

MTN-045 Data Communiqué #1 – August 14, 2020

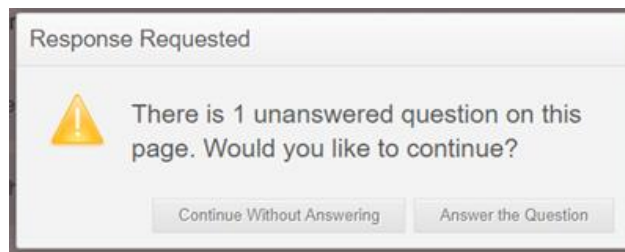
This is official study documentation for MTN-045. Please circulate it among relevant staff for their review, print it, and place it in your MTN-045 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-045 SSP manual.

Reminders

Skipping Questions in Qualtrics

Apart from the DCE choice questions, all questions in the DCE and BDQ administered through Qualtrics may be skipped if necessary (in the case where the participant does not wish to or cannot answer). To do so, the interviewer will:

1. Leave the response blank
2. Touch the button to move to the next question
3. The below pop-up will appear



4. Select “continue without answering”

Clarifications

Capturing comments and discussion related to COVID-19

It is expected that the topic of COVID-19 may arise during the normal course of an MTN-045 study visit. Participants may talk about COVID-19 prior to beginning data collection, during data collection itself, or when transitioning between parts of the visit. It is important to capture this information given that the global pandemic may have impacts on how participants respond to key questions in the data collection materials. Understanding what participants are saying about the COVID-19 pandemic and its impacts on their decisions and lives may be important for interpreting data during the analysis phase, particularly as other participants were enrolled before the pandemic.

All study visits: To facilitate consistent documentation of this information, the MTN-045 data center provides the following guidance for capture of COVID-19 related comments, discussion, or questions that arise during a MTN-045 study visit:

1. **The open text “comments” field at the end of the Individual and Couples’ Qualtrics surveys**
 - a. This is the preferred location for capturing discussions/comments that are COVID-19 related as the DCE/BDQ are being administered. Due to the fact that the text entered in this field is immediately transmitted to the data center and does not require double data entry, we anticipate this will be the easiest place for study staff to document relevant comments.
2. **The “Interviewer notes” field at the bottom of the CO CRF**
 - a. This open text field is also an appropriate place for the study staff to document COVID-19 related comments/discussion that arise during the joint portion of the study visit.

However, given that text written here will require double-data entry into REDCap, it will require more staff time. On the other hand, it will be the only place the interviewer can document COVID-19 related conversations once the Joint DCE has ended (i.e., during the completion of the IPA).

3. The “Comments” field for the appropriate couple on the Screening and Enrollment Tracker

- a. Comments and discussion related to COVID-19 that are not captured through the Qualtrics survey comment field or the CO CRF can be documented in the “comments” column for the respective couple on the “enrolled” tab of the weekly screening and enrollment tracker. Study staff who note that relevant information was not captured through Qualtrics or the CO CRF should add the note to the Screening and Enrollment Tracker as soon as possible while the information is still fresh.

Qualitative IDIs: The MTN-045 data center provides the following guidance for capture of COVID-19 related comments, discussion, or questions that arise during qualitative data collection in MTN-045:

1. Relevant probes

- a. Please probe as appropriate throughout IDIs to understand how any COVID-19 related factors may impact the relationship dynamic and how couples/members of a couple think about HIV prevention, pregnancy prevention, and preferences for a potential DPP product. Some suggested areas for probing:
 - i. Under the IDI question that reads, “How would you describe your relationship to other people now?”, we suggest probing about how COVID-19 and staying at home affected the relationship with their partner, either negatively or positively (also consider added stress, positive/negative coping strategies).
 - ii. Under the IDI question that reads, “What other factors may influence your i) preference for and ii) interest in future use of a dual purpose prevention product?”, we suggest probing about: how the participant(s) experiences with COVID-19 and the efforts to reduce its spread may have impacted their interest in a DPP, their priorities, and preferences (and explore specifics around any product features).

2. The Debrief Report

- a. Please use the IDI Debrief report to capture any discussion related to COVID that arises before, during, or after the conduct of an IDI.

Note: Once the v1.1 IDI Guide is approved by for use by IRBs/ECs, the above steps will already be covered by use of the new guide.

Updates

Use of Vysor app to allow for interviewer-participant distance during data collection

The data center recognizes that the data collection format for this study does not easily accommodate the physical distancing required for proper COVID-19 safety procedures. To that end, the data center has provided site teams with the “Pro” version of Vysor to facilitate greater distance between the interviewer and the participant. This app allows for use of a USB cord or a wireless connection to mirror the screen of the touch screen tablet to another screen (desktop monitor, laptop, etc.). Site staff should use this method to allow for sufficient distance between the interviewer and participant as long as COVID-19 safety procedures are in place.