





**PREVENTION AND TREATMENT OF HIV AND  
OTHER SEXUALLY TRANSMITTED INFECTIONS AMONG  
MEN WHO HAVE SEX WITH MEN AND  
TRANSGENDER PEOPLE**

Recommendations for a public health approach

2011

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## ACRONYMS AND ABBREVIATIONS

|               |   |
|---------------|---|
| <b>AIDS</b>   | acquired immunodeficiency syndrome                                |
| <b>ART</b>    | antiretroviral therapy  |
| <b>CDC</b>    | Centers for Disease Control and Prevention                        |
| <b>CI</b>     | confidence interval   |
| <b>GRADE</b>  | Grading of Recommendations Assessment, Development and Evaluation |
| <b>GRC</b>    | Guidelines Review Committee                                       |
| <b>GUD</b>    | genital ulcer disease   |
| <b>HBV</b>    | hepatitis B virus   |
| <b>HIV</b>    | human immunodeficiency virus                                      |
| <b>HR</b>     | hazard ratio  |
| <b>HSV</b>    | herpes simplex virus  |
| <b>HTC</b>    | HIV testing and counselling                                       |
| <b>IAS</b>    | International AIDS Society  |
| <b>MSM</b>    | men who have sex with men   |
| <b>MSMGF</b>  | Global Forum on MSM and HIV                                       |
| <b>NAAT</b>   | nucleic acid amplification tests/testing                          |
| <b>NGO</b>    | nongovernment organization  |
| <b>NNRTI</b>  | non-nucleoside reverse transcriptase inhibitor                    |
| <b>NSP</b>    | needle and syringe programme                                      |
| <b>NRTI</b>   | nucleoside reverse transcriptase inhibitor                        |
| <b>OHCHR</b>  | Office of the United Nations High Commissioner for Human Rights   |
| <b>OR</b>     | odds ratio  |
| <b>OST</b>    | opioid substitution therapy                                       |
| <b>PI</b>     | protease inhibitor  |
| <b>PICO</b>   | Population, Intervention, Comparison and Outcomes                 |
| <b>PrEP</b>   | pre-exposure prophylaxis  |
| <b>RPR</b>    | rapid plasma reagin   |
| <b>RR</b>     | relative risk   |
| <b>STI</b>    | sexually transmitted infection                                    |
| <b>UNAIDS</b> | Joint United Nations Programme on HIV/AIDS                        |
| <b>UNDP</b>   | United Nations Development Programme                              |
| <b>WHO</b>    | World Health Organization   |

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## EXECUTIVE SUMMARY

Since the beginning of the epidemic in the early 1980s, men who have sex with men (MSM) and transgender people have been disproportionately affected by the human immunodeficiency virus (HIV). The risk for infection remains high among them; and there has been a resurgence of HIV infection among MSM, particularly in industrialized countries. Data are emerging of new or newly identified HIV epidemics among MSM in Africa, Asia, the Caribbean and Latin America.

A meta-analysis of surveillance data in low- and middle-income countries found that MSM are 19.3 times more likely to be HIV-infected than the general population. Reported HIV prevalence among MSM ranges from 0% to 32.9%, with rates surpassing 20% in countries as diverse as Bolivia, Jamaica, Mexico, Myanmar, Thailand, Trinidad and Zambia. HIV incidence among MSM ranges from 1.2 to 14.4 per 100 person-years. Recent studies from sub-Saharan Africa reported that HIV prevalence among MSM ranges from 6% to 31%. In Asia, the odds of MSM being infected with HIV are 18.7 times higher than in the general population; and the HIV prevalence ranges from 0% to 40%. In Latin America, it is estimated that half of all HIV infections in the region have resulted from unprotected anal intercourse between men.

The few existing epidemiological studies among transgender people have shown disproportionately high HIV prevalence ranging from 8% to 68%, and HIV incidence from 3.4 to 7.8 per 100 person-years. It is important to note that underlying correlates of HIV and STI risk as well as the specific sexual health needs of transgender people may be distinct from those of MSM. Although the same basic HIV and STI prevention interventions may be indicated for the two groups, public health professionals should avoid conflating the two groups and work towards a more nuanced understanding of each group's needs.

Criminalization, and legal and policy barriers play a key role in the vulnerability of MSM and transgender people to HIV. More than 75 countries currently criminalize same-gender sexual activity. And transgender people lack legal recognition in most countries. These legal conditions force MSM and transgender people to risk criminal sanctions if they want to discuss their level of sexual risk with a service provider. They also give police the authority to harass organizations that provide services to these populations.

Long-standing evidence indicates that MSM and transgender people experience significant barriers to quality health care due to widespread stigma against homosexuality and ignorance about gender variance in mainstream society and within health systems. Social discrimination against MSM and transgender people has also been described as a key driver of poor physical and mental health outcomes in these populations across diverse settings. In addition to being disproportionately burdened by STI and HIV, MSM and transgender people experience higher rates of depression, anxiety, smoking, alcohol abuse, substance use and suicide as a

result of chronic stress, social isolation and disconnection from a range of health and support services.

From a health systems' perspective, MSM and transgender people may delay or avoid seeking health, STI or HIV-related information, care and services as a result of perceived homophobia, transphobia, ignorance and insensitivity. MSM and transgender people may be less inclined to disclose their sexual orientation and other health-related behaviours in health settings that may otherwise encourage discussions between the provider and patient to inform subsequent clinical decision-making. Providers are likely to feel biased when their own cultural, moral or religious leanings are incongruent with a patient's reported sexual orientation, behaviours or gender identity. Additionally, enquiry into the level of knowledge among physicians, nurses and other health care providers on MSM and transgender-related health issues has shown that the clinical curriculum, particularly in low- and middle-income countries, do not address these knowledge gaps.

Despite the strong impact of the HIV epidemic on MSM and transgender people, to date, no technical recommendations have been made to guide health systems' response to the epidemic among them. In September 2008, the World Health Organization (WHO) held a global consultation on "Prevention and treatment of HIV and other sexually transmitted infections (STI) for men who have sex with men and transgender populations", in Geneva, Switzerland. Recommendations from that global consultation, as well as from WHO regional consultations, called for the need to develop guidance for delivering an evidence-based, package of interventions for implementation by the health sector to prevent and treat HIV and other STIs among MSM and transgender people.

The guideline is designed for use by national public health officials and managers of HIV/AIDS and STI programmes, nongovernment organizations (NGOs) including community and civil society organizations, and health workers. It may also be of interest to international funding agencies, the scientific media, health policy-makers and advocates.

This guideline will provide recommendations for regional and country partners on appropriate interventions designed to address needs of MSM and transgender people. It also provides an opportunity to highlight and emphasize the correlation between prevention and treatment in the response to the HIV epidemic among MSM and transgender people, particularly in light of increasing evidence about the preventive benefit of antiretroviral therapy (ART). This may lead to a substantial reduction in transmission at the population level.

The development of this document followed the standard procedures currently in place at the World Health Organization for the production of evidence-based recommendations, which

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<sup>†</sup>A strong recommendation is one for which the desirable effects of adherence to a recommendation outweigh the undesirable effects. A conditional recommendation is one for which the desirable effects of adherence to a recommendation probably outweigh the undesirable effects. However, data to support the recommendation are scant.

utilize the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. These recommendations are proposed as a standard of prevention and care attainable in resource-limited settings. WHO recommends that this guidance be available for MSM and transgender people in high-income countries as well.

For the development of these guidelines, the overarching principle is *respect for and protection of human rights*.

### Recommendations on human rights and non-discrimination in health-care settings

1. Legislators and other government authorities should establish antidiscrimination and protective laws, derived from international human rights standards, in order to eliminate discrimination and violence faced by MSM and transgender people, and reduce their vulnerability to infection with HIV, and the impacts of HIV and AIDS.
2. Health services should be made inclusive of MSM and transgender people, based on the principles of medical ethics and the right to health.

### Recommendations on HIV prevention, care and treatment

#### Prevention of sexual transmission

3. Using condoms consistently during anal intercourse is strongly recommended for MSM and transgender people over not using condoms.  
*Strong recommendation, moderate quality of evidence*
4. Using condoms consistently is strongly recommended over serosorting for HIV-negative MSM and transgender people.  
*Strong recommendation, very low quality of evidence*  
  
Serosorting is suggested over not using condoms by HIV-negative MSM and transgender people under specific circumstances as a harm reduction strategy.  
*Conditional recommendation, very low quality of evidence*
5. Not offering adult male circumcision to MSM and transgender people for the prevention of HIV and STI is suggested over offering it.  
*Conditional recommendation, very low quality of evidence*

### **HIV testing and counselling**

6. Offering HIV testing and counselling to MSM and transgender people is strongly recommended over not offering this intervention.

*Strong recommendation, low quality of evidence*

7. Offering community-based HIV testing and counselling linked to care and treatment to MSM and transgender people is suggested over not offering such programmes.

*Strong recommendation, very low quality of evidence*

### **Behavioural interventions, information, education, communication**

8. Implementing individual-level behavioural interventions for the prevention of HIV and STIs among MSM and transgender people is suggested over not implementing such interventions.

*Conditional recommendation, moderate quality of evidence*

9. Implementing community-level behavioural interventions for the prevention of HIV and STIs among MSM and transgender people is suggested over not implementing such interventions.

*Conditional recommendation, low quality of evidence*

10. Offering targeted internet-based information to decrease risky sexual behaviours and increase uptake of HIV testing and counselling among MSM and transgender people is suggested over not offering such information.

*Conditional recommendation, very low quality of evidence*

11. Using social marketing strategies to increase the uptake of HIV/STI testing and counselling and HIV services among MSM and transgender people is suggested over not using such strategies.

*Conditional recommendation, very low quality of evidence*

12. Implementing sex venue-based outreach strategies to decrease risky sexual behaviour and increase uptake of HIV testing and counselling among MSM and transgender people is suggested over not implementing such strategies.

*Conditional recommendation, very low quality of evidence*

### **Substance use and prevention of bloodborne infections**

13. MSM and transgender people with harmful alcohol or other substance use should have access to evidence-based brief psychosocial interventions involving assessment, specific feedback and advice.

*In line with existing WHO guidance*

14. MSM and transgender people who inject drugs should have access to needle and syringe programmes and opioid substitution therapy.

*In line with existing WHO guidance*

15. Transgender people who inject substances for gender enhancement should use sterile injecting equipment and practise safe injecting behaviours to reduce the risk of infection with bloodborne pathogens such as HIV, hepatitis B and hepatitis C.

*In line with existing WHO guidance*

### **HIV care and treatment**

16. MSM and transgender people living with HIV should have the same access to ART as other populations. ART should be initiated at CD4 counts of  $\leq 350$  cells/mm<sup>3</sup> (and for those in WHO clinical stage 3 or 4 if CD4 testing is not available). Access should also include management of opportunistic infections, co-morbidities and treatment failure.

*In line with existing WHO guidance*

17. MSM and transgender people living with HIV should have access to essential interventions to prevent illness and HIV transmission including, but not limited to, care and support and antiretroviral therapy.

*In line with existing WHO guidance*

## Recommendations on prevention and care of other sexually transmitted infections

18. MSM and transgender people with symptomatic STIs should seek and be offered syndromic management and treatment.

*In line with existing WHO guidance*

19. Offering periodic testing for asymptomatic urethral and rectal *N. gonorrhoeae* and *C. trachomatis* infections using NAAT is suggested over not offering such testing for MSM and transgender people.

*Conditional recommendation, low quality of evidence*

Not offering periodic testing for asymptomatic urethral and rectal *N. gonorrhoeae* infections using culture is suggested over offering such testing for MSM and transgender people.

*Conditional recommendation, low quality of evidence*

20. Offering periodic serological testing for asymptomatic syphilis infection to MSM and transgender people is strongly recommended over not offering such screening.

*Strong recommendation, moderate quality of evidence*

21. MSM and transgender people should be included in catch-up HBV immunization strategies in settings where infant immunization has not reached full coverage.

*In line with existing WHO guidance*

# 1. BACKGROUND

## Epidemiology

Since the beginning of the epidemic in the early 1980s, men who have sex with men (MSM) and transgender people have been disproportionately affected by the human immunodeficiency virus (HIV). The risk for infection remains high among them; and there has been a resurgence of HIV infection among MSM, particularly in industrialized countries.<sup>1,2,3</sup> Data are emerging of new or newly identified HIV epidemics among MSM in Africa, Asia, the Caribbean and Latin America.<sup>4</sup>

A meta-analysis of surveillance data in low- and middle-income countries found that MSM are 19.3 times more likely to be HIV-infected than the general population.<sup>5</sup> Reported HIV prevalence among MSM ranges from 0% to 32.9%,<sup>4,5,6</sup> with rates surpassing 20% in countries as diverse as Bolivia, Jamaica, Mexico, Myanmar, Thailand, Trinidad and Zambia.<sup>4,5,6</sup> HIV incidence among MSM ranges from 1.2 to 14.4 per 100 person-years.<sup>4,7,8</sup> Recent studies from sub-Saharan Africa reported that HIV prevalence among MSM ranges from 6% to 31%, and an HIV incidence of 21.7 per 100 person years among MSM in a small cohort from Coastal Kenya, n=156.<sup>9,10,11,12,13</sup> In Asia, the odds of MSM being infected with HIV are 18.7 times higher than in the general population; and the HIV prevalence ranges from 0% to 40%.<sup>5,10</sup> In Latin America, it is estimated that half of all HIV infections in the region have resulted from unprotected anal intercourse between men.<sup>3</sup>

The few existing epidemiological studies among transgender people have shown disproportionately high HIV prevalence ranging from 8% to 68%, and HIV incidence from 3.4 to 7.8 per 100 person-years.<sup>17,18</sup> It is important to note that underlying correlates of HIV and STI risk as well as the specific sexual health needs of transgender people may be distinct from those of MSM. Although the same basic HIV and STI prevention interventions may be indicated for the two groups, public health professionals should avoid conflating the two groups and work towards a more nuanced understanding of each group's needs.

Scaling up services adequately for key populations at higher risk for HIV infection<sup>\*</sup> globally, particularly in concentrated epidemics, is essential to halt and reverse epidemics at the population level. An important challenge in reaching these populations is that they are often marginalized, stigmatized and criminalized. These populations' needs are often ignored by society and remain unattended by health services, despite their higher vulnerability.

## Definitions

*Men who have sex with men* is an inclusive public health construct used to define the sexual behaviours of males who have sex with other males, regardless of the motivation for engaging in sex or identification with any or no particular "community".<sup>19</sup> The words "man" and "sex" are interpreted differently in diverse cultures and societies, as well as by the individuals involved. As

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<sup>\*</sup>Key populations are defined within the WHO Global health sector strategy on HIV/AIDS 2011-2015 to include both vulnerable and most-at-risk populations. They are important to the dynamics of HIV transmission in a given setting and are essential partners in an effective response to the epidemic.



a result, the term MSM covers a large variety of settings and contexts in which male-to-male sex takes place. Perhaps the most important distinction to make is one between men who share a non-heterosexual identity (i.e. gay, homosexual, bisexual or other culture-specific concepts that equate with attraction to other men) and men who view themselves as heterosexual but who engage in sex with other males for various reasons (e.g. isolation, economic compensation, sexual desire, gender scripts).<sup>20</sup> Settings with forced gender segregation (e.g. prisons, military establishments) are important contexts for male-to-male sexual activity not linked to homosexual identity. Given the conditions of imprisonment, including human rights violations and lack of access to condoms, the risk of HIV transmission in prisons is very high.<sup>21</sup>

*Transgender* is an umbrella term for persons whose gender identity and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth. *Transgender people* may self-identify as transgender, female, male, transwoman or transman, trans-sexual, *hijra*, *kathoey*, *waria* or one of many other transgender identities, and may express their genders in a variety of masculine, feminine and/or androgynous ways.<sup>5, 22</sup> Until recently, in the context of HIV prevention, transgender people were included as MSM. However, there is a clear trend to stop including transgender people as part of the MSM population. This is in response to the higher vulnerability and specific health needs of transgender people, and to their justified demand for an independent constituency status in the global HIV response.<sup>23</sup>

### **Sexuality and sexual risk**

When planning to scale up services for MSM and transgender people, a key problem is that they are often presumed to be a homogeneous community, whereas in reality they represent a range of diverse identities and forms of social and sexual associations. These differences are important in terms of the implications for HIV risk and vulnerability, and should be taken into consideration where resources are scarce, ensuring that those with the highest need are addressed first.<sup>24</sup> In some cases, sexual dynamics among subgroups of MSM and transgender people determine important differences in risk, as is the case with feminized men or transgender-identified individuals who have sex with heterosexually identified men in South-East Asia<sup>25</sup> and, to some extent, in Latin America.<sup>26</sup> Sexual risks as well as risk reduction options are different for those subgroups, i.e. risks associated with receptive anal intercourse are higher than those associated with insertive anal intercourse.<sup>9, 27</sup> Likewise, condom use is more often controlled by the insertive partner, particularly if gender or power dynamics impede the negotiation of condom use by the receptive partner.<sup>9, 28</sup>

Programming for MSM and transgender people therefore implies recognizing and understanding their diversity, and identifying the needs of specific subgroups. Sensitive programming consists of using an appropriate combination of strategies and approaches, and prioritizing those groups most in need without neglecting the others, in order to effectively reach universal access.

### **Why this document is needed**

Despite the strong impact of the HIV epidemic on MSM and transgender people, to date, no technical recommendations have been made to guide health systems' response to the epidemic among them. In September 2008, the World Health Organization (WHO) held a global consultation on "Prevention and treatment of HIV and other sexually transmitted infections (STI) for men who have sex with men and transgender populations", in Geneva, Switzerland.<sup>29</sup> Recommendations from that global consultation, as well as from WHO regional consultations,<sup>30, 31, 32</sup> called for the need to develop guidance for delivering an evidence-based, package of interventions for implementation by the health sector to prevent and treat HIV and other STIs among MSM and transgender people.

The development of these guidelines was deemed necessary for numerous reasons, inclusive of the following:

1. Despite the high disease burden, the global response to HIV among MSM and transgender people is insufficient.
2. WHO is often asked at the regional and country levels for guidance on appropriate public health recommendations for the prevention and treatment of HIV and other STIs among MSM and transgender people, particularly in recent years, as interest has increased in responding to their needs and funding such a response.
3. While substantial controversy remains concerning the quality and appropriateness of various HIV/STI prevention and care interventions for MSM and transgender people, no systematic analysis of interventions available at various levels has been conducted to date.

In consideration of this, the 2009 UNAIDS *Action Framework: universal access for men who have sex with men and transgender people* established the role of WHO in providing technical guidance for the health sector response.<sup>15</sup>

This guidance will provide a broad framework for action to ensure an enabling environment and a set of evidence-based recommendations.

## 2. SCOPE OF THE GUIDELINES

The scope of these guidelines focuses on the prevention and treatment of HIV and other STIs among MSM and transgender people. They include evidence-based recommendations, the summary and grading of evidence, implementation issues and key research gaps. Although the focus of this guidance is on low- and middle-income countries, WHO recommends that this guidance be available for MSM and transgender people in high-income countries as well.

This document presents two *good practice recommendations* that focus on ensuring an enabling environment for the recognition and protection of the human rights of MSM and transgender people. Without such conditions, implementation of the more specific technical recommendations is problematic.

The first set of specific technical recommendations is focused on *prevention of sexual transmission*. Evidence was reviewed on the effectiveness of consistent condom use for anal sex. This document also discusses evidence on the effectiveness of serosorting for HIV risk reduction, one of several sero-adaptive behaviours that involves the selective practice of unprotected anal sex with some partners based on concordant HIV serostatus and on male circumcision.<sup>33</sup>

The second set of recommendations focuses on HIV testing and counselling (HTC), which should be regarded as a public health intervention to increase access to care and treatment. The recommendations also emphasize the synergies between treatment and prevention.

The third set of recommendations focuses on information, education and communication to promote protected sex, HTC and/or disclosure of serostatus, whenever applicable, in connection with increased access to HIV care. Evidence is reviewed on behavioural interventions (at the individual and community level). Finally, the use of novel communications strategies (i.e. internet-based programmes, social marketing and sex venue-based outreach) to reach those same goals is also addressed.

The fourth set of recommendations focuses on additional HIV prevention strategies, in relation to substance use (including mental health as well as harm reduction interventions) and safe injections for transgender people.

The fifth set of recommendations focuses on MSM and transgender people living with HIV, and addresses HIV care and treatment, and other prevention and care interventions.

Finally, the sixth set of recommendations addresses the prevention and care of STIs, including the application of specific aspects of syndromic STI management including an anal infection management algorithm, standard testing procedures to detect asymptomatic bacterial anal and urethral infections, and vaccination against hepatitis B.

## 3. GUIDING PRINCIPLES

### **The public health approach**

The public health approach includes the systematic use of strategic information and epidemic control to ensure a reduction in the spread of HIV. It should be beneficial for the most affected groups and other members of the population. A public health approach is focused and provides responses according to the location, magnitude and trends of the HIV epidemic. The agencies, actors and professionals who impact the HIV prevention needs of MSM and transgender people are many and varied. This document can increase the collective capacity to improve prevention, treatment and care outcomes at various individual, community and societal levels.

### **Human rights framework**

The overall framework for the development of these guidelines was provided by the UNAIDS *Action Framework: universal access for men who have sex with men and transgender people*, which is based on broad human rights principles reflected in a number of international agreements.<sup>15</sup>

### **Comprehensive health**

As these guidelines focus on the prevention and treatment of HIV and STIs, they depart from a principle of comprehensive health care.<sup>16</sup> This is particularly important in the context of social exclusion of MSM and transgender people, for whom only HIV/STI services are available in some places; they remain excluded from access to other services, or such access is hampered by pervasive stigma, discrimination and criminalization.<sup>34</sup> The HIV epidemic has helped health systems to recognize the existence of MSM and transgender people, and respond to their HIV/STI needs. However, both populations have a variety of health needs that should be addressed, including concerns regarding mental health and emotional well-being.

This guidance focuses on HIV and STI prevention and treatment, and addresses other related health issues in accordance with the mandate that led to its development by WHO. Health systems should take into account the need for integration of HIV/STI services and activities into other health services in order to ensure that total and complete “health for all” is also achieved for these groups and populations.

### **Sexual health**

WHO defines sexual health as: “...a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safer sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled”.<sup>35</sup>

While these guidelines are focused on HIV/STI prevention and treatment among MSM and transgender people, they understand HIV/STI activities as framed within a sexual health approach. This is particularly relevant for MSM and transgender people, whose sexual rights are often not respected, let alone protected and fulfilled, in many parts of the world.<sup>10</sup>

## 4. OBJECTIVES AND TARGET AUDIENCE

The objective of this document is to provide technical recommendations on the prevention and treatment of HIV and other STIs among MSM and transgender people. The guidelines are designed for use by national public health officials and managers of HIV/AIDS and STI programmes, nongovernment organizations (NGOs) including community and civil society organizations, and health workers. These guidelines may also be of interest to international funding agencies, the scientific media, health policy-makers and advocates.

It is particularly important to base responses on technical recommendations, as many stakeholders have begun to recognize the need to address the epidemics among MSM and transgender persons more seriously, including those occurring in the context of generalized epidemics. The production of this document will be followed by efforts to disseminate its main messages as well as strategies for local discussion, piloting, adaptation and training, where appropriate and/or necessary.

## 5. METHODOLOGY AND PROCESS

### 5.1 GRADE framework

WHO uses the GRADE approach for the development and review of recommendations.<sup>36</sup> The initial steps entailed identifying key topics, formulating the Population, Intervention, Comparison and Outcomes (PICO) questions (Annex 1)\*, scoping the literature to identify if evidence reviews exist or recent evidence can be assessed, formulation of a comprehensive search strategy (Annex 3)\*, and identification and retrieval of relevant evidence, including benefits and harms.<sup>37</sup>

The first step of the GRADE approach for this guidance was to grade the quality of evidence for each PICO question by outcome.<sup>38</sup> This entailed consideration of study limitations, inconsistency, indirectness, imprecision and other limitations.<sup>39</sup> The quality of the evidence was then graded as high, moderate, low or very low (Annex 4)\*. A standardized table, the GRADE evidence table, presents the quantitative summary of the evidence and the assessment of its quality (Annex 5)\*. The choice of important outcomes should be independent of whether or not they have been empirically assessed, while the choice of intermediate outcomes should capture those that have been empirically assessed (Annex 2)\*.

The second step of the GRADE approach was to move from “evidence to recommendation” for each of the PICO questions. This included consideration of the quality of evidence, balance of benefits and harms, community values and preferences, and resource use. These factors affected both the recommendation’s direction (for or against) and its strength (strong or conditional). The risk–benefit tables summarize these factors (Annex 6)\*.

An outcome framework was developed to ensure that outcomes were selected in a transparent and comprehensive manner and *a priori* (i.e. prior to reviewing the evidence). Each framework describes all possible pathways starting with the intervention, going through the intermediate outcomes and leading to the important outcomes (Annex 2)\*.

Good practice recommendations are also included in the framework. A good practice recommendation is a type of recommendation that does not require supporting evidence and thus its development does not follow the above-described process of rating the quality of evidence or grading the strength of the recommendations.<sup>36</sup>

### 5.2 Process

The WHO Department of HIV/AIDS led the development of the guidelines under the oversight of the WHO Guideline Review Committee (GRC) in collaboration with the Department of Reproductive Health and Research as well as other WHO Departments, the United Nations Development Programme (UNDP) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

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\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

A WHO Guidelines Working Group identified PICO questions, developed search protocols and conducted systematic reviews of the available scientific evidence (Annexes 1, 3, 5–7). The WHO Guidelines Working Group included public health experts, researchers, programme managers, implementers, civil society representatives and GRADE methodologists. Appropriate geographical and gender representation was considered. Search protocols are included in Annex 3, and the full final list of PICO questions is included in Annex 1. Working group meetings were held in Washington, DC, hosted by the Pan American Health Organization, and in Geneva, Switzerland hosted by WHO Headquarters. The Guidelines Consensus Meeting in Beijing, China, was hosted by the Office of the WHO Representative to China and the WHO Western Pacific Regional Office.

A study, commissioned to the Global Forum on MSM and HIV (MSMGF), assessed community values and preferences concerning the 13 PICO questions. The participants were MSM and transgender people from all regions, inclusive of persons living with HIV.

The initial ranking of the evidence for each PICO question was collectively done by the WHO Working Group that conducted the systematic reviews. These were presented and discussed at the final consensus meeting in Beijing. At this meeting, the multidisciplinary expert panel assessed the evidence, values and preferences, and risks and benefits for each recommendation. The expert panel determined the direction of the recommendations and strength of the evidence (Annex 4). All decisions were reached by unanimous consensus. Only in one case (i.e. group-level behavioural interventions) consensus was not reached and, therefore, as per the regulations of the GRC, no recommendation was formulated. The coordinators of the process incorporated comments from internal and external peer reviewers to finalize the guidelines.

A revision of these guidelines is planned for 2015, before which plans will be developed for quality evaluation of the guidelines, their usefulness and impact.

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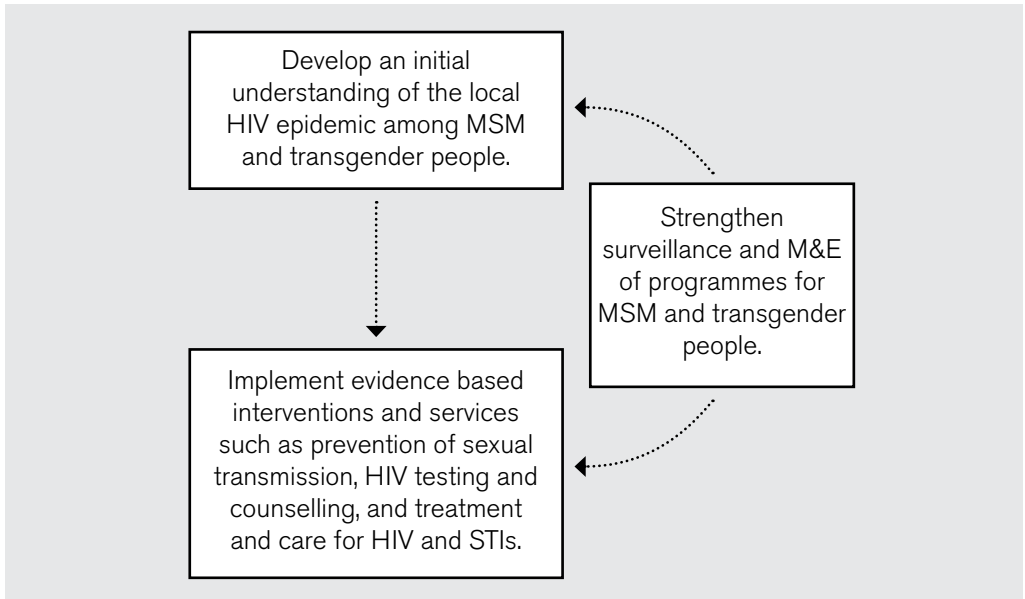
\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).



## 6. ADAPTING THE GUIDELINES

In order to have the desired impact on reducing stigma, discrimination, and HIV and STI transmission, as well as ensure timely access to treatment and comprehensive care, the recommendations included in these guidelines must be implemented at the national level. A national alliance composed of government, civil society, NGOs and donors is crucial to attain this objective. The aim should be to include these recommendations in the national HIV/AIDS plans and allocate resources for their implementation. Simultaneously, technical assistance to countries is necessary to plan and foster implementation.

**Figure 1.** Steps for a phased-in approach to implementation



Regions and countries are at different stages of addressing the epidemic among MSM and transgender people. Adoption and adaptation of the recommendations will need to reflect the national context (Figure 1). Immediate and full implementation of some of these recommendations may not be feasible due to limited resources and varying priorities, based on the reported prevalence of HIV and its burden among MSM and transgender people. However, country-level strategic planning should be directed towards eventually implementing all recommendations and achieving national universal access to HIV prevention, care and treatment for MSM and transgender people.

The implementation process should be based on epidemiology and the local context of the epidemic, in line with the national strategy, and be inclusive of all partners. It should also clearly define what the implications are for each recommendation.

In countries where the vulnerability of MSM and transgender people is not recognized, the first step in implementing these guidelines should be to raise awareness among all involved national partners regarding the need to take these recommendations into account.

The process to include the recommendations in national plans should begin with a review of epidemiological and response data and national-level needs assessments. It should take into account regional and national documents, as well as initiatives. Harmonization with ongoing activities and a step-by-step approach is advisable. Depending on the regional situation, multicountry workshops to promote the guidelines, assess needs and draft amendments of national plans are recommended to start the process.

National working groups might consider the following guiding principles to direct decision-making when introducing these recommendations.

### **1. Do no harm**

Consider the existence of prohibitive legal frameworks, criminalization, stigma and discrimination, and avoid situations that affect confidentiality or put people at risk for violence.

### **2. Ensure accessibility and equity**

Strive to make appropriate services accessible and affordable for all MSM and transgender people, irrespective of sexual identity, geographical location, age or social class.

### **3. Ensure quality of care**

Ensure that care achieves the highest standards possible.

### **4. Make efficient use of resources**

Aim to achieve the greatest health impact with the optimal use of available human and financial resources.

### **5. Ensure sustainability**

Aim to build services that are not dependent on temporary funding sources. Develop a strategy to secure their sustainability after the inception phase.

### **6. Strengthen health systems**

Priority should be given to interventions that will directly or indirectly strengthen health systems, including those developed by communities and civil society organizations.

## **7. Implement in phases**

It may not be possible to implement each recommendation in all settings. A phased-in approach may be necessary. A phased-in approach involves the following steps:

- Develop an initial understanding of the local HIV epidemic among MSM and transgender people.
- Implement interventions and services such as prevention of sexual transmission, behavioural interventions, HTC, ART and STI services (Figure 2).
- Strengthen surveillance and monitoring and evaluation of programmes for MSM and transgender people.
- Introduce additional strategies using the public health approach to address legal and structural barriers to universal access to health.

## **8. Understand the perspectives of MSM and transgender people**

Involve community representatives and members of MSM and transgender people groups in the implementation of these services to ensure that they are culturally appropriate and meet the community's needs. Strengthen community systems, including support to community-based civil society organizations. Whenever possible, use ethnographic procedures to better understand the local context, and pilot the new interventions to ensure that they work as planned.

## **9. Be forward-looking**

These WHO guidelines will be updated in 2015. Member States should strive to adopt the 2011 recommendations before that date.

**Figure 2.** Framework for implementing interventions for MSM and transgender persons



## 7. GOOD PRACTICE RECOMMENDATIONS\*

### *Definition*

Good practice recommendations are overarching principles derived not from scientific evidence but from common sense and established international agreements on ethics and human rights.<sup>34</sup> These recommendations are not the result of the formal GRADE process. However, they do represent expert opinion as outlined in the document *International guidelines on HIV/AIDS and human rights. 2006 Consolidated version*.<sup>34</sup>

Good practice recommendations are considered essential for clarifying or contextualizing specific technical recommendations. They are particularly important when change needs to be implemented in environments that can be hostile or negative, such as those involving MSM and transgender people. Given the prevalence of stigma and discrimination in relation to sexual and gender diversity in many parts of the world, as well as the existence of legal barriers to the inclusion of MSM and transgender people in receiving governmental services, the Guidelines Development Group found it necessary to include two good practice recommendations in this guideline: one oriented to national policy and the other specifically focused on the health sector.

### *Background*

MSM and transgender people are entitled to full protection of their human rights as stated in the Yogyakarta Principles.<sup>41</sup> These include the rights to the highest attainable standard of health, non-discrimination and privacy. Punitive laws and law enforcement practices, stigma and discrimination undermine the effectiveness of HIV and sexual health programmes, which limits their ability to reach MSM and transgender people.

Criminalization, and legal and policy barriers play a key role in the vulnerability of MSM and transgender people to HIV. More than 75 countries currently criminalize same-gender sexual activity,<sup>42</sup> and transgender people lack legal recognition in most countries. These legal conditions force MSM and transgender people to risk criminal sanctions if they want to discuss their level of sexual risk with a service provider, and also give police the authority to harass organizations that provide services to these populations. The promotion of a legal and social environment that protects human rights and ensures access to prevention, treatment, care and support without discrimination or criminalization is essential for achieving an effective response to the HIV epidemic and promoting public health.

Long-standing evidence indicates that MSM and transgender people experience significant barriers to quality health care due to widespread stigma against homosexuality and ignorance about gender variance in mainstream society and within health systems.<sup>43, 44, 45</sup> In addition to being disproportionately burdened by STI and HIV, MSM and transgender people experience higher rates of depression, anxiety, smoking, alcohol abuse, substance use and suicide as a

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\* These recommendations are adapted from the UNAIDS/Office of the United Nations High Commissioner for Human Rights (OHCHR) document, *International guidelines on HIV/AIDS and human rights. 2006 Consolidated version*.<sup>34</sup>

result of chronic stress, social isolation and disconnection from a range of health and support services.<sup>46, 47, 48, 49, 50, 51, 52, 53, 54, 55</sup>

From a health systems' perspective, MSM and transgender people may delay or avoid seeking health, STI or HIV-related information, care and services as a result of perceived homophobia, transphobia, ignorance and insensitivity. MSM and transgender people may be less inclined to disclose their sexual orientation and other health-related behaviours in health settings that may otherwise encourage discussions between the provider and patient to inform subsequent clinical decision-making. Providers are likely to feel biased when their own cultural, moral or religious leanings are incongruent with a patient's reported sexual orientation, behaviours or gender identity. Additionally, enquiry into the level of knowledge among training physicians, nurses and other health-care providers on MSM and transgender-related health issues has shown that the clinical curriculum, particularly in low- and middle-income countries, do not address these knowledge gaps.

**Recommendation 1:  
Human rights and inclusive environments**

Legislators and other government authorities should establish and enforce antidiscrimination and protective laws, derived from international human rights standards, in order to eliminate stigma, discrimination and violence faced by MSM and transgender people, and reduce their vulnerability to infection with HIV and the impacts of HIV and AIDS.<sup>34</sup>

Safe and inclusive public services, and the underlying principle of non-discrimination are vital for the community's health, well-being and dignity. Policy-makers, parliamentarians and other public leaders should work together with civil society organizations in their efforts to confront the realities of discrimination against MSM and transgender people, and transform punitive legal and social norms towards those that are protective. Stigma and discrimination create barriers to many public services and, as such, undermine public health, human rights and the response to HIV.

## **Recommendation 2: Non-discrimination in health-care settings**

Health services should be made inclusive of MSM and transgender people, based on the principles of medical ethics and the right to health.<sup>34</sup>

Creating inclusive health services requires strategies to sensitize and educate providers and other staff members in health-care and social service settings. Health providers should be respectful of diversity, aware of their professional obligations, and informed of the specific health and social needs of MSM and transgender people. Men's health groups and organizations of MSM and transgender people can be essential partners in delivering comprehensive training on human sexuality. They also can facilitate interaction with members of sexually diverse communities, thereby generating greater understanding of their emotional, health and social needs, and the cost of inaction against homophobia and transphobia. Policy-makers, parliamentarians and other public leaders should work together with civil society organizations in their efforts to confront the realities of discrimination against MSM and transgender people, and transform punitive legal and social norms towards those that are protective and enforced.

## 8. EVIDENCE AND TECHNICAL RECOMMENDATIONS

### 8.1. Prevention of sexual transmission

#### 8.1.1. Consistent condom use

##### *Background*

Condoms have played a vital role in preventing the sexual transmission of HIV since the early days of the epidemic.<sup>56</sup> Since the mid-1980s, it has been shown that condom use contributes to HIV prevention among MSM communities in the United States and Western Europe, which, in part, was due to community mobilization recommending condom use.<sup>57, 58</sup> Observational evidence of the effectiveness of consistent condom use in preventing HIV transmission has increased in past years.<sup>59, 60, 61</sup> A review was conducted of the evidence on the effectiveness of consistent condom use in preventing HIV infection among MSM and transgender people.

##### *Evidence*

The evidence was primarily from cohort studies of MSM and transgender people in developed countries.<sup>33, 62, 63, 64, 65</sup> Five studies with information on condom use and HIV and/or STI incidence among MSM were included. The search strategy (Annex 3)\* focused on cohort studies with HIV and STI acquisition as an outcome of interest (Annex 2)\*. Studies with behavioural outcomes such as self-reported condom use instead of biological outcomes were excluded. All of the evidence came from observational studies and was therefore rated down; however, the high effect size for the HIV incidence outcome allowed the evidence to be rated up. This yielded moderate evidence for the HIV incidence outcome and low evidence for the STI incidence outcome. Although the studies included did not control for confounding, there was no downgrading for this omission, as it is believed that controlling for confounding would have increased, not diminished, the strength of the effect.

##### *Summary of findings*

The systematic evidence review included information on two outcomes of interest: HIV incidence (five studies) and STI incidence (one study). The overall relative effect of condom use on HIV transmission was relative risk (RR): 0.36 (95% confidence interval [CI]: 0.20–0.67), and for STI transmission it was RR: 0.58 (95% CI: 0.54–0.62). Consistent condom use was found to reduce HIV transmission by 64%. For STI transmission, consistent condom use was found to reduce the risk by 42%.

##### *Benefits and risks*

The benefits outweighed any potential risks of using condoms.

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\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).



### *Acceptability and feasibility*

This recommendation is strong, given the support of values and preferences of the community and experts. The preliminary report of values and preferences stated that, “MSM believe condoms are useful for prevention and many advocate their distribution.” There was no evidence available on issues of quality of life such as inconvenience or decreased desire; however, the values and preferences of the MSM polled by MSMGF showed support for this intervention.<sup>66</sup> There is programmatic evidence that the distribution of condoms in low- and middle-income country settings is feasible.<sup>67, 68</sup>

### *Additional points of discussion and research directions*

Evidence from operations research points to the importance of water- and silicone-based lubricant use for the correct functioning of condoms during anal sex.<sup>69</sup> However, more research on this topic would be useful and should be conducted to rule out or minimize potential secondary effects, which have been shown in in vitro studies.<sup>70, 71, 72</sup>

There is limited information on the following, which should be considered as future areas for research: the efficacy of the female condom in preventing HIV acquisition during anal sex and its efficacy in preventing HIV among transgender people who have had vaginal construction.

### *Key points*

- Consistent condom use has been vital to HIV prevention efforts since the early days of the epidemic.
- Consistent condom use was found to reduce HIV transmission by 64% and STI transmission by 42%.
- The benefits outweighed any potential harms of using condoms
- Acceptable and feasible

## Recommendation

**Using condoms consistently during anal intercourse is strongly recommended for MSM and transgender people over not using condoms.**

*Strong recommendation, moderate quality of evidence*

### **Complementary remarks**

Water- and silicone-based lubricant use is key for the correct functioning of condoms during anal sex.

## 8.1.2. Serosorting

### *Background*

Serosorting is defined as a behaviour in which “a person chooses a sexual partner known to be of the same HIV serostatus, often to engage in unprotected sex, in order to reduce the risk of acquiring or transmitting HIV”.<sup>73</sup> The prevalence of serosorting ranges from 21% to 62% for HIV-positive and HIV-negative MSM, respectively; however, most studies on serosorting are based on research in developed countries.<sup>74</sup> The benefits of serosorting for HIV-positive individuals may include reduced secondary HIV transmission and the ability to forgo condom use. However, serosorting does not protect against other STIs and potential risks such as HIV superinfection and drug resistance. The benefits for HIV risk reduction among HIV-negative individuals are still under debate and depend on the frequency and availability of HTC, accurate knowledge and disclosure of HIV serostatus among both partners, and the window period for new infections.

### *Evidence*

The evidence included was collected via a systematic review of available evidence on serosorting and seroadaptive behaviours. The systematic review had broad inclusion criteria and used systematic search and screening criteria. Only evidence among HIV-negative individuals was considered for this question. The review of the evidence yielded three studies, all from developed countries.<sup>33, 64, 65</sup> All three of these studies defined serosorting among HIV-negative men as unprotected anal intercourse with HIV-negative partners only. Most of the studies did not control for confounding.

The conditionality of the recommendation is due to the low quality of evidence available and geographical restriction of the studies. The evidence was rated down for indirectness because all studies were conducted in high-income settings where HTC is widely available, unlike in many low- and middle-income settings.

### *Summary of findings*

The systematic evidence review included information on two outcomes of interest, HIV incidence (three studies) and STI incidence (one study). There were two comparisons of interest: serosorting versus consistent condom use and serosorting versus no condom use. The overall finding for serosorting versus consistent condom use was that serosorting leads to a significantly increased risk of both HIV and STI infection. Serosorting increased HIV transmission by 79% and increased STI transmission by 61% (RR: 1.79, 95% CI: 1.2–2.65; and RR: 1.61, 95% CI: 1.43–1.81, respectively). When serosorting was compared with no condom use, serosorting provided some protection against HIV and STI infection. Serosorting reduced HIV transmission by 53% (RR: 0.47, 95% CI: 0.26–0.84) and reduced STI transmission by

14% (RR: 0.86, 95% CI: 0.78–0.93). No considerations regarding quality of life such as inconvenience or decreased sexual desire were studied.

### *Benefits and risks*

The benefits and risks of serosorting depend on the comparison used. The risks outweighed the benefits when compared with condom use. When compared with no condom use, the benefits outweighed the risks.

Although serosorting is beneficial when compared with no condom use, there are risks when compared with consistent condom use. Serosorting may be a potential harm reduction strategy for individuals who choose not to use condoms, but it should not be promoted as an alternative strategy for HIV prevention. Consistent condom use is a more effective method to prevent HIV infection.

### *Acceptability and feasibility*

The report on values and preferences among the community yielded differing opinions on serosorting. The report stated, “MSM believe condoms are useful for prevention and many advocate their distribution”. Additionally, it stated “Serosorting was not recognized as a prevention strategy by any participant.”<sup>66</sup>

For some participants in the values and preferences survey, the construct of serosorting did not exist. For others, it led to conversations about the conditions under which MSM and transgender people do or do not disclose HIV status. Concerns regarding safety, stigma and discrimination contributed to non-disclosure of HIV status for many. However, serosorting was reported as a harm reduction strategy by others. Although the panel recognized that individual values around serosorting might vary, emphasis was placed on preventing HIV infection. Condom use is the best option, but this depends on their availability. Serosorting is feasible only in contexts where quality HTC is available, HIV retesting rates are high, and the legal and social environment is supportive of HTC and serostatus disclosure.<sup>66</sup>

### *Additional points of discussion and research directions*

Seroadaptive behaviours encompass a variety of behaviours, including serosorting and seropositioning. Only information on serosorting (the practice of choosing a sex partner with the same HIV status) among MSM who were HIV negative at the beginning of the study was included in this evidence profile. No information was included on the practice of seropositioning (choosing which partner will be the receptive or insertive partner based on HIV serostatus, with the HIV-positive partner generally acting as the receptive partner). No information was included in this review on the serosorting practices among MSM and transgender people who know that they are HIV positive.

Individuals and couples using serosorting as a harm reduction strategy need to be screened regularly for HIV and STIs. Moreover, HTC offered to MSM and transgender people should address facts about serosorting, explain its utility and limitations for prevention, and clarify misconceptions that might increase such limitations further among potential users. There is a need for increased availability of high-quality condoms and high-quality HTC in all settings, especially in low- and middle-income countries. There is also a need for additional research on serosorting for MSM and transgender people and their sexual partners.

*Key points*

- Serosorting is defined as “a person choosing a sexual partner known to be of the same HIV serostatus, often to engage in unprotected sex, in order to reduce the risk of acquiring or transmitting HIV”.
- Serosorting increased HIV transmission by 79% and increased STI transmission by 61%. When compared with no condom use, the benefits outweighed the harms. Serosorting reduced HIV transmission by 53% and reduced STI transmission by 14%.
- The risks of serosorting outweigh the benefits when compared with consistent condom use. When compared with no condom use, the benefits of serosorting outweigh the harms.
- Acceptability and feasibility depend on the individual and the setting. Serosorting is feasible only in contexts where quality HTC is available, HIV retesting rates are high, and the legal and social environment is supportive of HTC and serostatus disclosure.

## Recommendations

**Using condoms consistently is strongly recommended over serosorting for HIV-negative MSM and transgender people.**

*Strong recommendation, very low quality of evidence*

**Serosorting is suggested over not using condoms by HIV-negative MSM and transgender people under specific circumstances as a harm reduction strategy.**

*Conditional recommendation, very low quality of evidence*

### **Complementary remarks**

Individuals and couples using serosorting as a harm reduction strategy need to be screened regularly for HIV and STIs. There is a need for additional research on serosorting for MSM and transgender people and their sexual partners.

### 8.1.3. Male circumcision

#### *Background*

Over the past three decades, a set of observational studies and three randomized controlled trials have shown that male circumcision performed by well-trained medical professionals reduces the risk of female-to-male HIV transmission by half.<sup>75, 76, 77, 78</sup> Since these studies were conducted among males presumably exposed via vaginal intercourse, and only in sub-Saharan African countries, the effects cannot be directly applied to MSM and transgender people who are exposed through receptive and insertive anal intercourse. A review was undertaken of evidence concerning the efficacy of male circumcision in preventing HIV acquisition among MSM.\*

#### *Evidence*

Two reviews on male circumcision for the prevention of HIV among MSM were published in 2008,<sup>79, 80</sup> which included data from observational studies. Since then, six new observational studies have been published. A total of 21 studies with usable data on circumcision among MSM were finally included. The quality of the outcomes was assessed as critical for the HIV outcome, and the overall quality of evidence was judged to be very low, mostly because no data for MSM were available from randomized controlled trials. No studies on circumcision among transgender people were identified.

#### *Summary of findings*

The systematic evidence review<sup>81</sup> included information on three specific HIV and STI outcomes of interest: HIV infection (20 studies), syphilis (eight studies) and herpes simplex virus (HSV) infection (seven studies). All of the evidence came from observational studies and was therefore rated down. While the overall relative effect of male circumcision on HIV transmission among MSM was OR 0.86 (95% CI: 0.70–1.06), differences were primarily based on predominant sexual roles in anal sex. Among males who practised primarily receptive anal sex, there was no relation between circumcision and HIV infection (OR: 1.20, 95% CI 0.63–2.29). Among those who engaged mostly in insertive anal sex, circumcision was associated with a protective effect for HIV infection (OR: 0.27, 95% CI: 0.17–0.44). The findings were similar for other STIs.

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\* The review did not look at the efficacy of male circumcision in preventing HIV acquisition among transgender people.

### *Benefits and risks*

The evidence included suggests a potential benefit of adult male circumcision for the prevention of both HIV and other STIs. The benefits therefore potentially outweigh the harms.

As with any surgical procedure, male circumcision carries some risks, which generally occur during or soon after the procedure. The surgery can lead to bleeding, haematoma formation (a blood clot under the skin), infection of the surgical wound, meatitis (inflammation of the opening of the urethra), and increased sensitivity of the glans penis during the initial months after the procedure. The safety of male circumcision depends on the setting and expertise of the provider.<sup>82</sup>

### *Acceptability and feasibility*

As per the preliminary report on values and acceptability,<sup>66</sup> with regard to adult male circumcision as an HIV prevention strategy, participants raised questions about the relevance of circumcision in different cultural settings, its adequacy in protecting against HIV infection and relevance to transgender people. Some felt that the focus should be on education on sexual health rather than circumcision. Significant concerns were expressed regarding the feasibility of implementing a surgical intervention, especially within an already stigmatized population.

### *Additional points of discussion and research directions*

This recommendation does not apply to transmen who have undergone sexual reassignment surgery. Significant resources are needed for male circumcision in settings where it is not a standard intervention (both specialized human resources in surgical techniques as well as surgical equipment and supplies); therefore, there was significant concern regarding its potential implementation. Further research is needed to examine the effect of adult male circumcision in preventing HIV and STI acquisition among MSM who practise insertive versus receptive anal intercourse, as this is likely to be an effect modifier. In settings where circumcision is being scaled up, MSM and transgender people should not be excluded from adult male circumcision programmes. In other settings, as per existing WHO recommendations,<sup>83</sup> individual MSM or transgender people who request this intervention should not be denied it.

### *Key points*

- Over the past three decades, a set of observational studies and three randomized trials have shown that male circumcision reduces the risk of HIV acquisition of males from females by half. Some observational studies have shown that male circumcision could also protect MSM engaging in insertive anal sex. There are no similar studies on transgender persons.
- Male circumcision was associated with a protective effect only in those MSM who practised insertive sex. No protective effect was seen among those who practised receptive sex.
- It is not clear if the benefits outweigh the risks at this point in time, as male circumcision, like any other operation, carries some risks.

- There are significant concerns regarding its acceptability and implementation among MSM in different cultural settings.

## Recommendations

**Not offering adult male circumcision to prevent HIV and STI acquisition is suggested over offering it to MSM and transgender people.**

*Conditional recommendation; very low quality of evidence*

### **Complementary remarks**

Further research is needed to examine the effect of adult male circumcision on preventing the acquisition of HIV and STIs among MSM who practise insertive versus receptive anal intercourse.

## **8.2. HIV testing and counselling\***

### **8.2.1 HIV testing and counselling**

#### *Background*

Since the HIV test became available, HTC, as initiated by users, has been considered a key intervention for HIV prevention. Few studies have assessed the efficacy of HTC. In recent years, as part of the commitment to universal access for HIV prevention and care, the broader concept of HTC has evolved to include client-initiated testing and counselling and provider-initiated testing and counselling.<sup>84</sup> HTC has been incorporated with efforts to promote testing and counselling, along with direct links to HIV care and treatment for those testing positive. Given the role of stigma and potential harms associated with presumed HIV infection, it is essential that all HTC remains voluntary and confidential.

Because people may continue to engage in high-risk practices (and become infected after completing an HIV test) or engage in a high-risk sexual event within three months prior to an HIV test (and experience an acute infection yielding a negative result from the HIV antibody test), current WHO guidance recommends that individuals should be recommended to retest after three months.<sup>85</sup>

A systematic literature search was conducted on the role of HTC in reducing HIV-related morbidity and mortality, compared with the provision of basic information on HIV prevention and care. The surrogate outcomes were behavioural change and HIV incidence.

\* In this guide, the term HIV testing and counselling (HTC) refers to all services addressing HIV testing provided with counselling. Different countries may use different terms for HTC carried out in various settings. Examples of these terms include, but are not limited to, voluntary counselling and counselling (VCT), provider-initiated testing and counselling (PITC) and client-initiated testing and counselling (CITC). WHO advises that all HTC be voluntary and never coerced or mandatory.

### *Evidence*

Information from one controlled trial was included, which tested the effects of the target intervention (individual HTC) on the HIV outcome (reported unprotected anal intercourse as a surrogate of HIV infection) in heterosexual men.<sup>66</sup> The strength of this recommendation is based on low-quality evidence. The quality was downgraded because of the indirectness of the outcome (use of surrogates), indirectness of the study population (heterosexual men instead of MSM or transgender people) and significant loss to follow up (about 20% in 14 months).

### *Summary of findings*

The only randomized trial<sup>66</sup> comparing the effect of HTC to the provision of standard health information on reported unprotected intercourse, a surrogate outcome, used the U.S. Centers for Disease Control and Prevention's (CDC) client-centred HIV-1 counselling model. This model included a personalized risk assessment plus the development of a personalized risk reduction plan for each client, and was ideal for promoting cultural specificity. The study was carried out in three sites: Kenya, Tanzania and Trinidad. Among a subset of heterosexual men with non-stable partners, there was a 21% reduction in risk behaviour among those undergoing HTC (RR: 0.79, 95% CI: 0.63–0.97).

### *Benefits and risks*

It was judged that the benefits outweigh the risks because of the high sensitivity and specificity of the HIV tests and the increasing importance of this intervention, given the opportunity for earlier diagnosis and access to care, as well as the preventive effects of treatment. The potential harms include psychological distress, which can be managed. The use of resources is not a key concern since HTC is a standard intervention already in place in many settings.

### *Acceptability and feasibility*

According to the study of community values and preferences, people value the importance of HTC, but feel that adequate conditions for service provision have to be provided, i.e. inclusive, non-discriminatory services.<sup>66</sup> The feasibility of implementing HTC does not seem to be a major issue since it is already offered to the general population in many settings in low-, middle- and high-income countries. However, the quality of HTC needs to be assured.

### *Additional points of discussion and research directions*

HTC should be linked to care and treatment. Reduced population-level transmission rates may result from higher treatment coverage, which can foster a change in the public view regarding HTC. Additionally, the roles of couples' counselling and ART use for serodiscordant MSM and transgender people couples should be studied.<sup>67</sup>



### Key points

- Since the HIV test became available, HTC has been considered a key intervention for HIV prevention.
- There was a 21% reduction in risk behaviour among those undergoing HTC.
- The benefits outweigh the risks. The use of resources is not a concern since HTC is a standard intervention in most settings.
- Acceptable and feasible.

## Recommendation

**Offering HIV testing and counselling to MSM and transgender people is strongly recommended over not offering this intervention.**

*Strong recommendation, low quality of evidence*

### Complementary remarks

HTC should be linked to care and treatment.

## 8.2.2. Community-based HIV testing and counselling linked to care and treatment

### Background

This recommendation focuses on providing community-based HTC linked to care and treatment. The desired result is to increase community HTC levels and link those who test positive for HIV with treatment and care services. Community-based HTC linked with care and treatment focuses on the active promotion of HTC accompanied by expedited access to care and treatment. The effects of community-based HTC programmes were assessed and compared with client-initiated HTC.

### Evidence

There are no pre-existing systematic reviews or trials on community-based HTC programmes. Only one observational study was found, based on the U.S. CDC's 2006 recommendations for routine, voluntary HTC in health-care settings as implemented in Washington, DC, USA.<sup>88</sup> The intervention studied was "HTLC+" which stands for "HIV testing, linkage to care plus treatment" and encompasses active promotion of routine HTC, improved referral for HIV-positive persons and initiation of treatment according to current guidelines as implemented for residents of Washington, DC, USA. Aggregate indicators for the years 2004, 2006 and 2008 (partially) were included, reported and analysed for the outcomes of interest. As of September 2010, a trial to assess the feasibility of a community-based HTC programme linked to care and treatment is in preparation.<sup>89</sup> The quality of this evidence was rated as very low since it came from only one observational study.

### *Summary of findings*

The reported outcomes included the rate of newly diagnosed AIDS cases, which decreased consistently from 164 cases per 100 000 in 2004 to 137 in 2007 and 107 in 2008; the proportion of the population tested for HIV within the past 12 months, which increased from 15% to 19%; and the overall proportion of persons newly diagnosed with HIV who had a CD4 count within three months of diagnosis, which increased from 62% in 2004 to 64% in 2008. The study did not include a control group and did not estimate any measure of effect.<sup>88</sup>

### *Benefits and risks*

Although HTC can increase the risk for stigma, the potential benefits outweigh the risks.

### *Acceptability and feasibility*

According to the study on values and preferences, communities value testing and counselling and, increasingly, value earlier access to care and treatment. However, concern regarding stigma and discrimination, as well as mistreatment, and the limited capacity of health-care personnel to manage issues pertinent to MSM and transgender people was expressed.<sup>66</sup> Scaling up HTC linked to care and treatment should be done with regard to sustainability. If additional costs are met, implementing community-based HTC linked to care and treatment should be highly feasible in most settings.

### *Additional points of discussion and research directions*

The evidence to support this recommendation is based on one observational study. A trial of treatment linked to care-plus has been under preparation since September 2010 and aims to assess the feasibility of a multi-component community-based HTC programme linked to care and treatment in the United States.<sup>89</sup> This study will involve evaluation of feasibility and effectiveness. Further research is needed.

### *Key points*

- The community-based HTC approach focuses on the active promotion of HTC linked to expedited access to care and treatment for those who test positive for HIV infection.
- One observational study found that after implementation of voluntary HTC in health-care settings, there was a decrease in HIV diagnoses, an increase in the proportion of people tested, and decreased time between diagnosis and first CD4 count.<sup>88</sup>
- Although HTC can increase the risk for stigma, the potential benefits outweigh the risks.
- Communities value testing and counselling and earlier access to care and treatment. However, there are concerns regarding stigma and discrimination, and limited capacity of health-care personnel to manage issues pertinent to MSM and transgender people.

## Recommendation

**Offering community-based programmes for HIV testing and counselling linked to care and treatment to MSM and transgender people is suggested over not offering such programmes.**

*Strong recommendation, very low quality of evidence*

### **Complementary remarks**

Further research is needed.

## **8.3. Behavioural interventions and information, education, communication**

### **8.3.1. Individual-level behavioural interventions for the prevention of HIV infection**

#### *Background*

Behavioural interventions for HIV prevention are an integral component of any response to the HIV epidemic. Individual-level behavioural interventions are those that include one-on-one counselling-based interventions. These focus on risk reduction strategies with individual participants. Trained counsellors meet face to face with individuals at risk for contracting HIV infection to discuss their risk behaviours, strategies for reducing their risk, and provide them with information regarding HIV. The content of these meetings may vary by intervention. For example, in a counselling session, the participant could receive information to increase their knowledge of HIV infection and also talk about their sexual risk behaviours to relate their activities directly to HIV risk and then receive counselling on how to reduce their risk.

#### *Evidence*

There is moderate-quality evidence that individual behaviour change interventions reduce sexual risk behaviour and HIV incidence among MSM and transgender people. The evidence included is from four randomized controlled trials of individual-level behavioural change interventions among MSM and transgender people.<sup>90, 91, 92, 93</sup> This evidence was collected during a systematic review of studies focused on individual-level behavioural interventions for HIV prevention among MSM and transgender people. This review was also based on two existing systematic reviews<sup>94, 95</sup> and on complementary searches of subsequently published studies (Annex 3)\*. The evidence for this recommendation was of moderate quality because all of the studies included were based in high-income countries.

\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

### *Summary of findings*

Four studies provided information on the effects of the intervention on unprotected anal sex, and one study additionally included HIV incidence as an outcome. No studies were found with information on issues related to quality of life due to the intervention. Behavioural change due to individual-level interventions resulted in an overall 18% reduction in risk behaviour, reduced unprotected anal sex, in the four included studies. The risk ratio of 0.82, 95% CI: 0.64–1.05 shows a moderate, but not statistically significant, benefit of individual behavioural interventions for the behavioural outcome. Individual-level interventions also resulted in an 18% reduction in HIV incidence. The one study that looked at HIV incidence also showed a moderate but not statistically significant benefit (RR: 0.82, 95% CI: 0.64–1.05).<sup>\*</sup> These data were rated down for indirectness of self-reported behavioural outcomes, studies not conducted in low- and middle-income countries, and data imprecision due to the small number of events.

### *Benefits and risks*

The benefits of the intervention outweigh the risks. Quality of life (inconvenience, unnecessary intervention, anxiety and discrimination) was not measured.

### *Acceptability and feasibility*

Individual-level behavioural interventions are both acceptable and feasible for the target population. In the report on values and preferences, participants stated that an enabling environment is necessary to implement successful behavioural interventions.<sup>66</sup>

### *Additional points of discussion and research directions*

For these interventions to be successful, the necessary human resources, an enabling environment and adaptation to the local context will be necessary. Although some studies from low- and middle-income countries have been done, none included the information needed for this review. There is a need for research on the effectiveness of individual-level behavioural interventions for MSM and transgender people in low- and middle-income countries.

### *Key points*

- Individual-level behavioural intervention programmes are one-on-one counselling-based interventions that focus on risk reduction strategies with individual participants.
- Behavioural change interventions resulted in an 18% reduction in risk behaviour and an 18% reduction in HIV incidence. Both results were not statistically significant.
- The benefits of the intervention outweigh the risks.
- Individual-level behavioural interventions are acceptable to and feasible for the target population.

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<sup>\*</sup> Both outcomes, risk behaviour and HIV incidence, yielded the same RR and 95% CI (RR: 0.82, 95% CI: 0.64–1.05). This is not an error.

## Recommendation

**Implementing individual-level behavioural interventions for the prevention of HIV and STIs among MSM and transgender people is suggested over not implementing such interventions.**

*Conditional recommendation, moderate quality of evidence*

### **Complementary remarks**

For these interventions to be successful, the necessary human resources, an enabling environment and adaptation to the local context are necessary. Further research is needed on the effectiveness of individual-level behavioural interventions for MSM and transgender people in low- and middle-income countries.

### **8.3.2. Community-level behavioural interventions for the prevention of HIV infection**

#### *Background*

Community-level behavioural change interventions for HIV prevention among MSM and transgender people are those where popular opinion leaders are trained to give intervention messages to their peers, effecting behavioural change throughout their communities. Such interventions can include empowerment activities, outreach, small group sessions and leadership activities.

#### *Evidence*

The evidence for community-level behavioural change interventions for HIV prevention is of low quality. The evidence collected for this recommendation was based on existing reviews of community-level HIV prevention interventions among MSM and transgender people, and a systematic search for evidence from subsequently published articles (Annex 3)\*.<sup>94, 95</sup> The evidence included is from five randomized controlled trials of community-level behavioural change interventions among MSM and transgender people.<sup>96, 97, 98, 99, 100</sup> The evidence is of low quality for a reduction in sexual risk behaviour due to community behaviour change interventions among MSM and transgender populations. These data were rated down for indirectness of self-reported behavioural outcomes and limitations in design, i.e. high loss to follow up (42% in the study with a cohort). The evidence was also rated down as only one study was in a low- and middle-income setting.

\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

### *Summary of findings*

Five studies of community-level behavioural change interventions among MSM and transgender people were included in the evidence review. Behavioural change due to community-level interventions resulted in a 25% reduction in risk behaviour. The overall behavioural change outcome from the five included studies indicated a moderate, but not significant, level of behavioural change (RR: 0.75, 95% CI: 0.51–1.09). None of the studies reported on HIV or STI incidence or quality of life.

### *Benefits and risks*

The benefits of community-level behavioural change interventions for HIV prevention among MSM and transgender people outweigh the risks of such interventions.

### *Acceptability and feasibility*

Community-level behavioural interventions are both acceptable to and feasible for the target population. In the report on values and preferences, the participants stated that an enabling environment is necessary to implement successful behavioural interventions.<sup>66</sup> Behavioural interventions primarily require human resources for implementation; this may be a challenge in some settings. For these interventions to be successful, the necessary human resources, an enabling environment and adaptation to the local context will be necessary.

### *Additional points of discussion and research directions*

Additional studies are needed on the effectiveness of community-level behavioural change interventions among MSM and transgender people.

### *Key points*

- Community-level behavioural change interventions for HIV prevention among MSM and transgender people are those where popular opinion leaders are trained to give intervention messages to their peers, effecting behavioural change throughout their communities.
- Behavioural change due to community-level interventions resulted in a 25% reduction in risk behaviour.
- The benefits of the intervention outweigh the risks.
- Community-level behavioural interventions are both acceptable to and feasible for the target population.

## Recommendation

**Implementing community-level behavioural interventions for the prevention of HIV and STIs among MSM and transgender people is suggested over not implementing such interventions.**

*Conditional recommendation, low quality of evidence*

### **Complementary remarks**

Additional studies are needed on the effectiveness of community-level behavioural change interventions among MSM and transgender people.

### **8.3.3. Targeted internet-based strategies**

#### *Background*

People seek out health information every day from web sites and other online resources. This has created the opportunity for internet-based HIV prevention interventions that could make it easier for MSM or transgender people with internet access to anonymously obtain relevant HIV prevention messages, at convenient times and in private. These types of interventions have the potential to provide the most appropriate information or strategies that meet the person's unique needs.

#### *Evidence*

Two randomized controlled trials met the search criteria (Annex 3)\*. One was conducted in Peru and the other in the United States.<sup>101, 102</sup> One study assessed the efficacy of a targeted motivational online video on HIV/STI testing and counselling and the other a pro-sexual health interactive module aimed to reduce unprotected anal sex. Both were focused on MSM and neither had HIV or STI acquisition as an outcome of interest. Both studies were rated down for study limitations, imprecision and indirectness. The evidence available is of very low quality. The strength of the recommendation was conditional, given the low quality of the evidence and small effect. However, it was also agreed that in settings in which same-sex sexual practices are illegal and the internet is the only means of communication, this recommendation should be graded as strong.

#### *Summary of findings*

The systematic evidence review included information on two outcomes of interest. In one study, the effect of a targeted motivational online video on the rate of uptake of HIV/STI testing and counselling was examined. The population comprised both gay-identified men and non-MSM identified men. The other study reported whether viewing a pro-sexual health interactive module reduced the number of partners with whom unprotected anal sex was reported. The study

\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

assessing the efficacy of a targeted motivational online video showed no significant change in the rates of HIV/STI testing and counselling among gay-identified men who received the intervention versus those who did not (hazard ratio [HR]: 1.07, 95% CI: 0.4–2.85). Among non-MSM identified men, the video may have been efficacious in promoting HIV/STI testing and counselling, but as none of the participants from the control group were tested (11.3% tested in the intervention group versus 0% in the control group), the HR was incalculable. The study assessing pro-sexual health interactive modules showed that more MSM who received this intervention reported fewer partners with whom they had unprotected anal intercourse at three-month follow up compared with those who did not receive the intervention (RR: 1.04, 95% CI: 0.91–1.19).

#### *Benefits and risks*

Benefits may outweigh harms, but rigorous, larger randomized controlled trials are needed.

#### *Acceptability and feasibility*

The acceptability and feasibility of these interventions were not directly assessed by the studies described. The study delivering the targeted video evaluated participants' perceptions of the intervention, and was rated as "very good" by the majority.

#### *Additional points of discussion and research directions*

Neither of the interventions included in this review had biological outcomes. There is thus no evidence for the effect of any of these interventions on HIV or STI incidence or prevalence. New studies should try to address these questions. Only one study was conducted in a low- or middle-income country and was also the only one that included transgender people; however, findings from this population were not reported. More studies should be done in low- and middle-income countries and include transgender people. The role of virtual social networks in HIV prevention and access to care and treatment should be assessed in detail.

#### *Key points*

- Internet-based HIV prevention interventions make it easier for MSM with internet access to obtain relevant HIV prevention messages in an anonymous fashion, at a convenient time and in private especially in settings where same-sex sexual practices are illegal.
- There was no significant change in the rates of HIV/STI testing and counselling among gay-identified men who viewed the targeted motivational online video versus those who did not.
- More MSM who received the pro-sexual health interactive modules reported having unprotected anal intercourse with fewer partners at the three-month follow up compared with those who did not receive the intervention.
- The benefits may outweigh the harms, but rigorous, larger randomized controlled trials are needed.



## Recommendation

**Offering targeted internet-based information to decrease risky sexual behaviours and increase uptake of HIV and STI testing and counselling among MSM and transgender people is suggested over not offering such information.**

*Conditional recommendation, very low quality of evidence*

### **Complementary remarks**

New studies should include biological outcomes, be done in low- and middle-income countries and include transgender people.

### **8.3.4. Social marketing-based strategies**

#### *Background*

Social marketing campaigns for preventing HIV infection among high-risk populations have been implemented since the early stage of the HIV epidemic.<sup>103, 104</sup> However, no systematic review has previously been conducted to evaluate the effectiveness of these campaigns among MSM and transgender people. Social marketing has been shown to change or promote health behaviours related to a wide range of health issues among different populations in different settings.<sup>105, 106, 107</sup> For MSM and transgender people, a multitude of individual, sociocultural, community and structural factors may be barriers to practising safer sex or seeking HIV/STI testing and counselling. In that sense, social marketing interventions intend to remove the barriers to and increase the benefits of the desired behaviour to achieve behavioural change.

#### *Evidence*

The search strategy focused on studies evaluating local or regional social marketing/branding campaigns to raise awareness and increase uptake of HIV/STI testing and counselling among MSM and transgender people. Three observational studies that met the search criteria were identified (Annex 3)\*.<sup>108, 109, 110</sup> No data were found on the effects on HIV/STI incidence or prevalence.

All the studies were rated down for design and imprecision. The interventions were focused on MSM alone and not transgender persons. The evidence showing that the rates of HTC significantly increased after the multimedia social marketing campaign is of very low quality. And none of the studies was conducted in a low- or middle-income country.

#### *Summary of findings*

The three studies explored the effect of multimedia campaigns on increasing the uptake of testing and counselling for syphilis, HIV or both infections. Two studies failed to show an increase

\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

in testing and counselling after exposure to such campaigns. One study showed a significant increase in HTC after the intervention in the observed population. In this study, the number of MSM who had tested for HIV at the study site increased from 65 persons to 292 ( $P < 0.001$ ) after implementation of the multimedia campaign.<sup>110</sup> The combined odds ratio (OR) from the two studies of the effect of social marketing on HTC was OR: 1.58 (95%CI: 1.4–1.77). There was no benefit for STI testing and counselling (OR: 0.94, 95% CI: 0.68–1.28).<sup>108,109</sup>

### *Benefits and risks*

The benefits outweigh the risks.

### *Acceptability and feasibility*

Acceptability was not assessed. Some social marketing strategies targeting MSM have been used in the past, although feasibility relates to cost, which is dependent on the media utilized. Social marketing targeting MSM and transgender people would most certainly imply a social environment where same-sex sexual practices are not criminalized.

### *Additional points of discussion and research directions*

Social marketing needs to be framed within a comprehensive package of interventions with the intent of increasing the uptake of services. These interventions have been effective in reaching general and other non-MSM target populations. Campaigns should take into account existing levels of homophobia to avoid increasing it. Communities need to be involved in designing and implementing social marketing campaigns.

None of the studies included in this review had biological outcomes. There is no evidence of the effect of any of these interventions on HIV or STI incidence or prevalence. New studies should cover this gap. Of the three studies included in this review, none was conducted in a low- or middle-income country and none focused on transgender people. New studies should be done in low- and middle-income countries and should consider transgender people.

### *Key points*

- Social marketing has been shown to change or promote health behaviours related to a wide range of health issues among different populations in different settings. However, no systematic review has previously been conducted to evaluate the effectiveness of these interventions among MSM.
- The three studies included explored the effect of multimedia campaigns on increasing testing and counselling for syphilis, HIV or both infections. One study showed a significant increase in HTC after the intervention was rolled out in the population.
- While the benefits outweigh the harms, more research is needed.
- Acceptability was not assessed. These campaigns have been used previously and hence are potentially feasible, after considering issues of cost, which depends on the media used.

## Recommendation

**Using social marketing strategies to increase the uptake of HIV/STI testing and counselling and HIV services among MSM and transgender people is suggested over not using such strategies.**

*Conditional recommendation, very low quality of evidence*

### **Complementary remarks**

There is no evidence of the effect of this intervention on HIV or STI incidence or prevalence. New studies conducted in low- and middle-income countries should address these questions.

### **8.3.5. Sex venue-based outreach strategies**

#### *Background*

An important subgroup of MSM report high-risk behaviour in sex venues, i.e. environments outside the home where men meet other men for casual, usually anonymous, sexual encounters.<sup>111, 112, 113</sup> Sex venues may be known as bathhouses, baths, tubs, saunas, sex clubs and health clubs. This type of venue exists primarily to provide an opportunity for men to have sex with other men on the premises. The second type of venue comprises public spaces (e.g. parks, beaches, alleys, public restrooms) and commercial environments (e.g. adult bookstores, back-rooms of bars, adult movie houses).<sup>114</sup> Presumably, prevention interventions at sex venues could make a significant difference in reducing the spread of HIV among high-risk MSM.

#### *Evidence*

The search strategy focused on studies evaluating interventions delivered at MSM sex venues to distribute/deliver targeted public health messages. The evidence came from one observational study that met the search criteria (Annexes 3, 7)\*.<sup>115</sup> The quality of the evidence is very low. No data were found on the effect on HIV/STI incidence or prevalence. The interventions focused only on MSM and not transgender people, and the study was done in a high-income country.

#### *Summary of findings*

The study reviewed and evaluated the effect of offering HTC for HIV infection to MSM at a sex venue on the rate of reported unprotected anal sex during a three-month follow up. It was rated down for indirectness and considered as very low-quality evidence. A 40% reduction (RR 0.60, 95% CI: 0.40–0.90) was reported for those who received the intervention compared with those who did not. The study used reported unprotected anal sex as the main outcome, and the intervention was shown to be protective with the methodological limitations previously stated.

\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

### *Benefits and risks*

The benefits outweigh the risks.

### *Acceptability and feasibility*

These were not directly assessed. However, an evaluation of values and preferences states that an enabling environment is necessary for implementing behavioural interventions at sex venues.<sup>66</sup>

### *Additional points of discussion and research directions*

Sex venues exclude public spaces such as parks and public restrooms. Interventions in this context are limited to provision of information only. There is no evidence on the effect of this intervention on HIV or STI incidence or prevalence. New studies should address these questions. The only study found was conducted in a high-income country. New studies should be done in low- and middle-income countries. Further research is needed on the effect of including other interventions such as condom distribution and use, and HTC.

### *Key points*

- An important subgroup of MSM report high-risk behaviour in sex venues, i.e. environments outside the home where men meet other men for casual, usually anonymous, sexual encounters. Prevention interventions at sex venues could possibly make a difference in reducing the spread of HIV among high-risk MSM.
- A 40% reduction was reported for those who received the intervention compared with those who did not.
- The benefits outweigh the risks.
- Acceptability was not assessed. However, an enabling environment is necessary for implementing behavioural interventions at sex venues.

## Recommendation

**Implementing sex venue-based outreach strategies to decrease risky sexual behaviour and increase uptake of HIV testing and counselling among MSM and transgender people is suggested over not implementing such strategies.**

*Conditional recommendation, very low quality of evidence*

### **Complementary remarks**

There is no evidence of the effect of this intervention on HIV or STI incidence or prevalence. New studies done in low- and middle-income countries should address these questions. Further research is needed on the effect of including other interventions such as condom distribution and use, and HTC.

## **8.4. Substance use, prevention of bloodborne infections**

### **8.4.1. Mental health interventions for substance use**

#### *Background*

Alcohol and substance use/dependence is a problem for many MSM and transgender people, and is linked to significant morbidity and mortality.<sup>52</sup> While the role of injecting drug use in increasing the risk for HIV infection through contaminated injection equipment is well documented,<sup>116</sup> harmful use and dependence on alcohol and other substances is also associated with decreased ability to keep preventive practices in mind or increased sexual risk due to sexual disinhibition (often intentional, as is the case with use of stimulants such as cocaine and methamphetamine).<sup>117</sup> Selling sex to maintain drug supply also increases the risk for HIV infection.<sup>118</sup>

#### *Recommendation framework*

The WHO Mental Health Gap Action Programme guidelines (2010) on interventions for mental, neurological and substance use disorders<sup>119</sup> recommend specific interventions for the prevention and management of harmful and dependent substance use, on the basis of evidence for the effectiveness and feasibility of scaling up these interventions. These include the following:

- Screening and brief interventions for harmful substance use by trained primary health-care professionals
- Measures to reduce the harms associated with substance use
- A combination of brief and more complex interventions for substance dependence, including:
  - psychosocially assisted pharmacotherapy for opioid dependence using long-acting opioid agonists such as methadone or buprenorphine
  - recommendation for detoxification and assistance in preventing relapse for all other substances
  - referral and supervisory support for substance dependence by specialists, when needed.

#### *Additional points of discussion and research directions*

The epidemiology of drugs most often used by MSM and transgender people, including so-called “party drugs” such as methamphetamine, should be a research priority. The focus should be on the frequency, patterns of use (oral, inhalation, injecting), geographical expansion and preventive interventions.

### Key points

- Many MSM and transgender people experience problems with alcohol and substance use/dependence, which increase their risk for HIV due to disinhibition. Selling sex to maintain drug supply also increases the risk for HIV infection.

## Recommendation

**MSM and transgender people with harmful alcohol or other substance use should have access to evidence-based brief psychosocial interventions involving assessment, specific feedback and advice.**

*In line with existing WHO guidance<sup>119</sup>*

### Complementary remarks

The epidemiology of drugs most often used by MSM and transgender people, including so-called “party drugs” such as amphetamine-type stimulants, should be a research priority. The focus should be on frequency, patterns of use, geographical expansion, and prevention and care interventions.

## 8.4.2. Harm reduction for injecting drug use

### Background

MSM and transgender people who inject drugs are at increased risk for HIV acquisition through sharing of contaminated injection equipment. The recommendations below focus on the provision of sterile injecting equipment<sup>120, 121, 122, 123</sup> and opioid substitution therapy (OST).<sup>124</sup>

### Recommendation framework

Several comprehensive reviews of the evidence for needle and syringe programmes (NSPs) and OST have been identified. All have confirmed the effectiveness of NSPs in reducing the spread of HIV, and OST in reducing the frequency of injecting. This conclusion was drawn with increasing confidence in more recent reviews, as more and better quality data have become available.

There is compelling evidence that increasing the availability and utilization of sterile injecting equipment by people who inject drugs reduces HIV infection substantially. There is also considerable evidence that pharmacy availability of sterile injecting equipment provides specific benefits in addition to those derived from NSPs. OST with methadone or buprenorphine is highly effective in reducing injecting behaviours that put injecting drug users at risk for HIV. In addition, OST has been demonstrated to improve both access and adherence to ART, and reduce mortality.<sup>120</sup>

There is no persuasive evidence that access to NSPs or OST increases the initiation, duration or frequency of illicit drug use or drug injecting. The benefits outweigh the possible risks. NSPs and OST are cost-effective, and could have additional and worthwhile benefits such as increasing recruitment into drug treatment and possibly also into primary health care, as well as addressing issues such as STIs, tuberculosis and viral hepatitis.<sup>121</sup>

For single interventions, there is no evidence of a protective effect strong enough to guarantee HIV control, but the aggregate effect of several harm reduction interventions appears to be generally successful in maintaining HIV control. The availability of sterile needles and syringes should be considered as a system and should therefore be supported by a range of complementary measures if communities wish to control HIV infection related to injecting drug use. In the case of MSM and transgender people who inject drugs, these interventions should be complementary to sexual health programmes and other interventions mentioned in these guidelines.

*Additional points of discussion and research directions*

Patterns of injection drug use among MSM and transgender people should be better characterized.

*Key point*

- Many MSM and transgender people use injection drugs. This practice is often associated with increased risk for HIV through sharing contaminated injection equipment.

**Recommendation**

**MSM and transgender people who inject drugs should have access to needle and syringe programmes and opioid substitution therapy.**

*In line with existing WHO guidance<sup>120, 124</sup>*

**Complementary remarks**

Patterns of injection drug use among MSM and transgender people should be studied further.

**8.4.3. Safe injections for transgender people who use gender-enhancement procedures**

*Background*

There is limited literature on safe injection practices for transgender people who use gender-enhancement procedures. Most studies have been among transgender people in the United States. Hormone injection is the most common gender enhancement practice among transgender people.<sup>27, 125, 126</sup> Hormone therapy should be indicated and supervised by medical personnel.

However, it is common among transgender people to obtain hormones from non-medical facilities and inject these themselves.<sup>127</sup> Evidence suggests that supervised hormone provision provides incentives to address other health-care needs including HIV prevention.<sup>128, 129, 130</sup> Injecting silicone is a less frequent practice, and is more prevalent in South America, where injecting industrial silicone has been documented, than in other regions.<sup>127</sup> Injection of industrial silicone is a potentially harmful and irreversible process that should be discouraged.<sup>131</sup>

*Recommendation framework*

There is no conclusive evidence on the association of hormone and silicone injection and HIV infection but, given the frequent self-administration of these substances, there is potential for needle-sharing, and thus HIV transmission.<sup>132</sup>

As stated in the *Guiding principles to ensure injection device security*,<sup>133</sup> the use of sterile injecting equipment and safe injection practices reduces the risk of infection with blood borne pathogens such as HIV, hepatitis B and hepatitis C, and should be recommended. The benefits outweigh the risks.

*Additional points of discussion and research directions*

Patterns of injection use for gender enhancement among transgender people around the world should be better characterized.

*Key point*

- Hormone injection is the most common practice for gender enhancement among transgender people and has been described in several parts of the world.

| Recommendation  |
|---|
| <p><b>Transgender people who inject substances for gender enhancement should use sterile injecting equipment and practise safe injecting behaviours to reduce the risk of infection with bloodborne pathogens such as HIV, hepatitis B and hepatitis C.</b></p> <p><i>In line with existing WHO guidance<sup>134</sup></i></p> <p><b>Complementary remarks</b></p> <p>Patterns of injection use for gender enhancement among transgender people should be better characterized.</p> |



## 8.5. HIV care and treatment

### 8.5.1. Antiretroviral therapy for MSM and transgender people living with HIV

#### *Background*

Antiretroviral therapy (ART) is the core pharmacological component of a broad and comprehensive management of HIV infection. ART has significantly decreased the morbidity and mortality from HIV in the past decades. Given that ART represents a biologically targeted intervention, where sexual identities play a minimal role or no role at all on expected effects, there is no reason, biological or other, to differentiate ART recommendations for MSM and transgender people from those formulated for other populations (excluding HIV-infected pregnant women and newborns).

It is also critical to highlight the continuum between prevention and treatment in the response to the HIV epidemic.<sup>14</sup> Recent data are emerging that ART has a preventive benefit.<sup>87, 135</sup> However, these data remain to be confirmed among MSM and transgender people.

#### *Recommendation framework*

The recommendations on when to initiate ART, optimal ART regimens, management of coinfections (with tuberculosis and chronic viral hepatitis), and the management of ART failure in MSM and transgender populations should be in line with the recently updated recommendations issued by WHO.<sup>136</sup>

The consensus recommendations issued in the WHO ART guidelines encourage earlier HIV diagnosis and initiation of ART, and promote the use of less toxic regimens and more strategic laboratory monitoring. The guidelines identify the most potent, effective and feasible first-line, second-line and subsequent treatment regimens applicable to the majority of populations, the optimal timing for ART initiation and improved criteria for ART switching, and introduce the concept of third-line antiretroviral regimens.

*The core aspects of the recommendations are as follows:*

- 1) ART should be started at CD4 counts of  $\leq 350$  cells/mm<sup>3</sup>, regardless of the presence or absence of clinical symptoms, and for those in WHO clinical stage 3 or 4 if CD4 testing is not available.
- 2) The initiation of ART should be promoted for all those with HIV/TB and HIV/HBV active coinfection.
- 3) First-line therapy should consist of a non-nucleoside reverse transcriptase inhibitor (NNRTI) + two nucleoside reverse transcriptase inhibitors (NRTIs), one of which should be zidovudine (AZT) or tenofovir (TDF).

- 4) Second-line ART should consist of a ritonavir-boosted protease inhibitor (PI) plus two NRTIs, one of which should be AZT or TDF, based on what was used in first-line therapy, and
- 5) All patients should have access to CD4 cell-count testing to optimize pre-ART care and ART management.

*Additional points of discussion and research directions*

It is critical that national ART programmes and public health leaders consider these recommendations in the context of their countries' HIV epidemics, the strengths and weaknesses of health systems, and the availability of financial, human and other essential resources. In adapting these guidelines, care must be exercised to avoid undermining current treatment programmes, protect access for key populations at risk for HIV infection, achieve the greatest impact for the greatest number of people and ensure sustainability. It is similarly important to ensure that the adaptation of these guidelines does not stifle on going or planned research, since the new recommendations reflect the current state of knowledge, and new information will be needed for sustainability and future modifications of existing guidelines. The effectiveness of ART for HIV prevention has been established in a cohort of predominantly heterosexual serodiscordant couples by the HPTN 052 study.<sup>87</sup> Studies are also needed on the effectiveness of ART for HIV prevention among MSM and transgender serodiscordant couples.

*Key point*

- Given that ART represents a biomedical intervention where sexual identities play a minimal or no role at all on expected effects, there is no reason to differentiate ART recommendations for MSM and transgender people from those formulated for other adult and adolescent populations.

**Recommendation**

**MSM and transgender people living with HIV should have the same access to ART as other populations. ART should be initiated at CD4 counts of  $\leq 350$  cells/mm<sup>3</sup> (and for those in WHO clinical stage 3 or 4 if CD4 testing is not available). Access should also include management of opportunistic infections, co-morbidities and treatment failure.**

*In line with existing WHO guidance<sup>136</sup>*

## **8.5.2. Other prevention and care interventions for MSM and transgender people living with HIV**

### *Background*

Comprehensive care for MSM and transgender people living with HIV should begin before provision of ART. People living with HIV in resource-constrained settings should have access to essential interventions to prevent both illness and HIV transmission. Under universal access, agreed to by the Group of Eight (G8), efforts to scale up all prevention interventions, promote HTC, and integrate these into the care and treatment of people with HIV are under way. Expansion of HTC will greatly increase the number of people with HIV who are aware of their HIV status and can benefit from comprehensive HIV-related prevention, care and treatment services.

All people with HIV for whom ART is clinically indicated should have access. People living with HIV, regardless of ART indication, should also benefit from basic HIV prevention and care, including effective interventions that are simple, relatively inexpensive, improve the quality of life, prevent further transmission of HIV or common opportunistic infections, delay progression of HIV disease and prevent mortality.

### *Recommendation framework*

This recommendation focuses on prevention of onward transmission of illness and episodes of common opportunistic infections, rather than the ongoing treatment of those infections. Prevention of HIV transmission should be integrated with care and treatment services that are adapted to country needs. This recommendation is primarily intended for use by the managers of national and subnational HIV/AIDS programmes, NGOs that deliver HIV care services and policy-makers involved in scaling up HIV prevention, care and treatment services. This guidance should also be useful for clinicians and other providers of prevention and care services for people living with HIV.<sup>136</sup>

Based on a review of the evidence, areas for intervention seen as low cost and of particular importance for people living with HIV are as follows:

1. Psychosocial counselling and support
2. Disclosure, partner notification, and testing and counselling
3. Co-trimoxazole prophylaxis for opportunistic infections
4. Tuberculosis prophylaxis
5. Prevention of fungal infections
6. Prevention of sexually transmitted and other reproductive tract infections
7. Prevention of malaria
8. Vaccination for selected vaccine-preventable diseases (hepatitis B, pneumococcal, influenza and yellow fever vaccines)

9. Nutrition
10. Family planning
11. Preventing mother-to-child transmission of HIV
12. NSPs and OST
13. Water, sanitation and hygiene.

After initiation of ART, the utility of many of these interventions will not decrease and should be maintained throughout treatment.

*Additional points of discussion and research directions*

The objective of these recommendations is to provide global, technical, evidence-based recommendations for prevention and care interventions other than ART, which people living with HIV in resource-limited settings should expect as part of their health-care services. The recommendations also aim to promote the expansion of provider-initiated interventions for HIV prevention, and non-ART care and treatment for adults and adolescents living with HIV.

*Key point*

- Comprehensive care for MSM and transgender people living with HIV should begin before ART provision. People living with HIV in resource-limited settings should have access to essential interventions to prevent both illness and HIV transmission.

| <b>Recommendation</b>  |
|--|
| <p><b>MSM and transgender people living with HIV should have access to essential interventions to prevent illness and HIV transmission including, but not limited to, care and support and antiretroviral therapy.</b></p> <p><i>In line with existing WHO guidance<sup>137</sup></i></p> <p><b>Complementary remarks</b></p> <p>These recommendations aim to provide global, technical, evidence-based recommendations for prevention and care interventions other than ART, which people living with HIV in resource-limited settings should expect as part of their health-care services.</p> |

## 8.6. Prevention and care of other sexually transmitted infections

### 8.6.1. Syndromic management of sexually transmitted infections

#### *Background*

Sexually transmitted infections are a major public health problem. The incidence of acute STIs among MSM and transgender people is high in many countries.<sup>138, 139</sup> Failure to diagnose and treat STIs at an early stage may result in serious complications and sequelae, including infertility, anogenital cancer and premature death. The individual and national expenditure on STI care can be substantial.<sup>138, 140, 141</sup>

Among MSM and transgender people, STIs' most common symptoms and signs besides genitourinary manifestations also include rectal infections. Clinical assessments should also focus on anorectal signs and symptoms of chlamydial infection and gonorrhoea, since they are both highly prevalent as seen by nucleic acid amplification tests (NAAT).<sup>13, 139, 142</sup> WHO is updating the STI syndromic management guidelines, which will include a management algorithm for anorectal infections.<sup>142</sup>

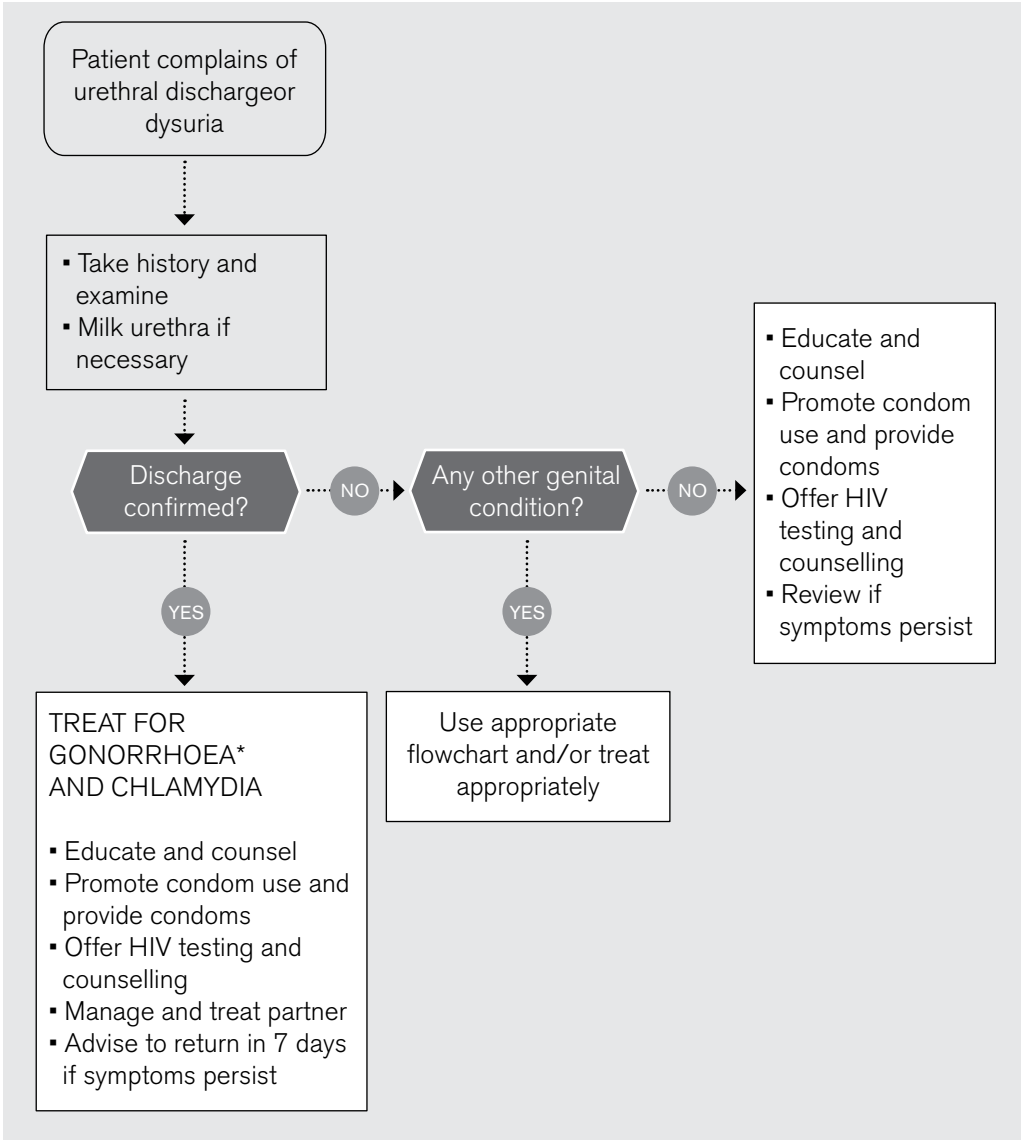
#### *Recommendation framework*

Syndromic management of STIs is based on the identification of consistent groups of symptoms and easily recognized signs (syndromes), and the provision of treatment, one-dose if feasible, which will deal with the majority of, or the most serious, organisms responsible for producing a STI-related syndrome.<sup>143</sup> Among MSM and transgender people, syndromic management should not be limited to the most common symptoms and signs such as urethral discharge and genital ulcers, since rectal infections can also occur. Thus, clinical assessment should also focus on anorectal-related syndromes, anal ulcers and anal discharge. Key STI syndromes that are particularly relevant for MSM and transgender populations are discussed below.

#### *Urethral discharge (Figure 3)*

MSM and transgender patients complaining of urethral discharge and/or dysuria should be examined for evidence of discharge. If none is seen, the urethra should be gently massaged from the ventral part of the penis towards the meatus to obtain a suitable sample for testing. The major pathogens causing urethral discharge are *Neisseria gonorrhoeae* (*N. gonorrhoeae*) and *Chlamydia trachomatis* (*C. trachomatis*). Syndromic management should include treatment for both infections. Where laboratory testing is available, a distinction can be made between the two organisms and specific treatment administered.

**Figure 3.** Management algorithm for urethral discharge



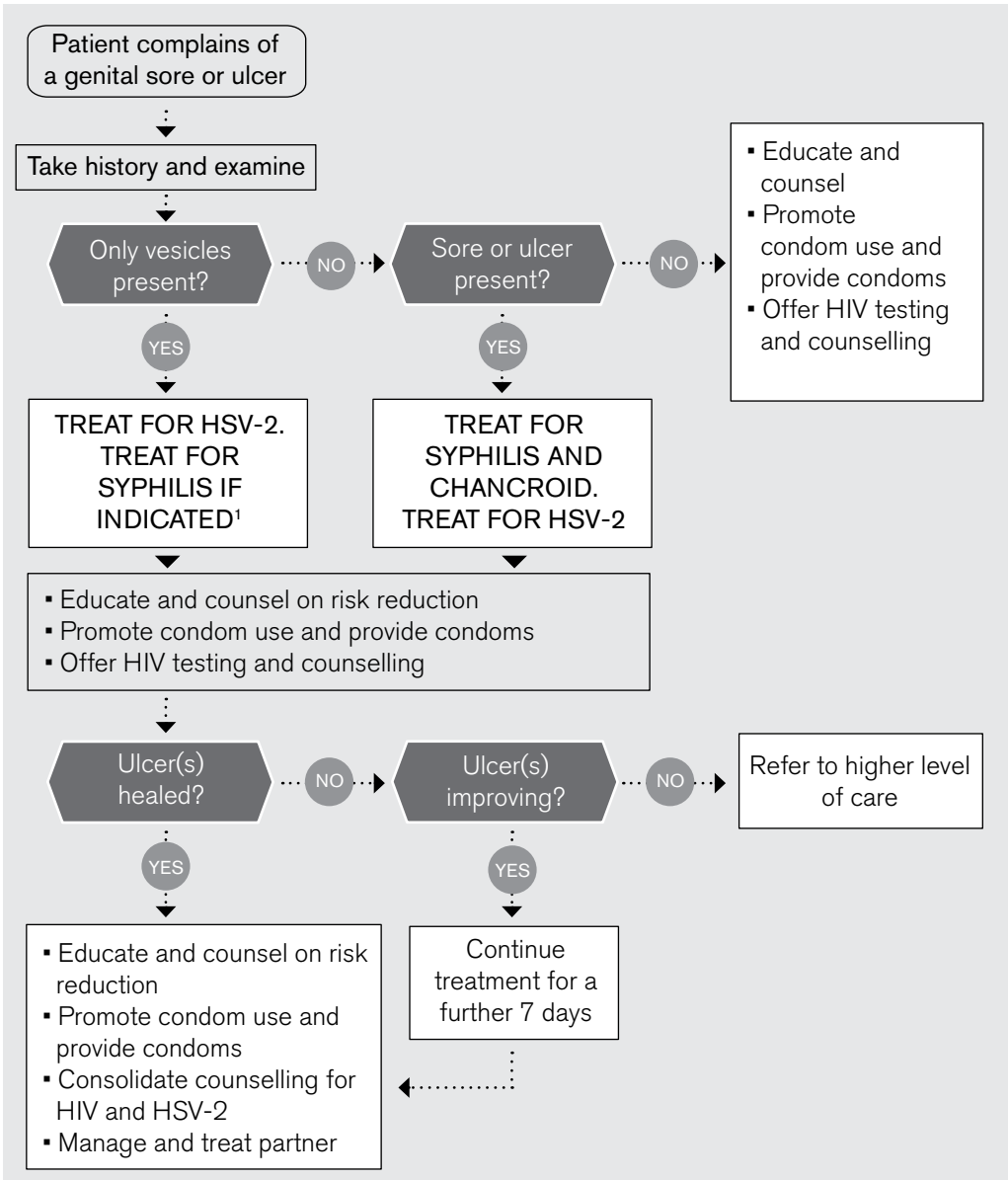
\*If microscopy is available, do Gram stain smear of urethral exudates. If no intra-cellular Gram-negative diplococci are seen, treatment for chlamydial infection only may be considered.

### Genital ulcers (Figure 4)

Differential diagnosis of genital ulcers is not feasible clinically, particularly in settings and populations where several aetiologies are common.<sup>144</sup> Clinical manifestations and patterns of genital ulcer disease (GUD) may be further altered in the presence of HIV infection.<sup>144</sup>

After clinical examination to confirm the presence of genital ulcers, appropriate treatment should be given. In areas where HSV-2, syphilis and chancroid are prevalent, patients with genital ulcers should be treated for bacterial conditions to ensure a rapid cure (HSV-2 ulcers will go into spontaneous remission). In areas where either granuloma inguinale or lymphogranuloma venereum is prevalent, treatment for either or both conditions should be included for the same reason. Laboratory testing is rarely helpful at the initial visit, since mixed infections are common.<sup>144</sup> In areas with a high prevalence of syphilis, a positive serological test may be the reflection of a previous infection and provide a misleading picture of the patient's condition. A negative test does not necessarily exclude an ulcer of primary syphilis in its early phase. Non-treponemal tests, e.g. rapid plasma reagin (RPR), may be negative and should, therefore, not be interpreted as absence of syphilis infection.

**Figure 4.** Management algorithm for genital ulcer disease



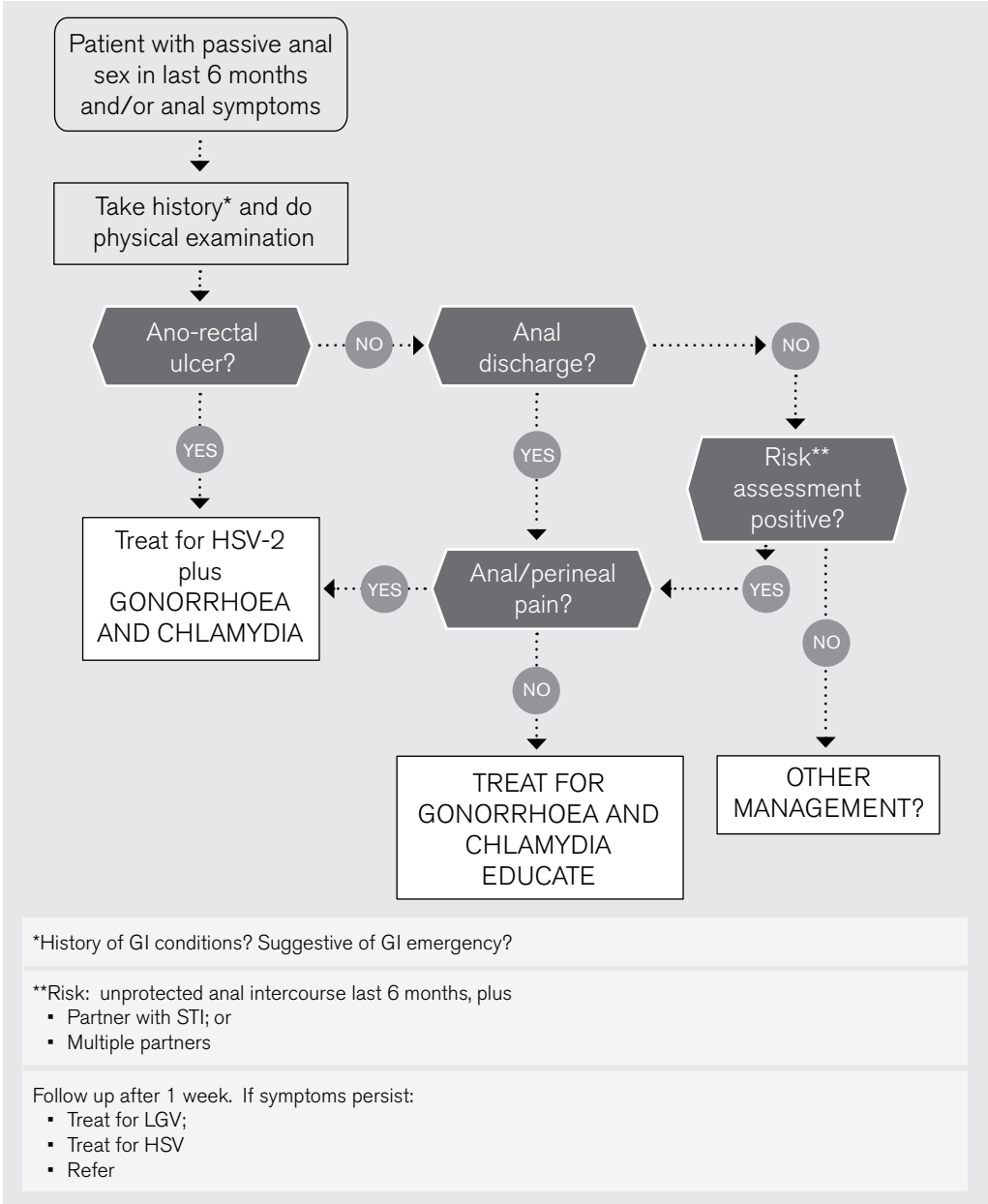
<sup>1</sup> Indications for syphilis treatment: RPR positive; or patient has not been treated for syphilis recently.



### Anorectal-related syndromes (Figure 5)

The algorithm for anorectal examination, which will be included in the forthcoming revision of the WHO STI guidelines, was presented at the MSM guidelines consensus meeting. No evaluation has been done so far on its specificity or sensitivity. However, there was consensus among the experts that this flowchart is, in the absence of published evidence, the best clinical approach to the syndrome. This algorithm recommends that individuals who have had receptive anal intercourse in the past six months and/or who report anal symptoms, in addition to clinical interrogation and general examination, should be subjected to anorectal examination in search of two syndromes: anal ulcers and anal discharge. If anal ulcers are found, patients should be offered treatment for HSV-2 infection, and also for chlamydial infection and gonorrhoea. In the event of anal discharge accompanied with pain, treatment for HSV-2 must be offered. If no pain is present, then chlamydial infection and gonorrhoea should be considered as the potential causes and appropriate treatment offered.

**Figure 5.** Management algorithm for anorectal infections<sup>142</sup>



Due to its low sensitivity, microscopy is not recommended in the management of ano-rectal infections.

Successful management of STIs requires health-care workers to be respectful of patients and non-judgemental. Clinical examinations should take place in appropriate surroundings where privacy can be ensured and confidentiality guaranteed. In some situations, health-care workers require training to overcome their own sensitivities to be able to address the issues associated with sexuality and STIs in an open and constructive manner. For further details, refer to the WHO *Guidelines for the management of sexually transmitted infections*<sup>143</sup> and forthcoming revision.

In the study on community values and preferences,<sup>66</sup> people expressed that they want comprehensive services, including STI screening procedures, to be part of a comprehensive package.

The use of syndromic management was particularly designed for resource-limited settings and has proven feasible and acceptable in most countries.<sup>145, 146</sup> STI screening among MSM (preferably non-invasive) is also feasible and acceptable, and can reach a group that often has limited access to regular STI testing and counselling at formal health services.

*Additional points of discussion and research directions*

Community-based interventions should be developed to ensure that the benefits of interventions for STI management are sustained so that the risk of reinfection is minimized. More emphasis is needed on advocacy to introduce syndromic STI management for MSM and transgender people.

*Key point*

- Sexually transmitted infections are a major public health problem. The incidence of acute STIs among MSM and transgender people is high in many countries.

| Recommendation  |
|---|
| <p><b>MSM and transgender people with symptomatic STIs should seek and be offered syndromic management and treatment.</b></p> <p><i>In line with WHO guidance<sup>143</sup></i></p> <p><b>Complementary remarks</b></p> <p>Community-based interventions need to be developed to ensure that the benefits of STI management interventions are sustained so that reinfection is minimized. More emphasis on advocacy is needed to introduce syndromic STI management for MSM and transgender people.</p> |

### **8.6.2. Periodic testing for asymptomatic forms of urethral and rectal *N. gonorrhoeae* infection using (1) NAAT and (2) culture; and periodic testing for asymptomatic forms of urethral and rectal *C. trachomatis* infection using NAAT.**

#### *Background*

Treatable and curable STIs such as those due to *N. gonorrhoeae* and *C. trachomatis* remain a public health problem of high importance among MSM and transgender people. The natural history of asymptomatic urethritis or rectal infection remains unclear. Some persons will develop clinical disease and some will spontaneously clear the infection. Undiagnosed *N. gonorrhoeae* and *C. trachomatis* infections can be a potential risk for HIV acquisition/transmission as asymptomatic infection can also be transmitted. Chronic infection is associated with infertility in both males and females. Failure to diagnose and treat these infections may result in serious complications and sequelae, as well as increase the risk for HIV infection.

Culture is the most widely known test for diagnosing *N. gonorrhoeae*. However, its sensitivity is variable, ranging from 72% to 95% in male urine.<sup>147</sup> Culture for *C. trachomatis* is available only in technology-intensive laboratories. NAAT, including polymerase chain reaction, ligase chain reaction, strand displacement assay and transcription-mediated amplification are the most sensitive tests for the diagnosis of infection due to *N. gonorrhoeae* and *C. trachomatis*. In recent years, the use of NAAT has been broadly implemented in the developed world as the preferred methodology for *N. gonorrhoeae* and *C. trachomatis* testing in genital sites due to its high specificity and sensitivity. The advantage of NAAT is that the testing is performed on RNA or DNA present in the sample, and it performs well even if the load of microorganisms is low. The disadvantage is the need to equip laboratories with appropriate and expensive equipment.

While there are many symptomatic cases of urethral and rectal infection caused by *N. gonorrhoeae* and *C. trachomatis* among MSM and transgender people, cases of infection can occur without symptoms, particularly in the case of *C. trachomatis*. A study of STI prevalence among MSM living with HIV, which assessed asymptomatic *N. gonorrhoeae* and *C. trachomatis* infections in the pharynx, rectum and urine, and included syphilis serology, revealed a 14% prevalence of any of these asymptomatic STIs.<sup>148</sup> The significance of these cases is not clear, although it is likely that they may potentially evolve to become symptomatic, and/or favour HIV transmission.

#### *Evidence*

Evidence was found from five observational studies implemented in low- and middle-income countries, of which three focused on MSM.<sup>149, 150, 151, 152, 153</sup> Two studies addressed the sensitivity and specificity of NAAT in detecting *N. gonorrhoeae* and *C. trachomatis*, one addressed the sensitivity and specificity of *N. gonorrhoeae* culture, and two addressed data on the prevalence

of urethral and rectal *N. gonorrhoeae* and *C. trachomatis*. The search strategy (Annex 3)\* focused on studies of urethral and rectal *N. gonorrhoeae* and *C. trachomatis* as the outcome of measure using NAAT for the identification of both *N. gonorrhoeae* and *C. trachomatis*, and culture for *N. gonorrhoeae*.<sup>147,148</sup>

The strength of these recommendations is conditional, given the available evidence, feasibility issues, and the values and preferences for the intervention. The recommendation for not conducting periodic culture testing for *N. gonorrhoeae* is conditional, based on expert opinion and lack of specific research. Most countries have the microbiological capacity to perform cultures. Therefore, when NAAT is not an option, offering culture testing is more beneficial than no testing.

#### *Summary of findings*

The evidence found in the systematic review of NAAT methodologies (two studies) came from observational studies, and was therefore rated down for indirectness – not measuring clinical or public health outcomes, and measuring only test performance and imprecision. Likewise, evidence identified in the systematic review on *N. gonorrhoeae* culture methodology (one observational study) was rated down for indirectness and imprecision.

#### *Benefits and risks*

With regard to NAAT, evidence for the effectiveness of NAAT testing for screening asymptomatic forms of both urethral and rectal *N. gonorrhoeae* and *C. trachomatis* is sufficient to propose a conditional recommendation for their implementation as a periodic testing methodology over not offering such testing to MSM and transgender people. The benefits increase as the prevalence increases. The benefits might outweigh the harms and cost if prevalence of asymptomatic urethral and rectal infections is higher than 1–2%. The NAAT test for urethral infection is a urine-based test (rather than a urethral swab test), while the test for rectal infection is performed on rectal swabs. Benefits include, but are not limited to, early diagnosis and treatment for individuals and partners, with an added value for MSM and transgender people living with HIV.

With regard to the use of *N. gonorrhoeae* culture for screening asymptomatic urethral *N. gonorrhoeae* infection, it is not recommended as a screening methodology for MSM and transgender people. Nevertheless, the benefits increase as prevalence increases. The main limitations include low sensitivity (over 68% of those with asymptomatic infection will go undetected), indirectness of evidence and logistic requirements. However, when NAAT for *N. gonorrhoeae* is not an option, offering culture testing is more beneficial than no testing.

#### *Acceptability and feasibility*

The recommendation for periodic NAAT testing for asymptomatic forms of *N. gonorrhoeae* and

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\* The full compilation of annexes are available on the WHO web site (<http://www.who.int/hiv/en/>).

*C. trachomatis* is conditional. Its implementation involves setting up more advanced technology in the laboratory and including the cost as a regular part of the budget. The cost of NAAT limits its availability.

*Additional points of discussion and research priorities*

There are no data on STIs in transgender people who have undergone vaginal construction. More research is needed to examine the clinical and public health outcomes. Since several commensal gonococcal species can be found in the anal region, an algorithm for confirmation by NAAT should be considered.

*Key points*

- Asymptomatic forms of urethral and rectal infection due to *N. gonorrhoeae* and *C. trachomatis* are fairly common among MSM and transgender people, and can increase the risk for HIV infection. Periodic NAAT testing for asymptomatic forms of urethral or rectal infections with *N. gonorrhoeae* and *C. trachomatis* are increasingly being used to identify and treat such forms of infection in developed countries. Given the technological barriers, culture has also been suggested as an alternative.
- For NAAT of *N. gonorrhoeae* and *C. trachomatis*: two observational studies showed favourable data on the accuracy of testing.
- The benefits outweigh the potential risks.
- Acceptable with limitations. Implementation of NAAT to identify *N. gonorrhoeae* and *C. trachomatis* requires training and costly technology. Capability for *N. gonorrhoeae* culture is broadly available, so when NAAT is not an option, offering culture testing is more beneficial than no testing.

**Recommendations**

**Offering periodic testing for asymptomatic urethral and rectal *N. gonorrhoeae* and *C. trachomatis* infections using NAAT is suggested over not offering such testing for MSM and transgender people.**

*Conditional recommendation, low quality of evidence*

**Not offering periodic testing for asymptomatic urethral and rectal *N. gonorrhoeae* infections using culture is suggested over offering such testing for MSM and transgender people.**

*Conditional recommendation, low quality of evidence*

**Complementary remarks**

More research is needed to examine the clinical and public health outcomes for transgender people who have undergone vaginal construction.

### 8.6.3. Periodic testing for asymptomatic syphilis infection

#### *Background*

Worldwide, syphilis is a highly prevalent infection among MSM and transgender people. The rates of syphilis have increased among MSM in several parts of the world, particularly among MSM living with HIV.<sup>154</sup> In the natural history of syphilis infection, 25% of those who remain untreated will undergo serious complications, while others will spontaneously clear the infection or be treated inadvertently. The complications can be severe and even life-threatening. Moreover, open syphilitic lesions can enhance the risk for HIV acquisition and transmission.

When rapid plasma reagin (RPR) testing is performed, a positive result can be related to latent syphilis, past infection, and primary and secondary syphilis. This must be considered for subsequent treatment. Treponemal tests (e.g. *Treponema pallidum* haemagglutination assay), if available, can be used to confirm the RPR test results. A quantitative (RPR) test can help differentiate between latent syphilis and past infection (high titres,  $\geq 1:8$ ) as well as help evaluate the response to treatment.<sup>143</sup>

#### *Evidence*

A pre-existing review on syphilis diagnostics<sup>155</sup> provides evidence of the sensitivity and specificity of non-treponemal tests, such as the RPR test. Although the review and the referenced studies do not specify whether such evidence was obtained from MSM and transgender people, the sensitivity and specificity of a test are not population dependent. In addition to sensitivity and specificity data, figures on the prevalence of syphilis are needed to estimate scenarios of true-positive, true-negative, false-positive and false-negative rates. The overall evidence was rated to be of moderate quality and it was downgraded because of the indirectness of the outcomes (outcome data used were related to test accuracy data instead of clinical outcomes).

#### *Summary of findings*

Syphilis seropositivity among asymptomatic MSM was estimated to be 9.3% in Boston<sup>156</sup> and 11% in Peru.<sup>157</sup> Larsen et al. report that the RPR syphilis test is 86% sensitive for primary infection, and 98% sensitive and 98% specific for secondary and latent infection.<sup>155</sup>

#### *Benefits and risks*

The benefits clearly outweigh the risks. An early diagnosis would secure timely treatment and benefit the individual and partners. For MSM and transgender people living with HIV, an early diagnosis provides added value.

### *Acceptability and feasibility*

In the study of community values and preferences, people expressed that they want comprehensive services, including STI screening procedures, which may be part of a comprehensive package.<sup>66</sup> Syphilis screening is widely accepted. There are few issues regarding feasibility since the test has been in place for decades.

### *Additional points of discussion and research directions*

Positive results can also be caused by autoimmune conditions that are not related to syphilis. The WHO-recommended testing algorithm to diagnose active syphilis should be followed.

### *Key points*

- Worldwide, syphilis is a highly prevalent infection among MSM and transgender people, with rates that have been increasing in the past few years, particularly among MSM living with HIV.
- Non-treponemal tests, such as the RPR test, are both sensitive and specific. However, data on the prevalence of syphilis are needed to estimate scenarios of true-positive, true-negative, false-positive and false-negative rates.
- The benefits outweigh the risks.
- The test is acceptable and widely available.

## Recommendation

**Offering periodic serological testing for asymptomatic syphilis infection to MSM and transgender people is strongly recommended over not offering such screening.**

*Strong recommendation, moderate quality of evidence*

### **Complementary remarks**

When rapid plasma reagin (RPR) testing is performed, a positive result can be related to latent syphilis, past infection, and primary and secondary syphilis. This must be considered for subsequent treatment.



## 8.6.4. Hepatitis B vaccination

### *Background*

Diseases caused by the hepatitis B virus (HBV) have a worldwide distribution. It is estimated that more than two billion people worldwide have been infected with HBV. Of these, approximately 360 million individuals are chronically infected and at risk for serious illness and death, mainly from liver cirrhosis and hepatocellular carcinoma.<sup>158</sup> HBV is transmitted between people by contact with the blood or other body fluids (i.e. semen and vaginal fluid) of an infected person. MSM and transgender people are among the groups at higher risk for infection, with a reported prevalence of 8%<sup>158</sup> and 13.3%,<sup>160</sup> respectively.

### *Recommendation framework*

A vaccine against hepatitis B has been available since 1982. Hepatitis B vaccine is 95% effective in preventing HBV infection and its chronic consequences. Current hepatitis B vaccines use recombinant DNA technology and are safe. Three doses are necessary for complete immunization and protection against potential HBV infection.

### *Key points*

- Diseases caused by HBV have a worldwide distribution. It is estimated that more than two billion people worldwide are infected with HBV.
- HBV is transmitted between people by contact with the blood or other body fluids (i.e. fluids (i.e. semen and vaginal fluid) of an infected person.
- MSM and transgender people are among the groups at higher risk.

## Recommendation

**MSM and transgender people should be included in catch-up HBV immunization strategies in settings where infant immunization has not reached full coverage.**

*In line with existing WHO guidance<sup>158</sup>*

## 8.7. Note on oral HIV pre-exposure prophylaxis

Pre-exposure prophylaxis (PrEP) is the daily use of an antiretroviral medication by persons who are HIV-uninfected to prevent acquisition of infection. The effectiveness of PrEP is being measured in randomized controlled trials among a variety of different potential users. Preliminary studies are also underway to assess whether the effectiveness of less frequent (intermittent) use can also be evaluated.

Since 2009, WHO has consulted on possible strategies for the introduction and scale up of PrEP in preparation of anticipated trial results. These consultations involve three levels: (i) global-level experts in PrEP, modelling and programme scale up; (ii) national-level authorities, including those who will be responsible for decisions to include PrEP; and (iii) populations most likely to be affected by decisions about PrEP.

While the findings of a recent study by Grant et al.<sup>161</sup> conducted among HIV-negative MSM and transgender people are relevant and promising, both from an individual perspective (i.e. as a personal choice) and from a public health perspective (i.e. as a scaled-up strategy), it is still early in the process, and more data from new studies assessing effectiveness, behaviour and economic impact will provide a more comprehensive picture of the role of PrEP in HIV prevention among MSM and transgender people in future. The first revision of these guidelines, planned for 2015, will address oral PrEP.

The iPrEx study tested an antiretroviral drug combination, taken daily as prophylaxis to reduce HIV acquisition, and compared it with a placebo in a randomized controlled trial. A total of 2499 MSM and transgender people were enrolled in Peru, Ecuador, Brazil, South Africa, Thailand and the United States. The median follow-up time was 1.2 years, with a maximum follow up of 2.8 years. The results were published in November 2010.<sup>161</sup>

The trial found that a once-daily pill containing tenofovir plus emtricitabine (brand name Truvada) provided an average additional protection of 44% to MSM and transgender people. These subjects also received comprehensive prevention services, which included monthly HTC, condom provision, counselling and management of other STIs (95% CI: 15–63%). The level of protection varied widely; depending on adherence. Among those whose data (based on self-reports, bottles dispensed and pill counts) indicated use of 90% or more, HIV risk was reduced by 73% (95% CI: 41–88%), while among those whose adherence was less than 90%, HIV risk was reduced by only 21% (95% CI: 52% reduction to a 31% increase). Risk behaviour among participants declined overall during the trial, both in terms of decrease in the number of sexual partners and increase in condom use, possibly due to the intensive risk reduction counselling provided as part of the trial.

Findings from this study constitute proof of concept of the safety and moderate effectiveness of oral PrEP, and represent an important milestone in HIV prevention research. These findings provide the first evidence that oral PrEP, when combined with other prevention strategies, can reduce HIV risk among MSM and transgender people. However, development of diagnostic algorithms to detect acute HIV infection during PrEP, better measures for improving and monitoring drug adherence, safety studies, hepatitis B coinfection, cost and feasibility need to be studied. This process will have to consider the competing demands for ART scale up.

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