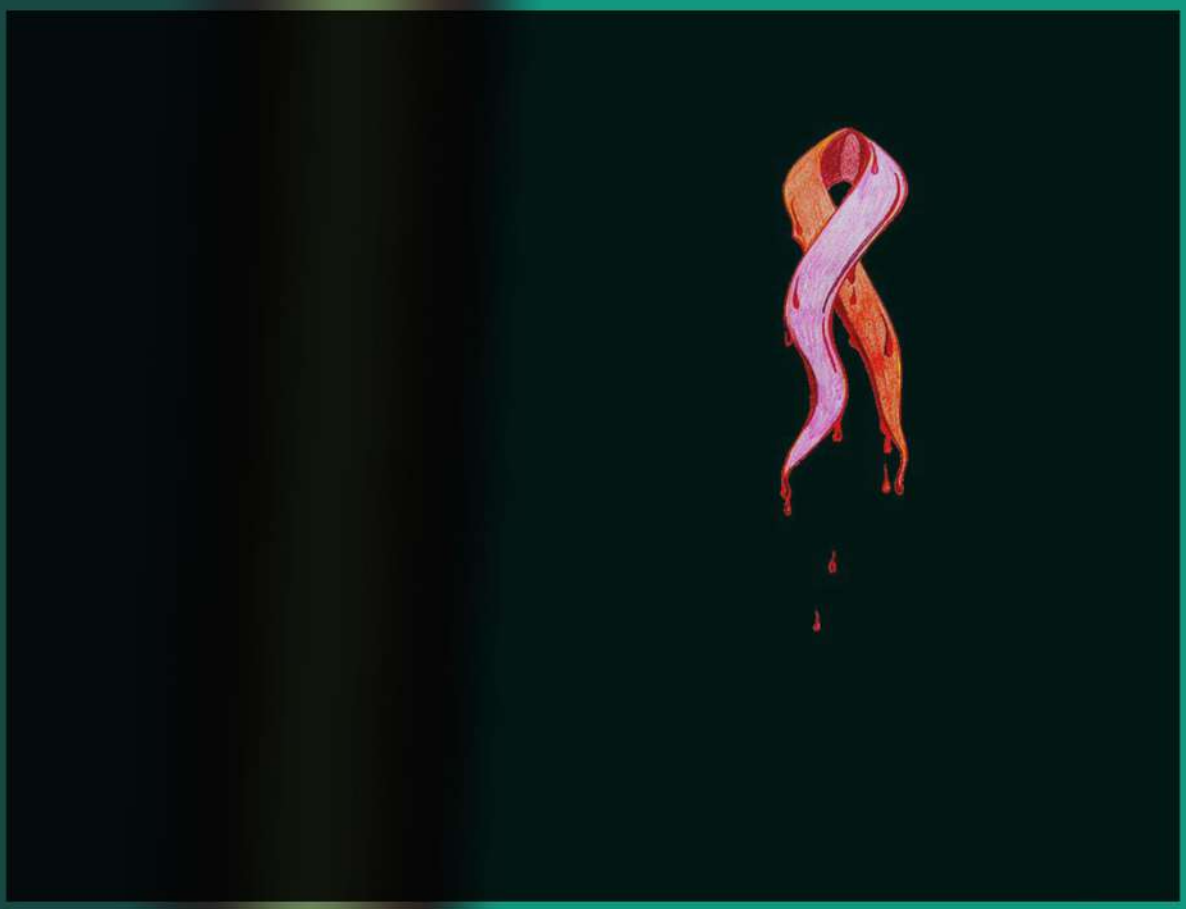
ISSN 2377-8377

Openventio
PUBLISHERS

HIV/AIDS RESEARCH AND TREATMENT

Open Journal

December, 2020 | Volume 7, Issue 1 |



www.openventio.org

ISSN 2377-8377

HIV/AIDS RESEARCH AND TREATMENT
Open Journal

Openventio PUBLISHERS

CONTENTS

ISSN 2377-8377

HIV/AIDS RESEARCH AND TREATMENT

OpenJournal

Openventio PUBLISHERS

Opinion

The Catalytic Framework: Africa's Weapon to End Acquired Immune Deficiency Syndrome by 2030

Benjamin Djoudalbaye, MD, MSc, MPH, Pg. Dipl. Infectious Diseases[1,2*]

[1]*Acting Head, Division of AIDS, TB, Malaria and Other Infectious Diseases, African Union Commission, P. O. Box 3243, W22 K19, Addis Ababa, Ethiopia*
[2]*Head of Policy and Health Diplomacy at Africa Centers for Disease Control and Prevention; P.O Box 3243, W22 K19, Addis Ababa, Ethiopia*

[*]***Corresponding author***
Benjamin Djoudalbaye, MD, MSc, MPH, Pg. Dipl. Infectious Diseases
Acting Head, Division of AIDS, TB, Malaria and Other Infectious Diseases, African Union Commission, P. O. Box 3243, W22 K19, Addis Ababa, Ethiopia; Phone. +251 115182207; E-mail: BenjaminD@africa-union.org

Article information
Received: January 24th, 2020; **Revised:** April 22nd, 2020; **Accepted:** April 22nd, 2020; **Published:** April 27th, 2020

Cite this article
Djoudalbaye B. The catalytic framework: Africa's weapon to end acquired immune deficiency syndrome by 2030. *HIV/AIDS Res Treat Open J.* 2020; 7(1): 1-2. doi: 10.17140/HARTOJ-7-131

In 2000, Africa was frightened to the core by acquired immune deficiency syndrome (AIDS).[1] This crisis stood the chance of dividing us, but it did not. As the African Union (AU) reflects on where we have come from, we are encouraged by the exceptional leadership role played by the pan-African organisation. The African-led statutory body has over the years united African leaders to leverage on the power of constructive policies and accountability as efficacious tools to fight AIDS in the continent. The AU is particularly well-pleased by the catalytic framework to end AIDS, tuberculosis (TB) and eliminate malaria in Africa by 2030[2] endorsed by Heads of States and Government of AU Member States in 2016.

The catalytic framework[3] is the greatest gift to Africa after the 2001 Abuja Declaration on human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS), TB and other related infectious diseases in which AIDS was declareda state of emergency in the continent. The distinctiveness of the framework emanates from the fact that it was formulated off the progress and experiences which culminated from implementation of Abuja commitments since 2000 and the AU road map for shared responsibility and global solidarity for AIDS, TB and malaria response[4] in Africa by AU member states. It therefore seeks to ensure that the commendable progress attained since 2001 — when the fight against AIDS was placed as the highest priority issue in respective national development plans — is intensified.

A review of the "*Abuja Call for Accelerated Action Towards Universal Access To HIV/AIDS, TB and Malaria Services*" and "*The AU Roadmap On Shared Responsibility And Global Solidarity For HIV/AIDS, TB And Malaria*" in 2015, highlights significant examples of progress attained in strengthening: financing models; leadership and governance; and access to medicine. A commendable example cited is South Africa who contributed US $2 billion between 2006 and 2011 per year of domestic funding towards AIDS response — the second largest national investment in the world. A second example included is the development of the Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPA) to increase pharmaceutical capacity. Consequently, Kenya, South Africa, Uganda, and Zimbabwe now produce World Health Organization (WHO) pre-qualified anti-retroviral drugs (ARVs). A final example included is the integration of ministries and HIV/AIDS-related programs into the Ministry of Health to enhance integrated multisectoral approaches in Rwanda, Burundi and Côte d'I voire. However, the review also unraveled that despite the progress, there was need for improved strategic approaches to fighting HIV/AIDS.[5]

The overarching strategic approach of the catalytic framework is an amalgamation of the targets in the AU agenda 2063[6] and agenda 2030. Therefore, it not only ensures continuity of continental efforts but fuses with global aspirations. This is strengthened by the exceptional strategic investmentare as of the framework. The areas are: leadership, country ownership, governance and accountability; universal and equitable access to prevention, diagnosis, treatment, care and support; access to affordable and quality assured medicines, commodities and technologies; health financing; community participation and involvement; research and development & innovation; promotion of human rights and gender equality; multi-sectoral collaboration and coordination; and strategic information. These, if reinforced with dedication and integrity, are an assured path to realization of the end of AIDS by 2030.

This article comes at a time when the African Union Commission (AUC) is gearing up for mid-term review of the cata-

lytic framework. The review will be undertaken through primary data collection using a questionnaire. The objective of the exercise is to collect information on the progress of implementation of the Framework by AU member states. It will also provide insight on the successes and challenges being faced during implementation of the activities in framework. The end goal is to ensure that the framework is a reliable policy instrument which is effective in guiding countries towards positive outcomes in response to AIDS, tuberculosis and malaria.

AIDS-specific goals of the catalytic framework are to-reduce number of AIDS-related deaths and new HIV infections compared with 2015 whilst wiping out discrimination. The stipulated strategies to achieve the goals are to: increase coverage of antiretroviral treatment to achieve 90-90-90; Eliminate new HIV infection in children and keep mothers alive; increase access to combination prevention services including HIV and SRH services to young people, men and women, and key populations; Address HIV and human rights, gender inequality, and offer HIV sensitive social protection.

The health financing strategic component is especially prominent given that in February 2019, African Heads of States and Government endorsed the Africa Leadership Meeting (ALM) — investing in health declaration[7] to spur a reorientation of Africa's health systems and health spending. The declaration is not only meant to push for utilization of domestic resources to increase investments in health but also uplift African-led health system strengthening mechanisms. Governments are in full support of the ALM declaration agenda to fight disease burden in Africa. This was attested during the Pan African Parliament Summit held in Brazzaville, Republic of Congo (11-12 July 2019) where the Parliamentarians in attendance signed a communiqué pledging to support the declaration through various ways, importantly, by passing policies aiming at increasing domestic health financing and enhancing accountability during implementation of the declaration.

The catalytic framework and the ALM declaration are implemented by the commission through AIDS Watch Africa (AWA)[8] Secretariat. Formed in 2001, AWA is an advocacy, mobilization and accountability platform of Heads of State and Government to mobilise action and resources for stronger leadership on the efforts to respond to the challenges posed by HIV/AIDS, TB and malaria. Each year, AWA convenes health experts from AU member states working in the field of AIDS, tuberculosis (TB) and malaria for statutory consultative meetings to discuss issues impeding progress in implementation of policy frameworks and the fight against the three diseases. The experts prepare a report with key recommendations for the consideration of the AWA Heads of State and Government Action Committee (GAC). This ensures that the relevant agendas are tabled before respective policy makers for their action.

2020 is a special year for millions of advocates and people living with HIV fighting hard for rights and resources. On one hand, time is up for political instruments with a trajectory set to achieve certain intermediary targets by 2020. We will check ourselves against the targets we set within the past decade as a continent, starting with those on the Catalytic Framework and ALM declaration. On the other hand, we only have ten years left to the grand finale of 2030. We have to devise means of fighting harder and smarter against the injustice of stigma and discrimination, HIV related deaths and new HIV infections.

Heart-breaking stories about the challenges of ending AIDS as a public health threat still reign in many parts of Africa. Nevertheless, we must remain in sight of how far we have come and how further we can go. Everyone accessing treatment is a success story of how they are going to have the same life expectancy as someone who does not have HIV, the same opportunity to contribute to their communities and the same opportunity to watch their children grow up in an AIDS free-generation. We did this together and together we can end AIDS.

REFERENCES

1. AIDS by the Numbers. unaids Web site. https://www.unaids.org/sites/default/files/media_asset/AIDS_by_the_numbers_2015_en.pdf. 2015. Accessed January 23, 2020.

2. Catalytic Framework to End AIDS, TB and Eliminate Malaria in Africa by 2030 Web site. https://au.int/sites/default/files/pages/32904-file-catalytic_framework_8pp_en_hires.pdf. 2016. Accessed January 23, 2020.

3. Indiana Department of Environmental Management (IDEM) Web site. https://www.in.gov/idem/. Accessed January 23, 2020.

4. AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response Web site. https://au.int/en/pressreleases/20171208/african-union-and-partners-call-continued-shared-responsibility-and-global. 2017. Accessed January 23, 2020.

5. Review of the Abuja call for accelerated action towards universal access to HIV/AIDS, TB and Malaria services & the AU Roadmap on shared responsibility and global solidarity for HIV/AIDS, TB and Malaria Web site. https://au.int/sites/default/files/pages/32904-file-abuja_call_2015_evaluation_report_final.pdf. 2015. Accessed January 23, 2020.

6. Agenda 2063: The Africa We Want Web site. https://au.int/en/agenda2063/overview. 2013. Accessed January 23, 2020.

7. Africa Leadership Meeting – Investing in Health (ALM) Declaration. aidswatchafrica Web site. http://www.aidswatchafrica.net/african-leadership-meeting-alm-declaration/. 2019. Accessed January 23, 2020.

8. AIDS Watch Africa (AWA). aidswatchafrica Web site. http://www.aidswatchafrica.net/. 2020. Accessed January 23, 2020.

ISSN 2377-8377

HIV/AIDS RESEARCH AND TREATMENT

Open Journal

Openventio PUBLISHERS

Commentary

Towards a More Sustainable Response: Strengthening the Social Agenda in the Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome Epidemic

Jennifer Knight-Johnson, MA, MPH, PhD*

Public Health Analyst, Mitchellville, Maryland 20721, USA

Corresponding author
Jennifer Knight-Johnson, MA, MPH, PhD
Public Health Analyst, Mitchellville, Maryland 20721, USA; Tel. 1-240-273-8173; E-mail: jennic4@yahoo.com

Article information
Received: March 25th, 2020; **Revised:** June 11th, 2020; **Accepted:** June 13th, 2020; **Published:** June 18th, 2020

Cite this article
Knight-Johnson J. Towards a more sustainable response: Strengthening the social agenda in the human immunodeficiency virus infection and acquired immune deficiency syndrome epidemic. *HIV/AIDS Res Treat Open J*. 2020; 7(1): 3-4. doi: 10.17140/HARTOJ-7-132

The human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) response has made significant strides in preventing the spread of the epidemic globally. Many of the achievements could not have happened without the resilience of the people living with HIV/AIDS (PLHIV) community, the funding and technical support of the donor community including public/private partnerships, the tenacity of the Governments (national response), the relentless outreach of the Non Governmental Organization (NGO) community and their networks, the untiring efforts of health care providers, and the activism of grassroots movements. The focus has shifted from an emergency response to achieving epidemic control[1] and the 95-95-95 targets, set globally. We are not there yet. The gains have been slowing, as declines in new infection rates are not consistent across countries,[2] the capability to retain patients in care is suboptimal, antiretroviral treatment (ART) coverage has not reached established targets, and viral suppression rates are struggling to attain optimal levels in many countries.

There has been a dramatic shift in emphasis towards a more targeted approach to reach geographic locations, and the populations most likely to transmit the disease. There has also been an increased emphasis on combination prevention, case finding, contact tracing, diagnostic testing, and expanded treatment regimens which are scientifically proven to improve the efficacy and tolerability for the patients in care.[3] The question is how far will these interventions help to accomplish the gold standard in which individuals, communities, the society, is sustainable and self-sufficient?

A greater emphasis on the social imperatives that impact HIV prevention care and treatment should be further explored. The social agenda can play a greater role in the policy directives and the operationalization of our interventions. It provides a strategic framework and a conduit for the intersection with how human beings behave in society and the wider social context in which people live.[4] The social includes, how we circumvent personal relationships; engage in social institutions; and cultural configurations; our role in our of families and households; relationships with men, women, and children; response to HIV/AIDS discrimination and its impact on the individual[5] (the patient); the social interactions of the individual and the group; and the welfare of human beings, as members of society. Social also means targeting our interventions to society or in the way society is organized. Here are also the structural interventions in prevention which include addressing gender inequalities, homophobia, stigma, and discrimination.[6] These are critical interventions. In addition, there are the social determinants of health and by extension the social determinants of HIV/AIDS which incorporates lifestyle factors, social support systems, living and working conditions.[7]

Addressing the social norms, processes and structural approaches are no accident of history.

Reflecting on the beginning of the epidemic reminds us that there was a greater emphasis on the "modes of transmission" rather than the social contexts around HIV prevention, care, and treatment. This was a missed opportunity as relationships, patterns

of marriage, family life, the sexual socialization of children, intergenerational modalities, gender imperatives, race, ethnicity, social class, inequities, power dynamics are embedded in communities that give the HIV virus a strong position for rapid transmission.

Multiple interventions exist to address HIV/AIDS, and only a minority pays sufficient attention to the social processes. These are the ones most likely to prompt the lasting changes needed to protect communities against the consequences of the disease. These are the ones that promulgate lasting changes that endure and are sustainable.

REFERENCES

1. U.S. President's Emergency Plan for AIDS Relief. PEPFAR2019 Annual Report to Congress Web site. https://www.state.gov/wp-content/uploads/2019/09/PEPFAR2019ARC.pdf. Accessed March 2, 2020.

2. Global AIDS Update 2018. Miles to go Closing Gaps and Breaking Barriers Righting Injustice. Web site: https://www.unaids.org/sites/default/files/media_asset/miles-to-go_en.pdf. Accessed March 10, 2020.

3. PEPFAR 2019 Country Operational Plan Web site. https://www.state.gov/wp-content/uploads/2019/08/PEPFAR-Fiscal-Year-2019-Country-Operational-Plan-Guidance.pdf. Accessed March 8, 2020.

4. Harlambos M, Holborn M, Chapman S, Moore S. *Haralambos And Holborn - Sociology Themes And Perspectives*. 8th ed. London, UK: Collins; 2013.

5. Danziger R. The social impact ofHIV/AIDS in developing countries. *Soc Sci Med.* 1994; 39(7): 905-917. doi: 10.1016/0277-9536(94)90203-8

6. AVERT 2016 HIV and AIDS social Issues - Global Information and Education on HIV and AIDS Web site. https://www.avert.org/professionals/hiv-social-issues. Accessed March 5, 2020.

7. Skolnik R. Global Health 101. 4th ed. Burlington, MA, USA: Jones & Bartlett; 2019.

ISSN 2377-8377

HIV/AIDS RESEARCH AND TREATMENT

Open Journal

Openventio PUBLISHERS

Mini Review

The Time is Now for Disruptive Innovation in Pre-Exposure Prophylaxis Adherence Monitoring

Giffin Daughtridge, MD, MPA*; Elijah Kahn-Woods, BS; Casper Enghuus, MS, PhD (Student); Shane Hebel, JD

UrSure, Inc., 125 Western Ave, Allston, MA 02134, USA

Corresponding author
Giffin Daughtridge, MD, MPA
CEO, UrSure, Inc., 125 Western Ave, Allston, MA 02134, USA; Tel. 2522878215; E-mail: giffin@ursureinc.com

Article information
Received: June 23rd, 2020; **Revised:** July 10th, 2020; **Accepted:** July 20th, 2020; **Published:** July 29th, 2020

Cite this article
Daughtridge G, Kahn-Woods E, Enghuus C, Hebel S. The time is now for disruptive innovation in pre-exposure prophylaxis adherence monitoring. *HIV/AIDS Res Treat Open J.* 2020; 7(1): 5-9. doi: 10.17140/HARTOJ-7-133

ABSTRACT

Monitoring adherence to pre-exposure prophylaxis is a critical component of reaching ending the human immunodeficiency virus infection (HIV) epidemic goals in the US. Currently, providers still depend on "self-report" pre-exposure prophylaxis (PrEP) adherence, whereby providers ask their patients about their recent pill taking habits. There appears to be growing consensus across the HIV prevention community that "self-report" is an inadequate method of identifying that is in-need of additional adherence support services. In a recent survey, 97% of providers report utilizing self-reported adherence because it is convenient, but only 10% of these providers believe it is accurate. While "self-report" is convenient, evidence and testimonials from diverse stakeholders across the HIV prevention landscape indicate that there is a desire for more accurate, effective adherence monitoring methods. In this mini-review, we will briefly synthesize the emerging evidence and propose a solution to ensure all patients receive the support needed to protect them from HIV acquisition.

Keywords
Pre-exposure prophylaxis; HIV; Adherence; Prevention; Self-report.

INTRODUCTION

Self-reported health behaviors consistently overestimate actual behavior. Those of us who have exaggerated the frequency of our flossing habits to our dentist can attest to this, and yet we still depend on "self-report" for pre-exposure prophylaxis (PrEP) adherence. In a recent survey, 97% of providers report utilizing self-reported adherence because it is convenient, but only 10% of these providers believe it is accurate. This mini-review explores the ramifications of this disconnect and proposes an objective way to monitor and improve PrEP adherence.

Poor Adherence to PrEP Threatens the Success of "Ending the HIV Epidemic"

PrEP is nearly perfect at preventing human immunodeficiency virus infection (HIV) acquisition, but only when taken daily.[1-5] Inconsistent or low PrEP adherence is shown to reduce PrEP efficacy, and several PrEP demonstration projects have found that PrEP adherence is often sub-optimal and wanes over time.[2,3,6-10] One 12-month PrEP demonstration project in Harlem found that adherence was only 52.9% at 3-months, 42.2% at 6-months, 35.8% at 9-months, and 32.4% at 12-months – a trend that is consistent with similar studies across settings and sub-populations.[11]

Ending the HIV Epidemic

A plan for America Ending the HIV Epidemic (EHE) initiative from the US Department of Health and Human Services (HHS) outlines a strategy to reduce the number of new HIV infections in the US by 75% in the next five-years and by 90% in the next 10-years.[12] A key component of EHE is decreasing seroconversions through a scale--up of PrEP. However, adherence is the biggest determinant of PrEP's success, and as we saw in the previously mentioned studies, adherence in the real world is sub-optimal.

As Eaton et al's 2018 study of HIV prevalence among African American black men who have sex with men (BMSM) shows, poor PrEP adherence translates to increased seroconversions: across over 4,000 surveyed BMSM, 1 in 3 on PrEP tested positive for HIV, compared to 1 in 5 not on PrEP testing HIV positive.[13] Without changing current practice and providing improved adherence support for those on PrEP, poor adherence will undermine EHE's ambitious HIV prevention goals.

We Have the Clinical Tools to Accurately Identify and Address Non-Adherence

It is increasingly critical that clinicians are able to accurately determine which of their patients are struggling with their PrEP adherence so that they can allocate additional support services to them. Objective methods of measuring medication adherence have emerged as valuable tools in both research and clinical settings.[14,15] For example, new innovations enable real-time monitoring of pill taking habits through smart pill bottles and digital pill sensors, facilitating rapid intervention from providers.[14] Novel methods of measuring drug concentrations in various biomatrices (e.g., blood, urine, hair) allow for objective adherence monitoring (OAM) of PrEP and antiretroviral therapy (ART).[14-19] Measuring drug concentrations in biomatrices indicates recent or cumulative exposure to these drug regimens, whereby higher drug concentrations suggest higher adherence and undetectable or low drug concentrations suggest sub-optimal or non-adherence. These biomarker-based OAM methods (i.e., plasma, dried blood spot-, urine, and hair-based methods) have been developed and deployed in research settings to quantify and assess PrEP adherence. In one study, 50% of PrEP patients, who were identified as non-adherent by a plasma-based OAM test and then received targeted adherence support, achieved sustained improvement in adherence throughout the remainder of the study. This result indicates that OAM coupled with targeted adherence supports an generate substantial improvements in adherence.[20]

In clinical settings, a liquid chromatography tandem-mass spectrometry (LC-MS/MS) urine adherence test is presently the only commercialized OAM method available for PrEP and has been introduced at >25 clinics nationwide. Preliminary data suggests that routine clinical use of the LC-MS/MS urine adherence test is useful in improving adherence and predicting future non-retention.[21] These results showed that 74% of individuals initially identified as non-adherent by the urine OAM test demonstrated recent adherence on the same test at their next visit after receiving targeted adherence counseling.[21] Moreover, non-adherent patients were 70% more likely to miss their next visit and 114% more likely to have dropped out of care within the next six months compared to adherent individuals. This demonstrates a further role for adherence testing in predicting future non-retention in care.[21]

Despite the Availability of OAM, "self-report" Still Prevails Clinically

Though OAM capabilities have dramatically advanced since PrEP got its Food and Drug Administration (FDA) approval, current PrEP clinical practice has not adopted this disruptive technology. PrEP clinics still depend on "self-report" to monitor adherence, whereby providers ask their patients about their recent pill taking habits. "Self-report" is free, easy to implement, and enables providers to rapidly triage individuals, who self-report non-adherent, to the appropriate support services. Nevertheless, research suggests that "self-report" is prone to social desirability and recall biases, and it is heavily influenced by the trust that patients do or do not feel for their providers[22–26] Like the flossing example above, self-report dramatically overestimates actual adherence behavior.

Key Stakeholders Align in their Denouncement of Self-Report

There appears to be a growing consensus across the HIV prevention community that "self-report" is an inadequate method of identifying who is in-need of additional adherence support services. While "self-report" is convenient, evidence and testimonials from diverse stakeholders across the HIV prevention landscape indicate that there is a desire for more accurate, effective adherence monitoring methods. In this mini-review, we will briefly synthesize the emerging evidence from four distinct sources (the FDA, clinical trials, PrEP patients, and providers) and propose a solution to ensure all patients receive the support needed to protect them from HIV acquisition.

FDA's initial approval of Truvada: Citing the importance of adherence in determining PrEP's utility, the FDA acknowledged the significance of using accurate monitoring methods and describes the inadequacy of relying on self-reported adherence. When the FDA first approved Truvada for use as PrEP in 2012, they noted that "*self-reported adherence and adherence by pill count were unreliable… high self-reported adherence was poorly predictive of measurable intracellular concentrations of the active forms of the Truvada components whereas low self-reported adherence was predictive of non-measurable drug concentrations.*"[27]

Clinical trials: Several PrEP demonstration projects internationally and in the United States collected both self-reported and biomarker-based adherence data to assess the association between adherence and protection from HIV-acquisition.[2,4,9,26,28] In a 2018 meta-analysis of PrEP adherence studies, Sidebottom et al list 6 unique studies that collected both self-reported and plasma-based adherence testing data from disparate patient populations (i.e., men who have sex with men, transgender women, heterosexuals, people who inject drugs, adolescents etc.) (Table 1). There was a consistent and

Table 1. *PrEP Studies That Measured both Self-Reported and Plasma-Based Adherence*

Year	Study Name	% with Detectable TDF or FTC in Plasma	Self-report (%)
2010	iPrEx	51	95
2012	TDF2	80	94
2012	FEM-PrEP	24	95
2013	Bangkok tenofovir study	67	94
2013	ATN 082 (Project PrEPARE)	20	62
2015	VOICE	30	87-90

Adadapted from Sidebottom et al[9]

substantial divergence between self-reported adherence and detectable drug levels in plasma, with discrepancies as high as 95% self-reported adherence and 24% adherence per plasma drug levels.[9]

Patient preferences: Importantly, several studies suggest that many patients want closer adherence monitoring. Hunt et al describe the acceptability of urine adherence monitoring with the vast majority of patients at their Philadelphia PrEP clinic claiming urine adherence testing would be a helpful component of routine PrEP care.[29] Moreover, Koester et al studied the acceptability of drug detection feedback among participants in the iPrEx Open Label Extension (OLE) study. Half of the participants found biomarker based adherence monitoring to be useful and motivating with no negative reactions recorded from the 59 patients who were interviewed.[30] This speaks to the potential for OAM to not only facilitate adherence interventions for non-adherent individuals but also incite a positive feedback loop that keeps adherent clients sustainably protected from HIV acquisition. As one 22-year-old African American patient from Chicago claimed:

"*It's just that it solidifies that all your efforts are being… So you know you're taking this pill, you see it in your bloodstream. You know it's working. You know it's there. You know you're not doing it just in vain.*"

Provider preferences: A recent survey of 30 PrEP-prescribing providers across the United States illustrates a disconcerting trend in providers' perceived ability to adequately monitor PrEP adherence. These 30 providers were approached *via* a third-party survey service to gauge their perceptions of the importance of PrEP adherence and their preferences for adherence monitoring methods. 80% of providers (24/30) claimed that they are "*worried about the potential of patients seroconverting after being initiated on PrEP, due to non-adherence.*" Nevertheless, 97% of providers (29/30) consistently use "self-report"to assess PrEP adherence, despite only 10% (3/29) believing this method is accurate. Conversely, only three of the 30 providers use biomarker-based adherence monitoring to assess adherence, all of whom believe this method is accurate.

Call to Action: Use Objective Methods to Monitor PrEP Patients' Adherence

In sum, insights from the FDA, clinical trials, patients, and providers all indicate that "self-report", the current standard of care adherence monitoring method, is insufficient in identifying those struggling with PrEP adherence. Initiating at-risk individuals on PrEP is an important factor in curbing new HIV infections in the United States; however, these PrEP uptake gains will be nullified if we lack the tools to accurately identify non-adherence and allocate the appropriate support services.

There are certainly populations and research settings in which self-report does correlate with actual adherence. Still, having an objective test removes the onus of "truth telling" and "lie detection" from patients and providers. The results of OAM provide an empirical foundation upon which to build trust and mitigate the barriers to adherence that all patients inevitably face at some point in their PrEP journey. For adherent individuals, per the Koester et al study mentioned above, OAM can provide positive feedback that their diligence is "working" and that they are succeeding in taking the daily pill that will keep them protected from HIV acquisition.

Introducing OAM for PrEP has a corollary in the field of HIV-viral load testing for people living with HIV on ART. With ART, providers rely on viral load monitoring to determine if the medications are "working" (e.g., the virus is suppressed and the patient is unlikely to acquire opportunistic infections or transmit HIV to others). In the United States, it would be unusual for an infectious disease doctor to make a clinical decision regarding ART support (i.e., allocating adherence support services or referring to additional resistance testing) without first conducting a routine viral load test. While discussing patients' unique lifestyle and barriers to adherence is surely indispensable, having an objective data point to complement and contextualize these qualitative descriptions is integral to making informed clinical decisions. Optimal PrEP care should be no different; objective adherence data empowers providers to make informed clinical decisions and ensure PrEP is "working" for their at-risk patients.

CONCLUSION

Taking a pill every single day for an extended period of time is inherently difficult, particularly for otherwise-healthy people. The barriers to optimal adherence, especially for those who are traditionally-marginalized or vulnerable to HIV infection, are numerous, diverse, and ever-changing.[9,29,31-34] We all face occasional lulls in health-seeking behavior. Thus, we cannot settle for antiquated adherence monitoring tactics that are subjective and prone to biases, even if they are cheap and easy. We need to equip our PrEP providers with the most accurate and patient-friendly tools available. These tools can help PrEP achieve its potential to end the HIV epidemic.

CONFLICTS OF INTEREST

Giffin Daughtridge, Elijah Kahn-Woods, Casper Enghuus, and Shane Hebel are paid employees of UrSure, Inc.

REFERENCES

1. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): Effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lacentt.* 2016; 387(10013): 53-60. doi: 10.1016/S0140-6736(15)00056-2

2. Anderson PL, Glidden D v., Liu A, Buchbinder S, Lama JR, Guanira JV, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Sci Transl Med.* 2012; 4(151): 151ra125. doi: 10.1126/scitranslmed.3004006

3. Liu AY, Cohen SE, Vittinghoff E, Anderson PL, Doblecki-Lewis S, Bacon O, et al. Preexposure prophylaxis for HIV infection integrated with municipal and community-based sexual health ser-

vices. *JAMA Intern Med*. 2016; 176(1): 75-84. doi: 10.1001/jamainternmed.2015.4683

4. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010; 363(27): 2587-2599. doi: 10.1056/NEJMoa1011205

5. Thigpen MC, Kebaabetswe PM, Paxton LA, Smith DK, Rose CE, Segolodi TM, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in botswana. *N Engl J Med*. 2012; 367(5): 423-434. doi: 10.1056/NEJMoa1110711

6. Grant RM, Anderson PL, McMahan V, Liu A, Amico KR, Mehrotra M, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: A cohort study. *Lancet Infect Dis*. 2014; 14(9): 820-829. doi: 10.1016/S1473-3099(14)70847-3

7. Hojilla JC, Vlahov D, Glidden D v, Amico KR, Mehrotra M, Hance R, et al. Skating on thin ice: stimulant use and sub-optimal adherence to HIV pre-exposure prophylaxis. *Journal of the International AIDS Society*. 2018; 21(3): e25103. doi: 10.1002/jia2.25103

8. Hosek SG, Siberry G, Bell M, Michelle L, Bill K, Keith G, et al. The acceptability and feasibility of an HIV preexposure prophylaxis (PrEP) trial with young men who have sex with men. *J Acquir Immune Defic Syndr*. 2013; 62(4): 447-456. doi: 10.1097/QAI.0b013e3182801081

9. Sidebottom D, Ekström AM, Strömdahl S. A systematic review of adherence to oral pre-exposure prophylaxis for HIV - How can we improve uptake and adherence? *BMC Infect Dis*. 2018; 18(1): 581. doi: 10.1186/s12879-018-3463-4

10. Serota D, Rosenberg E, Lockard A, del Rio C, Luisi N, Cutro SR, et al. PrEP persistence and discontinuations. Paper presented in as cohort of young black msm in Atlanta, GA. Paper presented at: Retroviruses and Opportunistic Infections; 2019; Seattle, Washington

11. Colson PW, Franks J, Wu Y, Winterhalter FS, Knox J, Ortega H, et al. Adherence to pre-exposure prophylaxis in black men who have sex with men and transgender women in a community Setting in Harlem, NY. *AIDS Behav*. 2020. doi: 10.1007/s10461-020-02901-6

12. US Department of Health & Human Services. Ready, set, PrEP expands access to medication to prevent HIV. prevention.nih Web site. https://prevention.nih.gov/news-events/news-releases/2019/12/ready-set-prep-expands-access-medication-prevent-hiv. Accessed December 3, 2019.

13. Eaton LA, Matthews DD, Bukowski LA, Friedman MR, Chandler CJ, Whitfield DL, et al. Elevated HIV prevalence and correlates of PrEP use among a community sample of black men who have sex with men. *J Acquir Immune Defic Syndr*. 2018; 79(3): 339-346. doi: 10.1097/QAI.0000000000001822

14. Spinelli MA, Haberer JE, Chai PR, Castillo-Mancilla J, Anderson PL, Gandhi M. Approaches to objectively measure antiretroviral medication adherence and drive adherence interventions. *Curr HIV/AIDS Rep*. 2020; 17(4): 301-314. doi: 10.1007/s11904-020-00502-5

15. Castillo-Mancilla J. Getting it right: practical approaches to adherence with modern ARVs. Paper presented at: Retroviruses and Opportunistic Infections; 2020; Boston, Massachusetts, USA.

16. Castillo-Mancilla JR, Zheng J-H, Rower JE, Meditz A, Gardner EM, Predhomme J, et al. Tenofovir, emtricitabine, and tenofovir diphosphate in dried blood spots for determining recent and cumulative drug exposure. *AIDS Res Hum Retroviruses*. 2013; 29(2): 384-390. doi: 10.1089/aid.2012.0089

17. Castillo-Mancilla JR, Morrow M, Coyle RP, Coleman SS, Gardner EM, Zheng J-H, et al. Tenofovir diphosphate in dried blood spots is strongly associated with viral suppression in individuals with human immunodeficiency virus infections. *Clinical Infectious Diseases*. 2019; 68(8): 1335-1342. doi: 10.1093/cid/ciy708

18. Frasca K, Morrow M, Coyle RP, Coleman SS, Ellison L, Bushman LR, et al. Emtricitabine triphosphate in dried blood spots is a predictor of viral suppression in HIV infection and reflects short-term adherence to antiretroviral therapy. *Journal of Antimicrobial Chemotherapy*. 2019; 74(5): 1395-1401. doi: 10.1093/jac/dky559

19. Gandhi M, Bacchetti P, Ofokotun I, Jin C, Ribaudo HJ, Haas DW, et al. Antiretroviral concentrations in hair strongly predict virologic response in a large human immunodeficiency virus treatment-naive clinical trial. *Clin Infect Dis*. 2019; 68(6): 1044-1047. doi: 10.1093/cid/ciy764

20. Landovitz RJ, Beymer M, Kofron R, Amico KR, Psaros C, Bushman L, et al. Plasma tenofovir levels to support adherence to TDF/FTC preexposure prophylaxis for HIV prevention in MSM in Los Angeles, California. *J Acquir Immune Defic Syndr*. 2017; 76(5): 501-511. doi: 10.1097/QAI.0000000000001538

21. Hebel S, Kahn-Woods E, Larabee L, Osorio B, Mayer KH, Sullivan PS, et al. Uuse of a tenofovir urine test to improve PrEP adherence and predict non-retention. Paper presented at: Retroviruses and Opportunistic Infections; 2020; Boston, Massachusetts, USA.

22. Gorbach PM, Mensch BS, Husnik M, Coly A, Mâsse B, Makanani B, et al. Effect of computer-assisted interviewing on self-reported sexual behavior data in a microbicide clinical trial. *AIDS Behav*. 2013; 17(2): 790-800. doi: 10.1007/s10461-012-0302-2

23. Baker Z, Javanbakht M, Mierzwa S, Pavel C, Lally M, Zimet

G, et al. Predictors of over-reporting HIV pre-exposure prophylaxis (PrEP) adherence among young men who have sex with men (YMSM) in self-reported versus biomarker data. *AIDS Behav.* 2018; 22(4): 1174-1183. doi: 10.1007/s10461-017-1958-4

24. van der Straten A, Brown ER, Marrazzo JM, Chirenje MZ, Liu K, Gomez K, et al. Divergent adherence estimates with pharmacokinetic and behavioural measures in the MTN-003 (VOICE) study. *Journal of the International AIDS Society.* 2016; 19(1): 20642. doi: 10.7448/IAS.19.1.20642

25. Musinguzi N, Muganzi CD, Boum Y, Ronald A, Marzinke MA, Hendrix CW, et al. Comparison of subjective and objective adherence measures for preexposure prophylaxis against HIV infection among serodiscordant cos in East Africa. *AIDS*. 2016; 30(7): 1121-1129. doi: 10.1097/QAD.0000000000001024

26. Amico KR, Marcus JL, McMahan V, Liu A, Koester K, Goicochea P, et al. Study product adherence measurement in the iPrEx placebo-controlled trial. *J Acquir Immune Defic Syndr.* 2014; 66(5): 530-537. doi: 10.1097/QAI.0000000000000216

27. Birnkrant D. Center for drug evaluation and research application number. accessdata.fda Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761062Orig1s000Approv.pdf. Accessed June 22, 2020.

28. Corneli AL, Deese J, Wang M, Taylor D, Ahmed K, Agot K, et al. FEM-PrEP: Adherence patterns and factors associated with adherence to a daily oral study product for pre-exposure prophylaxis. *J Acquir Immune Defic Syndr.* 2014; 66(3): 324-331. doi: 10.1097/QAI.0000000000000158

29. Hunt T, Lalley-Chareczko L, Daughtridge G, Swyryn M, Koenig H. Challenges to PrEP use and perceptions of urine tenofovir adherence monitoring reported by individuals on PrEP. *AIDS Care.* 2019; 31(10): 1203-1206. doi: 10.1080/09540121.2019.1587369

30. Koester KA, Liu A, Eden C, Amico KR, McMahan V, Goicochea P, et al. Acceptability of drug detection monitoring among participants in an open-label pre-exposure prophylaxis study. *AIDS Care.* 2015; 27(10): 1199-1204. doi: 10.1080/09540121.2015.1039958

31. Lin D, Zhang CY, He ZK, Zhao XD. How does hard-to-reach status affect antiretroviral therapy adherence in the HIV-infected population? Results from a meta-analysis of observational studies. *BMC Public Health*. 2019; 19(1). doi: 10.1186/s12889-019-7135-0

32. Kanters S, Park JJH, Chan K, Socias ME, Ford N, Forrest JI, et al. Interventions to improve adherence to antiretroviral therapy: A systematic review and network meta-analysis. *The Lancet HIV*. 2017; 4(1): e31-e40. doi: 10.1016/S2352-3018(16)30206-5

33. Iacob SA, Iacob DG, Jugulete G. Improving the adherence to antiretroviral therapy, a difficult but essential task for a successful HIV treatment-clinical points of view and practical considerations. *Front Pharmacol.* 2017; 8: 831. doi: 10.3389/fphar.2017.00831

34. Hunt T, Lalley-Chareczko L, Daughtridge G, Swyryn M, Koenig H. Challenges to PrEP use and perceptions of urine tenofovir adherence monitoring reported by individuals on PrEP. *AIDS Care.* 2019; 31(10): 1203-1206. doi: 10.1080/09540121.2019.1587369

ISSN 2377-8377

HIV/AIDS RESEARCH AND TREATMENT

Open Journal

Openventio PUBLISHERS

Systematic Review

Revision of Maryland Minor Consent Law on Human Immunodeficiency Virus Infection Prevention: An Outcome of Advocacy

Oluwatosin Olateju, DrPH(c), MS-CPHN, BSN, RN[1*]; Deb Dunn, PA-C, MBA[2]; Patricia McLaine, DrPH, MPH, RN[3]; Sharon Barrett, DrPH, MS[1]

[1]*Morgan State University, School of Community Health and Policy, Baltimore, MD 21251, USA*
[2]*Chase Brexton Health Care, Baltimore, MD 21201, USA*
[3]*Retired Faculty, University of Maryland School of Nursing, Baltimore, MD 21201, USA*

Corresponding author
Oluwatosin Olateju, DrPH(c), MS-CPHN, BSN, RN
Doctor of Public Health Candidate, Morgan State University, School of Community Health and Policy, Baltimore, MD 21251, USA; Cell: 443-722-1170;
E-mail: olola41@morgan.edu

Article information
Received: June 23rd, 2020; **Revised:** October 5th, 2020; **Accepted:** October 30th, 2020; **Published:** November 2nd, 2020

Cite this article
Olateju O, Dunn D, McLaine P, Barrett S. Revision of Maryland minor consent law on human immunodeficiency virus infection prevention: An outcome of advocacy. *HIV/AIDS Res Treat Open J*. 2020; 7(1): 10-17. doi: 10.17140/HARTOJ-7-134

ABSTRACT

Objectives
To date, only few United States (US) states have explicit regulations that allow minors to independently give consent for human immunodeficiency virus infection (HIV) prevention treatments. This manuscript will reflect upon key advocacy efforts leading to the revision of the Maryland Minor Consent Law, evaluate current human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) prevention laws for minors in U.S. states, and highlight resources for health advocacy.

Methods
Between 2018-2019, public health professionals in Baltimore, Maryland reviewed the Maryland Minor Consent Law and other adolescent consent laws within the U.S. The professionals advocated for a legal review of the gap by the State Senate and the Office of Attorney General.

Results
In May 2019, the public health advocates were successful in their effort for a revision of the Maryland Minor Consent Law to include Treatment for the Prevention of HIV-Consent by minors. Upon their review of all adolescent consent laws within the U.S., they found that only eleven states currently have explicit language indicative of an adolescent's ability to give consent for pre-exposure prophylaxis (PrEP).

Conclusion
This inquiry can change upstream factors such as laws, regulations, policies and institutional practices.

Keywords
HIV, Prevention, Pre-exposure prophylaxis, Adolescents, Minor consent law.

INTRODUCTION

The prevention of human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS)remains an ongoing problem for the United States (US) and many countries around the world. In the US, nearly 1.1 million people are currently living with HIV.[1] In 2018 approximately 37,968 people were diagnosed with HIV in the US and dependent areas of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the US Virgin Islands.[2] Among those people diagnosed with HIV, 69% were gay, bisexual and other men who have sex with men (MSM), 24% were heterosexuals, and 7% were individuals who inject drugs.[2] Youths aged 12-24-years make up more than 20% of HIV diagnosis in the US; this age group has the lowest rates of antiretroviral (ARV) therapy uptake and adherence, and the lowest level of awareness of their HIV status

among all age groups.[3] Despite well-documented progress in the treatment of individuals living with HIV in the US, much work is still needed to prevent HIV infections, especially in young adults and adolescents. Data shows that between 2012 and 2016, HIV diagnoses among adolescents and young adults in the US increased by six percent, while rates of HIV diagnoses among adults decreased or stabilized during the same period.[4] Maryland was ranked sixth among U.S. states and territories in adult/adolescent HIV diagnoses rates at 19.6 per 100,000 in 2018.[5] Sadly, Maryland youths aged 13-24-years accounted for 19.2% of the 994 new HIV diagnoses in 2018, with 56 of the new HIV diagnoses among people younger than age 20.[6]

Adolescents, Risky Behaviors and Pre-Exposure Prophylaxis

Hosek et al[7] the World Health Organization (WHO) and the United Nations (UN) describe adolescence as a phase in the growth and development of humans following childhood and before adulthood, from ages 10 to 19.[7] In this paper, we adopt the definition of "adolescents" used by Allen et al[8] which refers to youth under age 18-years and "young adults" between ages 18-24-years.[8] Adolescence is a unique developmental phase where many young individuals are identifying and expressing their sexuality.[9] Undeniably, this stage comes with risks and dangers that manifest as sexually transmitted infections (STIs), HIV, and unplanned pregnancies.[9] During this phase, many seek autonomy and their actions can have life-threatening consequences.[10] Although adolescents' brain maturation increases their impulsivity and thrill-seeking tendencies, they possess the essential qualities required for effective decision making especially decisions related to maximizing their protection against certain important risks.[10]

Heterosexually active young women and young gay, bisexual, and other men who have sex with men (YGBMSM) are the subgroups with the most vulnerabilities and greatest burden of disease.[11] Other at-risk adolescents and young adults include those who inject drugs, youth involved in sex work or those who are sexually exploited, and young transgender women with male sexual partners.[11] Moore et al[12] suggest that high rates of HIV infection among individuals aged 13-24-years, who account for 26% of new HIV infections in the US, make this age group an excellent target population for primary prevention. Tanner et al[13] also support efforts to prevent HIV among adolescents because adolescents who end up acquiring HIV may be at increased risk for poor medication adherence, for difficulty achieving viral suppression, for viral rebound, and for loss to follow-up when compared to adults with HIV. Adolescents may bear other risks such as transmitting the virus to others, developing antiretroviral resistance, and having a compromised immune system.[13] To identify challenges faced by HIV-infected adolescents, Kapogiannis et al[14] conducted a multisite initiative to investigate the referral, linkage, engagement and retention in HIV care among youths aged 12-24-years who were receiving care at 13 urban HIV care centers in the US. Barriers included poor linkage to care, poor engagement in care, and lower rates of viral suppression which might ultimately affect HIV-infected youths' care continuum outcomes.[14] Among 1,411 HIV-positive youth, 1,053 (75%) were linked to care, 839 (59%) were engaged in care, and 473 (34%) were retained in care; 474 youth (34%) were started on antiretroviral therapy, but only 166 (12%) achieved viral suppression.[14]

Oral-Pre-Exposure Prophylaxis and Human Immunodeficiency Virus Infection Prevention

Moore et al[12] define pre-exposure prophylaxis (PrEP) in the context of HIV as "*the use of antiretroviral medications in HIV-negative individuals to prevent HIV transmission.*" For individuals who are at risk, oral PrEP in the form of Truvada is available, and when taken correctly, is more than 90% effective in preventing HIV infection.[15] In 2012, the U.S. Food and Drug Administration (FDA) approved Truvada as daily oral PrEP for use in at-risk adults over age 18.[15] Relatedly, in 2018, Truvada was approved for use in at-risk adolescents weighing at least 77 pounds (35 kg).[13,15] To decrease the risk of HIV infection from sex, Descovy was also approved by the FDA in 2019 for HIV PrEP in at-risk adults and adolescents with the same weight indication, as an HIV-1 prevention treatment, excluding individuals who have receptive vaginal sex.[13,16]

Although, the U.S. Preventive Services Task Force (USPSTF) found sufficient evidence that PrEP is linked with minor harms, including adverse kidney and gastrointestinal effects, they concluded with high assurance that oral PrEP therapy to reduce the risk of acquisition of HIV infection in high-risk individuals is of significant benefit.[1] USPSTF made a recommendation that PrEP should to be offered with effective antiretroviral therapy to people at high-risk of contracting HIV,[1] including:

1. Sexually active men who have sex with men (MSM) and who report one of the following: a serodiscordant sex partner, inconsistent condom use while having receptive or insertive anal sex, or history of a STI with gonorrhea, chlamydia or syphilis within the past six months

2. Heterosexually active men and women who report one of the following: a serodiscordant sex partner, inconsistent condom use during sex with a partner of unknown HIV status and who is at high-risk for HIV acquisition, or history of a STI such as gonorrhea or syphilis within the past six months

3. People who inject drugs and possess one of the following characteristics described above or those who share equipment during injection drug use.

Human Immunodeficiency Virus Infection Trends among Maryland Adolescents

Although the Centers for Disease Control and Prevention (CDC) estimates that 89.2% of individuals living with HIV in Maryland in 2019 have been diagnosed, approximately 3,830 individuals living with HIV in Maryland have not yet been identified and diagnosed.[5] Recent statistics from the Maryland Department of Health indicate that there were 931 people aged 13+ newly diagnosed with HIV infection in Maryland during 2019 with approximately 31,630 individuals aged 13+ living with diagnosed HIV in Maryland at the end of 2019.[5]

Unfortunately, the increase in new HIV diagnosis among youths in some U.S states, including Maryland, may be indirectly enhanced by the unclear written guidelines associated with the states' Minor Consent Laws. Burda surveyed Minor Consent Laws across U.S. states in 2015 and found a lack of uniformity among states regarding what medical services may be provided to adolescents without parental consent.[10] Burda observed that many providers were confused about existing laws and worried about liability, noting that "*only seven United States jurisdictions explicitly permitted minors to consent to preventive care*",[10] which in this context means minor's capacity to give consent for PrEP.[10] Burda also suggested that federal endorsement is key to establishing PrEP programs for youths.[10] Failure to revise such perplexing state laws could be problematic for prescribing providers and for at-risk adolescents interested in accessing PrEP without the consents of their parents or guardians.

Venereal disease, now referred to as sexually transmitted disease[17] is defined as "*a class of contagious diseases typically transmitted during sexual intercourse and which according to traditional theory may include syphilis, gonorrhea, chancroid, venereal lymphogranuloma and inguinal granuloma etc.*"[18] Prior to the amendment of the law on May 25, 2019, the Maryland Minor Consent Law for section HIV/AIDS Testing and Treatment [Md. Code Ann., Health-Gen. II § 20-102(c)(1)-(5)] stated that "*a minor (i.e., a person under the age of 18) has the same capacity as an adult to consent to treatment for or advice about venereal disease.*"[19] The focus of the legislation was on the minor getting treated after infection and none on the minor seeking treatment for the prevention of venereal diseases such as HIV.

While the Maryland statute permits minors to independently give consent for HIV testing and/or treatment, it is not clear about: 1) consent for "HIV prevention" which would include explicit language that permits minors to independently access PrEP or give consent for HIV prevention treatments; or 2) well-defined prohibition of minors' access to PrEP without parental or guardian consent. These points should be considered when amending existing Minor Consent Laws with similar gaps. Despite the lack of clear language used in many U.S. Minor Consent Laws under the sections relating to HIV/AIDS Testing and Treatment or Diagnosis and/or Treatment for Sexually Transmitted Diseases, the CDC found that "*no jurisdiction explicitly prohibits minors' access to PrEP without the permission of parents or guardians.*"[20] Therefore, the Minor Consent Law should be clear on a minor's ability to seek for HIV prevention without the involvement of a parent and/or guardian.

METHODS

The data collection for this study consists of a comprehensive manual review of Minor Consent Laws in all 50 U.S. states and the District of Columbia which occurred from May 1, 2020 to May 12, 2020. With the exception of the recently revised Maryland Minor Consent Laws, links to all other states' statutes were obtained from the CDC website entitled "*State Laws that address high-impact HIV prevention efforts.*"[21] All existing U.S. adolescent consent laws were evaluated for legislative language regarding (1) statutes permitting minors to self-consent in certain healthcare-related situations, particularly relating to STI diagnoses and treatment; and (2) laws with specific indication on HIV/AIDS Prevention or "preventative care".

Brief Advocacy Story

In early 2018, several healthcare providers were worried about the increasing rate of new HIV infections among young people in Baltimore, similar to the national trend. Later in 2018, the FDA approved oral PrEP for use among at-risk adolescents weighing at least 77 lbs,[15] and some Maryland providers in community-based centers and private clinics started prescribing PrEP due to an increase in requests for PrEP prescription among at-risk adolescents. While the availability of PrEP was an exciting news for some providers who were considering adding PrEP to their services, many healthcare providers expressed concerns about the lack of clarity in the Maryland Minor Consent Law for HIV/AIDS and how that might prevent them from prescribing PrEP. Some providers felt their hands were tied because the Maryland Minor Consent law at that time did not make provisions for adolescents to give consent for HIV prevention treatment. This issue therefore became the stimulus for our inquiry.

In October 2018, a small group of public health professionals (two registered nurses and a physician assistant) who were affiliated with Morgan State University School of Community Health and Policy, University of Maryland School of Nursing Department of Family and Community Health, and Chase Brexton Health Care, Baltimore Maryland met to analyze the Maryland Minor Consent Law section HIV/AIDS Testing. During their review, they noted that the legislation at that time lacked a clear indication that would permit minors to give consent for HIV prevention. Between November and December 2018, the public health professionals participated in meetings with several groups of adolescent providers in Howard County, Maryland, providers at Chase Brexton Health Care Baltimore, Maryland, and providers at the Maryland Chapter of the American Academy of Pediatrics, bringing their attention to the issue. Their advocacy efforts also involved the use of communication methods such as phone calls, letters and emails to the Maryland Department of Health Infectious Diseases Bureau and legislators. This group of public health professionals decided to advocate for a legal review of the gap by the State's Senate and Maryland's Attorney General. In early December 2018, 1,199 Service Employees International Union (SEIU), United Healthcare Workers East, joined with Chase Brexton Health Care Baltimore to submit a request for the HIV/AIDS section of the Maryland Minor Consent Law to be reviewed by Senator Clarence Lam (S, Tiffin. Maryland State Senate, personal communication, September 2019). Their request was corroborated by testimony documents, including the SEIU fact sheet which highlights the legal gap and proposes solutions to effect legislative change.[22]

Senate Bill 251 (SB 251) was sponsored by four Maryland Senators, and the hearings were also attended by representatives from SEIU and Chase Brexton. In late December 2018, the coalition of public health professionals who were advocating for the legal review of the gap met again to track progress with SB 251 and sent follow-up emails to the primary sponsoring Senator. In summary, the advocacy process was initiated in October 2018, and the legal review session was introduced in January 2019.[23]

RESULTS

Revision of the Maryland Minor Consent Law

The first reading for SB 251 took place in January 2019; first hearing in February 2019; vote on the Senate floor and passage of the third reading occurred on March 13, 2019.23 A vote and passage of the third reading also took place on the House floor on March 18, 2019.[23] In addition, regarding Maryland House Bill 1183, the third reading passed on the House floor on March 12, 2019 and on the Senate floor on March 27, 2019.[24]

On May 25, 2019, the law was enacted, and on October 1, 2019, it went into effect. The previous section, "*Article-Health-General Section 20-102 Annotated Code of Maryland*" was repealed and reenacted with amendments to read: "*An Act concerning Public Health–Treatment for the Prevention of HIV–Consent by Minors: For the purpose of providing that a minor has the same capacity as an adult to consent to treatment for the prevention of human HIV and generally relating to consent to medical treatment by minors.*"[23]

Minor Consent Laws- The National Perspective

CDC reported that all U.S. jurisdictions had laws or regulations that "*explicitly allowed minors of a particular age to independently consent to STI diagnosis and treatment although the age for access varies by jurisdiction.*"[20] Our review indicated that only eleven U.S. states currently have provision in their Minor Consent Laws that permits adolescents to give consent for PrEP: California,[25] Colorado,[26] Delaware,[27] District of Columbia,[28] Iowa,[29] Kansas,[30] Maryland,[23] Montana,[31] North Carolina,[32] Oklahoma,[33] and South Carolina.[34] Table 1 provides an overview of specific language used by these eleven U.S. states to denote a minor's capacity to consent to "preventative care".

DISCUSSION

Implications for Pre-Exposure Prophylaxis Prescription and Use

The mid-adolescence period is a time of inevitable inclination for HIV-associated risk behaviors.[9] Unfortunately, the customary methods of preventing HIV among youth "*have been, and are likely to continue to be, ineffective*"[9] without considering pharmacological HIV prevention strategies. PrEP is not merely a daily medication, it encompasses a multi-team, comprehensive prevention approach for at-risk individuals.[9,35] PrEP involves a combination of several components for high-risk individuals: a prescribed daily oral antiretroviral therapy, routine HIV testing to monitor for infection, coordination of care, use of condoms, sexual risk-reduction counseling and education, substance-abuse counseling, medication-adherence counseling, and ongoing case management to monitor for medication side effects.[35]

Table 1. *U.S. States with Language on "Preventative Care" in their Minor Consent Laws*

State	Citation	Significant Text
California	California Code, Family Code - FAM § 6926- (b).	"*A minor who is 12-years of age or older may consent to medical care related to the prevention of a sexually transmitted disease.*"[25]
Colorado	Colorado Revised Statutes Title 25. Health § 25-4-409. Minors--treatment—consent- (1a).	"*The health care provider or facility shall treat the minor for a sexually transmitted infection, if necessary; discuss prevention measures, where applicable; and include appropriate therapies and prescriptions.*"[26]
Delaware	Title 13, Chapter 7. § 710-(a).	"*A minor 12-years of age or over who professes to be either pregnant or afflicted with contagious, infectious or communicable diseases . . . may give written consent, except to abortion, to any licensed physician, hospital or public clinic for any diagnostic, preventive, lawful therapeutic procedures, medical or surgical care and treatment. . . .* "[27]
District of Columbia	22-B600.7 (c) Minor's Health Consent.	"*A minor of any age may consent to health services which he or she requests for the prevention, diagnosis, or treatment of the following medical situations: . . . A mental or emotional condition and sexually transmitted disease.*"[28]
Iowa	Iowa Code Title IV. Public Health [Chs.123-158] § 139A. 35. Minors.	"*A minor shall have the legal capacity to act and give consent to provision of medical care or services to the minor for the prevention, diagnosis, or treatment of a sexually transmitted disease or infection by a hospital, clinic, or health care provider.*"[29]
Kansas	Kansas Statutes Chapter 65. Public Health § 65-2892.	"*Any physician, upon consultation by any person under eighteen (18) years of age as a patient, may, with the consent of such person who is hereby granted the right of giving such consent, make a diagnostic examination for venereal disease and prescribe for and treat such person for venereal disease including prophylactic treatment for exposure to venereal disease whenever such person is suspected of having a venereal disease or contact with anyone having a venereal disease.*"[30]
Maryland	Article II, Section 17(c) of the Maryland Constitution - Chapter 728-(9).	"*Providing that a minor has the same capacity as an adult to consent to treatment for the prevention of HIV.*"[23]
Montana	Montana Title 41. Minors § 41-1-402-(2c).	"*The consent to the provision of health services . . . by a health professional may be given by a minor who professes or is found to meet any of the following descriptions: . . . this self-consent applies only to the prevention, diagnosis, and treatment of those conditions specified in this subsection. The self-consent in the case of pregnancy, a sexually transmitted disease, or drug and substance abuse . . .* "[31]
North Carolina	North Carolina General Statutes Chapter 90. Medicine and Allied Occupations § 90-21.5-(a).	"*Any minor may give effective consent to a physician licensed to practice medicine in North Carolina for medical health services for the prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under G.S. 130A-135.*"[32]
Oklahoma	2014 Oklahoma Statutes Title 63. Public Health and Safety §63-2602-(3).	"*Any minor who is or has been pregnant, afflicted with any reportable communicable disease, . . . , however, that such self-consent only applies to the prevention, diagnosis and treatment of those conditions specified in this section.*"[33]
South Carolina	2016 South Carolina Code of Laws. §63-5-340.	"*Any minor who has reached the age of sixteen years may consent to any health services from a person authorized by law to render the particular health service for himself . . .* "[34]

While this paper underscores the benefits of PrEP for at-risk individuals, it is important to note that the implementation or prescription of PrEP come with some challenges. Mullins et al[36] conducted semi-structured interviews on 15 U.S. providers caring for high-risk and HIV-positive youth and found the following barriers to prescribing PrEP: concerns about confidentiality, legality of prescribing PrEP to minors without parental consent, and young people's comprehension and understanding of risk and benefits of the medication, side effects of PrEP use on the bone; "*off-label use of PrEP among minors, and the high costs associated with PrEP use*." Additionally, the clinicians who were interviewed in the study perceived PrEP as a short-term intervention rather than a comprehensive approach to HIV prevention for youth; however, the clinicians indicated the following facilitating factors to prescribing PrEP to youth which included: the provision of PrEP-specific education to communities and other clinicians, guaranteeing adequate financial resources and infrastructure for PrEP delivery, establishing formal guidance on efficient behavioral interventions provided with PrEP, and obtaining individualized experience with prescribing PrEP.[36]

Regarding patient-level concerns, the use of oral PrEP has been associated with an increase in STIs. A recent study conducted on Gay and Bi-sexual men using PrEP reported a rise in STI incidence among study participants from 69.5 per 100 person-years before enrollment to 98.4 per 100 person-years during follow-up.[37] In the same vein, there are some issues that could limit PrEP effectiveness among youth which include adherence, stigma, risk compensation, and ethical concerns and legal concerns.[38] To address the issue of adherence to oral PrEP, some studies have evaluated preferences for PrEP modality and have found promising results. Tolley et al[39] examined the acceptability of a long-acting injectable PrEP among 136 HIV-negative women in Zimbabwe, South Africa and two U.S. phase 2 trial sites and found that the majority of the participants (>75%) rated long-acting injectable PrEP as very acceptable. At baseline, 56% of US participants and 81% of African participants favored using a bi-monthly injectable to other non-injectable methods, including daily oral pills, a vaginal ring or gel.[39] At 28-weeks, 79% of the study participants strongly approved of the statement that they would "*definitely use an injectable PrEP product for some time*" if it were available in the future; while (88%) strongly agreed that they would be more interested in using an injectable that prevents both HIV and pregnancy.[39] Similarly, Kidman et al. surveyed 2,089 adolescents living in Malawi between ages 10-16 and their caregivers to assess PrEP interest, facilitating factors to PrEP use, and preferences for PrEP modality.[40] The authors found that young adolescents who are engaging in behaviors that increase their risks of acquiring HIV would likely find PrEP beneficial: most (82%) were interested in using PrEP, preferred to receive an injection rather than taking a daily pill, and were largely discouraged by the prospect of side effects.[40]

Additionally, some serious side effects of using Truvada may include "*kidney failure, severe liver problems, lactic acidosis, or bone problems*"[41]; and for Descovy, some common adverse reactions may include "diarrhea, nausea, headache, fatigue, and abdominal pain."[42] These patient-level, organizational-level, and systems-level barriers could influence the implementation and effectiveness of PrEP for minors, as well as the passage or revision of Minors' HIV prevention laws across U.S. states.

Significance of Human Immunodeficiency Virus Infection prevention laws

Many US states have yet to revise their laws to include specifications that would allow minors to give consent for HIV prevention services. The hesitation or delay in revising such laws could largely be due to the states' uncertainties regarding ethical and legal considerations for PrEP use among minors. Unfortunately, the lack of clarity in US states minors' consent laws for preventive services has caused significant barriers to providing PrEP services, and continue to create problems for clinicians who do not have guidance on prescribing HIV prevention to minors without parental consent.[12] Recent clinical data indicate the efficacy of PrEP as a powerful HIV prevention tool in populations at high-risk for HIV acquisition, including MSMs, HIV-1-serodiscordant heterosexual couples, and IV drug users.[38] Sadly, without the right laws in place to grant minors the right to independently give consent for PrEP, the goal of ending the HIV epidemic by 2030 will be far from achievable. Ending the HIV Epidemic: A Plan for America (EHE) is an initiative from the US Department of Health and Human Services (HHS) that specifies a strategy to decrease the number of new infections in the U.S. by 75% within 5-years and by at least 90% within 10-years.[43] Therefore, to reduce the alarming rates of new adolescent HIV infections in the U.S. and to improve the health of adolescents who are at increased risk for contracting HIV, it is important that states increase access to HIV prevention strategies including risk reduction counseling, HIV testing, and PrEP for minors. States should also evaluate existing consent laws for minors and make provisions to allow minors independently give consent for PrEP.

Expanding Minor Consent Laws to allow adolescents to give consent for HIV prevention has many benefits which include: the disruption of the state's HIV rates and improvement in public health, the dramatic extension of the lifespan of young black men particularly those living in poverty, and the overall positive impact on the community viral load.[22]

Other U.S. states should consider laws similar to Maryland. Public health professionals should work with legislators in their states to bring about change in public health policies which would enable minors to independently choose prevention; they should also continue to evaluate how state laws influence the prevention of HIV.

Practice Recommendations

Health professionals who wish to design programs and institute policies that will significantly improve the lives of others must learn how to effectively engage with communities.[44] Advocacy should be a fundamental part of public health dialogue and interventions through which social determinants of health are addressed and systemic change is achieved.[45] Public health professionals can advocate for changes in health legislations in their varying states through translating research findings into policy and practice, and

seeking transformative changes in supportive public opinion,[46] through active involvement in state legislative hearings, policy internships or workshops and by keeping informed about current issues and organizing groups through collaborative engagements with professional lobbyists,[47] and by building the capacity of current and upcoming public health professionals and the communities served, to participate in public health advocacy.[45] A long-term approach to investing in the public's health, is to incorporate public health advocacy into public health education and trainings, daily practice and research.[45]

In light of existing barriers and concerns, the benefits of PrEP should be considered for high-risk HIV-negative populations. For example, access to PrEP could save money in high-incidence settings.[38] Efforts to expand PrEP to minors must also include evaluation of ethical, political and medical implications of PrEP use. Public health agencies could provide trainings to adolescent providers and communities, and also address provider-related barriers to prescribing PrEP for adolescents; understanding the facilitators and barriers to prescribing PrEP for minors is the key. Also, ensuring adequate financial resources and infrastructure for PrEP delivery will encourage provider participation. For PrEP to become more widely available to youth at high-risk for HIV acquisition, the following topics should be better addressed: gender and race disparities associated with PrEP use, cost of PrEP medications, cultural and regional differences, and provider training.[38] Furthermore, to end the HIV epidemic, the following are required: "*adherence to published HIV testing recommendations, sexual health assessments, screening for STIs, and appropriate primary and secondary prevention education.*"[48] In agreement with these, aligning PrEP programs with the national objective to end the HIV epidemic could further help to keep programs focused and achieve set goals. Finally, PrEP program administrators should explore funding opportunities that would benefit clients who need financial support in the areas of medications and laboratory costs, in order to remain compliant with their medical visits.

CONCLUSION

Within a span of one year from the onset of advocacy to legislative action (October 2018-October 2019), it is highly commendable how the public health professionals were able to push for an effective change in HIV prevention laws for minors and took a step further by telling the story in this publication. Their works demonstrate the importance of public health advocacy. As a result of their efforts, high-risk adolescents in Maryland now have the same capacity as adults to consent to treatment for the prevention of HIV,[23] which is ultimately a step in the right direction to ending the HIV epidemic among this subgroup. The persistence and commitment of the teams involved also fast-tracked a naturally delayed process to completion in record time.

Eleven U.S. states currently have explicit provisions in their Minor Consent Laws that permit adolescents to give consent for PrEP. In order for PrEP to be well received by providers and adolescents, barriers such as provider training, stigma, ethical and legal concerns, and patient-level barriers such as side effects, adherence, stigma, risk compensation, ethical concerns, legal issues and cost need to be addressed. Through advocacy, public health professionals can change upstream factors such as laws, regulations, policies and institutional practices. Minor Consent Laws impact adolescent PrEP programs. The successful efforts documented in this publication can create a paradigm for future efforts to address Minor Consent Laws that prohibit young people across the United States from participating in PrEP programs to reduce further spread of HIV infections among minors. More states should revise their Minor Consent Laws to allow minors to give consent for PrEP.

ETHICAL CONSIDERATIONS

This study did not require approval from the Institutional Review Board (IRB).

ACKNOWLEDGEMENTS

The authors would like to offer special thanks to Dr. Abosede Gbenga-Akinbiola for her assistance in the language editing of this article.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

REFERENCES

1. US Preventive Services Task Force, Owens DK, Davidson KW, Krist AH, Barry MJ, Cabana M. Preexposure prophylaxis for the prevention of HIV infection: US preventive services task force recommendation statement. *JAMA*. 2019; 321(22): 2203-2213. doi: 10.1001/jama.2019.6390

2. Centers for Disease Control and Prevention (CDC). HIV in the United States and dependent areas. 2019. Web site. https://www.cdc.gov/hiv/statistics/overview/ataglance.html. Accessed October 2, 2020.

3. Rotheram MJ, Fernandez MI, Lee SJ, Abdalian, SE, Kozina L, Koussa M, et al. Strategies to treat and prevent HIV in the United States for adolescents and young adults: Protocol for a mixed-methods study. *JMIR Res Protoc.* 2019; 8(1): e10759. doi: 10.2196/10759

4. Guilamo-Ramos V, Thimm-Kaiser M, Benzekri A, Futterman D. Youth at risk of HIV: The overlooked US HIV prevention crisis. *Lancet HIV*. 2019; 6(5): 275-278. doi: 10.1016/S2352-3018(19)30037-2

5. Maryland Department of Health, Center for HIV Surveillance, Epidemiology and Evaluation. Maryland annual HIV epidemiological profile 2018. 2019. Web site. https://phpa.health.maryland.gov/OIDEOR/CHSE/Pages/statistics.aspx. Accessed May 20, 2020.

6. Prevention and Health Promotion Administration, Maryland Department of Health. HIV among youth (ages 13-24) in Mary-

land, 2018. 2019. Web site. https://phpa.health.maryland.gov/OIDEOR/CHSE/SiteAssets/Pages/statistics/Youth-Fact-Sheet-2019b.pdf. Accessed May 13, 2020.

7. Hosek S, Celum C, Wilson C, Kapogiannis B, Delany-Moretlwe S, Bekker LG. Preventing HIV among adolescents with oral PrEP: Observations and challenges in the United States and South Africa. *J Int AIDS Soc.* 2016; 19(7S6): 21107. doi: 10.7448/IAS.19.7.21107

8. Allen EB, Gordon A, Krakower D, Hsu, K. HIV pre-exposure prophylaxis for adolescents and young adults. *Curr Opin Pediatr.* 2017; 29(4): 399-406. doi: 10.1097/MOP.0000000000000512

9. Pike C, Bekker L-G. PrEP: An opportunity to address unmet adolescent health needs. *Pediatrics.* 2020; 145(1): e20193172. doi: 10.1542/peds.2019-3172

10. Burda JP. PrEP and our youth: Implications in law and policy. *Columbia Journal of Gender and Law.* 2016; 30(2): 294-363. doi: 10.2139/ssrn.2641504

11. Society for Adolescent Health and Medicine (SAHM). HIV pre-exposure prophylaxis medication for adolescents and young adults: A position paper of the society for adolescent health and medicine. *J Adolesc Health.* 2018; 63: 513-516. doi: 10.1016/j.jadohealth.2018.07.021

12. Moore Q, Paul ME, McGuire AL, Majumder MA. Legal barriers to adolescent participation in research about HIV and other sexually transmitted infections. *Am J Public Health.* 2016; 106(1): 40-44. doi: 10.2105/AJPH.2015.302940

13. Tanner MR, Miele P, Carter W, Salvant VS, Dunville R, Kapogiannis BG, et al. Preexposure prophylaxis for prevention of HIV acquisition among adolescents: Clinical considerations. *MMWR Recomm Rep.* 2020; 69(3): 1-12. doi: 10.15585/mmwr.rr6903a1

14. Kapogiannis BG, Koenig LJ, Xu J, Mayer KH, Loeb J, Greenberg L, et al. The HIV continuum of care for adolescents and young adults attending 13 Urban US HIV care centers of the NICHD-ATN-CDC-HRSA SMILE collaborative. *J Acquir Immune Defic Syndr.* 2020; 84(1): 92-100. doi: 10.1097/QAI.0000000000002308

15. Johnson A, Green E, Phillips G, Macapagal K, Stonehouse P, Greene G. HIV pre-exposure prophylaxis implementation for adolescents: Provider perspectives of multi-level barriers and facilitators. *Journal of Adolescent Health.* 2020; 66(2): S129. doi: 10.1016/j.jadohealth.2019.11.258

16. Aschenbrenner DS. Descovy approved for HIV prexposure prophylaxis. *Am J Nurs.* 2020; 120(2): 20. doi: 10.1097/01.NAJ.0000654288.99137.49

17. Gruber F, Lipozenčić J, Kehler T. History of venereal diseases from antiquity to the renaissance. *Acta Dermatovenerol Croat.* 2015; 23(1): 1-11.

18. Peng R, Gao, K. The model of venereal disease transmission among male homosexuals considering multiple channels. *Current Findings of Infectious Diseases.* 2019; 2009(01): 1-6.

19. American Academy of Pediatrics. Adolescent provider toolkit: Maryland minor consent laws. 2006. Web site. http://www.nccpeds.com/ContinuityModules-Fall/Fall%20Continuity%20Source%20Materials/Maryland%20Minor%20Consent%20Laws-full.pdf. Accessed May 18, 2020.

20. Centers for Disease Control and Prevention. Minors' consent laws for HIV and STD services. 2020. Web site. https://www.cdc.gov/hiv/policies/law/states/minors.html. Accessed May 20, 2020.

21. Centers for Disease Control and Prevention. State laws that address high-impact HIV prevention efforts. 2020. Web site. https://www.cdc.gov/hiv/policies/law/states/index.html. Accessed May 20, 2020.

22. United Healthcare Workers East. Disrupt Maryland's rates of HIV. Pdf document. n.d. Accessed October 28, 2019.

23. LegiNation. BillTrack50:MD - SB251. 2019. Web site. https://www.billtrack50.com/BillDetail/1037726 . Assessed May 15, 2020.

24. Legiscan. MD HB1183, 2019, regular session. 2019. Web site. https://legiscan.com/MD/bill/HB1183/2019. Accessed May 15, 2020.

25. FindLaw. California code, family code—FAM § 6926. n.d. Web site. https://codes.findlaw.com/ca/family-code/fam-sect-6926.html. Accessed May 16, 2020.

26. FindLaw. Colorado revised statutes title 25. Health § 25-4-409. n.d. Web site. https://codes.findlaw.com/co/title-25-health/co-rev-st-sect-25-4-409.html. Accessed May 16, 2020.

27. State of Delaware. Delaware code online: Title 13—chapter 7, parents and children—subchapter I. General provisions. n.d. Web site. https://delcode.delaware.gov/title13/c007/sc01/index.shtml. Accessed May 16, 2020.

28. District of Columbia. District of Columbia municipal regulations and District of Columbia register. n.d. Web site. https://dcregs.dc.gov/Common/DCMR/RuleDetail.aspx?RuleId=R0016345. Accessed May 16, 2020.

29. FindLaw. Iowa code title IV. Public health [Chs. 123-158] § 139A.35. n.d. Web site. https://codes.findlaw.com/ia/title-iv-public-health-chs-123-158/ia-code-sect-139a-35.html. Accessed May 16, 2020.

30. FindLaw. Kansas statutes chapter 65. Public health § 65-2892. n.d. Web site. https://codes.findlaw.com/ks/chapter-65-public-health/ks-st-sect-65-2892.html. Accessed May 16, 2020.

31. FindLaw. Montana title 41. Minors § 41-1-402. n.d. Web site. https://codes.findlaw.com/mt/title-41-minors/mt-code-ann-sect-41-1-402.html. Accessed May 16, 2020.

32. FindLaw. North Carolina general statutes chapter 90. Medicine and allied occupations § 90-21.5. n.d. Web site. https://codes.findlaw.com/nc/chapter-90-medicine-and-allied-occupations/nc-gen-st-sect-90-21-5.html. Accessed May 16, 2020.

33. Justia US Law. 2014 Oklahoma statutes: Title 63. public health and safety: §63-2602. Right of self-consent under certain conditions - doctor patient privileges. n.d. Web site. https://law.justia.com/codes/oklahoma/2014/title-63/section-63-2602/. Accessed May 19, 2020.

34. Justia US Law. 2016 South Carolina code of laws: Title 63 - South Carolina children's code: Chapter 5 - legal status of children: Section 63-5-340. Minor's consent to health services. n.d. Web site. https://law.justia.com/codes/south-carolina/2016/title-63/chapter-5/section-63-5-340/. Accessed May 19, 2020.

35. Dearing JW, Smith DK, Larson RS, Estabrooks CA. Designing for diffusion of a biomedical intervention. *Am J Prev Med*. 2013; 44(1): S70–S76. doi: 10.1016/j.amepre.2012.09.038

36. Mullins TLK, Zimet G, Lally M, Kahn JA. Adolescent human immunodeficiency virus care providers' attitudes toward the use of oral pre-exposure prophylaxis in youth. *AIDS Patient Care STDS*. 2016; 30(7): 339-348. doi: 10.1089/apc.2016.0048

37. Traeger MW, Cornelisse VJ, Asselin J. et al. Association of HIV preexposure prophylaxis with incidence of sexually transmitted infections among individuals at high risk of HIV infection. *JAMA*. 2019; 321(14): 1380-1390. doi: 10.1001/jama.2019.2947

38. Machado DM, de Sant'Anna Carvalho AM, Riera R. Adolescent pre-exposure prophylaxis for HIV prevention: Current perspectives. *Adolesc Health Med Ther*. 2017; 8: 137-148. doi: 10.2147/AHMT.S112757

39. Tolley EE, Li S, Zangeneh SZ, Atujuna M, Musara P, Justman J, et al. Acceptability of a long-acting injectable HIV prevention product among US and African women: Findings from a phase 2 clinical Trial (HPTN 076). *J Int AIDS Soc*. 2019; 22(10): e25408. doi: 10.1002/jia2.25408

40. Kidman R, Nachman S, Kohler HP. Interest in HIV pre-exposure prophylaxis (PrEP) among adolescents and their caregivers in Malawi. *AIDS Care*. 2020; 32(2): 23-31. doi: 10.1080/09540121.2020.1742861

41. Gilead Sciences Inc. What are possible side effects of truvada for prep®? 2019. Web site. https://www.truvada.com/what-is-truvada/side-effects. Accessed May 13, 2020.

42. Gilead Sciences Inc. HIV prevention with your patients' tomorrow in mind. 2020. Web site. https://www.descovyhcp.com/about-descovy-for-prep?utm_medium=cpc&utm_campaign=2020_branded_phase+3_learn+about+a+gilead+medication_prep+hcp_supporting_broad&utm_content=prep_kw&utm_term=%2bprep&utm_source=google&gclid=cjwkcajw5ij2brbdeiwa0frc9ujd2vi9tvqwpr9xqvrfuplmdordyvakbrbgell6tqbud4g42impsrocbjeqavd_bwe&gclsrc=aw.ds. Accessed May 13, 2020.

43. US Department of Health & Human Services. What Is Ending the HIV Epidemic: A Plan for America? Website. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview. Accessed October 2, 2020.

44. Bassett MT. Public health advocacy. *Am J Public Health*. 2003; 93(8): 1204. doi: 10.2105/AJPH.93.8.1204

45. Blenner SR, Lang CM, Prelip ML. Shifting the culture around public health advocacy: Training future public health professionals to be effective agents of change. *Health Promot Pract*. 2017; 18(6): 785-788. doi: 10.1177/1524839917726764

46. Chapman S. Advocacy in public health: Roles and challenges. *Int J Epidemiol*. 2001; 30(6): 1226-1232. doi: 10.1093/ije/30.6.1226

47. Abood S. Influencing health care in the legislative arena. *Online J Issues Nurs*. 2007; 12(1): 3. doi: 10.3912/OJIN.Vol12No01Man02

48. Hosek S, Henry-Reid L. PrEP and adolescents: The role of providers in ending the AIDS epidemic. *Pediatrics*. 2020; 145(1): 1-7. doi: 10.1542/peds.2019-1743