

Clarification Memo # 1 to:

HPTN 062: Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection, Version 2.0, 10 September 2010

DAIDS Document ID 10667

Clarification Memo Dated 8 April 2010

Summary of Revisions and Rationale

1. This clarification memo clarifies information about *provider* and *contract* notification which are discussed primarily in Section 4.1.2 and Section 8.3. Provider notification will not be offered at the site in either arm at this time. However, it may be offered to both arms in the future. The rationale for this clarification is to allow sites to follow the local and national policies regarding provider notification. The Malawi government is in the process of revising these guidelines. Currently, however, provider notification is not standard-of-care, but it may become standard practice in the future. Since the protocol was written, further research at the Lilongwe site has shown that provider notification is more effective than passive notification at informing partners of their partner's HIV status. For this reason, if it is offered to only the intervention arm as part of HPTN 062, this could potentially confound our data, as we may not be able to fully attribute the outcome of our intervention to the enhanced counseling alone. Therefore, we will not offer it to the enhanced counseling arm alone. However, if provider notification becomes standard practice at the site, then it may be offered to both arms.

Implementation

The procedures clarified in this memorandum have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of this memo is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs/ECs for their information.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

The modifications included in this Clarification Memo will be incorporated into the next full protocol amendment. Text noted below by strikethrough will be deleted; text appearing below in **bold** will be added.

Section 4.1.2, tenth and eleventh paragraphs

Partner Disclosure/Notification and Referral: The counselor will discuss the importance of notifying people with whom the participants have had sex within the past 12 weeks

that they have had sex with someone who has been diagnosed with HIV and the importance of referring them for HIV counseling and testing. Counselors will describe to participants the two main methods for notifying and referring partners – *patient* notification and referral (where the participant informs and refers her/his sex partners) and, **if appropriate at the site**, *provider* notification and referral (where a provider informs and refers the participant’s sex partners). Participants who wish to notify their sex partners themselves can choose to do so in the way that is most comfortable for them. The counselor will explore with the participant her/his perceptions of the partner’s response, and assist as needed in order to limit any negative consequences that could arise from disclosure. The counselor will follow up on this issue at each session in order to encourage partner notification but also to ensure the safety of the participant. If requested, the counselor will visit the participant’s sex partner in her/his home, or at another location, in order to notify the sex partner of the participant’s status **if this is appropriate at the site**. Depending on the wishes of the participant, she/he may or may not be present when the counselor speaks with the sex partner. Couple counseling will be provided as another means in which to inform partners. Emphasis will be placed on disclosure to steady and other current sex partners, because data from CHAVI 011 demonstrate that disclosure is necessary for participants to be able to practice safer sex behaviors.

If appropriate at the site, counselors will also discuss the concept of contract notification. A participant who agrees to this will have 1 or 2 weeks to disclose her/his status to a partner. . . .

Section 8.3, fourth paragraph:

If requested by the participant, study staff may ~~contact~~ **speak with** the partners of any participant reporting harm as a result of disclosure. **This is independent of the type of participant notification method used as harm could potentially occur regardless of who informs the partner of the participant’s HIV-positive status.** ~~For participants who wish for staff to notify their partner(s),~~ Only individuals who provide verbal consent for providers to contact partners will have partners contacted. . . .