Guide for Focus Group Discussion with DMPA-SC Stakeholders

Market Research on Service Delivery Implications for a 4-month Depot Medroxyprogesterone Acetate Subcutaneous (DMPA-SC) Product

FGD Number: [__|__]

FGD Description: _____

Date: _____

Step 1: Obtain consent individually (separate document) and conduct demographic questionnaire individually (separate document)

Step 2: Convene group and conduct the discussion

[Begin recording here]

Introduction: Today is [date] and this is [Focus Group ID]. My name is _____. Thank you again for your participation in the discussion today. We are looking forward to hearing your thoughts on the questions we will ask you. As a reminder, your participation is completely your choice, your answers will be kept confidential, and you do not have to answer any questions you do not want to, or you may refuse to participate.

Please know there are no right or wrong answers or opinions about the topics we are discussing, so feel free to share your thoughts openly. During the focus group discussion, we would like you to share your thoughts openly and discuss the topic with each other. My role as moderator will be to guide the discussion. I would ask that you do not share information discussed in the group with others outside the group. However, we cannot guarantee that information discussed in the group will not be shared, so consider this before discussing personal matters. As mentioned earlier, the discussion is going to be audio-recorded. Because we are recording, it is helpful if you speak one at a time.

<u>Introduction</u>

1. To get started, I'd like to have each of briefly introduce yourself and tell us your position. [Have each participant answer].

Interviewer: Read the following information to the group:

I am here to talk to you today about injectable contraceptives, in particular depot medroxyprogesterone acetate subcutaneous or DMPA-SC and its duration of effectiveness. DMPA-SC is currently labeled as a 3-month method that offers a four-week reinjection window or 'grace period'. FHI 360 conducted a clinical trial to determine if DMPA-SC can provide high contraceptive

effectiveness for four months rather than three, which the currently marketed product, Sayana® Press, is labeled. Preliminary data from the study suggest that DMPA-SC is safe and effective if injected every 4 months, though it is not approved for 4 months. This would offer users a 4-month method with a one-week reinjection window or 'grace period'. [Update with further findings from trial, if applicable]

As a follow-on to the clinical trial, FHI 360 is conducting a study to generate evidence for, and support the registration of, a new 4-month DMPA-SC product. We would like to talk with you about how a potential 4-month DMPA-SC product would be <u>received</u> and <u>implemented</u> in [Uganda/Nigeria]. We would also like to ask you some questions about a potential six-month injectable product which is currently in development.

<u>DMPA-SC</u>

1. Please describe your knowledge of DMPA-SC and its current use in [Uganda/Nigeria].
    a. Which guidance/guidelines are followed in [Uganda/Nigeria] with respect to the duration of DMPA-SC? [i.e., DMPA-SC label, WHO's Selected Practice Recommendations (SPR) for Contraceptive Use, training materials – specify which materials]
    b. Is the same guidance/guidelines followed all over the country? [Probe for: variation across states, districts, all types of facilities, providers, and clients]
        i. [If not] How do they differ? Why do they differ? Is this a problem/why?
    c. In what ways will MOH and/or regulatory guidelines be impacted by the introduction of a 4-month DMPA-SC product in [Uganda/Nigeria]? What changes will be required?
2. As I noted earlier, preliminary data from FHI 360's clinical trial suggest that DMPA-SC is safe and effective if injected every 4 months. How would you feel about incorporating a new 4-month DMPA-SC product in [Uganda/Nigeria]? [Probe for positive vs. negative feelings, and reasons why]
    a. What additional information would you want before accepting a 4-month DMPA-SC product here?
        i. Who would you like this information to come from [ex. manufacturer? WHO? Ministry of Health? From other group(s) e.g., USAID, UNFPA, DFID? - specify groups]?
3. [For MOH participants, only] Would you be motivated to make a national policy change to endorse off label use of the 3-month product for 4 months?
    a. [If yes] What steps would be required to make this change?

b. Would you require global endorsement by WHO Selected practice recommendations (SPR) for contraceptive use *prior* to making a national policy change?

4. From a service delivery perspective, what would need to happen/change to incorporate a new, 4-month DMPA-SC product in your health system?
    a. [Probe for specific mechanisms that would be engaged and how].
    b. [If not spontaneously discussed] How might a longer duration DMPA-SC product impact clinic volume? How might it impact the use of provider-administered methods?
    c. [If not spontaneously discussed] What impact would such a product introduction have on existing FP data and monitoring systems (e.g., public sector HMIS, DHIS, registers, etc.)? Please explain.
    d. [If not spontaneously discussed] What impact would such a product introduction have on logistics and distribution (e.g., stocking patterns) at the various health system levels in [Uganda/Nigeria]?
    e. [If not spontaneously discussed] How would quality assurance be ensured for this new 4-month DMPA-SC product? Please describe. [Allow for unaided interpretation of QA and experience/familiarity with it; noting that these may differ depending on role and experience. If different than 'standard' definition, provide a prompt/mini narrative to clarify and re-ask the question].
5. What would family planning (FP) providers need to be able to offer this additional product in [Uganda/Nigeria]? Please explain.
    a. [Probe for specific needs, e.g., HRH, capacity-building, awareness/demand creation, logistics/supply, etc.]
    b. [Probe the changes needed at different levels of the health system (e.g., national level, district/state level, clinic level, community level (i.e., VHTs/CHEWs) and client level].
    c. [If not spontaneously discussed] What kinds of challenges/barriers would providers face in offering this product?
6. How would the introduction of a 4-month DMPA-SC product impact FP curriculums, training, and supervision?
    a. [Probe for challenges at each level of integration and reasons why]
        i. [If challenges discussed] How should such challenges be addressed or mitigated?

7. Beyond formal guidelines and training, what communications will be needed/useful at the provider-level? What about at the national working group level?
    a. [Probe regarding usefulness of specific modalities: videos, handbills, etc.]
8. What role would cost play in provider decisions to offer this method? What role would it play in terms of acceptability to clients? [Probe for incentives and disincentives, especially with private sector providers, e.g., will selling fewer doses per year impact desirability to provide?]
9. Given the various requirements just discussed regarding the introduction of a new 4-month DMPA-SC product in [Uganda/Nigeria], what, if any, insurmountable challenges do you foresee? Please explain.
    a. How can such challenges be successfully addressed/avoided or mitigated?
10. If both were available for the client's choice, would providers be more likely to recommend a product that lasts 3 months or 4? Why is that?
    b. If one of these products was proven to have fewer side effects, how would that impact provider recommendations?
    c. If one of these products was proven to have a quicker return to fertility than the other, how would that impact provider recommendations?

DMPA-SC in Uniject has expanded women's access to family planning options by increasing opportunities for lower-level health workers and community-based distribution as well self-administration by clients themselves.

11. In your experience and to date, what has been the predominant type of DMPA-SC administration in [Uganda/Nigeria]? Why do you think that is the case?
    a. [Probe for preferences of administration by providers, by CHWs [VHTs/CHEWs] and/or by self-administration and reasons why.]
    b. [If not spontaneously discussed] What has been the response among women/clients to self-injection? Why do you think that is?
        i. [If not spontaneously discussed, probe for client concerns/fears around 'correct' administration without health worker oversight; issues of discretion/privacy)]
    c. For clients that self-inject, what impact might a longer duration have on their comfort and confidence to self-inject as well as recall of re-injection due dates? [Probe for longer window between training/demonstration and self-administration]

Client-centered communication needs

12. Broadly speaking, how do you feel women in [Uganda/Nigeria] would receive a 4-month DMPA-SC product? Why is that?
    a. [Probe for perceived benefits, drawbacks, and reasons why.]
    b. [If not spontaneously mentioned] Probe for thoughts on: reduced number of reinjections to 3 times a year, from 4; reduced long-term MPA exposure; increased privacy, decreased travel expenses and other opportunity costs (ex. missed work, childcare)]
13. If this 4-month DMPA-SC product is introduced in [Uganda/Nigeria], what kinds of questions and/or concerns would women have when considering this method? Why is that?
    a. How should information about this product be communicated to potential clients in order to best address these questions/concerns?
14. There is reason to believe that women may experience a quicker return to fertility following the end of the effectiveness period with an extended duration. How do you think women would feel about a quicker return to fertility with a 4-month DMPA-SC product than with the existing DMPA IM (Depo Provera) or DMPA-SC every three months? [Update with further findings from trial, if applicable]
    a. [If not spontaneously mentioned] How might this affect decisions to select the 4-month DMPA-SC product as a family planning method? [Probe for impact on acceptability and reasons why.]
15. There is also reason to believe that women may experience a reduction in dose-dependent side effects with an extended duration. How do you think they would feel about potentially diminished side effects commonly attributed to DMPA-IM and DMPA-SC when received every three months? [Update with further findings from trial, if applicable]
    a. [If not spontaneously mentioned] How might this affect decisions to select the 4-month DMPA-SC product as a family planning method? [Probe for impact on acceptability and reasons why.]
16. For which kinds of clients might this be a compelling product, and why? [Probe for identification of 'ideal' target clients/sub-groups for whom a longer duration might be especially valuable, e.g., travel needs, maturity]

Expanding market of injectable contraceptives

17. Depo Provera and DMPA-SC (Sayana Press) are already available in [Uganda/Nigeria] with a labelled contraceptive effectiveness of 3 months. What do you think will happen if these products are available in [Uganda/Nigeria] together with a 4-month DMPA-SC product?
    a. Do you think there could be problems with confusion among healthcare providers because Depo and Sayana Press are 3 months, and this new DMPA-SC product would be 4 months? Why or why not? If yes, what kinds of problems? What are potential solutions?
        i. [If not spontaneously mentioned, and to be asked based on each participant's expertise, probe: Could there be problems with forecasting and stocking methods, with confusion on the shelves? Why or why not? Can you make suggestions about how confusion might be minimized?]
    b. Do you think there could be problems with confusion among clients? Why or why not? If yes, what kinds of problems? What are potential solutions?
    c. As we noted earlier, the current DMPA-SC product is labeled for 3 months with a 4-week reinjection window or 'grace period'. A 4-month DMPA-SC product would offer contraception for an additional month and have a one-week reinjection window. Which do you think is more important to have; a 3-month method with a longer (4-weeks) reinjection window **or** a 4-month method with a shorter (1 week) reinjection window? Why is that?

In addition to the 4-month DMPA-SC we have been talking about, several 6-month injectable candidates are currently in varying stages of development. Some of these will likely offer self-injection as an option while others will be provider-administered, only. One of these products will be entering a phase 3 effectiveness trial this year. This product uses the same dose of existing 3-month Depo IM but is injected subcutaneously to achieve a longer duration of effectiveness. The method would be delivered in a glass vial and syringe similar to the existing Depo IM and would likely not offer the option of self-injection. As with Depo IM, some women using this method may have irregular periods or their period may stop. If a woman experiences side effects, the side effects may not stop for up to six months or longer. Also like the current 3-month Depo IM, return to fertility may be delayed among women using this product. However, since the method uses the same dose of

hormone over a longer period, we have reason to believe that return to fertility may be shorter and other dose-dependent side effects may be reduced.

18. Do you think a 6-month injectable will fit well into the [Uganda/Nigeria]n health system? Why or why not? What could be some of the positives of this 6-month injectable? What could be the negatives?
    a. What do you think women would think about a 6-month injectable? [Probe: would they like it or not like it?)] Please explain.
    b. Do you think women currently using Depo or DMPA-SC would switch to a 6-month injectable if it were available? If yes, how common would this be?
19. For a longer-acting injectable that lasts 6 months, some people have expressed more concern than with currently available injectables about not being able to stop the medicine after injection; for example, if a woman experiences bad side effects the method cannot be removed. Do you feel that this would be a problem? Why do you feel that way?
20. From your perspective, and *with all things being equal* (e.g., side effects, return to fertility, presentation (Uniject/vial and syringe), injection site location (arm/thigh/abdomen) and whether it is self-injectable), what is the optimal length that a contraceptive injection should last? Why?
    a. What if all things were NOT equal? For example, you selected [ppts' selection for optimal length from Q19] as your preferred length of action for a contraceptive injectable. What if that method:
        i. Did *not* offer self-injection; would that change your selection? Why/not?
            1. [If not spontaneously mentioned] How important do you think it is that new injectables entering the market should be self-administrable? Why is that?
        ii. Was only available in the thigh or abdomen but *not* the arm? Would that change your selection? Why/not?
        iii. Was available *only* at clinics (i.e., not from VHTs/CHEWs or in drug shops or pharmacies)? Would that change your selection? Why/not? [Probe for impact on clinic workload/volume]
21. From your perspective, and with all things being equal (e.g., side effects, return to fertility, delivery route (SC/IM), injection site location (arm/thigh/abdomen) and whether it is self-

injectable), what duration of effectiveness do you think **clients** would most prefer for a contraceptive injectable? Why?

   a. In your opinion, would their preference change if the [duration selected by ppts for clients] method:
      i. Did *not* offer self-injection; would that change your selection? Why/not?
      ii. Was only available in the thigh or abdomen but *not* the arm? Would that change your selection? Why/not?
      iii. Was available *only* at clinics (i.e., not from VHTs/CHEWs or in drug shops or pharmacies)? Would that change your selection? Why/not?

22. What is the optimal number of different injectable contraceptive methods to have in the [Uganda/Nigeria]n market? How many is too many? Why do you feel that way?
    a. Probe as appropriate for: service delivery perspective, procurement/supply chain considerations, complexities of regulating different products when introduced at the same time, anticipated supply and demand generation issues, etc.
    b. [For private sector KIs, probe:] How would these different options affect pricing and sales dynamics at the level of private sector channels?
    c. What can we do to prevent confusion if multiple injections of different durations are available on the market, at the clinic, or offered by [VHTs/CHEWs]?
    d. Would a combination of 3- and 6-month injectables on the market create less confusion than a combination of 3-, 4- and 6-month? Why/why not?
23. How would you recommend promoting and differentiating the 4-month DMPA-SC product in the market to avoid any mix up/confusion with similar, existing products? [Probe for compelling attributes around which to create the brand(s)]
    a. What about the 6-month injectable?
    b. [Probe for what type of demand generation will be needed to increase awareness and interest in another injectable]

<u>Closing</u>

24. In closing, do you have any other thoughts or recommendations for things we should consider regarding injectable contraceptives of varying durations, and specifically a 4-month duration?

Thank you very much for your time and the thoughtful information you have shared with me today.