

APA RESOLUTION on Combination Biomedical and Behavioral Approaches to Optimize HIV Prevention

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BACKGROUND

Thirty years after the initial discovery of the virus that causes AIDS, the epidemic continues to spread, both nationally and globally, and it continues to affect millions of individuals across the developmental spectrum (UNAIDS, 2017). Although daunting challenges remain, there have been major advancements in biomedical approaches to reduce HIV transmission during the past 10 years as a result of the increased tolerability and decreased cost of antiretroviral treatment (ART) and vaccines (e.g., Hepatitis B, human papillomavirus (HPV) vaccine), the expanding range of medical options (e.g., male circumcision, microbicides), and improvement in technological approaches (e.g., female condom, computerized counseling, and mobile phone messaging services to promote treatment adherence). The interest in biomedical approaches dramatically increased with the release of findings from the Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 trial (Karim et al., 2010), the Pre-exposure Prophylaxis Initiative (iPrEx) (Grant et al., 2010), and HIV Prevention Trials Network (HPTN) HPTN 052 trials.

South African scientists associated with CAPRISA, a Durban-based research center, announced in July 2010 that women who used tenofovir, a vaginal microbicide gel containing an antiretroviral medication widely used to treat HIV/AIDS, were 39 percent less likely overall to contract HIV than those who used a placebo (Karim et al., 2010). Even more impressive, those women who used the gel most regularly reduced their chances of infection by 54 percent (Karim et al., 2010). In November 2010, scientists associated with the iPrEx trial reported that the HIV infection rate in HIV-negative gay men who were given a daily dose of Truvada (a pill containing two HIV drugs) was reduced by 44 percent, compared with men given a placebo (Grant et al., 2010). Among subjects with a detectable tenofovir-FTC level, the odds of HIV infection corresponded to a relative reduction in HIV risk of 92% (Grant et al., 2010). During this trial, men using tenofovir did not increase sexual risk behaviors (Liu et al., 2013). In May of 2011, results released from the HPTN 052 study (NIAID, 2011) indicated that initiation of ART reduced transmission from HIV-positive men and women to their seronegative sexual partners by 96 percent, and a subsequent follow-up study showed that early ART provided a 93 percent lower risk of linked partner infection than delayed ART (Cohen et al., 2016).

Epidemiological U.S. data point to the rise of incident HIV infections among individuals who engage in injection drug use (IDU), particularly with increased national prevalence of opiate and other substance use (CDC, 2012). The seminal randomized controlled trial of pre-exposure prophylaxis (PrEP) use of tenofovir among individuals who engage in IDU conducted in Thailand found reduced risk of HIV infection among those receiving tenofovir relative to placebo (Choopanya et al., 2013). Further, this study highlighted that greater adherence to tenofovir (as measured by tenofovir drug concentration levels) were associated with decreased HIV incidence (Choopanya et al., 2013), highlighting the important role of behavioral interventions to increase adherence to PrEP as a biomedical prevention strategy.

For many, the results from these recent studies constitute “game-changing events” suggesting the need to prioritize biomedical over behavioral approaches to HIV prevention. However, close inspection of the results demonstrates that biomedical approaches to HIV prevention are optimized when they are combined with behavioral approaches. For instance, women in the CAPRISA study who accessed the adherence counseling program and used the gel most regularly had an HIV infection rate that was 54 percent lower than controls, while those with low adherence had an HIV infection rate that was only 28 percent lower than controls (Karim et al., 2010). Similarly, behavioral approaches played a central role in the HPTN 052 study (NIAID, 2011) in which all participants were given HIV care that included safe sex counseling. In order for biomedical HIV prevention products to work as intended, people must uptake the product and adhere to the treatment. Adherence and uptake of biomedical interventions can be addressed by behavioral interventions that enhance knowledge of the products and build skills for their effective use while incorporating attention to factors such as age, socioeconomic status, literacy, religious beliefs, chronic or acute health conditions and disability, developmental understanding, cognitive impairment, race immigration history and status, language, gender, gender identity, sexual orientation, family context, culture, stigma, mental health, substance use, attitudes, prior knowledge, among other factors (Liebowitz et al., 2011; Underhill et al., 2011). Thus, although biomedical approaches to HIV prevention such as “test-link-and- treat strategies” and pre- and post-exposure prophylaxis are important tools for HIV prevention, in order to optimize prevention outcomes, they must be combined with evidence-based behavioral strategies including structural interventions that increase access to services, decrease costs, and reduce stigma and discrimination to ensure broad-

scale implementation (Bekker, Beyrer, and Quinn, 2012). The debate over the value of biomedical versus behavioral approaches to HIV prevention can affect funding decisions associated with the implementation of the National HIV/AIDS Strategy (NHAS) released by former President Barack Obama in 2010. The NHAS is intended to guide our national efforts to reduce HIV/AIDS incidence, increase access to care, and reduce HIV-related health disparities.

WHEREAS recent findings from the CAPRISA 004 trials (Karim et al., 2010) (women receiving Tenofovir gel were 39 percent less likely to contract HIV than those receiving placebo), the iPrEx trials (Grant et al., 2010) (HIV- negative gay men given Truvada had 44 percent lower infection rates than men given placebo), and the HPTN 052 trials (NIAID, 2011) (HIV-positive individuals initiating ART decreased transmission rates to sexual partners by 96 percent), and the Dapivirine Ring studies, MTN-ASPIRE (Baeten et al., 2016) and IPM-The Ring Study (Nel et al., 2016) (incidence of HIV infection was 27 percent and 31 percent lower, respectively, in the intervention arms compared to the control arms) clearly establish the importance of biomedical approaches to HIV prevention; and,

WHEREAS the success of biomedical interventions is dependent on behavioral factors, such as those affecting medication adherence and treatment uptake (i.e., treatment acceptability and use) (Weiss et al., 2008), and thus behavioral and social science research can also help to understand vulnerable populations and risk settings, improve behavioral and social factors risk reduction, prevention, and care, strengthen design and outcomes of biomedically focused research in HIV treatment and prevention, and contribute to integrated HIV/AIDS prevention and treatment approaches (Gaist & Stirratt, 2017); and,

WHEREAS the efficacy of the CAPRISA 004, iPrEx, and HPTN 052 studies were optimized by behavioral approaches (Karim et al., 2010; Grant et al., 2010; NIAID, 2011); and,

WHEREAS women in the CAPRISA study, all of whom had access to the adherence counseling program, that used the gel most regularly had an HIV infection rate that was 54 percent lower than controls, while those with low adherence had an HIV infection rate that was only 28 percent lower than controls (Karim et al., 2010); and,

WHEREAS treatment adherence played a central role in the iPrEx study as evidenced by the fact that 91 percent of the men assigned to the treatment group who later tested positive for HIV had no detectable levels of Truvada in their bloodstream, indicating they were non-adherent to the medication regimen thus the reason for treatment failure and their acquisition of HIV (Grant et al., 2010); and,

WHEREAS behavioral approaches played a central role in the HPTN 052 study (NIAID, 2011) in which all participants were given HIV care that included safe sex counseling in order to achieve the high levels of ART adherence required to achieve viral suppression and thereby reduce HIV transmission risk to partners; and,

WHEREAS biomedical interventions for HIV and other sexually transmitted infections (STIs) without combined behavioral approaches have shown suboptimal medication adherence and treatment uptake e.g., 80 percent of women do not receive medication to prevent HIV Parent to Child transmission (Temmerman et al., 2003); 80 percent of uncircumcised Zambian males have expressed no interest in considering circumcision as an HIV risk reduction option (Weiss, 2011); only 27 percent of drug users in need of the Hepatitis B vaccine completed the required three dose regimen (McGregor et al., 2003); and only 28.2 percent of young women at a clinic who were offered the HPV vaccine accepted and of those who accepted only 55.7 percent completed all three required doses (Moore et al., 2010); and,

WHEREAS medication adherence and treatment uptake of biomedical interventions can be addressed by behavioral interventions that enhance knowledge and build skills while incorporating attention to factors such as age, socioeconomic status, literacy, religious beliefs, chronic or acute health conditions and disability, developmental understanding, cognitive impairment, race, ethnicity, immigration history and status, language, gender, gender identity, sexual orientation, family context, culture, stigma, mental health, substance abuse, attitudes, prior knowledge, etc. (Liebowitz et al., 2011; Underhill et al., 2011); and,

WHEREAS cost-effectiveness analysis suggests that PrEP could significantly reduce the lifetime risk of HIV infection in persons at high risk in the United States (Paltiel et al., 2009); and,

WHEREAS successful behavioral engagement in biomedical prevention models may be out of reach for certain populations (e.g., human trafficking victims, sex workers, people living in poverty and/or homeless, children, transgender individuals, those with an undocumented immigration status, etc.) necessitating the development of concurrent models that can be accessed by multiple at-risk populations (Bowleg, Neilands & Choi, 2008); and,

WHEREAS there is insufficient behavioral research to assess the potential for unintended consequences and unanticipated ethical issues in everyday clinical use of HIV biomedical interventions (e.g., individuals might engage in more risky behavior (Liu et al., 2013; Marcus et al., 2013); individuals may not use biomedical agents as prescribed; there may be health disparities in access to biomedical interventions; there may be as yet undefined, long- term, negative health implications and side effects from an exclusive reliance on biomedical interventions; etc.);

WHEREAS the federal government's goal of ending HIV in the United States by 2030 will require the integration of behavioral science/behavioral health with biomedical HIV prevention;

WHEREAS, the opioid epidemic in the U.S. is a public health crisis with increased risk for acquisition and transmission of both HIV and Hepatitis C Virus (HCV), comprehensive biomedical and behavioral intervention strategies to target the full HIV and HCV continuums of care for individuals with opioid use disorder (OUD) are necessary and novel public health approaches that address the intersection of opioid use, injection drug use, HIV and HCV are urgently needed to proactively address disparities experienced by individuals with OUD accessing and receiving HIV and HCV prevention and treatment services (Brown, 2019); and

WHEREAS these recent biomedical studies represent significant breakthroughs, combination approaches to prevent HIV and other STIs that comprise both biomedical and psychosocial components work best for optimizing health outcomes (Coates et al., 2008; Piot et al. 2008; Rausch, Grossman, & Erbelding, 2013);

THEREFORE behavioral research is needed to optimize medication adherence and treatment uptake, to document real-world decision making processes associated with biomedical interventions, and to better understand the possible unintended and/or undesired consequences of biomedical interventions; and,

THEREFORE HIV/STI prevention teams should continue to bridge biomedical and behavioral approaches (Farber, Ali, Van Sickle & Kaslow, 2017) and develop new combination approaches that consider the intersection of biological, cognitive, attitudinal, affective, behavioral, gender, familial, developmental, cultural, educational, social, racial, linguistic, socioeconomic, religious, and environmental factors (Fisher et al., 2010; National Institutes of Health Research Teams of the Future, 2011); and,

THEREFORE funding should be increased for HIV prevention research that incorporates mental health, substance abuse, behavior change, and adherence strategies to optimize the health outcomes of biomedical strategies with special attention paid to the development of combination prevention interventions that can be accessed by multiple at-risk populations; and,

THEREFORE Congress, the executive branch, state and local governments, and non- governmental organizations should promote public policies that increase support for multidisciplinary, interdisciplinary and transdisciplinary training, practice, and research; and,

THEREFORE psychology should continue to conduct research on strategies for improving health outcomes based on behavioral optimization of biomedical approaches to HIV/STI prevention and to continue basic and applied research to identify and disseminate effective universal and selective prevention strategies.

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