

## HIV incidence among gay men and other men who have sex with men in 2020: where is the epidemic heading?

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**Abstract.** The goal to effectively prevent new HIV infections among gay, bisexual, and other men who have sex with men (MSM) is more challenging now than ever before. Despite declines in the late 1990s and early 2000s, HIV incidence among MSM is now increasing in many low- and high-income settings including the US, with young, adolescent, and racial/ethnic minority MSM being among those at highest risk. Potentiating HIV risks across all settings are individual-, network-, and structural-level factors such as stigma and lack of access to pre-exposure prophylaxis (PrEP) and antiretroviral treatment as prevention. To make a sustained impact on the epidemic, a concerted effort must integrate all evidence-based interventions that will most proximally decrease HIV acquisition and transmission risks, together with structural interventions that will support improved coverage and retention in care. Universal HIV treatment, increased access to HIV testing, and daily oral PrEP have emerged as integral to the prevention of HIV transmission, and such efforts should be immediately expanded for MSM and other populations disproportionately affected by HIV. Respect for human rights and efforts to combat stigma and improve access to prevention services are needed to change the trajectory of the HIV pandemic among MSM.

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### Introduction

Gay, bisexual, and other men who have sex with men (MSM) continue to be among those at highest risk for HIV. Globally, HIV incidence among MSM has peaked, including in regions with the most broadly generalised HIV epidemics, such as Southern and Eastern Africa, where the annual number of new HIV infections among adults has declined by 34% since 2001.<sup>1</sup> These gains have been achieved through improved coverage and implementation of HIV prevention and diagnostic approaches, combined with increased access to antiretroviral therapy (ART).<sup>2</sup> In 2014, The Joint United Nations Programme on HIV/AIDS (UNAIDS) released the 90–90–90 targets as guidelines to scale-up HIV testing and treatment, with the objective of reaching 90% of people living with HIV to know their status, 90% of people diagnosed with HIV to receive sustained antiretroviral therapy (ART), and 90% of people receiving ART to achieve viral suppression.<sup>3</sup> Indeed,

there have been marked improvements in expansion of HIV testing and treatment coverage in recent years, although the persistently high HIV incidence among MSM suggests the need for continued work to optimise HIV treatment outcomes.<sup>1,4,5</sup>

The bar to effectively prevent HIV among MSM is higher than that of most other populations given the rapid transmission potential in MSM networks and structural barriers impeding engagement in care. It can be argued that a HIV pandemic exists among MSM in that from every country where quality data are available, there is continued sustained incidence.<sup>6,7</sup> To quantify this disproportionate burden, a review of 21 countries with concentrated epidemics demonstrated that the pooled odds ratio of HIV infection among MSM was estimated to be 25.5 when compared with other adults, and 10.8 across nine countries with more generalised epidemics.<sup>8</sup> Incidence data available as of 2016 reinforce this narrative in that incidence measures from cohorts of MSM in higher income settings and more concentrated

epidemics are high and sustained, and incidence data from low- and middle-income countries are similarly stable or increasing.<sup>7,9–21</sup>

In order to better understand the factors associated with the incidence density of HIV among MSM, this paper will: (1) review the geographic trends in HIV incidence; (2) focus on specific epidemiological subgroups (e.g. young MSM); (3) discuss the factors that potentiate the intensifying epidemics among MSM; and (4) discuss the promise of new prevention technologies in achieving epidemic control.

### **Current HIV incidence data among men who have sex with men in high-income settings**

In order to describe the changes in HIV incidence that have taken place among MSM, we first introduce the reproductive rate of infection ( $R_0$ ), which is the average number of secondary infections produced by one HIV-infected individual.<sup>22</sup> For sexual transmission of HIV,  $R_0$  depends on the probability of transmission per coital act ( $\beta$ ), and the number of unprotected coital acts with different sex partners, also known as the contact rate ( $c$ ), and the average duration of infectiousness ( $D$ ).<sup>22</sup> In the late 1990s and early 2000s, there were tangible HIV incidence declines among MSM across several high income countries – including Australia, France, the UK, and the US.<sup>20</sup> This was also a time of great loss and fear in gay communities given the high mortality rates before the scale up of effective ART, then referred to as highly active antiretroviral therapy (HAART). This resulted in reductions in the absolute number of MSM and decreased contact rate between MSM ( $c$ ), as well as increased condom use, which reduced the probability of transmission ( $\beta$ ). After the introduction of HAART, HIV slowly evolved into a chronic disease and one that was far less likely to be overtly symptomatic. New cohorts of MSM came of age in a period where HIV was no longer a death sentence, and some started having condomless anal sex without the intense fear of mortality related to HIV infection. Subsequent to this, the growing popularity of online sex-seeking and geo-spatial social networking applications has resulted in easy access to high numbers of instantaneous sexual partners.<sup>23–27</sup> Once again, this has increased contact rates between MSM as well as probably of HIV transmission, thereby driving HIV incidence among MSM in recent years.

In the US, new HIV infections have increased among young MSM by ~10% per year since 2002 in the context of an otherwise stable or declining HIV epidemic in other populations.<sup>28</sup> The estimated number of new HIV infections among MSM in the US increased by 12% from 2008 to 2010, from 26 700 to 29 800 infections.<sup>29</sup> Consequently, the per cent of all HIV infections among men attributable to male-to-male sexual contact increased from 63% to 78%.<sup>29</sup> With growing HIV incidence, the racial disparities in the burden of HIV among MSM, now understood to be largely secondary to socioeconomic determinants of HIV, became increasingly marked from 2002 to 2011.<sup>28,30,31</sup> Notably, the US is estimated to account for over 30% of total infections in high-income countries with now consistently demonstrated disparities across income levels, and along ethnic and racial lines.<sup>20,32</sup> While the US has a higher absolute burden, similar

sociodemographic trends have also been observed in several other countries.

In Canada, the HIV incidence rate was 443 per 100 000 among MSM and 6.2 per 100 000 among men who do not have sex with men, making MSM 71-fold more likely to acquire HIV<sup>33</sup> (Table 1; Fig. 1). Both of these estimates are conservative, given that they rely on self-reported status of being gay or otherwise MSM as part of a HIV surveillance system driven primarily by passive case-based HIV surveillance, and are likely to be underreported because some MSM may not be comfortable in discussing their behaviours.

The trend of increasing incidence among MSM extends to other high-income countries outside of North America. In Australia, 70% of HIV diagnoses in 2014 were attributed to male–male sexual contact.<sup>34</sup> In the United Kingdom, new HIV diagnoses among MSM rose annually from 1440 in 1999 to 3250 in 2013.<sup>35</sup> The ITACA cohort of 3544 MSM established in Barcelona, Spain, noted an overall HIV incidence of 2.4 per 100 person-years, with foreign born men being at increased risk for infection.<sup>157</sup> During the study period, HIV incidence increased from 1.2 to 3.1 person-years from 2009 to 2011.<sup>157</sup> Finally, in a report from 30 European Union (EU)/European Economic Area (EEA) countries, the highest proportion of new HIV diagnoses in 2012 continued to be reported among MSM (40%; 11 877 cases).<sup>37</sup>

Men in higher income settings have three primary HIV acquisition risks including parenteral drug use, heterosexual transmission and through same-sex practices. In many high-income settings, needle and syringe exchange programs exist, with some places also having safe drug consumption facilities to minimise the reuse of potentially contaminated injecting devices.<sup>38–40</sup> When given the option, the uptake of harm-reduction approaches among people who use drugs is extremely high. In general, men have a lower HIV acquisition risk when having sex with women because of lower transmission probabilities in penile-vaginal sex, as well as fewer female sexual partners and concurrent partnerships, resulting in a smaller sexual network.<sup>41,42</sup> These specific acquisition risks have also decreased with increased coverage of ART for women living with HIV in many higher income settings. Together, these factors have lowered HIV incidence among men who do not have sex with other men over the past decade, but appear to have not affected MSM.

### **Current HIV incidence data among men who have sex with men in low- and middle-income settings**

In the earlier years of the HIV pandemic, there was a widely held misconception that HIV among MSM was an issue restricted to high-income countries. More recently, improved HIV surveillance in low- and middle-income countries (LMIC) has identified major epidemics among MSM.

A study conducted in Kenya observed incidence of 6.8 per 100 person-years in a cohort of MSM from 2005 to 2008.<sup>16</sup> In Thailand, the estimated HIV incidence among MSM in Bangkok increased from 4.1% in 2003 to 7.7% in 2007.<sup>43</sup> Another study conducted in Bangkok observed an overall HIV incidence of 5.9 per 100 person-years from 2006 to 2012,<sup>44</sup> whereas in northern Thailand, HIV incidence among a cohort

**Table 1. HIV incidence among men who have sex with men (MSM)**

BED-CEIA, BED-enzyme immunoassay; ELA-RI, enzyme immunoassay for recent HIV-1 infection; N/A, not available; STD, sexually transmissible disease; STIs, sexually transmissible infections; NPEP, non-occupational post-exposure prophylaxis

Country	MSM or subpopulation	Income setting	Incidence per 100 person-years	Sample size (n)	Data collection year(s)	Note	Reference
Argentina	MSM sex workers	High	6.06	N/A	2006–2009		136
Argentina	MSM	High	6.33	262	2006–2009		136
Australia	MSM	High	0.81	N/A	2014	STD clinic sample	137
Brazil	MSM	Low, middle	2.5	1085	1994–2010		138
Canada	MSM	High	0.443	N/A	2011		33
China	MSM	Low, middle	2.9 (year 2005); 3.6 (year 2006)	1067	2005–2006	BED-CEIA estimate	139
China	MSM	Low, middle	7.01 (year 2006); 7.98 (year 2007); 7.80 (year 2008)	2898	2003–2006	BED-CEIA estimate	140
China	MSM	Low, middle	3.5	378	2009–2011		141
China	MSM	Low, middle	6.78	622	2009–2010		142
China	Migrant MSM	Low, middle	7.83	511	2009–2010		143
China	MSM	Low, middle	5.6	725	2009–2012		144
China	MSM	Low, middle	5.9	1003	2009–2012		145
China	MSM	Low, middle	3.9	962	2009–2010		146
China	MSM	Low, middle	4.23	661	2013		147
China	MSM	Low, middle	5	N/A	2010–2015	Pooled incidence from 24 studies	11
El Salvador	MSM	Low, middle	3.6	347	2001–2002		148
France	MSM	High	3.8	886	2009	EIA-RI estimate	149
Guatemala	MSM	Low, middle	2.1	158	2001–2002		148
Honduras	MSM	Low, middle	4.9	332	2001–2002		148
India	MSM	Low, middle	1.8	1126	2009–2010		150
Italy	MSM	High	5.2 (year 1986); 9.2 (year 1992); 1.3 (year 2001); 11.7 (year 2009)	1862	1986–2009	STD clinic sample	151
Kenya	MSM	Low, middle	6.8	327	2005–2008		16
Kenya	MSM	Low, middle	7.5	N/A	2005–2012		152
Kenya	MSM	Low, middle	8.6	449	2005–2011		153
Netherlands	MSM	High	8.6 (year 1985); 1.3 (year 1992); 2.0 (year 2009)	1642	1985–2009		154
Nicaragua	MSM	Low, middle	14.4	171	2001–2002		148
Panama	MSM	Low, middle	2.7	409	2001–2002		148
Peru	MSM	Low, middle	3.6	510	2009–2012		36
Portugal	MSM	High	2.8	804	2011–2014		155
Senegal	MSM	Low, middle	16	40	2011–2012		156
Spain	MSM	High	2.4	3544	2008–2011	Community-based cohort	157
Thailand	MSM	Low, middle	4.1	308	2003		15
Thailand	MSM	Low, middle	6.4	94	2005		15
Thailand	MSM	Low, middle	7.7	99	2007		15
Thailand	MSM	Low, middle	8.2	551	2008–2009		45
Thailand	MSM	Low, middle	5.9	1744	2006–2012		44
Thailand	MSM	Low, middle	6.3	4762	2005–2011		158
Thailand	Young MSM (15–21 years old)	Low, middle	12.2	662	2005–2011		158
United Kingdom	MSM	High	0.45	N/A	1998–2010		17
United States	MSM	High	1.9	4295	1999–2003		159
United States	Young Black MSM (18–24 years old)	High	5.1	678	2008		160
United States	Black MSM	High	3.0	1164	2009–2010		161
United States	MSM	High	6.7	276	2008–2010	Among those with rectal STIs	162

(continued next page)

**Table 1.** (continued)

Country	MSM or subpopulation	Income setting	Incidence per 100 person-years	Sample size ( <i>n</i> )	Data collection year(s)	Note	Reference
United States	Black MSM	High	15.34	51	2008–2010	Among those with rectal STIs	162
United States	Young MSM (<20 years old)	High	10.46	30	2008–2010	Among those with rectal STIs	162
United States	Young MSM (18–19 years old)	High	2.85	594	2009–2011		163
United States	MSM	High	0.7	386 (year 2004); 521 (year 2008)	2004, 2008	Estimated using closed population model	164
United States	MSM	High	2.2	894	1997–2013	Among NPEP users	165
United States	MSM	High	0.6	510 (year 2011); 411 (year 2014)	2011, 2014	Estimated using closed population model	164
United States	MSM	High	1.6	6577	2007–2013	Among those with STIs	166
United States	Black MSM	High	4.16	2898	1994–2010	Weighted estimate	55
United States	MSM	High	3.8	562	2010–2012		31
United States	Black MSM	High	6.5	260	2010–2012		31
United States	Young Black MSM (16–20 years old)	High	6.18	571	2009–2015		47
United States	Young MSM (16–20 years old)	High	4.11	450	2009–2015		47



**Fig. 1.** HIV incidence per 100 person-years among men who have sex with men (MSM). Data are from Table 1. In the case of multiple incidence estimates per country, only data from the most recent study were included.

of MSM was estimated to be 8.2 per 100 person-years from 2008 to 2009.<sup>45</sup> In a cohort of 510 MSM in Lima, Peru, the HIV incidence was 4 cases per 100 person-years, further indicating high risk as compared with other adults.<sup>36</sup> Furthermore, a 2012 review of 55 studies among MSM in China found a dramatic 3.3-fold increase in HIV incidence among MSM from 2.04 to 7.02 per 1000 person-years during 2002–2010.<sup>46</sup>

Taken together, these data suggest that HIV incidence is more similar than different across varying income levels of countries. Indeed, the similarities of HIV incidence levels among MSM also extend to countries with very distinct HIV epidemics, reinforcing the unique nature of HIV epidemics among MSM.<sup>7</sup>

### HIV incidence among young MSM

The highest HIV incidence rates in many settings appear to be among younger age groups of MSM.<sup>19,47–49</sup> In an Atlanta cohort, MSM aged 18–24 years had 2.5-fold the risk of acquiring HIV as compared with older MSM.<sup>31</sup> These high incidence rates are sustained as evidenced by an earlier cohort conducted from 1996 to 2000 in Baltimore among young MSM aged 15–29 years, which revealed a HIV incidence of 4.2% per year.<sup>50</sup> In the UK, the largest increases in new HIV diagnoses from 1999 to 2013 occurred among young MSM aged 15–24 years (16% of new diagnoses).<sup>35</sup> HIV incidence

among MSM who are 18–21 years old in Thailand is 8.8 per 100 person-years compared with 5.9 per 100 person-years among all MSM from 2006 to 2012.<sup>44</sup> Furthermore, a report including 15 EU member states found that the largest increase in new HIV infections occurred among young MSM aged 20–29 years, with the number of cases almost doubling from 2003 to 2012 (1037 to 1881 cases; 81% increase).<sup>37</sup>

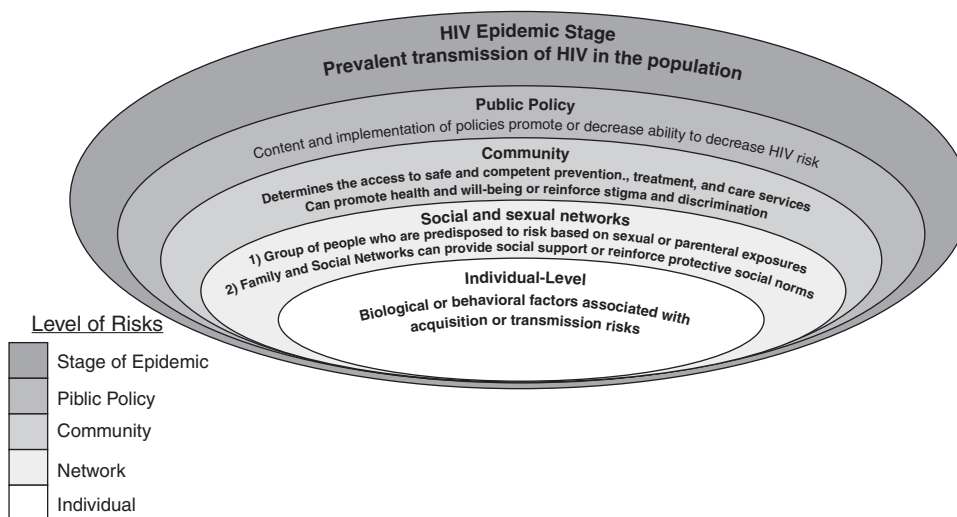
**HIV incidence among racial and ethnic minorities**

In the US, HIV incidence disproportionately affects Black and Hispanic MSM and most severely young Black MSM.<sup>9,29,51–55</sup> The Centers for Disease Control and Prevention (CDC) estimated, using data from 2009 to 2013, that one in two Black MSM and one in four Hispanic MSM will be diagnosed with HIV in their lifetime, compared with 1 in 11 White MSM and 1 in 132 White men.<sup>56</sup> In a cohort study of young MSM in Chicago, the highest incident rate recorded was among young Black MSM, with an incidence of 6.2 infections per 100 person-years compared with 2.9 infections per 100 person-years among Hispanic young MSM and 0.9 infections per 100 person-years among young White MSM in the same cohort.<sup>47</sup> In an Atlanta cohort of 260 Black and 302 White MSM, there was an overall incidence of 3.8 per 100 person-years, with a higher rate among Black (6.5 per 100 person-years) as compared with White MSM (1.7 per 100 person-years).<sup>31</sup> Similarly, in the Baltimore Young Men’s Survey, there were substantial racial differences in HIV incidence, with 11.0% per year (95% CI: 5.5–19.7) among non-Hispanic Blacks, 7.1% among ‘other’ or mixed race participants (95% CI: 2.9–14.6) and 0.6% among non-Hispanic Whites (95% CI: 0.002–4.9).<sup>50</sup> Although the majority (85%) of new HIV cases in the UK were from White MSM, there has been a significant year-on-year increase in diagnoses among Asian and Black African MSM.<sup>35</sup>

**What sustains HIV incidence among MSM in the context of a slowing HIV pandemic?**

Many studies about HIV in MSM have focused significantly on the measurement of a range of individual determinants of HIV infection among MSM such as condomless insertive and receptive anal intercourse with serodiscordant and viremic sexual partners, high frequency of casual male partners, and drug use, including the use of amphetamines and other substances before and during sex.<sup>57</sup> This latter phenomenon has been well documented in the UK and is known as ‘chemsex’, referring to the sex between men that occurs under the influence of disinhibiting drugs and particularly ‘club drugs’ such as ecstasy, cocaine or ketamine.<sup>58</sup> Furthermore, online sex-seeking is increasing among MSM in both low- and high-income settings, which presents increased opportunity for HIV exposure given increased access to sexual partners.<sup>25,59,60</sup> Asymptomatic bacterial sexually transmissible infections may also play a role in potentiating HIV acquisition and transmission among MSM through genital tract inflammation involving increased local density of immune cells that are at risk for acquiring HIV, ulcerations and abrasions.<sup>61–63</sup>

However, beyond individual behaviours, there are other forces driving the disproportionate HIV burden among MSM (Fig. 2), including biologically mediated factors. At the network-level, there is a far higher per-act and per-partner transmission probability of HIV from receptive anal sex<sup>7,64–66</sup> when compared with vaginal sex or insertive penile sex. Acquisition rates for receptive condomless anal sex between men and women do not vary greatly, as they depend on the biology of the virus and the physiology and immunology of the intestinal tract. However, transmission rates within networks vary greatly as men can be either the insertive or receptive partner during sex; that is, by efficiently acquiring HIV and then efficiently transmitting it. This sexual role versatility, coupled with the high per-act risk of HIV transmission during rectal exposure, leads to high



**Fig. 2.** Modified social ecological model for levels of HIV risk among men who have sex with men (MSM). This Figure is licenced under a Creative Commons Attribution 4.0 International Public Licence (<http://creativecommons.org/licenses/by/4.0/legalcode>).<sup>135</sup>

individual, couple-based and network-level HIV transmission risks.<sup>67–69</sup>

Individual behavioural risk factors do not appear to explain the increased risk for HIV among Black MSM in the US or among racial/ethnic minorities in other settings.<sup>32,54</sup> Instead, research has pointed to higher network-level transmission risk including high prevalence of STIs and HIV in Black sexual networks, socioeconomic factors and higher levels of undiagnosed infection.<sup>31,54,70</sup> Currently, young MSM including young Black MSM in the US are less engaged in HIV testing, less likely to be aware of their infection and more likely to unknowingly transmit the virus to others.<sup>32,71,72</sup> In addition, structural risk factors for young MSM such as limited engagement in sexual health education, complex parental consent laws for HIV testing and treatment, as well as lack of privacy for those on their parents' health insurance, complicate programmatic initiatives. Moreover, it is difficult to study the needs of adolescent gay men and other MSM given the ethical and legal limitations in including these populations in research studies.<sup>73–75</sup> HIV risks are further potentiated by serodiscordant partnerships with older men and limited awareness and uptake of HIV preventive services.<sup>72,73,76</sup> In high-income settings in particular, improved treatment has allowed many living with HIV to lead longer and healthier lives. Because of this, many MSM and particularly younger generations may perceive HIV as less dangerous and are not as knowledgeable about or engaged in prevention services.<sup>74</sup>

Further potentiating the biological drivers of HIV acquisition and transmission in all settings are the multiple forms of stigma affecting MSM that limit the provision and uptake of HIV prevention, treatment, and care services.<sup>77–79</sup> Exposure to stigma including culturally insensitive health workers can result in MSM avoiding HIV testing and other prevention services, limiting diagnosis and awareness of status.<sup>78,80–82</sup> Even more acute, men who are aware of living with HIV may avoid HIV treatment altogether.<sup>83</sup> Reduced utilisation of health and HIV services by MSM, due to enacted or perceived discrimination, limits knowledge of the risks of condomless anal intercourse and opportunities for access to prevention services.<sup>78,81</sup>

Much of the stigma measurement for gay men has focused on internalised stigma or internalised homonegativity.<sup>84–88</sup> However, recent studies demonstrating the high levels of experienced and perceived stigma in countries ranging from Europe to Sub-Saharan Africa suggest that internalised stigma is an outcome of lived stigma and may be a proxy for mental health stressors related to this stigma.<sup>80,89–93</sup> Indeed, mental health issues appear consistently as outcomes of stigma and as a mediating determinant of HIV risks.<sup>94–96</sup> Given the efficient HIV transmission that can take place in sexual networks of MSM if a network member is acutely infected, stigma limiting engagement in services is problematic given that it can contribute to late HIV diagnoses.<sup>20,97</sup>

Where sufficient HIV surveillance systems are in place, late diagnoses have been found to be sustained or increasing in high-income settings. As with HIV incidence, data suggest an even higher burden of late diagnoses among racial/ethnic minority MSM secondary to HIV stigma and limited social support.<sup>98–100</sup>

Breaking chains of HIV transmission necessitates not just coverage of HIV testing, but the diagnosis of people during the acute and early infection stages followed by effective and sustained intervention. Thus, universal HIV treatment approaches are challenged in terms of optimising clinical outcomes and eliminating onward HIV transmission in the context of late diagnoses.<sup>20</sup>

### **Changing the future: what will it take to change the trajectory of HIV incidence by 2020?**

A concerted effort rooted in evidence and affirming of human rights is needed to truly change the trajectory of the HIV pandemic among MSM. One high bar has already been set – the Commission for AIDS in Asia has suggested that comprehensive packages of HIV prevention interventions should cover between 60 and 80% of MSM in order to make an impact on the HIV epidemic.<sup>101</sup> In addition, effective control of the HIV epidemic will also require a strong public health system with improved surveillance, epidemiology and disease control activities for MSM, particularly in many LMIC settings. The role of public health policy moving forward will be to utilise lessons learned from jurisdictions that have been successful in reducing HIV incidence among MSM. For example, King County in Washington, USA experienced a decline of 26% in new HIV diagnoses among MSM from 2004 to 2013, with an even greater decline among Black MSM (44%).<sup>102</sup> These trends are thought to be the result of having a well-developed public health infrastructure including community-based organisations, medical providers, academia, and state and local health departments, as well as low levels of stigma towards MSM in the region.<sup>102</sup>

Across all settings, developmental indicators are needed for MSM, including measurement of the rates of uptake and engagement in early diagnosis and treatment, pre-exposure prophylaxis (PrEP), in addition to programs to address HIV-related and sexual behaviour-related stigma. Better understanding of the mechanisms by which stigma and mental health influence health disparities of MSM is needed, and validated and consistent metrics of stigma will be necessary for completing this task. The world has fortunately observed declines in new HIV infections; however, this has been accompanied by a slowly increasing concentration of the virus among MSM. A concerted effort must integrate the evidence-based interventions that will most proximally decrease HIV acquisition and transmission risks, together with the structural interventions that will support improved coverage and ultimately retention of these services. Fortunately, there are data finally supporting novel approaches that may actually allow for these incidence reductions to be realised.<sup>103,104</sup>

In 2010, the iPrEx (Pre-exposure prophylaxis initiative) trial demonstrated a 44% reduced HIV incidence among MSM in the Truvada-based (tenofovir–emtricitabine) PrEP arm compared with the placebo arm.<sup>105</sup> Two subsequent studies, PROUD (Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection) and iPERGAY (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays), demonstrated 86% efficacy when MSM knew that adherence to PrEP would be

protective.<sup>106,107</sup> Of paramount importance was the finding that when men had sufficient levels of intracellular tenofovir diphosphate, secondary to the actual use of the drug, protection from HIV infection was complete. This has fundamentally changed the response to and transitioned the focus of study to how best to support adherence to PrEP. Unfortunately, HIV incidence is highest in youth while medication adherence is also lowest in this population.<sup>103,108–110</sup> The US-based Adolescent Trials Network (ATN) supported a study, ATN110, suggesting feasibility and safety in a PrEP study among young MSM aged 18–22 years as part of Project PrEPare; however, low adherence levels (63.4% detectable tenofovir at week 4 and 20% at week 24) confirmed that the most challenging aspect of this is sustained adherence.<sup>111</sup> In addition, adherence and effectiveness of PrEP was lowest among the Black adolescents in the trial, suggesting a potential need to reduce racial disparities in adherence rates.<sup>111</sup>

Additional studies have confirmed that PrEP is now a part of primary HIV prevention services that should be offered to MSM.<sup>106,107,112</sup> However, in early 2016, PrEP is implemented and recommended for MSM in only a few countries including the US, South Africa, France, Israel, Canada and Kenya, highlighting the disconnect between the evidence and the implementation of this approach.<sup>113</sup> The UK, where the PROUD study demonstrated high effectiveness,<sup>107</sup> has decided not to implement PrEP through the UK's National Health Service despite strong interest in PrEP among gay men and providers.<sup>114</sup> This slow and uneven implementation arguably reveals the challenges of advocating for the scale-up of an intervention that is based on efficacy and effectiveness data primarily from gay men and other MSM. Development of new formulations of oral PrEP and of topical and long-acting injectable PrEP are likely to continue to improve the side-effect profile, dosing strategies and ease of adherence to these interventions. Price reductions for Truvada and related tenofovir formulations are also called for, given that cost-effectiveness arguments have been common in country decisions not to implement PrEP.

However, PrEP in its current form and cost is necessary but may not be sufficient to reduce HIV incidence among MSM, given the limited access and challenges in terms of adherence.<sup>115</sup> Getting PrEP to the younger MSM, particularly minors who may need parental consent, will be a particular challenge in many settings. But PrEP does fit well within a rubric of combination HIV prevention that leverages a package of biomedical, behavioural and structural interventions addressing multiple layers of risk.<sup>103,115–118</sup> Combination approaches including biomedical, behavioural and structural components, are likely to be even more efficient to address the needs of MSM with acute HIV acquisition risks.<sup>17,119–121</sup> Biomedical components include PrEP and universal linkage to ART to optimise clinical outcomes and decrease onward HIV transmission, whereas behavioural components are included to facilitate uptake and sustained engagement in these biomedical interventions, and continued use of counselling about condoms, condom compatible lubricants and regular HIV testing. Structural interventions are those that will support optimal implementation and higher coverage including clinical and cultural competency training for health providers and

meaningful stigma mitigation approaches. These combination approaches are particularly underutilised for MSM across many LMIC including across Sub-Saharan Africa where many programs consist of peer education and condom distribution with limited attention to the discriminatory policies and stigma affecting MSM.<sup>116,117</sup> The 2012 Global Men's Health and Rights Study, which included data from a global online survey of 5779 MSM from 165 countries, indicated that overall 41.5% of respondents reported complete access to HIV treatment and only 26.5% were from Sub-Saharan Africa.<sup>122</sup> Ultimately, the challenge will be not just linking people to a range of effective services, but will be about securing long-term retention – and this will require significant research leveraging the best implementation research approaches.

Given the rapid HIV transmission within sexual networks of MSM, meaningful combination prevention necessitates rapid HIV diagnosis. Fourth-generation HIV tests, which are better suited for detecting recent infection, are recommended for routine use in the UK.<sup>123</sup> However, evaluating approaches to further decentralise HIV testing, including HIV self-testing (HIVST), may further decrease the time between HIV exposure, infection and diagnosis. HIVST may take a range of different forms, but does facilitate screening for HIV in private and may also facilitate reaching the currently 'unreached' MSM.<sup>124</sup> The Internet and mobile technologies also have far-reaching potential to reduce HIV incidence among MSM by 2020.<sup>125–127</sup> Internet-based interventions have ranged from providing information via SMS text to supporting adherence to HIV medication by using gamification methods, and continue to be developed as technology expands.<sup>127,128</sup> However, challenges remain regarding effective implementation of these approaches and ensuring linkage to ART after a positive diagnosis.

There are a range of additional biomedical prevention strategies under development, such as rectal microbicides and an HIV vaccine, which would also offer protection against rising HIV incidence.<sup>129,130</sup> More than 250 clinical trials for the HIV/AIDS vaccine have been conducted to date with significant supportive evidence from *in vitro* and animal model research.<sup>131</sup> In addition, there were some signs of success associated with the RV-144 Thai Vaccine study, with attention currently being given to understanding that success and leveraging it.<sup>131</sup> A subsequent trial of the RV-144 regimen among MSM in Thailand is currently in development – and this will be critical, because the efficacy of protection with this prime-boost regimen for rectal exposure is currently unknown. The most recent studies to be launched in this arena are based on broadly neutralising antibodies aiming to target conserved epitopes across different HIV strains.<sup>132–134</sup> Even in the best case scenario, we are more than a decade away from any actual HIV vaccine product being used in real world settings and thus, will not be able to significantly modify HIV incidence by 2020.<sup>131</sup>

## Conclusions

There is a pandemic of HIV among gay men and other MSM, and HIV is increasingly concentrating within this population.

Historical data tell us that this pandemic will continue to grow well past 2020 unless a concerted and global effort is effectively brought to scale for MSM. Globally, we will need improved public health systems, HIV surveillance mechanisms and meaningful indicators to support the evaluation of programs in changing the trajectory of this pandemic by 2020. Moreover, evidence-based and human-rights affirming interventions are needed to address the structural level risk determinants including stigma in communities, punitive laws and policies and exclusion from national HIV responses that generally limit the provision and uptake of efficacious interventions. Universal provision of HIV treatment, fourth generation HIV tests, HIV self-testing and daily oral PrEP have emerged as being integral to the prevention of acquisition and transmission of HIV. Now they need to be equitably scaled to also minimise the disparities that exist within communities of gay men and other MSM in so many settings around the world. Given the biology of HIV, the bar for HIV prevention among gay men and other MSM is extremely high. Changing the trajectory of HIV incidence among gay men and other MSM demands truly respecting and working to understand all of those we aim to serve, to increase the chance that we actually do.

### Conflicts of interest

Chris Beyrer is receiving a donation of Tenofovir/Emtricitabine (Truvada) from Gilead, Inc. for an effectiveness study of a multi-level combination HIV preventive intervention with and without daily oral Truvada pre-exposure prophylaxis among young men who have sex with men in Bangkok, Thailand (R01AI118505; PI: Beyrer). Kenneth H. Mayer has received unrestricted research grants from Gilead Sciences and ViiV Healthcare. Shauna Stahlman, Patrick S. Sullivan, Sean Hosein and Stefan D. Baral declare that they have no conflicts of interest.

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