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Final Report: A pilot study to assess training and communication materials on progestogen-only injectable use and risk of HIV acquisition in Tanzania

Marie Stopes International/Glenna Gordon

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List of Abbreviations

CLIC	Client Information Centre
DMPA	Depot Medroxyprogesterone Acetate
EC	Emergency Contraception
FP	Family Planning
HIV	Human Immunodeficiency Virus
IUD	Intrauterine Device
LARC	Long-acting and Reversible Contraception
LAPM	Long-acting and Permanent Methods
MEC	Medical Eligibility Criteria
MOH/MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MSI	Marie Stopes International
MST	Marie Stopes Tanzania
OC	Oral Contraceptive
PLHIV	People Living with HIV
STI	Sexually Transmitted Infections
USAID	U.S. Agency for International Development
WHO	World Health Organization

Executive Summary

Background and methods

In February 2018, Marie Stopes Tanzania (MST), in partnership with the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC), undertook a study to understand provider and client comprehension of the WHO's new guidance on progestogen-only injectable contraception use among women at high risk for HIV, and how the new recommendations affect clients' decision-making on contraception.

Twelve MST mobile outreach providers (nurses and one doctor supervisor) were trained over 1.5 days to deliver WHO's new counselling messages regarding DMPA use and risk of HIV acquisition. All providers had achieved highest marks on MST's internal competency assessments. The new guidance was taken from WHO's recently updated Global Handbook for Family Planning Providers and transferred to two provider job aids, containing five key counselling messages.

We investigated understandings of the new guidance among clients who demonstrated an interest in injectable contraception (including repeat clients) or who had no specific method in mind prior to receiving counselling, as well as among providers themselves. A mixed methods design was employed using the following methods: (1) focus group discussions with providers (n=4); (2) clinical observations, using a structured checklist (n=36); (3) post-counselling semi-structured interviews with clients (n=78); and (4) controlled pre-/post-test of routine service data to assess trends in method mix over 6 months (n=231,165).

Key findings

Semi-structured interviews with clients suggested that while most understood there was a link between DMPA use and risk of HIV acquisition, they did not always accurately characterise the nature or extent of the risk. They spoke of themselves being at "higher" risk or it being "easy" to get HIV while using the method, but the level of risk was unspecified, and a majority were unable to put the new guidance into their own words. However, there were only a few critical misunderstandings of the effect of the method, with six reporting that the method "lead[s]", "spreads", or otherwise causes HIV. However, many clients understood that the virus ultimately was transmitted by having unprotected sex with a person living with HIV (PLHIV). Encouragingly, the new guidance seemed to reinforce the need to discuss HIV prevention.

Half of all client respondents expressed positive feelings regarding the new guidance, and a minority were negative, possibly reflecting the "bad" news about the method, rather than a negative reaction to the counselling. Only a small fraction of clients interviewed relayed that they would discourage friends or peers from using injectables.

In assessing the impact of the guidance on influencing method mix, while we interviewed or observed few switchers immediately post-training, our assessment of changes in method mix three months post-training demonstrated a small shift away from injectable to long-acting and reversible contraception (implants and IUDs). On average, we saw a nearly seven percentage point increase in LARC use in teams that received the intervention versus those who did not. Clients interviewed suggested that making a switch usually requires partner approval.

Providers in the study understood the new guidance and its impact on their client-provider interactions, and used all five messages in over 80% of observed counselling sessions following the training. All expressed positive feelings about the new guidance and the need to counsel their clients with the new messages because they felt that their clients should know all of the information about the method they choose. Providers also recommended that all clients be counselled using the new messages—including all who attend group education prior to individual counselling.

But while no providers made wildly inaccurate statements when recalling the relationship between DMPA and HIV, similarly to clients, the nuances of DMPA users being at a higher risk as compared to other FP users or non-users was not always correctly explained. Providers worried that their clients had not understood what they were saying and this new guidance could confuse or scare them. There was a particular unease with the second counselling message: "The meaning of these findings is not clear. We do not know whether or not this method causes this higher risk." Providers felt unable to explain this ambiguity to clients, and felt this message is most confusing to them. There was also one provider in particular who inaccurately advised some clients regarding hormonal contraception and HIV risk.

Discussion and recommendations

These findings suggest that there are important challenges to introducing the new WHO injectable guidance that implementing partners need to consider before wide-spread roll-out. Providers require at least a day's training in order to understand and practice counselling on the new recommendations. Our findings indicate they require more detailed teaching on the theorised role that injectables play in HIV acquisition in order to then simplify this messaging for clients. Post-training assessments may be necessary to ensure that concepts taught have been adequately understood. Experienced providers may need to act as possible referral points to explain the guidance or address client concerns in more depth.

Encouragingly, however, there were limited critical misunderstandings in our study, and both clients and providers welcomed the transparency about the method. A shifting method mix away from injectables to LARCs should be considered neither wholly positive or negative, but at least indicates that these MST clients were able to switch and not left exposed to the risk of an unintended pregnancy. Ensuring adequate method choice is therefore essential.

Background

The World Health Organization (WHO) recently updated recommendations on the use of progestogen-only injectables in its clinical guideline, *Medical Eligibility Criteria for Contraceptive Use (5th Edition).*[1] The unusual interim update is based on a recent updated systematic review of the evidence on the association between use of hormonal contraception and HIV acquisition. The meta-analysis contained in the systematic review found a risk of human immunodeficiency virus (HIV) acquisition 1.4 times higher among depot medroxyprogesterone acetate (DMPA) users compared to control groups (HR 1.40 (95% CI: 1.23–1.59)).

This systematic review and guidance update follows many years of accumulating evidence and debate on the relationship between hormonal contraceptive use and HIV acquisition. Several biologically plausible mechanisms have been suggested to explain how various hormonal contraceptive methods could increase women's risk of HIV acquisition, including possible disruption of epithelial barriers, alterations in immune cell populations, or soluble inflammatory responses.[2] These effects are further influenced by the presence of infections. Since the evidence of the association had previously been equivocal (some studies suggested increased risk, while others suggested decreased or no risk) and of low quality (all were observational with high degrees of selection bias and reporting bias on condom use), WHO had previously maintained that all women at increased risk of HIV acquisition should freely be able to use any hormonal method (all methods were given a category '1': "a condition for which there is no restriction for the use of the contraceptive method").

With the publication of the updated review and meta-analysis by Polis et al. (2016), WHO has shifted its recommendation for DMPA users (only), stating that women at high risk of HIV acquisition are a category '2' for DMPA use ("A condition where the advantages of using the method generally outweigh the theoretical or proven risks"), with the following clarification for the '2':

> *"CLARIFICATION: There continues to be evidence of a possible increased risk of acquiring HIV among progestogen-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestogen-only injectables are among the few types of methods widely available. Women should not be denied the use of progestogen-only injectables because of concerns about the possible increased risk. Women considering progestogen-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV" (see attached summary).*[3]

Within this guidance update, WHO is encouraging governments, sexual and reproductive health and HIV implementing organisations, and donors to translate this recommendation into concrete programming guidance. Since the guidance stipulates that all women at high risk for HIV intending to use DMPA should be informed about the potential increased risk of infection, there is a need to develop and test communications materials for programmes on this topic. The WHO recommendation and guideline does not define 'High risk of HIV acquisition' or provide detailed guidance on how women should be informed of the risk. A category 2 means that women can still use the method, but civil society groups have highlighted the risk of increased restrictions on DMPA use due to the changed guidance, which may result in turn in increased unplanned pregnancies and negative maternal health outcomes.[4] Since settings with generalised HIV epidemics in Eastern and Southern Africa also have high levels of DMPA use, it is critical to develop effective communication on this topic without limiting women's access to hormonal contraception more broadly.

Aim and Objectives

The aim of the study was to understand provider and client comprehension of the WHO's new recommendations for progestogen-only injectable contraception use among women at high risk for HIV, and how the new recommendations affect clients' decision-making on contraception, including the decision to use a specific method or to use contraception at all. The study was conducted in February 2018.

Our research objectives were as follows:

1. To assess provider understanding of the new WHO DMPA/HIV eligibility recommendations as outlined in MSI's training materials and communication materials;
2. To investigate how providers are communicating MSI messaging on the new recommendations with their clients;
3. To investigate clients' comprehension of the revised counselling messages; and
4. To investigate how the new recommendations affect clients' decision-making on contraception, including the decision to use a specific method or to use contraception at all.

[1]WHO (2016) Medical Eligibility Criteria for Contraceptive Use, 5th Edition. Geneva: World Health Organization http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/ [2]Polis CB, Curtis KM, Hannaford PC, et al (2016). An updated systematic review of epidemiological evidence on hormonal contraceptive methods and HIV acquisition in women. AIDS; 30(17):2665-2683. doi:10.1097/QAD.0000000000001228. [3]Ibid. [4]AVAC (2017). Now More Than Ever: A call for effective responses to provision of hormonal contraceptives in the context of HIV, women's sexual and reproductive health and rights. New York:Global Advocacy for HIV prevention (AVAC). http://www.avac.org/sites/default/files/u3/Now_More_Than_Ever.pdf

Methods

Methodology

This was a mixed method study that utilised (1) focus group discussions; (2) clinical observations, using a structured checklist; (3) post-counselling semi-structured interviews with clients; and (4) controlled pre-/post-test of routine service data to assess trends in method mix (Table 1).

Table 1: Study Design

Method	n
Focus group discussion with providers	4
Clinical observation of client-provider interactions	36
Semi-structured interview	78
Controlled pre-/post- test of routine service data	231,165
Intervention group	25,704
Control group	205,461

Intervention design

We trained 12 Marie Stopes Tanzania (MST) providers across three mobile outreach teams (mobile service teams using 4by4 vehicle units) and five Bajajis (mobile mini-clinics delivered out of auto-rickshaws) that operate in the regions of Mbeya, Tanga, and Dar es Salaam. Mobile outreach teams operate in mostly rural locations, delivering services on a one-day visit within small and medium government health facilities, returning to each site every 3 months; Bajajis operate in peri-urban areas in cities, delivering services over a 2-day visit, and return to their communities every 2 months. Mobile outreach teams are typically staffed with 2-3 providers and 1 driver; Bajajis are staffed by 1 driver and 1 nurse. Providers trained were 11 nurses and one doctor, of whom four were supervisors. Teams offer a full range of methods, including long-acting and permanent methods (LAPMs) (not usually available in the public sector); Bajaji clients are referred to government facilities for permanent methods.

We developed a 1.5-day training package that was delivered to the eight study teams by Tanzania's Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) staff, MST's quality coordinator, and one trainer from MSI/London. The training was administered in the context of a general refresher training on contraceptive counselling, using Marie Stopes International (MSI) global training materials (which reflect Tanzania's 2015 National Family Planning Procedure Manual), to avoid unintentionally overemphasising the new WHO guidelines, which may have raised undue alarm and unnecessary emphasis on a single method. The training provided the opportunity to reinforce the principles of voluntarism and informed choice and family planning counseling best practices. Providers were trained using a combination of didactic teaching and interactive learning (e.g., role plays, observation, etc.) to use WHO's new DMPA/HIV risk counselling messages that are included in the most recent update of its *Family Planning – A Global Handbook for Providers (Table 2).*

A foundational resource for many service delivery organisations, we determined that the original generic messages were applicable to the Tanzanian context. See Annex 1 for an outline of the training agenda, and Annex 2 for a detailed training plan.

Table 2: WHO Counselling Messages

DMPA/HIV Risk Counselling Messages	
1	Some research has found that women who use a progestin-only injectable and are exposed to HIV are slightly more likely than other women to get an HIV infection.
2	The meaning of these findings is not clear. We do not know whether or not this method causes this higher risk.
3	You can protect yourself from HIV.
4	You can still choose this method, but we want you to think about this information.
5	We have other long-acting and effective methods, and we can discuss them if you would like.

Providers were asked to incorporate these five messages into their standard family planning counselling and, when necessary, to put them into their own words.

Two provider job aids were developed for use during client counselling sessions. The first was a blue laminated sticker of the five counselling messages that was stuck on the DMPA page of providers' MOH flip charts.[5] It acted as a reminder to providers to use the five counselling messages with their clients. The second job aid was a single-page laminated chart that summarised the types of drugs used in hormonal contraceptives and the current medical eligibility criteria (MEC) recommendation for each method. During the training, providers asked for this reference material to be created into a job aid so they could explain the differences between DMPA and other hormonal contraceptives. Both job aids were translated into Kiswahili (local language) (and back translated into English).

Providers used the new counselling messages immediately post-training for nine days (February 5-14, 2018) prior to being observed and participating in small focus group discussions, and continued to use the messages during and post-data collection. Providers were asked to use the messages with all injectable clients or clients who had not yet stated a preferred method prior to receiving individual counselling. The number of injectable clients who received services by the study teams post-training and pre-data collection is shown in Table 3.

Table 3: No. of DMPA Users During Intervention Implementation Period

Intervention Implementation Period Prior to Data Collection			
Team	**# of DMPA Users**	**Team**	**# of DMPA Users**
Tanga	11	Danida 1	42
Kyela	19	Mwenge 1	22
Mbeya	17	Mwenge 2	7
Temeke 1	10		
Temeke 2	87	**Total**	**215**

Data collection took place over nine days of service provision and was completed in February 2018.

[5]During pre-testing, MST and Ministry of Health staff recommended the color blue for the job aid because it was a bright color that would help remind the provider to use the messages and it was culturally appropriate in this setting.

Selection of participants and intervention sites

All participant teams were selected based on (1) high levels of injectable use (determined by recent service statistics); (2) geographic areas covered by the mainland Tanzanian Ministry of Health (MOH) (i.e., excluding Zanzibar); (3) HIV prevalence rates (to allow for comparison between high prevalence (Mbeya) and medium prevalence (Tanga, Dar) areas); and (4) varying service delivery channels (Table 4).

Table 4: Sampling Plan Summary

Team	Region	HIV Prevalence	No. of Providers
Mobile Outreach	Mbeya (2 teams)	9.3%	4
	Tanga	5.0%	3
Bajaji	Dar es Salaam (urban/ peri-urban communities)	4.7%	5
Total			**12**

Source: Tanzania HIV Impact Survey 2016-2017

Clients who demonstrated an interest in injectable contraception (including repeat injectable clients) or had no specific method in mind prior to receiving individual counselling were recruited to participate in a post-service interview with research staff, and informed consent was obtained.[6] Clients were not recruited prior to receiving individual counselling because we wanted to reduce any chance of confusion by all clients waiting to receive services by introducing the new messages during pre-service group education. The sample was designed to have a minimal impact on service delivery while ensuring adequate information was gathered to achieve study objectives.

We recruited client participants during the entire data collection period and there was no maximum threshold set for study teams.

Routine data was comprised of all clients served by the eight participating teams in the 3 months prior to training (November 1, 2017 – January 30, 2018) and in the 3 months after training (February 5, 2018 – May 5, 2018).

Clinical observations

To assess adherence to training and WHO's eligibility recommendations, providers were observed during client consultations by trained clinical staff recruited by the Ministry of Health. Observers were retired nurses or other medical professionals who understood the context of the client-provider interaction, were familiar with the study environment, and could collect data as unobtrusively as possible.

We developed a 31-question structured checklist, with dedicated space for observers' field notes and additional observations. The checklist covered previous FP use and sexual history; use of IEC materials by the provider; STI/HIV risk and dual method protection counseling practices; use of the five new messages; and quality-related indicators.

The demographic characteristics of the observation sample are below (Table 5).

Table 5: Demographic Characteristics of Observation Sample (Final Analytic Sample)

Characteristics (n=36)	n (%)
Age	
18-20	3 (8%)
21-25	5 (14%)
26-30	15 (42%)
31-35	8 (22%)
36-40	4 (11%)
>40	1 (3%)
Education level	
None or incomplete primary	2 (6%)
Primary or incomplete secondary	24 (67%)
Secondary	8 (22%)
>Secondary	2 (6%)
Type of client	
New user	7 (19%)
Repeat/refill	21 (58%)
Switching method	8 (22%)
HIV status (self-reported)	
Negative	21 (58%)
Positive	1 (3%)
Unknown	14 (39%)

Due to concerns regarding the quality of data collection of three of the study teams, observations from those teams were dropped from the analysis, resulting in the observational data reflecting a total of 5 study teams (2 mobile outreach teams from the Mbeya region and 3 Bajaji teams) (Table 6).

Table 6: Observation Data Sampling Summary

Type of Team	Region	% of Observations	No. of Providers
Mobile Outreach	Mbeya (2 teams)	47.2%	4
Bajaji	Dar es Salaam	52.8%	5
Total			**7**

Several measures were undertaken to validate the data collected by the remaining study teams.

Stata 14.2 was used to analyze the clinical observation data and produce descriptive statics.

[6] A total of 8 non-DMPA users are included in the client interview sample: 7 implant users, and 1 contraceptive pill user.

Semi-structured client interviews

To investigate clients' comprehension of the new counselling messages and their effect on clients' decisions regarding family planning use, we developed a semi-structured topic guide to be administered by the research team after a client received family planning services from participating MST providers. The guide was divided into two main topic areas, service experience and family planning counselling, a total of 12 questions. The topic guide was not designed to assess clients' verbatim recall of each of the five counselling messages; rather, we aimed to investigate what, if any, information regarding DMPA and HIV risk in general clients understood after receiving counselling.

Interviews were semi-structured, so not all 12 questions were asked of all clients. Suggested probes were included in the topic guide.

Some clients who were interviewed were also observed, but the data were not linked.

Among those interviewed, there were 70 clients who received DMPA and 8 clients who received other hormonal contraceptives (implant or pill).

Interviews were recorded and transcribed verbatim, and translated into English for analysis.

Small focus group discussions

To assess providers' understanding of and their feelings about the new guidelines, we developed a semi-structured topic guide to be administered by two research staff at the completion of the service delivery period of data collection (one interviewer, one note-taker). Providers were interviewed by team (three mobile outreach teams and all five Bajaji providers as one team). Four discussions were held in total.

The topic guide covered comprehension of DMPA/HIV counselling messages and acceptability of DMPA/HIV counselling messages.

Discussions were conducted in Kiswahili, and recorded, transcribed and translated into English.

All 12 providers participated in the focus group discussions. The majority (66%) of providers had been providing FP services for 5 years or less.

Controlled pre-/post-test of routine service data

Data from Marie Stopes Tanzania's Client Information Centre (CLIC), an electronic health management information system, were extracted to assess trends and changes in method mix. Data from all clients receiving services from each of the eight teams were extracted between November 1, 2017 – May 31, 2018 (three months pre- and post-training). CLIC records data for every transaction that a client has while visiting an MST mobile outreach or Bajaji team (i.e., multiple service and payment points are recorded as separate entries, linked by a unique client ID). The dataset was collapsed to the client visit (i.e., one record per client), allowing estimation of proportions of clients for each outcome of interest.

CLIC data for two of the mobile outreach teams in the intervention group were not available or complete for the analysis period and were excluded; results apply to six of the eight teams that received the intervention.

We also compared data from intervention teams to control teams who did not receive the training intervention or job aids. This comprised 40 teams operating throughout the rest of Tanzania.

The primary outcome was contraceptive method mix, which was compared three months prior to the intervention (November 1, 2017 – January 30, 2018), to three months afterwards (February 5, 2018 – May 5, 2018), and compared between teams who received and did not receive the intervention. Clients who received more than one method, for example as dual method protection, were included in the analysis as the most effective method only. The extent of proportional change in method mix was estimated for each group, with the change within each group tested for significance using linear regression analysis. The extent of change between the groups was compared using difference-in-difference regression analysis.

A secondary analysis assessed changes in the number of condoms provided across the pre-/post-period, to assess any change in the number of condoms distributed before and after the intervention.

In total, between November 1, 2017 – May 5, 2018, 245,224 individual client visits in which a family planning method was received were recorded in CLIC. Of these visits, 94.3% (n=231,172) were made by women. The remaining 5.7% (n=14,052) were men and were excluded from the analysis. Overall, seven clients (<0.01%) were recorded as less than 10 years old. These clients were excluded as they were unlikely to be visiting for services relevant to this analysis. After these exclusions, 231,165 clients remained in the dataset for analysis: 25,704 in the intervention teams and 205,461 in the remaining teams (controls).

Most clients were in the 20-24 and 25-29 age bands (28% and 23%, respectively).[7]

Coding and analysis of qualitative data

Interview and focus group discussion data were analysed using the framework method. Thematic matrices were developed based on the research questions. Each row represented an interview response or a team's focus group discussion and data were analysed across different themes. We then assigned codes to relevant portions of the interviews as a tool to help identify themes and patterns. The codes were developed deductively from the topic guide, and inductively from the interview data.

[7]Client records in CLIC record 5-year age bands rather than date of birth.

Results

Client comprehension of counselling messages

In recalling what they had been told by the provider about DMPA, its health risks, if any, and HIV in general, the majority of clients were able to recall or describe a link between DMPA and risk of HIV acquisition; however, clients did not accurately characterise the risk of acquiring HIV as a DMPA user. When asked to report what the provider said about the risks associated with DMPA use and HIV, clients often used "easy", "easier", "risk", and "higher risk" to describe the link between DMPA and HIV. In practice, these terms were used interchangeably to describe the new guidance:

> ***"When you use [the] injectable method it is easy to be infected by HIV/AIDS." (Mobile outreach client)***
>
> ***"It is easy to get infections of HIV from […] Depo." (Bajaji client)***
>
> ***"…if you're using Depo there is high risk of getting HIV/AIDS." (Mobile outreach client)***
>
> ***"This method makes someone to be at higher risk of getting HIV." (Bajaji client)***

While clients were able to recall a link between DMPA and risk for HIV acquisition (93% of respondents), the nature or extent of the risk was often lost. Clients did not usually qualify the risk. For example, they usually did not describe the ways a person becomes at risk of acquiring HIV (e.g., having unprotected sex with a person living with HIV) in order to be at risk. The risk associated with Depo exists in a vacuum, meaning that it is "easy" for a person to acquire HIV regardless of their exposure to it. Twenty-six out of 72 respondents (36%) reported that DMPA makes it "easy" or "easier" to acquire HIV.

Among clients interviewed, 25% percent of respondents made inaccurate statements about the new guidance when asked what do they plan to tell their peers about the injectable. Six clients reported that DMPA "lead[s]", "spreads", or otherwise causes HIV, and one client reported that the provider said "the injection is dangerous."

> ***"Injectable methods also lead to the virus, causing high risk of HIV transmission." (Mobile outreach client)***
>
> ***"It spreads HIV." (Mobile outreach client)***
>
> ***"Most women are getting HIV infection because of the injectable method." (Mobile outreach client)***

A small proportion of client respondents (7) inaccurately described the mechanism of action of DMPA as it relates to HIV. Clients described DMPA as having a drying effect on the vagina or making a woman's cervix "delicate," which makes a woman more susceptible to acquiring HIV:

> ***"It makes the cervix delicate, and during sexual intercourse the woman can easily get bruises…and you can easily get HIV/AIDS." (Mobile outreach client)***
>
> ***"When the vagina get[s] dry you can easily get HIV infections, this is caused with the injectable." (Bajaji client)***
>
> ***"The provider told me that with injectable method it is very easy to get HIV infections because it has the tendency of cause dry vagina." (Bajaji client)***

It's unclear if some providers interpreted the new guidance in a way that resulted in this description of the mechanism of action; or, if respondents interpreted what they were told in a way that made sense to them. Similarly, two clients reported that "researchers" or "specialists" are "investigating" the "quality of [Depo]," another description or interpretation related to its mechanism of action (or the quality of it).

Although clients did not always accurately characterise the risk associated with DMPA, almost 40% of respondents described how to protect oneself from HIV; mentioned at least one HIV prevention strategy (e.g., use of condoms, limiting the number of sexual partners, avoiding unprotected sex, etc.); or, described at least one risk factor for acquiring HIV (e.g., unprotected sex with a person living with HIV (PLHIV), multiple sexual partners, etc.), meaning many respondents understood that, ultimately, having sex with a person living with HIV (or another risk behaviour) would lead to transmission—not the injectable itself. However, when clients discussed having to have sexual intercourse with a PLHIV, clients did not always clarify that the intercourse would have to be unprotected.

Most clients mentioned explicitly in their interviews that DMPA does not prevent HIV. This is obviously accurate, but this wasn't one of the five new messages that providers were trained on. Although it's standard in family planning counselling to tell clients that DMPA does not prevent STIs, including HIV, the implementation of the new guidance has reinforced this standard information in a way that resulted in it being repeated throughout most interviews.

In addition to reporting what they were told by the provider, we asked clients to put the new guidance in their own words. The majority of clients recalled or were able to describe a link between DMPA and risk of HIV acquisition. The characterisation of the risk was similar to what was reported when asked what they were told by the provider, but a smaller proportion of respondents described at least one HIV risk factor (27%), and only seven clients described having to protect oneself from HIV or mentioned at least one HIV prevention strategy.

In their own words, only two clients stated that Depo "causes" or "transmits" HIV:

> ***"…the injectable cause[s] the HIV infections when you do the sexual intercourse with the affected person." (Mobile outreach client)***
>
> ***"[Depo] is easy to transmit infections." (Bajaji client)***

Among those who were asked, approximately 30% of clients said they couldn't put the guidance into their own words.

Effects on clients' decision to use family planning

In our interview sample, only one client switched from DMPA to another method (implant) because the provider advised her on the risks associated with long-term use of DMPA and its effect on bone density, which she stated was the primary reason for switching methods during her visit.

However, one-third of clients expressed a desire or plans to switch from DMPA to another FP method in the future. One Bajaji client shared, "Once I get the results [of future studies] I will stop using it." A mobile outreach client said she would "not inject again."

Clients who expressed a desire to switch from DMPA to another method in the future delayed their decision to do so because they had already committed to receiving DMPA that day. Some clients indicated that any deviance from set plans would have to be discussed with their husbands or partners, a norm that was also identified and discussed by providers during training. A few clients wanted to wait until further studies provided more conclusive evidence regarding the link between DMPA and HIV risk.

Among the five clients who discussed their current or intended use of dual methods, two clients indicated their plans to protect themselves from HIV using condoms in addition to other methods; two clients perceived themselves as not being at risk for acquiring HIV (and therefore did not intend to use condoms); and one client described the need for women to protect themselves in general because women may not know if their partners are faithful and/or using protection in their extramarital affairs.

Clients' feelings about the new guidance

Half of all respondents expressed positive feelings regarding the new guidance. As one Bajaji client expressed, "I thank God, I have never heard and the good thing is that they informed me in detail and with depth." Another said she "[felt] good because I was told the reality."

Clients who expressed positive feelings did so because of their appreciation for being told information that will help them make an informed choice.

When asked what they plan to tell their peers and social networks about DMPA or other hormonal methods, half of all respondents expressed positive feelings about DMPA or family planning in general. For example, a Bajaji client shared, "I will tell her that Depo is the good method but you need to protect yourself from HIV because it only protects you from pregnancy not HIV."

Almost one-third of respondents expressed negative feelings regarding the new guidance, often saying they felt "bad." The expression of negative feelings may reflect the general nature of the new guidance (i.e., what could be characterised as "bad news"), or how the new guidance has impacted their feelings towards DMPA or family planning in general.

Although these clients expressed negative feelings about the new guidance, 12 of them also expressed that they are happy to know all of the information about DMPA. When asked what they plan to tell their peers and social networks about DMPA or other hormonal method use, only 10% of respondents expressed negative feelings about the new guidance, including four clients who stated they would not recommend or discourage their peers to use it:

> ***"I will tell them the injectable method is very dangerous." (Mobile outreach client)***
>
> ***"They have to look at other options of family planning method." (Bajaji client)***
>
> ***"I will tell them… it causes HIV infections when you have sexual intercourse with a person with HIV." (Mobile outreach client)***
>
> ***"I will tell them about the method of family planning and how it causes HIV/AIDS." (Bajaji client)***

But among clients who planned to dissuade their peers from using DMPA, some of them also expressed positive feelings regarding the new guidance, further illustrating the complexities of clients' responses to this topic. For example, the mobile outreach client who plans to tell her peers that the "injectable method is very dangerous" also expressed that she "felt good" about the new guidance because "now [she] knows." The mobile outreach client who planned to tell her peers that DMPA "causes HIV infections" (which could be perceived as causing HIV) also expressed that she feels "good because they (the providers) are helping us." So, while only few clients planned to share negative feelings about the new guidance to their peers and social networks, the descriptions of what they plan to share is concerningly inaccurate.

Approximately 20% of respondents expressed neutral feelings regarding the new guidance, often qualifying their responses by discussing their own personal risk (i.e., if they didn't perceive themselves as being at risk), or putting the guidance into a broader context by discussing HIV prevention strategies. For example, one Bajaji client shared, "Of course I was shocked but it's a matter of how are you protecting yourself from HIV."

Approximately 28% of respondents expressed similarly neutral sentiments when asked what they plan to tell their peers or social networks, often saying that it's up to their friends or family to choose the method they want to use, while others want to continue using DMPA "for a while" before deciding what to their friends.

Clients' feelings regarding the family planning counselling they received

Almost every client used positive language to describe the FP counselling they received. Respondents reiterated that they appreciated being told about the new guidance because it helps them make an informed decision about their health and their decision to use (or not use) family planning.

Some clients noted that the counselling was longer than what they had experienced previously, but it didn't lead to using negative language to describe the counselling they received during the study. The length of counselling was compared to what they had received in a different clinic or at a pharmacy, which can be less comprehensive and therefore shorter in nature.

Eight clients expressed negative feelings regarding the counselling, mostly due to the length of counselling. If clients had never received comprehensive FP counseling previously, the length of the counseling received by an MST provider would seem lengthy by comparison. This expression of negative feelings did not necessarily translate into a dissatisfaction with the services she received.

One client was dissatisfied with the provider's answers to her questions regarding DMPA use and fertility. The data collector referred her to a clinic manager.

Provider comprehension of counselling messages

All providers reported understanding the new the guidance and its impact on their client-provider interactions; no provider made a wildly inaccurate statement about the new guidance. When asked to put the guidance into their own words, their responses reflected that they have a clear understanding of the guidance; however, similarly to clients, the nuances of DMPA users being at a higher risk as compared to other FP users or non-users sometimes isn't perfectly explained. For example, one provider relayed:

> ***"Many women who use…Depo can get HIV transmission when they have intercourse with an infected person."***

Another provider described it this way:

> ***"A client that uses [the] injection method has a high chance of acquiring HIV infection and not the other one."***

The use of the terms 'many women' and 'high chance' suggests an elevated risk above that demonstrated in the literature.

Only one provider suggested that women may want to consider switching to implants due to the increased risk of HIV acquisition.

Providers' feelings about the new guidance

All providers expressed positive feelings about the new guidance and the need to counsel their clients with the new messages because they felt that their clients should know all of the information about the method they choose.

Providers recommended that all clients be counselled using the new messages—not only DMPA users (or clients who had no method in mind and received comprehensive FP counselling (as per study design))—including those who attend group education in the morning prior to individual counselling. Providers also recommended that all clients should receive counselling on STIs, including HIV; however, observational data demonstrated that not every client received such counselling.

Despite their overall positive feelings about the new guidance, providers worried that their clients had not understood what they were saying and this new guidance could confuse or scare them. Providers reported that many of their clients like and prefer DMPA so there is a concern that clients won't know how to respond to the new guidance. To facilitate their clients' understanding of the new guidance, providers recommended developing client-facing material(s) that clients could take home with them.

Four providers expressed their recommendation or preference for DMPA to be removed from FP services if future studies confirm the meanings of the research; others would prefer to see DMPA be modified so that the risks associated with HIV can be mitigated and clients can continue to use DMPA. All providers expressly asked for an update as soon as future studies provided more conclusive results.

Providers expressed specific uneasiness and frustration about the second counselling message: "The meaning of these findings is not clear. We do not know whether or not this method causes this higher risk." Providers felt unprepared in front of their clients because they could not explain what "The meaning of these findings is not clear" means to their clients, and they sense this is the message that is most confusing to clients.

When asked to describe the side effects or disadvantages of DMPA, no provider mentioned the increased risk of acquiring HIV. This could be due to not having internalized the new guidance and registering its meaning in their standard way of describing a method; or, providers may not know how to categorise the new guidance within the current framework used by MSI to discuss or describe methods.

Application of the new guidance in a service delivery context

Observation data showed that the majority of providers implemented the new counselling messages during service delivery. In 81% of the observations (n=29), providers conveyed all five counselling messages to clients. In four observations, two providers did not convey "You can protect yourself from HIV." In six observations, two providers did not convey "You can still choose this method, but we want you to think about this information." Only during two observations did one provider not convey any of the five counselling messages to clients, which could have been due to the client expressing a preference for a method other than DMPA once she entered the counselling room, or the client selected her method prior to receiving counselling on DMPA.

No providers advised clients that family planning or hormonal contraception causes HIV and that PLHIV cannot use hormonal contraception; however, in contrast to the focus group discussions, during clinical observations, it was reported that a single provider inaccurately advised some clients regarding hormonal contraception and HIV risk (Table 7).

Table 7: Observation Results – Advising Clients on Use of DMPA

Observed Behaviour	% of All Observations
Provider advised clients that DMPA causes HIV	19
Provider advised clients to use another method because of risk of HIV	11
Provider advised clients not to use hormonal contraception because of the risk of HIV	11

Additionally, during 6% of observations, one study team advised clients that PLHIV cannot use DMPA. The inaccuracies reported are serious and concerning; however, the majority of the issues regarding the accuracy and the quality of the counselling was by a single provider, which suggests the inaccuracies were not a systemic issue throughout the study's eight service delivery teams.

For the majority of observations, providers discussed HIV risk with clients. During focus group discussions, providers reported that they regularly ask their clients about their personal and sexual histories to determine HIV risk; however, clinical observation data showed this wasn't done consistently (Table 8).

Table 8: Observation Results – STI and HIV Risk Assessment

Observed Behaviour	% of All Observations
Provider discussed a client's number of sexual partners	56
Provider discussed STIs with their clients	69
Provider gave condoms to clients	36

Providers did not give condoms to clients during the majority of observations, which could be due to several factors. During focus group discussions, providers shared that it would be difficult for married women to negotiate condom use with their male partners, even if they suspected they may be at risk, which may have influenced these distribution practices. Providers reported that the majority of their clients who take condoms are unmarried women or young people.

Despite the variability of discussing HIV risk factors with their clients, during the majority of observations, providers discussed STIs, including HIV and AIDS with clients, and only one provider did not advise their client on dual method protection.

Effects on provider job function and quality and feasibility of counselling

We detected no effect of the new guidance on provider job function and the feasibility of counselling. Providers did not report any hindrances to incorporating the messages into their standard FP counselling. In fact, providers have recommended that the messages be further integrated into MST's service delivery platforms to reach all FP clients (not only DMPA users).

As was reported during focus group discussions, providers used the two new job aids during 92% of the observations, with the first job aid – the blue sticker – having been used during 97% of observations, which indicates high use of the MOH flipchart during client counselling. Some providers suggested editing the blue laminated sticker because it doesn't have enough information on it, its placement on the MOH flipchart doesn't fit well (placed at the very bottom of the page), and the translations should be reviewed again.

The observation checklist included several quality-related indicators, which resulted in a wide range of results regarding the quality of counselling by providers (Table 9).

Table 9: Observation Results – Quality of Care

Observed Behaviour	% of All Observations
Provider provided guidance on all of the following: • Explain how the method works • Explain advantages/benefits • Explain disadvantages/health risks • Risk of acquiring HIV when using the method • Explain how to use method • Discuss possible side effects • Advise client when to return for re-supply	24
Provider completed all of the following: • Use client's name when talking to her/him • Ask if client understood the information • Encourage client to ask questions • Ask the client to repeat back information provided • Ensure confidentiality • Answer client's questions	42
Provider explained the advantages and the disadvantages of the FP method	78
Provider explained how the method chosen works	86
Provider greeted clients in a friendly manner	100

Over half of all clients that were seen during clinical observations were repeat or refill clients. In practice, providers do not provide comprehensive counselling when a client is returning for a refill, which may explain the low rates of completion of some of the quality-related indicators.

Effects on method mix (pre- and post-intervention analysis of routine service data)

The overall method mix for the total analysis period can be seen in Figure 1, with LARC users representing the largest proportion of MST users (74.6%).

Comparing the method mix across all outreach teams (both intervention and control) (Table 10), there is a significant increase in the proportion of clients choosing any LARC (73.8% to 75.2%), 3-year implants (29.9% to 30.6%), 5-year implants (28.5% to 29.3%), oral contraceptives (3.7% to 3.4%) and female condoms (<0.1% to 0.1%) following the intervention, and a significant decrease in those choosing 3-month injectables (6.4% to 5.6%).

Figure 1: Method Mix Across All MST Outreach Teams, Total Analysis Period

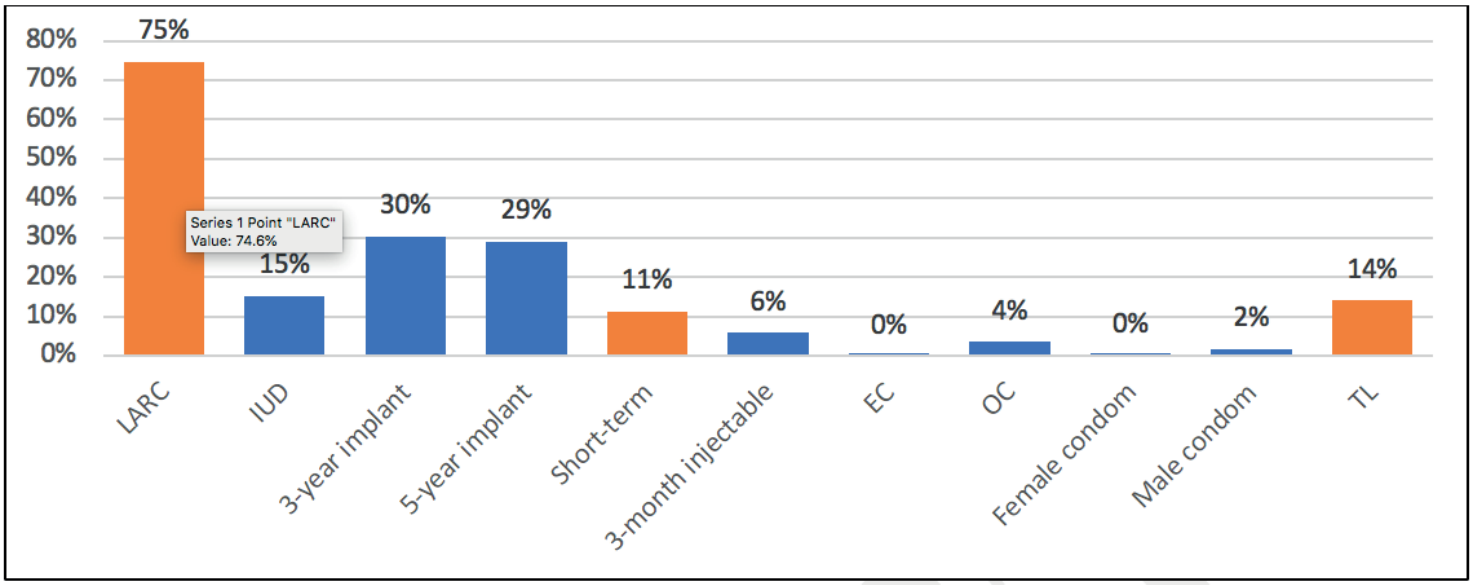

Table 10: Overall Method Mix, 3-Month Periods Pre-/Post-Intervention (pooled intervention and control teams)

Behaviour	Pre-intervention				Post-intervention			
	N	%	Lower CI	Upper CI	N	%	Lower CI	Upper CI
3-month injectable*	5,715	6.4%	6.2%	6.6%	7,887	5.6%	5.4%	5.7%
LARCs*	66,005	73.8%	73.5%	74.1%	106,558	75.2%	75.0%	75.4%
IUD	13,776	15.4%	15.2%	15.6%	21,602	15.2%	15.1%	15.4%
3-year implant*	26,756	29.9%	29.6%	30.2%	43,431	30.6%	30.4%	30.9%
5-year implant*	25,473	28.5%	28.2%	28.8%	41,525	29.3%	29.1%	29.5%
Short-term*	10,708	12.0%	11.8%	12.2%	15,279	10.8%	10.6%	10.9%
EC	13	0.0%	0.0%	0.0%	18	0.0%	0.0%	0.0%
OC*	3,321	3.7%	3.6%	3.8%	4,857	3.4%	3.3%	3.5%
Female condom*	23	0.0%	0.0%	0.0%	107	0.1%	0.1%	0.1%
Male condom	1,636	1.8%	1.7%	1.9%	2,410	1.7%	1.6%	1.8%
Tubal ligations	12,721	14.2%	14.0%	14.5%	19,901	14.0%	13.9%	14.2%
Total clients	**89,434**				**141,738**			

**Significant difference before and after the intervention, p<0.01*

When comparing intervention to control teams (Table 11), there were still significant changes in method mix before and after the intervention in both groups. Overall, the choice of any LARC increased in both arms, from 73.8% to 74.4% in the control group and from 73.9% to 81.2% in the intervention group. Three- and 5-year implant use increased in the intervention group (32.8% to 35.8%, 27.0% to 30.7%, respectively) but not in the control group.

The choice of any short-term method decreased in the intervention group (17.0% to 8.9%) but not in the control group. Injectable use fell in both groups, from 6.3% to 5.8% in the control group and 6.9% to 3.6% in the intervention group. Oral contraceptive use fell in the intervention group (4.8% to 3.4%) but not in the control group. Female condom use increased in the control group (<0.1% to 0.1%) but not the intervention group and male condom use increased in the control group (1.4% to 1.7%) but decreased in the intervention group (5.3% to 1.9%). No change was seen in the proportion of clients choosing tubal ligations in either group.

Table 11: Method Mix in Control and Intervention Groups, 3-Month Periods Pre-/Post-Intervention

FP Method	Pre-intervention				Post-intervention			
	Total	%	Lower CI	Upper CI	Total	%	Lower CI	Upper CI
Control								
3-month injectable*	5,028	6.3%	6.2%	6.5%	7,325	5.8%	5.7%	5.9%
LARCs*	58,698	73.8%	73.5%	74.1%	93,718	74.4%	74.2%	74.7%
IUD	12,386	15.6%	15.3%	15.8%	19,275	15.3%	15.1%	15.5%
3-year implant*	23,514	29.6%	29.2%	29.9%	37,767	30.0%	29.7%	29.4%
5-year implant*	22,798	28.7%	28.3%	29.0%	36,676	29.1%	28.9%	29.4%
Short-term*	9,022	11.3%	11.1%	11.6%	13,877	11.0%	10.8%	11.2%
EC	11	0.0%	0.0%	0.0%	15	0.0%	0.0%	0.0%
OC*	2,850	3.6%	3.5%	3.7%	4,321	3.4%	3.3%	3.5%
Female condom*	23	0.0%	0.0%	0.0%	106	0.1%	0.1%	0.1%
Male condom	1,110	1.4%	1.3%	1.5%	2,110	1.7%	1.6%	1.7%
Tubal ligations	11,822	14.9%	14.6%	15.1%	18,330	14.6%	14.4%	14.8%
Total clients	79,542				125,925			
Intervention								
3-month injectable*	687	6.9%	6.4%	7.4%	562	3.6%	3.3%	3.8%
LARCs*	7,307	73.9%	73.0%	74.7%	12,840	81.2%	80.6%	81.8%
IUD	1,390	14.1%	13.4%	14.7%	2,327	14.7%	14.2%	15.3%
3-year implant*	3,242	32.8%	31.8%	33.7%	5,664	35.8%	35.1%	36.6%
5-year implant*	2,675	27.0%	26.2%	27.9%	4,849	30.7%	29.9%	31.4%
Short-term*	1,686	17.0%	16.3%	17.8%	1,402	8.9%	8.4%	9.3%
EC	2	0.0%	0.0%	0.0%	3	0.0%	0.0%	0.0%
OC*	471	4.8%	4.3%	5.2%	536	3.4%	3.1%	3.7%
Female condom*	0	0.0%	0.0%	0.0%	1	0.1%	0.0%	0.1%
Male condom	526	5.3%	4.9%	5.8%	300	1.9%	1.7%	2.1%
Tubal ligations	899	9.1%	8.5%	9.7%	1,571	9.9%	9.5%	10.4%
Total clients	9,892				15,813			

**Significant difference before and after the intervention, p<0.01*

In order to assess whether the size of the change seen when comparing between groups represented a significantly different level of change, a regression analysis on the difference between the differences seen in each group was conducted. This was limited to methods of relevance to the intervention (the differences seen in each group are first summarised, with more statistical detail, in Table 12).

Table 12: Summary of Before and After Differences in Control/Intervention Groups

FP Method	Difference	Std. Err.	t	P>t	Lower CI	Upper CI
Control						
3-month injectable	-0.5%	0.001	-4.64	0.000	-0.7%	-0.3%
Any LARC	0.6%	0.002	3.17	0.002	0.2%	1.0%
IUD	-0.3%	0.002	-1.62	0.106	-0.6%	0.1%
3-year implant	0.4%	0.002	2.08	0.038	0.0%	0.8%
5-year implant	0.5%	0.002	2.26	0.024	0.1%	0.9%
Intervention						
3-month injectable	-3.4%	0.003	-11.5	0.000	-4.0%	-2.8%
Any LARCs	7.3%	0.005	13.57	0.000	6.3%	8.4%
IUD	0.7%	0.004	1.48	0.139	-0.2%	1.5%
3-year implant	3.0%	0.006	5.02	0.000	1.9%	4.2%
5-year implant	3.6%	0.006	6.27	0.000	2.5%	4.8%

Analysis comparing the change seen in the intervention group with the change seen in the control group showed that the change seen was significantly different for any LARC (6.7% greater increase in the intervention arm), 3-year implants (2.6% difference), 5-year implants (3.2% difference) and 3-month injectables (-2.9% difference). There was no significant difference in the change seen for IUDs when compared between groups. This is best interpreted, for example for any LARC, as a 6.7% greater increase in uptake (with 95% confidence interval 5.6%-7.8%) in the intervention group than the control group (Table 13).

Table 13: Difference in Difference Analysis Comparing the Change Observed Between Groups

FP Method	Difference in Differences	Std. Err.	t	p	Lower CI	Upper CI
3-month injectable	-2.9%	0.003	-9.18	0.000	-3.5%	-2.3%
Any LARC	6.7%	0.006	11.65	0.000	5.6%	7.8%
IUD	0.9%	0.005	1.94	0.052	0.0%	1.9%
3-year implant	2.6%	0.006	4.08	0.000	1.4%	3.9%
5-year implant	3.2%	0.006	5.15	0.000	2.0%	4.4%

Discussion

Our study has identified some important challenges to introducing the new WHO guidance on injectable use by women at high risk of HIV. Clients' understanding of the new counselling messages was often incomplete and at times conflicting. While providers were usually able to relay the five messages correctly, and were mostly able to convey the message of a higher risk between DMPA use and HIV acquisition, both the nature and extent of that risk were commonly misunderstood. Specifically, the nuances of the difference in risk between DMPA and other family planning methods was lost. When the guidance is not accurately put into this context, it could create a belief that any family planning user is at the same risk of acquiring HIV as a DMPA user, which is not the case. Since over-estimating the risk of acquisition could result in a broader impact on DMPA uptake or continuation, or even of other family planning methods, those rolling out this guidance should consider how best to reduce this particular misunderstanding (e.g., by developing/implementing messages that make the extent of elevated risk explicitly clear).

While there were encouragingly very few client reports that DMPA itself causes HIV, the fact that some providers reported struggling to relay the meaning of the guidance to their clients is still concerning, in particular given that only providers with the highest competency levels were selected for the study. Additional challenges in rolling out the guidance to providers with lower competency levels could be expected, and it may be helpful to ensure clients with misunderstandings or concerns can still talk to higher skilled providers – either in person, or though the Marie Stopes contact (phone) centre. Providers' discomfort with the second message on the ambiguity in the research findings was notable, and it may be advisable for WHO to consider how to reword this message in its Handbook in a way that providers feel equipped to discuss scientific uncertainty with clients. Given that the MEC recommendation has now been changed because the level of evidence was deemed sufficiently strong, the confusion we have identified over this message suggests it may even be questionable to ask service delivery organisations and providers to try and convey a message on uncertainty. Providers' requests to share any new evidence on this topic represents a call to action to the international community to rapidly avail findings from future studies on the association between DMPA and HIV acquisition.

Clients' misunderstandings of the new guidance may therefore have stemmed from provider misunderstandings, which were also present in our data (though to a lesser extent), or to broader challenges in the quality of counselling or in understanding the more complex medical counselling around contraceptive use necessitated by this guidance change. We must consider if and to what extent clients are familiar enough with the technical or scientific terminology that must be used in order to accurately characterise the risk associated with DMPA and describe the meaning of the new guidance. The majority of clients (73%) had at most primary or incomplete secondary education, so perhaps it has less to do with their understanding of the new guidance and more to do with trying to describe such guidance using a limited vocabulary that results in inaccurate descriptions of the guidance and its meaning. In other words, clients may have understood more than they are able to communicate. Nevertheless, the fact that clients struggled to put the new guidance into their own words is particularly concerning, given that family planning programmes are influenced by social networks and peer-to-peer knowledge dissemination.

Our findings suggested that many women wanted to reflect on the new guidance and/or obtain their partner's approval to switch methods. The analysis of service data does however indicate that the new counselling guidance had a small negative effect on injectable uptake and a simultaneous increase in LARC uptake. Differences in the interview and observation data to the routine data may reflect use of the new guidance over a longer period of time (2 weeks at the time of qualitative data collection versus 3 months in service data analysis), which could indicate that providers became more comfortable with the guidance and therefore spoke more confidentially about it, potentially exhibiting increasing negative biases about DMPA over time. The compensation for LARC use in the place of DMPA at least indicates that the new guidance may not be affecting overall FP use and these MSI clients were able to switch to another FP method after deciding not to use DMPA. However, if these other methods have a lower acceptability than DMPA, it may be important to study long-term continuation and use trends

post-counselling. Both clients and providers described clients' preference for DMPA because it is more accessible than most other FP methods (i.e., a woman can get injected at a pharmacy), and it can be used discreetly if her partner or family don't support her FP use. Providers should be trained to counsel women on IUD use if covert use is strongly desired by women. For clients who are not able to switch without partner consent, it will be crucial to maintain access to a broad range of methods across the health system so that the clients can switch methods when ready and/or have discussed with their partners. This implies that providers will need to continue to integrate the new guidance into counselling sessions for repeat clients, allowing women opportunity to consider their risk over time.

Both clients and providers expressed positive feelings about being informed of the new guidance. Clients did so because of their appreciation for being told information that will help them make an informed choice, reinforcing the decisions of international global health organisations to update policy and programme guidance on DMPA. Clients may have also responded positively to mean that they understood the guidance or due to their general acceptance of the new guidance and likely did not feel impacted by it. Providers were keen to educate their clients on the new guidance. By adopting the new guidance, providers are continuing to prioritise a rights-based approach to providing FP services and responding to clients' preference and expectation to receive all information related to their method of choice, as stated in the client interviews. Providers also reported liking and regularly using job aids during counselling, and so future interventions should also consider the development of at least provider-facing job aids to help providers communicate the complex messages. Given that clients had a poorer understanding of the new guidance than their providers, this suggests that client-facing material(s) would indeed be helpful, and this was supported by providers.

While the study design didn't require providers to assess a client's risk of acquiring HIV in order to give the messages, since we considered all at 'high risk' in Tanzania's generalised epidemic, the new counselling messages did act as a reminder to providers to support clients to assess their own risk of acquiring HIV in order to respond to the new guidance. But although the providers reported assessing risk on a regular basis, the study revealed that it is done to varying degrees of completion—even with the new messages acting as a reminder to do so. Furthermore, we found that clients may not understand or be willing or able to acknowledge or act on their own risk. In particular, we found that married women or those in stable sexual relationships did not consider themselves at risk, and many refused to take condoms, also due to the difficulty of negotiating dual method use.

The messages—even in aggregate—do not act as comprehensive counselling on risk of acquiring HIV, so these messages should be incorporated into an existing framework for assessing and counselling on risk. This will be particularly important in lower HIV prevalence settings, since programmes and/or providers themselves will need to determine if and to what extent to counsel women on the new guidance. There are currently limited evidence-based approaches on how to conduct a sensitive risk-assessment so MSI will need to elaborate further guidance for use in lower-prevalence settings. Providers will need supportive supervision or training on how to identify those at higher HIV risk in those who are unable to identify themselves at risk (e.g. married women) and in an abbreviated manner so that counselling isn't lengthened unnecessarily or to a point that dissuades clients from seeking services. The new five counselling messages are short and succinct, so if clients are already concerned about the length of the counselling session, it may be difficult for providers to also conduct a detailed risk assessment—despite the clear need to do so. It may also be important to develop communication materials aimed at male partners to reduce the cultural tension of women seeking condom use within their stable sexual relationships.

Integrating the new five counselling messages into MST's mobile outreach service delivery platform did not present any operational challenges that impacted provider job function and feasibility of counselling; however, the new messages were not used within the group education that takes place prior to individual counselling, which operationally may pose other challenges for integrating the messaging. Integrating the messaging into group education with larger numbers of women may offer the opportunity for questions be clarified, but could also have the potential to lead to debate or other misunderstandings. Also, given that some respondents noted increasing counselling length, further monitoring of counselling time following the introduction of the new guidance is warranted since long counselling can cause lower satisfaction in MSI clients. FP service delivery programmes will therefore need to consider which clients should receive the new guidance (i.e., only DMPA users or all clients) and at which step of the service delivery model (e.g., group education or individual counselling, or both).

Limitations

This study had several limitations. Client interviews were conducted immediately after service provision, which reduces the likelihood of recall bias; however, outreach services are often provided in small, loud, or busy spaces, so clients were often anxious to return home after traveling long distances to the service site and sometimes waiting for a while for services. The quality of interviews could have been impacted by the amount of time the client had waited for services or if she was anxious to leave because she had traveled with a small child. This also may have led to not all clients answering all interview questions and related probes by data collectors, which resulted in different completion rates for interview questions. Respondents who did complete interviews may have done so due to courtesy bias so they continue to receive (free) FP services. During the recruitment process, it was made explicitly clear that their access to services would not be impacted by their decision to or not to partake in the study; however, given MST's recognition in underserved communities, courtesy bias could have resulted.

Our study did not test the accuracy or the acceptability of each of the 5 messages separately; the study only investigated the complete counselling package and therefore designed its topic guides to seek general reactions and feedback, not to assess the exact recall of the language of the 5 messages. We only aimed to measure the general impact of them. Further, the messages—even in aggregate—do not act as comprehensive counselling on risk of acquiring HIV, so it was assumed that these messages were being incorporated into an existing framework for assessing risk.

Analysis was completed without the use of a baseline of current knowledge regarding general HIV risk and to what extent providers were assessing their clients' risk of acquiring HIV prior to the intervention.

Throughout the study, translation of English data collection tools into Kiswahili proved challenging. Despite study staff checking translations, including backtranslation into English, it's expected that mistranslations may have affected data collection. Additionally, providers suggested a re-translation of one of the job aids for future use.

Observation data were subject to reporting bias by the observer. Additionally, due to concerns regarding the quality of data collection of three of the study teams because of high levels of inconsistent reporting across duplicate indicators in the observation checklist, 69 observations from those teams were dropped from the analysis.

Lastly, the nature of qualitative data collection means that its findings and conclusions cannot be broadly applied (i.e., other service delivery contexts, dissimilar geographic regions, subpopulations served, etc.). The study was conducted among a small number of teams/number of providers.

Recommendations

- The study's findings add to voices in the international global health community to rapidly avail ongoing research results on the association between DMPA and HIV risk.
- WHO should consider edits to its second counselling message to remove or replace language around scientific uncertainty.
- Programmes to consider developing client-facing materials to be used alongside the new counselling messages, including materials to show male partners.
- Family planning implementing partners should consider how to support providers, especially in lower HIV risk settings, on assessing their clients for HIV risk, and at what point during service delivery to introduce the new guidance. This will require assessing the organization's current HIV risk assessment practices and updating them as necessary.
- Providers will need further training and/or supportive supervision to provide targeted counselling support to their at-risk clients.
- Family planning implementing partners should also encourage providers to integrate the new messages into counselling sessions for repeat clients, allowing women the opportunity to consider their risk over time.
- MSI is encouraged to update its provider training materials to more clearly explain DMPA's mechanism of action as it relates to HIV risk, and how to distill the theory into client-friendly messages.
- MSI to ensure ongoing monitoring of roll-out, in particular further impacts on method mix, client satisfaction, counselling time and overall team operational efficiency.
- As a technical leader in family planning and HIV and AIDS integration, USAID has a key role to play in coordinating the sharing of FP/HIV best practices, including how to integrate HIV risk assessment frameworks into existing FP service delivery programs, and any ongoing implementation research undertaken to assess the impacts of WHO's new guidance.

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