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Challenges in Estimating Effectiveness of Condom Distribution Campaigns to Prevent HIV Transmission

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INTRODUCTION

An estimated 1.2 million people aged 13 years and older are living with human immunodeficiency virus (HIV) infection in the United States[1], and approximately 45,000 people are newly diagnosed with the virus each year.[2] Over the last 30 years, condom use has been a key element of comprehensive approaches to HIV prevention.[3–9] For instance, the National HIV/AIDS Strategy for the United States 2010 (updated in 2015) calls for promotion of condom use in combination with other prevention approaches.[10] Condom distribution campaigns, a frequently used public health intervention, make condoms freely available in settings frequented by people believed to be at high risk of transmitting or acquiring HIV. However, data regarding the effectiveness of condom distribution campaigns remain limited due to several methodological challenges. Knowledge of the strength of evidence of condom distribution campaign effectiveness is important for priority setting and the efficient allocation of HIV prevention resources among competing interventions.[11–13] This paper examines limitations in the literature regarding condom distribution campaigns and the difficulties in estimating the effectiveness of campaigns through observational studies and mathematical modeling.

CONDOM EFFECTIVENESS

Several studies have examined the effectiveness of condoms in preventing HIV transmission among highly adherent persons and in controlled settings. For example, a multi-national meta-analysis of condom effectiveness studies has shown that, among sero-discordant (i.e., only one partner is HIV-positive) heterosexual couples who always used condoms, transmission risk was reduced by approximately 80% compared with those who never used a condom.[3] A similar analysis in the United States found that the transmission risk reduction was 70% among men who have sex with men (MSM) who always used condoms.[14] In

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addition to their high effectiveness in preventing HIV transmission, condoms are also widely available[15,16], relatively inexpensive[17], safe, easy to use, and can prevent other sexually transmitted infections (STIs) as well as unintended pregnancies.[18–20] Due to these factors, condom distribution campaigns are often recommended as part of HIV prevention interventions.[7,9,10] However, condom distribution campaigns face implementation and evaluation challenges including: (1) identifying and reaching people who are at risk for HIV; (2) ensuring that condoms are distributed to those who would not otherwise have access to them; and (3) verifying that recipients at risk for acquiring or transmitting HIV use condoms both correctly and consistently.

CONDOM DISTRIBUTION CAMPAIGN EFFECTIVENESS

Given these challenges, numerous studies have attempted to document the effectiveness of condom distribution interventions (as opposed to the effectiveness of condom use) and have reported various sexual behavior and biological outcomes.[21,22] Charania et al. conducted a meta-analysis of condom distribution studies that focused on the behavioral outcomes associated with increased condom availability and acceptability.[21] They found that the interventions were effective in increasing self-reported condom use during the last sex act. This analysis was based primarily on observational studies, which included seven U.S.-based studies conducted in sexually transmitted disease (STD) clinics, high schools, and communities at high risk for STDs. In contrast, Moreno et al. conducted a systematic review of condom distribution interventions focusing on biological outcomes and found that there was no clear evidence of effectiveness in preventing HIV transmission despite the fact that the interventions increased self-reported condom use during last sex.[22] The analysis was based on randomized controlled trials that included studies mostly from sub-Saharan Africa. The Moreno results highlight the inherent limitations of assessing effectiveness with behavioral outcomes, such as condom use during the last sex act: improvements in self-reported risk behaviors may not correlate with reductions in HIV transmission.

MODELING FOR ESTIMATING THE EFFECTIVENESS OF CONDOM DISTRIBUTION CAMPAIGNS

In the absence of data on the effectiveness of condom distribution campaigns in preventing HIV transmission, mathematical modeling can be used to provide an estimate of effectiveness. The Bernoulli process model is the standard method for estimating HIV infections prevented from behavioral interventions. In this model, acts of vaginal or anal sex are treated as independent events, each with a small probability of HIV transmission from an infected person to an uninfected partner.[23] Condom use is evaluated in the model by noting the number of sex acts in which condoms are used and applying a decreased per act transmission probability to condom-protected acts. To estimate the intervention's effect on HIV transmission, the model requires detailed sexual behavior data both before and after the campaign (i.e. pre- and post-test data).[24]

Figure 1 shows the data that may be observable, and those that typically are unobservable, in condom distribution campaigns. Most of these data are required for a Bernoulli process model to estimate the campaign's effectiveness in preventing HIV infection. The observable

data may include the number of condoms made available and the number distributed to potential users over a period of time.[17,25,26] Data required in the Bernoulli process model, but generally unobservable within the context of a given campaign, include specific demographic and sexual behavior characteristics. Although Pinkerton et al. suggested that Bernoulli modeling can be used to estimate the intervention effects with limited sexual behavior data from the intervention, (at minimum including number of sex partners, number of sex acts per partner, and number of sex acts protected by condoms before and after the intervention[24]), these data are generally not available from condom distribution campaigns. Furthermore, additional data on HIV status of the index persons and their partners, partnership type (main, casual), sex type (receptive, insertive, vaginal, anal), gender, risk groups (men who have sex with men, high-risk heterosexuals, injection drug users), race/ethnicity, and partnership overlap are essential for more accurate estimates.[27] Nor is it easy to determine the extent to which these recently distributed condoms increased condom use or substituted for condoms that would have been used in the absence of a campaign.

APPROACHES TO MODELING THE EFFECTIVENESS OF CONDOM DISTRIBUTION CAMPAIGNS

Several modeling studies have assigned values to the unobservable variables in condom distribution campaigns.[25,28,29] Bedimo et al. evaluated the effectiveness and cost-effectiveness of a condom social marketing campaign in Louisiana (1994–1996) by applying in their model an increase in the proportion of sex acts protected by condoms based on the increase in the proportion of a separate sample of people who reported having used a condom at last sex act. The difference in the proportion who reported condom use at last sex act before and after the campaign occurred was used as the average increase in the proportion of all sex acts covered over a year's period by the estimated 275,000 persons reached by the campaign.[28] The analysis used several other external data sources and assumptions for model inputs, including number of partners of campaign beneficiaries and number of sex acts per partner. Population-level HIV prevalence data for the study area were used as a proxy for the HIV serostatus of condom recipients and their partners. Holtgrave et al., in their evaluation of a female condom distribution campaign, assumed that 65% of the distributed condoms were used to decrease the risk of transmission with each sex act.[25] However, it is not possible to know how well these assigned variables matched the characteristics and behaviors of those who received condoms through a distribution campaign.

Data on the number of sex acts per partner and the proportion of acts protected by condoms before and after the campaign are among the most problematic to validly estimate. Surveys report different measures of condom use with varying degrees of accuracy and relevance to modeling, including condom use at last sex act, during a certain number of sex acts, or across all sex acts over time.[30–32] Although condom use at last sex act has been the most common measure and could minimize recall bias[30,33], it may not provide a valid proxy for longer term condom use.[30,34,35] For example, condom use has been found to decrease substantially over time after an intervention. Peterman et al. reported that consistent condom use decreased from 24.1% in three months following an STD clinic visit to 5.1% in one

year after the visit for a sample of patients in three public STD clinics[32], highlighting the time-dependency of these cross-sectional effect measures. Some researchers have suggested a composite measure, including condom use at last sex act, consistent condom use during a specified time period, and test-retest questions to ensure consistency in self-reported measures.[30] Importantly, these approaches to improving measures of condom use do not fully address the specific data needs for Bernoulli process modeling.

CONCLUSION

While condom distribution offers a logical and potentially inexpensive approach to prevent HIV, the effectiveness of condom distribution programs remains largely unknown. To quantify the effectiveness of condom distribution campaigns, Bernoulli process models can be used, but they require accurate data, at minimum, on the number of sex partners, number of sex acts per partner, and the proportion of those acts protected by condoms among program recipients before and after the campaign. These data are often not collected for specific condom distribution programs or even in general sexual behavior surveys. Condom use provides a number of benefits, but a rigorous evaluation of the effectiveness of condom distribution campaigns is difficult and may not be possible. While other HIV prevention interventions may be subject to other challenges regarding rigorous assessment of their effectiveness, the strength of scientific evidence of the effectiveness of all interventions should be considered when assessing how to distribute HIV prevention resources among competing interventions.

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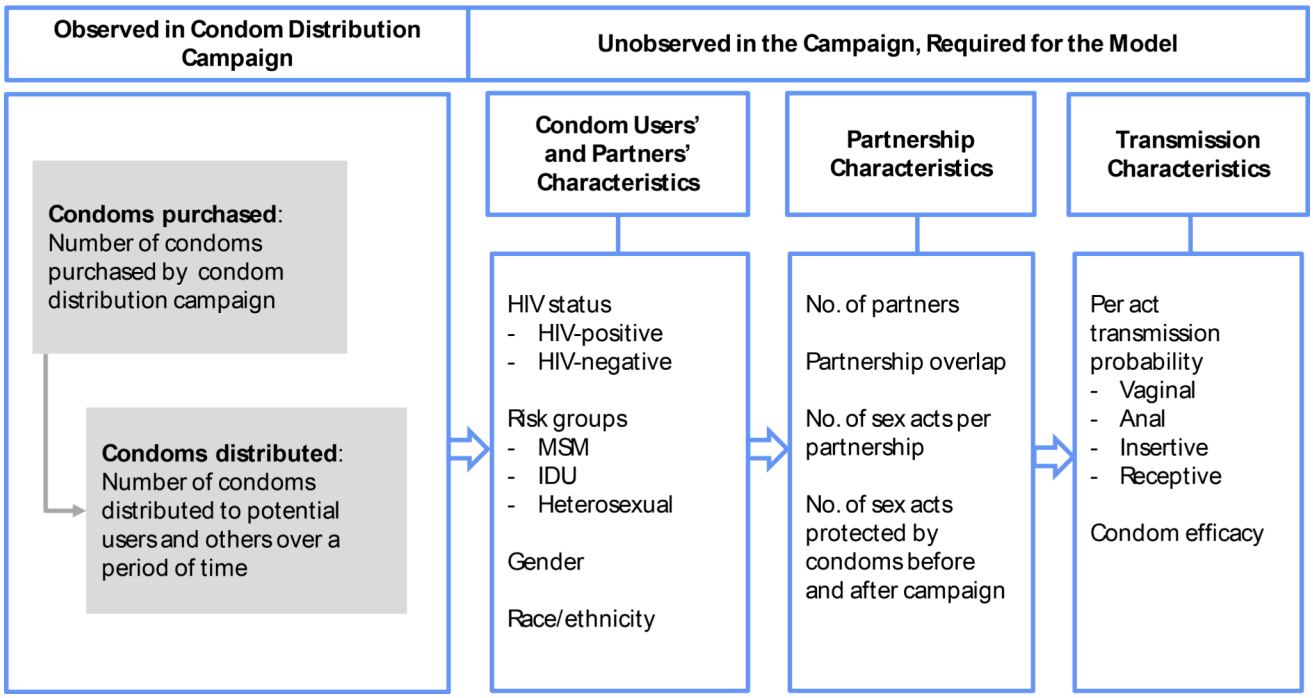

Figure 1.
Model parameters used in estimating the effectiveness of condom distribution campaign