal Contraceptive Methods and Potential HIV-Related Risks: http://healthcommcapacity.org/wp-content/uploads/2017/05/HC-HIV-strategy_May2017_final.pdf.

Annex IV: Follow-up support offered at the Hormonal Contraception / HIV Technical Consultation

Agency / Partner	Support offered
WHO Country Offices	• Provision of technical support • Support convening of WG and task teams in each country to ensure that the process gets started.
WHO Regional Office	• Available to provide technical support in countries, and to work with HQ to provide harmonized support. Regional office is close to countries and can support, including capacity building, and development and updating tools and guidelines. • Work on dissemination of the updated guideline including translation. • Considering 1 or 2 dissemination meetings to ensure clear understanding of outcomes and the implications of outcomes.
WHO Reproductive Health and Research Department, HQ	• Set up a communications group to connect and keep informed, develop some of the products discussed at the consultation, etc. Cath Hamill will follow up with an email and those interested can self-subscribe to the email list. • Planning to hold webinars to follow up to discuss where things stand and to share some of the materials they've developed. • If challenges arise with communicating the study status, scenarios, issues, etc. countries and HQ staff can link up and discuss how to help communicate the issues. Work at this time mostly focused on preparing for results. • When the findings are released, will share a statement interpreting the results and providing an explanation for what countries are expected to do whilst waiting for updated WHO guideline.
UNFPA	• UNFPA HQ will follow up with a webinar to update UNFPA country officers not at the meeting so they can engage and work with the country teams from this meeting. • Support with strategic demand forecasting as the implications of ECHO for pipelines and procurement infrastructure as part of supply chain management will be critical.
AVAC	• Continue to mobilize civil society (including women's SRH justice activists and advocates), and work in coalition with them • Planning media science cafes in every ECHO trial country during which researchers and CS and other experts talk informally with trusted experienced journalists. Available from AVAC on demand.
FP2020	• The FP 2020 reference group will meet in DC in April and ECHO is prominent on the agenda. • Convening a workshop in May in Addis for 17 countries in Africa working there and ECHO will feature prominently in the workshop. FP2020 will continue the conversation. • FP2020 works with many of the country teams already. FP2020 can support country plans and other activities at the country level.
BMGF	• Work with WHO to support the setting up of the country level working groups, and will explore how the communications and messaging activities of these groups could possibly be funded via existing country partners. • Continue to work with AVAC to support media training and media preparedness.

	• In terms of community engagement, BMGF are open to ideas from each of the countries as to what this might look like and what resources are needed to ensure the messages do not stop before they reach the contraceptive users.
USAID	• USAID will consider having regular phone calls with chair or lead of country working groups – will follow up and discuss this, possibly from regional and country support teams. • Research work on counselling and implementation is underway in Tanzania. Have approached many countries that are not willing to undertake this as yet. USAID will make results available when they are completed • Will share ongoing work on modelling with any countries that are interested through a webinar. • USAID can consider additional support if needed.