## "Male Involvement" in Women and Children's HIV Prevention: Challenges in Definition and Interpretation

## To the Editors:

The study by Alusio et al (JAcquir Immune Defic Syndr. 2011;56:76-82)<sup>1</sup> presents biological evidence for a beneficial effect from male partner engagement with HIV health services on the prevention of pediatric HIV in east Africa. For more than 2 decades, multilateral agencies have published statements and codified action plans endorsing men's responsibility and participation in the health and well-being of women and children.<sup>2–4</sup> The latest Global Report published by the Joint United Nations Programme on HIV/ AIDS (UNAIDS) emphasizes the importance of engaging men in the global HIV response.<sup>5</sup> Efforts to enroll couples in HIV prevention and treatment interventions<sup>6</sup> and expand couples HIV counseling and testing (HCT)<sup>7,8</sup> (an objective of the current President's Emergency Plan for AIDS Relief reauthorization) reflect heightened awareness of the link between sex dynamics and HIV risk. Included in this is an implicit acknowledgment of the reality, well described by ethnographers, that men are the traditional sexual and reproductive health decision makers in many parts of Africa.9-12

For female-initiated HIV prevention methods (eg, microbicides, female condoms, other physical barriers), male partners are increasingly recognized as an important influence in women's ability and willingness to adhere to product use, including in the context of effectiveness trials. We recently completed an observational male involvement study nested in a large diaphragm and gel trial for HIV prevention,<sup>13</sup> in which disclosure of study product use and perception of male partner approval for product use were significantly associated with

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women's product adherence.14 Complementary findings related to the importance of male partner support and inclusion in the decision to use femaleinitiated methods have been reported in smaller observational and qualitative studies in the region.<sup>15–18</sup> Results from the recent Centre for the AIDS Programme of Research in South Africa's (CAPRISA) 004 trial of tenofovir gel demonstrate the clear correlation between product adherence and effectiveness in HIV prevention.<sup>19</sup> As new prevention and treatment innovations emerge, it is critical to improve our understanding of the influence and impact of male partners on women's uptake and sustained use of promising new health technologies.

Despite the encouraging findings reported by Alusio et al, and the nearuniversal recognition of the importance of "involving" men in women (and children's) health, there remains limited experimental evidence for its therapeutic benefit, and observational evidence suffers from several inherent biases discussed below. Furthermore, there is no good operational definition of what "male involvement" means or standardized measures to assess it. Consequently, there is a paucity of evidence-based strategies for effectively engaging male partners in women's health. The article of Alusio et al provides an opportune moment to reflect on the current gaps and needs in this emergent research area:

Define clear objectives for male involvement. Efforts to include male partners in HIV prevention for women have focused primarily on engaging men to support their female partners in adopting a prevention strategy, without also offering broader consideration for men's own health needs or of a social agenda aimed at achieving greater sex equality, both of which might ultimately reduce female risk as well.<sup>20,21</sup> In the context of prevention of mother-to-child transmission (PMTCT), male involvement is typically directed toward the health needs of the mother and infant, such as support for mothers' antenatal HIV testing, uptake of nevirapine, and formula-feeding or exclusive breastfeeding. Similarly, clinical trials of femaleinitiated HIV prevention methods are driven by female biological endpoints, and therefore, considerations of "male

involvement" often entail gaining male partner support for women's participation in a study and/or use of investigational products. Although these are valid objectives, they may portray men as merely instruments to support women's or infant's health outcomes. Alternative models, including "gender transformative" interventions like Stepping Stones, aim to address health outcomes through more holistic changes in societal norms whereby men are also considered as "agents of social change."22 Although it may not be feasible to extend a full range of services to men or to take on a broader social agenda, it is important that the objectives for involving men are first clearly considered and defined and that the limitations of a chosen approach are recognized.

Develop sophisticated more measures. A partial consequence of the ambiguity of intention surrounding efforts to involve men is that there are no standardized measures or reliable indicators of "male involvement." Rather, it is a broad and multifaceted concept that might include, for example, male participation in health services, couples communication, relationship dynamics, or sex equality. Indeed, Alusio et al measure "male involvement" in 2 quite different ways: men's physical presence in the antenatal clinic (ANC) (of whom 54% accepted testing) and women's self-report of his previous HIV testing. Both indicators are representative of men's engagement with the health care system, and both imply some degree of support or disclosure to their female partner; however, they have different implications for intervention or program design.

Fairly consistently, the term "male involvement" includes, at a minimum, an indicator as to whether a man physically attends a clinic-based activity with his female partner. However, this may spuriously imply that his presence is desirable or representative of a positive action and that men who do not attend services are "not involved." More sophisticated measures of male involvement are needed, not only to capture men's presence or absence at a clinic but also: (1) a more nuanced assessment of the positive, negative, or neutral implications of male partner clinic attendance; and (2) other dimensions of involvement, such as couples communication and perceptions of partner support.

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Indeed, the ability for men to participate in clinic-based activities may be largely contingent on competing priorities such as work schedules, childcare, or transport fees or may be biased by his knowledge of his HIV status or experience of clinical symptoms and may not be a reliable indicator of a male partner's interest or support for the woman's health-seeking behavior. In our male involvement study, for example, male presentation at the study clinic alone was not significantly associated with prevention method use; however, other indicators of male partner support and women's perception of his support were as follows<sup>23</sup>:

Measure positive and negative consequences. As eluded to above, and in Alusio et al. one must assess both the positive and negative consequences of engaging male partners in women's (and infant's) HIV prevention. Involving men in antenatal care or female-controlled HIV/sexually transmitted infection prevention, particularly in relation to HIV testing, could have a perverse effect of reinforcing regressive sex norms, disempowering women, and encouraging redisharmony lationship or abuse. A nationwide social marketing campaign in Zimbabwe to involve men in family planning reported the unintended consequence that men exposed to the campaign were more likely to consider themselves the primary decision makers regarding family planning and parity.24 Only a handful of publications discuss the fact that involving men might have negative health or empowerment consequences for a woman, might change relationship and family dynamics in unexpected ways, could be impractical, and/or might have no effect at all.<sup>25,26</sup>

*Generate more robust epidemiological evidence for effective strategies.* The "efficacy" of male partner involvement for women's or children's HIV prevention outcomes, whether behavioral or biological, has never been experimentally tested. Although findings from studies of femaleinitiated methods<sup>18,23,27–32</sup> of PMTCT (including Alusio et al),<sup>1,33</sup> HCT promotion,<sup>34</sup> family planning,<sup>35,36</sup> and HIV treatment<sup>37</sup> suggest that the inclusion of men or support of male partners encourages women's prevention method uptake, these are most likely biased in several ways: Men who present at the clinic may be inherently more supportive (irrespective of their attendance), may be more likely to be HIV positive (and seeking health services), or may be nonrepresentative of other male partners in other important ways. A randomized controlled trial would require that a cohort of women *willing* to involve a male partner are randomized to receive an intervention with or without him. Although these female participants may be different, or in different relationships, than others in their communities, only such a design would provide definitive evidence of the therapeutic benefit of "male involvement" in women's health outcomes.

Broader inclusion of male partners could add considerable burden in the context of overextended public health clinics or complex clinical trials. Similarly, recruiting couples for HCT has historically been challenging for logistical, financial, and cultural reasons. The study of Alusio et al suggests that previous male partner HIV testing, while significantly associated with his presentation at ANC, was also independently associated with PMTCT<sup>1</sup>; therefore, widespread efforts to test men may be just as effective as recruitment of male partners into ANC. Thus, it is essential for researchers to rigorously assess how best to engage male partners or couples and to critically evaluate whether male attendance (in ANC, at a trial visit, in HCT) is necessary or whether alternative potentially more cost-effective strategies such as couples focused but individually delivered counseling (to men and women), home-based HCT, or other strategies could be equally effective. Indeed, in a US-based study of safer sex counseling among "high-risk" couples, those who received individually delivered but couple-focused counseling had safe sex behaviors equivalent to those who received couple-delivered counseling.<sup>38</sup>

In conclusion, we commend the work of Alusio et al and encourage more research, with robust designs, including multidimensional measures, to assess how to most effectively engage male partners in women's and children's HIV prevention through individual-, couple-, or family-based approaches.

Elizabeth Montgomery, PhD\* Ariane van der Straten, PhD, MPH\* Kristine Torjesen, MD† \*RTI International, San Francisco, CA

**†FHI**, Durham, NC

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## Reply to "Male Involvement' in Women and Children's HIV Prevention: Challenges in Definition and Interpretation"

## To the Editors:

We appreciate the letter by Montgomery et al in response to our study that showed an association between male partner involvement and improved infant outcomes (HIV-free survival) in Kenya.1 As was highlighted by the authors, male involvement in prevention of mother-to-child transmission of HIV (PMTCT) is recommended by multiple public health advisory bodies,<sup>2</sup> including the World Health Organization, which states that there is a need to "increase the involvement of male partners in PMTCT services (eg, couples counseling, partner testing)."3 Most national guidelines in sub-Saharan Africa are similar,4,5 yet what comprises involvement is not well defined.

As was recommended in this letter, there is a need for research to define clear objectives for male involvement in PMTCT. To date there is a paucity of studies on partner participation in prevention of vertical transmission programs. Rates of male HIV testing in the antenatal setting have been historically low. With few exceptions, partner testing rates are consistently less than 30% in research settings.<sup>6</sup> There are also minimal data from men themselves on their perceived barriers to antenatal clinic attendance and HIV testing in that setting. One of the few studies that provides information obtained directly from men on barriers to involvement found that the most frequently reported reason for failure of participation in PMTCT was a lack of knowledge regarding the existence of services or the necessity for men to take part in them.<sup>7</sup> Therefore, in addition to clarifying definitions of male involvement in PMTCT, further research is needed to determine the self-perceived roles of, and barriers to, involvement of male partners.

As was discussed by Montgomery et al, confounding and bias may have existed in our observational study, similar to other studies on male involvement that have investigated surrogate end points such as antiretroviral prophylaxis and feeding choice.<sup>8–12</sup> We agree with the authors that randomized controlled trials are needed to rigorously evaluate if varying forms of male involvement improve outcomes. Appropriate trial design will be crucial to ensure equipoise<sup>13</sup> and it may be beneficial to randomize participants to comparative forms of male involvement rather than a control that excludes men from participating in their family's healthcare.

In conclusion, we concur with the recommendations by Montgomery et al regarding the need for more robust study designs aimed at delineating beneficial forms of male involvement. In addition, we stress the need for such work to focus on men themselves with the immediate aims of understanding perceptions of their roles in prevention programs and barriers to their involvement in PMTCT settings.

Adam Aluisio, MS\* Barbra A. Richardson, PhD, MS† Rose Bosire, MBChB, MPH‡ Grace John-Stewart, MD, PhD§ Dorothy Mbori-Ngacha, MBChB, MMed, MPH|| Carey Farquhar, MD, MPH§ \*Stony Brook University Medical Center Stony Brook, NY

†Departments of Biostatistics and Global Health,

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