

GUIDANCE ON
COUPLES HIV TESTING AND COUNSELLING
INCLUDING ANTIRETROVIRAL THERAPY FOR TREATMENT
AND PREVENTION IN SERODISCORDANT COUPLES

Recommendations for a public health approach

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARVs	Antiretrovirals
BCC	Behaviour change communication
CDC	U.S. Centers for Disease Control and Prevention
CHTC	Couples HIV testing and counselling
CHW	Community health workers
CI	Confidence interval
DALY	Disability-adjusted life year
DHS	Demographic and Health Surveys
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRC	Guidelines Review Committee
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
IDU	Injecting drug users
IEC	Information, education and communication
IPV	Intimate partner violence
MC	Male circumcision
MCH	Maternal and child health
M&E	Monitoring and evaluation
MSM	Men who have sex with men
OR	Odds ratio
PEP	Post-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHC	Primary health care
PICO	Problem / Intervention / Comparison / Outcome
PITC	Provide Initiated Counselling and Testing
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
RCT	Randomized controlled trial
RR	Relative risk
STI	Sexually transmitted infection
TB	Tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCT	Voluntary counselling and testing
WHO	World Health Organization

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DECLARATIONS OF INTEREST

All members of the Guidelines Group and peer reviewers were asked to complete a WHO declaration of interest form. Seven people declared potential conflicts of interest. These were discussed by the WHO Steering Group and then with the Guidelines Group. No one declared a potential conflict of interest that was thought to be significant.

EXECUTIVE SUMMARY

These guidelines recommend increasing the offering of HIV testing and counselling (HTC) to couples and partners, with support for mutual disclosure. They also recommend offering antiretroviral therapy (ART) for HIV prevention in serodiscordant couples.

Benefits for couples

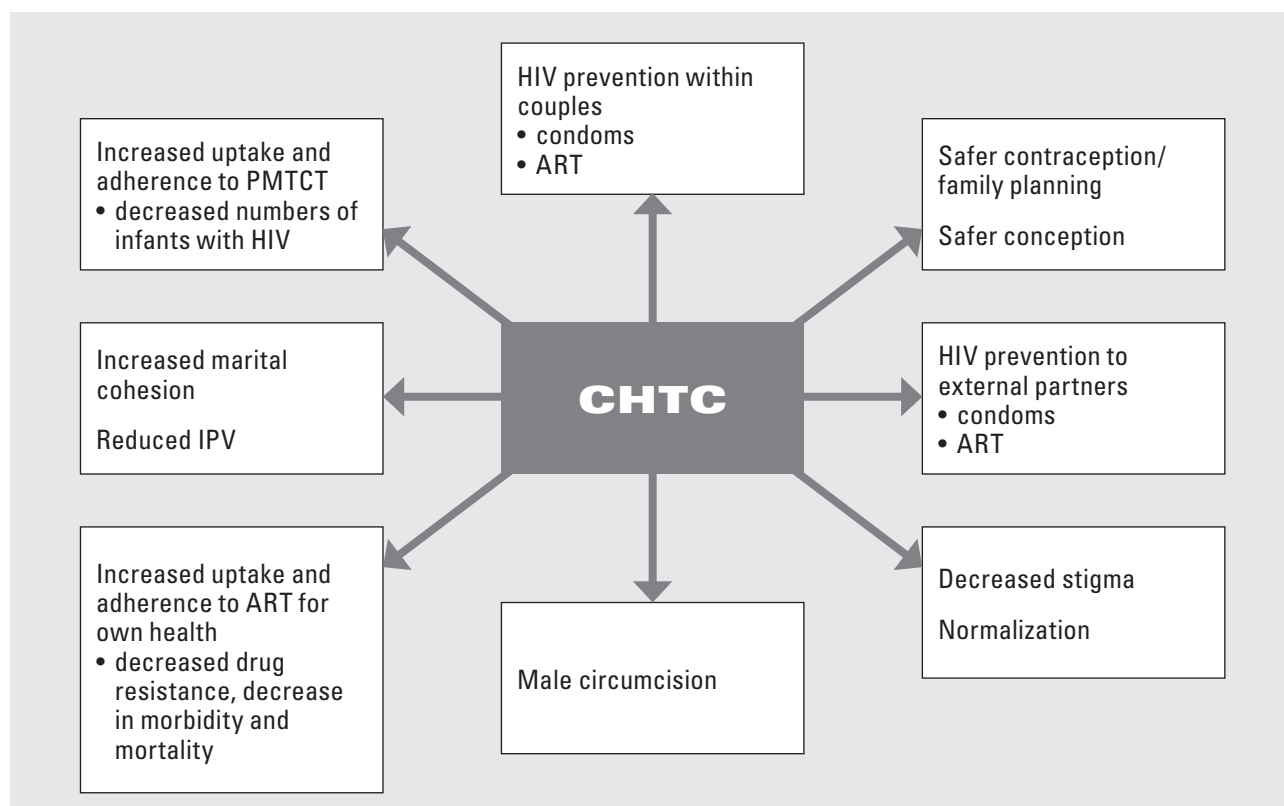
There are many potential benefits to supporting couples to test together for HIV infection and to mutually disclose their HIV status—most importantly, that together they can then make informed decisions about HIV prevention and reproductive health, including contraception and conception. These benefits are relevant for all couples, whether they have the same HIV test results (HIV seroconcordant) or have different results (HIV serodiscordant). The findings of many published studies suggest that people who learn their HIV status are more likely to adopt preventive behaviours than people who are unaware of their HIV status. Furthermore, people in couples who test together and mutually disclose their HIV status are more likely than those testing alone to adopt

behaviour to protect their partner. In addition, in a serodiscordant couple the provision of ART to the positive partner can significantly decrease the risk of transmission to the negative partner, or, potentially, the provision of antiretrovirals (ARVs) to the negative partner—termed pre-exposure prophylaxis (PrEP)—can help to prevent HIV acquisition. Another potential benefit of couples testing together and sharing their results is that they can support each other, if one or both partners are HIV-positive, to access and adhere to ART and interventions to prevent mother-to-child transmission (PMTCT) of HIV.

Increasing access

Support to encourage testing of the partners of people with HIV is also an efficient and effective way of identifying additional people with HIV, who then can benefit from treatment, as at least half will have HIV themselves. Also, couples HIV testing and counselling (CHTC) could also be a key intervention in increasing access to earlier ART and reaching more men with treatment. Currently, in all countries a significant proportion of people access treatment

Figure 1 Potential benefits of couples HIV testing and counselling



late in their infection, limiting the effectiveness of ART. Also, in most high HIV burden countries, currently a greater proportion of women than men test and access treatment, due to women's more frequent contact with medical services and the scale-up of provider-initiated counselling and testing (PITC) for pregnant women.

Many would stand to benefit from couples counselling and testing. It is estimated that as many as half of people with HIV who are in a long-term sexual relationship have an HIV-negative partner. Recent data suggest that a large proportion of new HIV infections in generalized epidemics occur within these serodiscordant relationships. This occurs partly because the majority of people in relationships are unaware of their own or their partner's HIV status. Thus, many are left unknowingly vulnerable to HIV infection. In general, serodiscordance is poorly understood by the general population and health workers alike.

While CHTC appears to offer potentially substantial personal and public health benefits, to date it has received insufficient programmatic attention. Previous guidance on HTC has concentrated almost exclusively on supporting provider-initiated or client-initiated HTC for individuals. While CHTC is being scaled up in many PMTCT programmes, global policy and guidance addressing the needs of couples in general, including HIV serodiscordant couples, is not readily available. Recognizing this gap, countries requested that the World Health Organization (WHO) assess the evidence of the efficacy of couples HIV testing and counselling in supporting prevention and other beneficial outcomes, including increased access to treatment, and the role of ART for prevention in serodiscordant couples.

Development of guidelines

WHO has led the development of these guidelines on CHTC and treatment and prevention for serodiscordant couples in collaboration with a wide range of partners from research and academic institutions, civil society organizations, UN and other international agencies and programme implementers. The final recommendations take into consideration the quality of evidence, the cost and feasibility of implementation, and the values and preferences of health care workers and the community.

This assessment of the evidence has led to recommendations that, if implemented, can contribute significantly to a wide range of potentially beneficial outcomes, including reducing HIV transmission in serodiscordant couples and preventing new infections more generally, and can support more effective provision of ART and PMTCT of HIV. This guidance recommends offering voluntary HTC for couples or partners with mutual support for disclosure, voluntary HTC for couples or partners with support for mutual disclosure in antenatal care settings, and voluntary HTC for the partners of people who have tested alone, implemented in a way that monitors for and minimizes any potentially negative outcomes. Also, it recommends, as a means to reduce HIV transmission, offering ART for the HIV-positive individual in a serodiscordant couple, even when that person is not yet eligible for ART to protect her or his own health. (See box, "Recommendations".)

The importance of couples counselling in the context of family planning services has gained attention in relation to a possible, but uncertain, increased rate of HIV transmission associated with injected hormonal contraception, as detailed in the WHO February 2012 recommendations on HIV and hormonal contraception (WHO Hormonal contraception and HIV technical statement 16 February 2012). For women in a serodiscordant couple who choose to use injected hormonal contraception, any risk of HIV transmission or acquisition would be minimized by use of ART by the positive partner.

CHTC programmes have been implemented in many settings but often on a small scale and not integrated into routine services. Also, although there is important new evidence supporting the effectiveness of the use of ART for HIV prevention in serodiscordant couples, implementation outside clinical trial settings has been limited. These guidelines discuss major operational issues that need to be considered for implementation and highlight the need to monitor the acceptability and effectiveness of these interventions.

Implementation issues are complex

The implementation issues for CHTC and provision of ART in serodiscordant couples are complex. As countries and programmes begin to consider

implementation, it will be important for programmes both to share experiences and for each country or programme to assess feasibility, acceptability, potential impact and potential adverse clinical and social consequences in its setting. Implementation decisions and approaches will need to be specific to context and will depend on available resources, health system capacity and epidemic profile. When providing CHTC services, as with all HTC services, confidentiality must be ensured, and testing and initiation of treatment must always be voluntary and never mandatory or coercive.

This document relies heavily on data and experience in low-income and middle-income countries and particularly in sub-Saharan Africa. Thus, it highlights operational approaches and options for heterosexual serodiscordant couples in such countries. Countries with concentrated or low-prevalence epidemics and high-middle- and high-income countries are encouraged to adapt this guidance as suits their national policies and programmes.

ART recommended for prevention

These guidelines recommend offering ART for the HIV-positive member of a couple to help prevent HIV transmission to an HIV-negative partner, both when the index partner qualifies for ART to protect his or her own health according to WHO 2010 ART guideline recommendations and when he or she does not. The latter option, initiating lifelong medication when it is not yet needed for one's own health, raises complex issues for both individuals and programmes. Individuals and couples will benefit from counselling that helps them consider all aspects of their decision, including the use of other prevention interventions such as the consistent and correct use of male and female condoms. Programmes will need to weigh equity issues, in terms of access to and quality of services, and how best to assure human rights. In particular, where resources for ART are limited, priority should always go to treating those who need ART for their own health over offering earlier treatment to some people for the purposes of preventing HIV transmission to others.

The Guidelines Group that formulated these recommendations has not reviewed the evidence of the prevention effect of ART in homosexual couples or other populations, including the key

RECOMMENDATIONS
1. Couples and partners should be offered voluntary HIV testing and counselling with support for mutual disclosure. <i>Strong recommendation, low-quality evidence.</i>
2. Couples and partners in antenatal care settings should be offered voluntary HIV testing and counselling with support for mutual disclosure. <i>Strong recommendation, low-quality evidence.</i>
3. Couples and partner voluntary HIV testing and counselling with support for mutual disclosure should be offered to individuals with known HIV status and their partners. <i>Strong recommendation, low-quality evidence for all people with HIV in all epidemic settings / Conditional recommendation, low-quality evidence for HIV-negative people depending on country-specific HIV prevalence.</i>
4. People with HIV in serodiscordant couples and who are started on antiretroviral therapy (ART) for their own health should be advised that ART is also recommended to reduce HIV transmission to the uninfected partner. <i>Strong recommendation, high-quality evidence.</i>
5. HIV-positive partners with >350 CD4 cells/ μ L in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners. <i>Strong recommendation, high-quality evidence.</i>

populations (sex workers, men who have sex with men, transgendered people and people who inject drugs) outside of the couples context. However, international scientific consensus is emerging that ART significantly reduces the risk of sexual transmission of HIV regardless of the population or setting.

Evidence has emerged during 2011 that pre-exposure prophylaxis with ARVs (e.g. oral tenofovir or tenofovir plus emtricitabine), taken by HIV-negative individuals in serodiscordant couples and by men who have sex with men, helps to prevent sexual acquisition of HIV. WHO is currently undertaking review and analysis of these data. WHO

“rapid advice” on PrEP will be available in 2012 to help guide PrEP demonstration projects in MSM communities and in serodiscordant heterosexual couples. More detailed guidance will follow.

Countries are strongly encouraged to expand couples testing and counselling services, whether or not they are able to offer earlier treatment to HIV-positive partners in serodiscordant couples.

1. OVERVIEW

1.1 Background

In most sub-Saharan African countries with generalized HIV epidemics, three-quarters of adults ages 20–49 years report being in cohabiting relationships (1,2,3). Among people with HIV who are in stable relationships, up to half have an HIV-negative partner—that is, they are in a serodiscordant relationship (one partner is HIV-positive, the other is HIV-negative) (4). Such proportions have been reported in both the general population (5,6,7) and specifically among women and their partners attending antenatal clinics (8,9,10).

In most studies of serodiscordant relationships, half of the infected partners are male and half are female. Data from 27 cohorts totalling 13 061 serodiscordant couples in sub-Saharan Africa and Demographic and Health Survey (DHS) data on 1145 serodiscordant couples in 14 countries indicated that the proportion of HIV-positive women in stable heterosexual serodiscordant relationships was 47% (1).

In regions other than Africa, HIV epidemics are for the most part concentrated and primarily affect three highly vulnerable key populations: men who have sex with men (MSM), injecting drug users (IDU) and sex workers (11). Countries with generalized epidemics also frequently have significant epidemics among key populations as well as in the general population. These epidemics are often not fully recognized, and services for key populations in generalized epidemics are often not adequately prioritized.

Although these guidelines will have greatest relevance in generalized epidemics, where most transmission is through heterosexual sex, they could also be adapted for other regions, as many people in key populations will be in cohabiting relationships, and those with HIV may have similar rates of serodiscordance with their partners as in generalized epidemics.

In Africa 50 million HIV tests have been performed in the last six years, over 20 million of them for pregnant women (12). The vast majority of these 50 million tests were conducted on people who tested as individuals. Globally, 67 million people in 100 countries were tested in 2009, and in 82 countries the proportion of the population who had received a test in the preceding year had

increased. The percentage of pregnant women in low- and middle-income countries receiving a test increased from 21% in 2008 to 35% in 2010 (from 45% to 61% in the highest burden area of eastern and southern Africa). With the notable exception of several countries, in all regions, however, the proportion of pregnant women who test with their partners is extremely low.

Population surveys in 2007–2008 in low- and middle-income countries revealed that knowledge of HIV status is still low among people with HIV, with a median of 40% in 10 countries (12). Furthermore, the majority of men and women in relationships are unaware of their partner's status, and many people with an HIV-positive partner are not aware of their own status, leaving many people unknowingly vulnerable to HIV infection (7,13). Several studies also have found that, when serodiscordant partners are unaware of each other's status and HIV transmission occurs, it is frequently between partners (14,15,16,17). The fact that transmission from one partner to another accounts for a high percentage of HIV transmission within stable partnerships is confirmed by a study in Zambia, in which DNA sequencing revealed that 87% of new HIV infections in the negative partner in a serodiscordant relationship were acquired from the HIV-positive partner (18). Another study, conducted at 14 sites in southern and eastern Africa, found that 64% of seroconversions could be linked by viral sequencing to the HIV-positive partner in a long-term relationship (19).

The majority of people living in stable relationships are unaware of their partner's status, and many people with an HIV-positive partner are not aware of their own status.

Despite growing evidence of its importance, the concept of "serodiscordance" and the frequency of its occurrence are poorly understood in most communities (20,21). Often, policy-makers and health workers, too, are unaware of its high frequency and importance, resulting in insufficient emphasis on offering CHTC and on supporting the testing of partners of people who have been through individual HTC (22,23).

Greater programmatic emphasis on CHTC could bring about significant reductions in HIV

infection rates. Modelling of the effect of CHTC on risk reduction among HIV discordant and seroconcordant uninfected couples in Zambia and Rwanda suggests that mutual knowledge of HIV status through CHTC would reduce annual HIV incidence among discordant cohabiting couples from 20% to as low as 7% in Zambia and 3% in Rwanda. These reductions would avert 36% to 60% of heterosexually transmitted infections that would otherwise occur in Zambia and 57% to 79% in Rwanda (24).

As there is increasing evidence that a significant proportion of new HIV infections in sub-Saharan Africa are occurring within heterosexual serodiscordant couples, these guidelines examine the evidence as to whether HTC interventions that facilitate partners in relationships receiving HTC and learning their HIV test results together—that is, CHTC—can be recommended to reduce the risk of HIV transmission. This evidence may be relevant outside sub-Saharan Africa as well. There are fewer data from other geographical regions and concerning men who have sex with men (MSM), but existing data recognize that there are significant levels of serodiscordance in other regions and among other populations. For example, data from China show that three-quarters of HIV infections in couples attending premarital counselling and testing were diagnosed in serodiscordant couples (25).

Given the great extent of testing of pregnant women, there are important opportunities and benefits of testing their male partners. In antenatal care (ANC) settings CHTC—where the father and mother can share knowledge of their HIV status and their unborn child’s risk of infection—can improve access and adherence to PMTCT interventions and thus decrease the number of infant infections (10). For serodiscordant couples who want to start a family, ANC providers are especially well-positioned to provide comprehensive conception counselling.

CHTC, with shared disclosure and mutual support, may also improve uptake of and adherence to ART, benefiting the individual with HIV as well as the HIV-negative partner. In general, sharing HIV status has been associated with improved adherence to treatment (26). Conversely, failure to disclose can prevent access to treatment and care and to PMTCT interventions, and it is a barrier to adherence (27,28,29). Male partner involvement has also proved to be key to women’s ability to access and use female-initiated prevention methods (30), suggesting another potential benefit to increasing the availability and uptake of CHTC.

When considering CHTC, it is important to examine, along with the potential benefits, any possible negative consequences of the intervention. Early qualitative studies in Tanzania found that some

Table 1 Individual HTC and couples HTC compared

Individual HTC	Couples HTC
Individual learns only his/her own HIV status.	Individuals learn their own HIV status and the status of their partner.
Individual assumes burden of disclosing to partner.	Mutual disclosure is immediate.
Couple has to deal with issues of tension and blame on their own.	Counsellor can help ease tension and diffuse blame.
Only one partner hears the information.	Partners hear information together, enhancing likelihood of shared understanding.
Counselling messages take into account only one partner’s status; individuals may wrongly assume that their partner’s status is the same as their own.	Counselling messages are tailored, based on the test results of both partners.
Counsellor is not present to facilitate the couple’s discussion about difficult issues.	Counsellor creates a safe environment and can help couples talk through difficult issues that they may not have discussed before.
Prevention, treatment and care decisions are more likely to be made in isolation.	Prevention, treatment and care decisions can be made together.
Individual bears burden of getting family members, children tested.	Decisions about family or child testing, as well as family planning, can be made together.

women lacked autonomy to make decisions about HIV testing, and fear of violence was a major concern (31). Some studies suggest an association between having HIV infection and being subjected to intimate partner violence and other adverse outcomes, particularly for women (32,33). However, no association between having HIV and intimate partner violence was found among women in a recent review of data from 10 developing countries (34). Indeed, receiving counselling and support together may help many couples to cope better with HIV infection and may strengthen communication within relationships (22,35).

These guidelines also examine the evidence of the effectiveness of ART to prevent transmission in serodiscordant couples. In addition to CHTC supporting preventive behaviours, such as condom use, to reduce HIV transmission within a relationship, initiation of ART, with consequent reduction in plasma and genital tract HIV concentrations, has been shown to reduce HIV transmission (36). Thus, treatment of the HIV-positive partner in a serodiscordant couple can reduce the risk of transmission to the HIV-negative partner.

Why this document is needed

HTC for individuals is recommended and promoted globally to enable people to access interventions that prevent sexual and vertical HIV transmission and transmission through injecting drug use and to support the timely uptake of HIV treatment and care (37,38,39,40). However, there are no recommendations in the existing HTC guidelines to support HTC for couples (41). This new guidance provides a set of evidence-based recommendations and discusses key principles and operational issues to guide acceptable and effective implementation of CHTC within a public health approach and a human rights framework.

1.2 Key definitions for couples HTC

Relationships

- **Couple:** Two persons in an ongoing sexual relationship; each of these persons is referred to as a “partner” in the relationship.

Interventions

- **Couples HIV testing and counselling:** When two or more partners are counselled, tested and

How individuals define their relationships varies considerably according to cultural and social context. These guidelines aim not to be prescriptive in the definition of couples who can benefit from these interventions. Rather, the principle should be that any persons who are in a sexual relationship and wish to test together and mutually disclose their results should be supported to receive CHTC. Health workers should support the decisions of partners to test together irrespective of the length or stability of their relationship, and policy-makers and implementers should assure that services are inclusive and non-judgmental in order to maximize the uptake and impact of these beneficial interventions.

receive their results together. When couples receive their results together, there can be mutual disclosure of HIV status, and the couple can receive appropriate support and be linked to follow-up services by a counsellor, health care provider or community-based worker.

- **Partner testing:** Another strategy for increasing knowledge of HIV status and disclosure among partners is partner testing. This is when one partner has already been tested, and the other partner is then tested separately. This would be a common scenario in antenatal settings, where women are routinely offered HTC and then encouraged to bring in their partner for partner testing. Partner testing may occur with or without disclosure. Whenever appropriate and feasible, however, mutual disclosure of HIV test results under the guidance of a counsellor should be encouraged and facilitated. In this document partner testing with mutual disclosure is considered a form of CHTC.
- **Supporting male involvement:** In order to achieve the goals of CHTC, innovative strategies are needed to engage more men in health care services. Male involvement refers to engaging men to participate in health services together with their partners, especially in ANC settings. Male involvement may also refer to the outcome of interventions designed to increase the participation of men in programmes that conventionally serve only women.

Sharing results

- **Disclosure:** When one partner shares his or her HIV status with another partner (or any other person), this is referred to as disclosure. When individuals learn their HIV test results alone, they often bear the burden of disclosing their HIV status to their partners without assistance from a trained counsellor or health care provider.
- **Mutual disclosure:** When two (or more) partners share their HIV status with one another. CHTC ensures mutual disclosure of HIV status between partners. When partners learn their HIV status together, they also agree that decisions about mutual disclosure to any third parties must be made together.
- **Partner notification:** When an authorized individual in a health facility or health system shares a person's HIV test result with that person's partner, or partners, in order to protect the health of that partner. This may occur with or without the expressed consent of the original partner. Many HTC policies permit partner notification in certain circumstances. However, partner notification is challenging and, in many high-prevalence countries, rarely implemented. Public health legislation should authorize, but not require, that health-care professionals decide, on the basis of each individual case and ethical considerations, whether to inform their patients' sexual partner(s) of the HIV status of their patient. Such a decision should be made only in accordance with the following criteria (42):
 - The HIV-positive person in question has been thoroughly counselled.
 - Counselling of the HIV-positive person has failed to achieve appropriate behavioural changes.
 - The HIV-positive person has refused to notify, or to consent to the notification of, his/her partner(s).
 - A real risk of HIV transmission to the partner(s) exists.
 - The HIV-positive person is given reasonable advance notice.

- The identity of the HIV-positive person is concealed from the partner(s) if this is possible in practice.
- Follow-up is provided to ensure support to those involved, as necessary.

Possible test results for couples

- **A seroconcordant uninfected couple** is a couple in which neither partner is infected with HIV. CHTC will help concordant uninfected couples remain uninfected by reassuring them that they are uninfected and emphasizing that avoiding unprotected sex with people outside their relationship is important to keep their future free of HIV. Also, the importance of using condoms to prevent acquisition of HIV in any sexual activities outside the relationship should be discussed.
- **A seroconcordant infected couple** is one in which both partners are HIV-infected (HIV-positive). These couples should receive care and treatment services according to the WHO 2010 treatment guidelines, which recommend initiating ART at a CD4 count of <350 cells/ μ L (43). The importance of using condoms to prevent acquisition of other STIs and transmission of HIV in any sexual activities outside the relationship should be discussed. Information about family planning should also be given to the couple, as should information regarding interventions to prevent mother-to-child transmission. HIV-positive concordant couples who are aware of each other's HIV infection will be better able to support each other to access and adhere to treatment and PMTCT interventions.
- **A serodiscordant couple** is a couple in which one partner is HIV-positive and one partner is HIV-negative. Although one partner is currently HIV-negative, this does not mean that this partner is "immunized" or protected against getting HIV in the future. It is of paramount importance for serodiscordant couples to avoid transmission to the HIV-negative partner. It is possible for couples to stay HIV serodiscordant indefinitely if they consistently practice safer sex using male and female condoms. The annual risk of transmission of HIV from an infected partner to an uninfected partner in serodiscordant couples can be reduced from

20–25% to 3–7% in programmes where condom use is recommended for prevention (24). The HIV-positive partner should receive care and treatment services for his or her own health. Treatment for the HIV-positive partner also is highly effective in reducing the risk of transmission to the HIV-negative partner. Combined, treatment and consistent condom use are likely to offer greater protection than either one alone. The couple also should receive information about family planning. For serodiscordant couples who are having unprotected sex or who desire children, the

It is possible for couples to stay HIV serodiscordant indefinitely if they consistently practice safer sex using condoms.

Treatment for the HIV-positive partner also is highly effective in reducing the risk of transmission to the HIV-negative partner.

Combined, treatment and consistent condom use are likely to offer greater protection than either one alone.

Table 2 Possible services/interventions and potential benefits by couple serostatus

CHTC test results	Possible services/interventions	Potential benefits
M+/F+	<ul style="list-style-type: none"> • Efficient “case finding” • Prevention counselling • Couple counselling • Mutual disclosure • Support groups 	<ul style="list-style-type: none"> → earlier ART → increased HIV prevention with other sexual partners → increased strength of relationship, quality of life → increased emotional support → increased uptake and adherence to FP, PMTCT, ART → increased psychosocial support, economic support
M-/F-	<ul style="list-style-type: none"> • Prevention counselling • Couple counselling • Mutual disclosure • VMMC 	<ul style="list-style-type: none"> → decreased HIV acquisition from other sexual partners → increased strength of relationship, quality of life → increased emotional support → decreased HIV acquisition from other sexual partners
M+/F-	<ul style="list-style-type: none"> • Earlier ART (ART for prevention) • Pre-conception counselling with ART for prevention • Prevention counselling • Couple counselling • Mutual disclosure • Support groups 	<ul style="list-style-type: none"> → decreased transmission within current relationship and with other sexual partners → safer conception → increased HIV prevention with other sexual partners → increased strength of relationship, quality of life → increased emotional support → increased uptake and adherence to FP, PMTCT, ART → increased psychosocial support, economic support
M-/F+	<ul style="list-style-type: none"> • Earlier ART (ART for prevention) • Pre-conception counselling with ART for prevention • Prevention counselling • Couple counselling • Mutual disclosure • Support groups • VMMC 	<ul style="list-style-type: none"> → decreased transmission within current relationship and with other sexual partners → safer conception → increased HIV prevention with other sexual partners → increased strength of relationship, quality of life → increased emotional support → increased uptake and adherence to FP, PMTCT, ART → increased psychosocial support, economic support → decreased HIV acquisition from current partner and other sexual partners

VMMC = voluntary medical male circumcision

use of ART to make conception safer (both to keep the partner negative and protect the child from HIV infection) is an important benefit. Serodiscordant couples who are aware of each other's HIV status may be able to support access and adherence to treatment, to give each other emotional support, and to support uptake of and adherence to PMTCT interventions.

1.3 Objectives

These guidelines recommend increasing the offering of HTC to couples, with support for mutual disclosure. They also recommend offering ART for prevention in serodiscordant couples.

The guidelines are intended to provide countries and programmes with evidence-based recommendations, together with consideration of implementation issues, that enable them to accomplish the following objectives:

1. to make possible more tailored, and thus more effective, counselling and provision of information, suited to the serostatus of both partners;
2. to enable disclosure to take place mutually, with expert guidance and in a controlled situation, thus easing the burden and possible risk of facing these challenges alone;
3. to encourage and support joint decision-making by the couple—decisions concerning safer sex, childbearing and infant feeding options, for example;
4. to improve uptake of and adherence to ART and PMTCT services and treatments;
5. to reduce mother-to-child transmission of HIV;
6. to permit and encourage more serodiscordant couples to benefit from the protection against HIV transmission offered by ART;
7. to reduce HIV transmission within serodiscordant couples and decrease new infections more generally.

1.4 Target audiences

The primary audiences for these guidelines are national policy-makers and health programme managers working in the fields of HIV, TB, MCH and other clinical services in low- and middle-income countries with generalized HIV epidemics. These guidelines will also be relevant for health

professionals, non-governmental and civil society organizations, donors, HIV advocacy organizations and patient support groups that address HIV. Although these recommendations will have greatest applicability for heterosexual couples in generalized epidemics, they are also relevant and appropriate for concentrated and low-level HIV prevalence settings and for high-income countries. The guidelines should be adapted to suit the local context.

1.5 Scope

The following five PICO¹ questions guided the review of evidence for developing the guidelines:

1. Should voluntary CHTC with support for mutual disclosure be offered to all couples?
2. Should voluntary CHTC with support for mutual disclosure be offered in ANC settings?
3. Should people with known HIV status who have an identifiable sexual partner be offered voluntary CHTC with support for disclosure?
4. Should people with HIV in serodiscordant couples who are started on ART for their own health be advised that ART is also recommended to reduce HIV transmission to their uninfected partner?
5. Should ART be offered for HIV-positive partners with >350 CD4 cells/μL in serodiscordant couples to reduce HIV transmission to uninfected partners?

These guidelines include evidence-based recommendations for adults, the summary and grading of the evidence, discussion of implementation issues in general and for specific settings and identification of key research gaps.

The guidelines will be reviewed and updated in the future according to WHO procedure (44).

1.6 Process of formulating guidelines

The WHO Department of HIV/AIDS led the development of these guidelines in collaboration with other WHO departments, the United Nations Children's Fund (UNICEF), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the

¹ PICO is a standard format for framing research questions in evidence-based guideline development: P=population or problem; I=intervention; C=control or comparison; O=outcomes.

Centers for Disease Control and Prevention (CDC) and the United States Agency for International Development (USAID).

A WHO Guidelines Steering Group identified the PICO questions listed above, in section 1.5. These were then circulated for review by the wider WHO Guidelines Group on CHTC. Members gave comments and agreed upon the questions, with the support of a methodologist expert in the Grading of Recommendations Assessment, Development and Evaluation (GRADE).

The Guidelines Group was constituted in accord with WHO procedures for guidelines development. It included HIV experts, researchers, programme managers, guideline methodologists, epidemiologists, human rights experts, development agencies, UN partners and community representatives and representatives from networks of people with HIV. Appropriate geographical and gender representation were considered. All external members of the Guidelines Group and all external peer reviewers submitted declarations of interest. The Steering Group reviewed these declarations of interest and found none that posed significant conflicts.

Systematic reviews of the evidence were outsourced to researchers who developed search protocols and conducted the reviews of the available scientific evidence. Search strategies employed in the systematic reviews, meta-analyses and GRADE profiles were conducted following methodology described in the *Cochrane Handbook for Systematic Reviews of Interventions* (45).

The systematic searches for studies relevant to the five PICO questions were conducted online using common electronic databases. (See Annex 7 for full list of databases searched.) All retrieved studies and abstracts were reviewed for their relevance to the question. Reference lists found in the retrieved studies were also reviewed to identify further studies that met the eligibility criteria. In addition, recognized experts in the field were contacted to identify studies that were not available (e.g. because unpublished) in the initial electronic search for each question.

The quality of evidence and the strength of recommendations were assessed using the GRADE methodology (46,47). In the GRADE assessment

process, the quality of a body of evidence is defined as the extent to which one can be confident that the reported estimates of effect (desirable or undesirable) available from the evidence are close to the actual effects of interest. The usefulness of an estimate of the effect (of an intervention) depends on the level of confidence in that estimate. The higher the quality of evidence, the more likely a strong recommendation can be made; the decision regarding the strength of the recommendation also depends on other factors, however.

Although the GRADE evidence assessment process was used for all of the questions, it was not always possible to develop GRADE profiles for all the questions because there was a lack of data and information to calculate the necessary risk ratios. The levels of assessment of the evidence used in the GRADE profiles are defined in Table 3. Table 4 describes other considerations in assessing the strengths of recommendations.

In addition, a qualitative report was commissioned to explore the views, attitudes, values and preferences of people who had been through HTC and who represent a sample of some of the communities that would be most affected by this guidance, including people in serodiscordant relationships. In future, region-specific versions of this report would refine understanding of the key issues in different social, cultural and economic contexts as well as in terms of local epidemic profiles. These regional versions would assist adaptation of the guidelines.

As part of the process recommended by the WHO Guidelines Review Committee (GRC), WHO conducted a global consultation in February 2011 in Harare, Zimbabwe, to review the evidence regarding CHTC. Participants at this meeting assessed the evidence, along with the risks and benefits of each recommendation, and developed CHTC recommendations. They also assessed the strength of the evidence for each recommendation. Approximately 50 experts and a broad range of stakeholder groups—researchers and academics, methodologists, programme implementers, representatives of ministries of health, policy-makers, civil society representatives, people living with HIV, representatives of UN agencies and donor agencies—participated in the meeting. Later, the new data from the HPTN 052 randomized controlled trial of ART for preventing HIV infection

Table 3 GRADE levels of assessment

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the effect.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Very low	Any estimate of effect is very uncertain.

Table 4 Additional domains considered in assessing the strengths of recommendations

Domain	Rationale
Benefits and risks	When a new recommendation is developed, desirable effects (benefits) need to be weighed against undesirable effects (risks). The more that the benefits outweigh the risks, the more likely that a strong recommendation will be made.
Values and preferences (acceptability)	If the recommendation is likely to be widely accepted or highly valued, a strong recommendation will probably be made. If there are strong reasons that the recommended course of action is unlikely to be accepted, it is more probable that a conditional recommendation will be made.
Costs/financial implications (resource use)	Lower costs (monetary, infrastructure, equipment or human resources) or greater cost-effectiveness will more likely result in a strong recommendation.
Feasibility	If an intervention is achievable in a setting where the greatest impact is expected, a strong recommendation is more probable.

in serodiscordant couples (36), provided in April 2011, were assessed using the GRADE process. The trial's findings strengthened the quality of the evidence that was reviewed for this intervention at the Harare consultation and was considered by the Guidelines Group in May 2011 to further strengthen this guidance and especially to inform recommendations 4 and 5.

The final recommendations take into consideration the quality of the evidence, cost, feasibility and the values and preferences of the community and health care providers.

Following the Harare consensus meeting, the full guidelines were prepared and circulated to the Guidelines Group and to external peer reviewers for comments. A further draft, updated with the results from the HPTN 052 study, was subsequently circulated for additional review. All responses were considered and addressed in the final draft.

Originally, it was proposed that the CHTC guidelines were primarily targeted to low- and middle-income countries. The Guidelines Group felt strongly, however, that they were relevant for all HIV epidemic and economic settings and should therefore be recognized as global guidance.

Regional and national meetings are planned to adapt these global recommendations to local needs and the HIV epidemic context and to facilitate implementation.

1.7 Strength of the recommendations

The strength of the recommendations reflects the degree of confidence of the Guidelines Group that the desirable effects of following the recommendations strongly outweigh potential undesirable effects. Desirable effects considered included beneficial health outcomes (e.g. reduced incidence of HIV, STIs and unplanned pregnancy; reduced morbidity and mortality), less burden and potential cost-savings. Potential undesirable effects considered included harms to health services, individuals or families, more burden and increased costs. Burdens considered included the costs of implementing the recommendations that programmes and patients (e.g. couples) may have to bear, such as relationship difficulties for couples going through CHTC or increased training requirements for health care providers carrying out CHTC and initiating and continuing ART for people with HIV with >350 CD4 cells/ μ L in serodiscordant couples.

2. DISCUSSION OF RECOMMENDATIONS

2.1 Couples HIV testing and counselling

The Guidelines Group agreed that CHTC with support for mutual disclosure is an efficacious intervention that should be strongly recommended.

2.1.1 HTC for couples and partners

One randomized controlled trial (RCT), reported in two articles, provided data examining the efficacy of CHTC (35,48). This trial compared couples who were randomized to health information only (and no HTC) with couples who were randomized to CHTC. Unprotected sex was defined as sex without a condom with either the primary partner (enrolment partner) or secondary partners. Analyses combined participants who were HIV-positive and HIV-negative and did not stratify by serodiscordance. Among participants who received couples HTC, 305 of 508 (60%) reported unprotected sex with primary partners, compared with 328 of 493 (67%) participants who, as couples, received health education only. The relative risk was 0.90, which is statistically significant (95% CI 0.82–0.99). Among participants who received couples HTC, 61 of 508 (12%) reported unprotected sex with secondary partners, compared with 42 of 493 (8.5%) participants in couples who received health education only (difference not statistically significant). There were no differences in changes in partner violence (RR 1.5, 95% CI 0.86–2.58), breakup of a sexual relationship (RR 1.2, 95% CI 0.92–1.54) or strengthening of a sexual relationship (RR 1.07, 95% CI 0.93–1.2).

This same study also compared participants who received HTC as individuals with those who received HTC together, as couples (CHTC). Those who received CHTC, as contrasted with individual HTC, reported a significantly greater increase in unprotected sex with primary partners after the intervention than before (RR 1.86, 95% CI 1.67–2.07) but a greater reduction in unprotected sex with secondary partners (RR 0.53, 95% CI 0.41–0.68). The increase in unprotected sex with primary partners in the CHTC group may reflect couples who, on learning and discussing that they had the same serostatus, decided to stop using condoms—a rational behavioural choice. It is not possible to know this, however, because the results were not stratified by the HIV status of participants or by seroconcordance versus discordance. As in the comparison between CHTC and health education only, there were no

RECOMMENDATIONS

1. Couples and partners should be offered voluntary HIV testing and counselling with support for mutual disclosure. *Strong recommendation, low-quality evidence.*
2. Couples and partners in antenatal care settings should be offered voluntary HIV testing and counselling with support for mutual disclosure. *Strong recommendation, low-quality evidence.*
3. Couples and partner voluntary HIV testing and counselling with support for mutual disclosure should be offered to individuals with known HIV status and their partners. *Strong recommendation, low-quality evidence for all people with HIV in all epidemic settings / Conditional recommendation, low-quality evidence for HIV-negative people, depending on country-specific HIV prevalence.*

significant differences between participants who received individual HTC and those who received CHTC in changes in partner violence after counselling (RR 1.51, 95% CI 0.96–2.37), breakup of a sexual relationship (RR 1.2, 95% CI 0.92–1.54) or strengthening of a sexual relationship (RR 1.07, 95% CI 0.93–1.2). Although the GRADE analysis classified the study as low-quality evidence, the evidence was broadly in favour of the superior effectiveness of CHTC, and the Guidelines Group agreed that the benefits of the intervention substantially outweighed any risk.

The Guidelines Group considered CHTC feasible in settings where HIV testing is regularly provided, as long as counsellors receive adequate training on couple-specific issues. In settings where individual HTC is already provided, budgets and other resources are generally adequate to meet most programme requirements to provide CHTC. However, additional training to ensure an adequate workforce of CHTC counsellors and quality of counselling, and training on issues specific to couples, may be necessary, along with promotional activities to increase demand. All of these components will require additional resources in most places. In one cost-effectiveness study (49), the cost per HIV infection averted ranged from US\$54 to \$501 for CHTC and from US\$58 to \$2970 for individual HTC.

In the values and preferences report, respondents expressed potential concerns about CHTC, but they felt overall that most concerns could be minimized with good counselling and programme planning. The report strongly stated that CHTC should not be mandatory. The Guidelines Group endorsed these views.

2.1.2 CHTC in ANC and PMTCT settings

CHTC is particularly important in ANC settings, as HIV testing, which is routinely recommended (that is, provider-initiated testing and counselling (PITC)) for pregnant women and is being implemented widely, can identify and potentially help to prevent HIV infection in infants as well as in their parents. Also, pregnancy is a time of increased risk of sexual HIV transmission and acquisition. During pregnancy women have doubled risks of both HIV acquisition (male-to-female) and transmission (female-to-male) (50). Furthermore, if a woman becomes infected during pregnancy, the high viral load associated with new infection creates an especially high risk of transmission from mother to fetus. Testing an HIV-uninfected woman's partner can help identify women at risk during this especially vulnerable period and so can help to prevent infection in both the woman and the child. Furthermore, by engaging male partners, CHTC can enhance uptake of and adherence to PMTCT and safer infant feeding interventions, further reducing the risk of transmission to the infant.

ANC settings are one of the few places where CHTC has been introduced. While to date most CHTC has taken place in research or operational studies, the feasibility of CHTC in ANC services has been demonstrated. In Rwanda, where male partner involvement is considered central to effective PMTCT, a strategy to promote CHTC has resulted in 81% of male partners being tested; in Thailand testing is routinely offered in ANC settings for partners of pregnant women with HIV (12). Also, ANC, labour and delivery and related MCH settings are settings where large numbers of women are routinely screened for HIV. The preventive benefit of HTC, for both HIV-positive and HIV-negative pregnant women, can be enhanced with CHTC. For all these reasons the Guidelines Group strongly endorsed voluntary CHTC in ANC settings. CHTC should be offered in counties with generalized epidemics. Countries with low-level or concentrated epidemics may opt to offer partner testing with support for mutual disclosure for HIV-positive women.

One observational study in an ANC setting found that CHTC was associated with reduced HIV incidence among initially HIV-negative women and reduced gonorrhoea incidence among HIV-positive women compared with women whose partners were not tested (51). Among HIV-positive pregnant women, those who received CHTC were generally more likely than those who received individual HTC to use ART (OR 12.20, 95% CI 1.54–96.62) and more likely to adhere to safer infant feeding recommendations (9,10). One study reported no difference in HIV infection rates among infants, but this study was underpowered to measure this difference (10).

CHTC was associated with increased uptake of maternal and infant nevirapine for PMTCT in the single RCT (maternal NVP: OR 4.80, 95% CI 1.28–18.03; infant NVP: OR 5.26, 95% CI 1.39–19.91) (52) but not in combined data from the observational studies (maternal NVP: OR 1.03, 95% CI 0.85–1.25; infant NVP: OR 1.52, 95% CI: 0.67–3.46) (10,53,54).

One concern with CHTC, particularly in ANC settings, is partner violence.¹ Partner violence was assessed in one RCT and two observational studies in ANC settings. Findings were mixed. In the RCT, CHTC was not associated with increased physical violence (OR 0.90, 95% CI 0.1–8.11) (52). In the observational studies partner violence was measured as either physical violence (54,55) or verbal abuse (54). For physical violence the two observational studies combined found that 12 of 369 women (3.3%) who received CHTC reported violence, compared with 18 of 1595 women (1.1%) who received individual HTC. The OR was 2.38 and was statistically significant (95% CI 1.11–5.08). For verbal abuse 16 of 91 women (17.6%) who received CHTC reported verbal abuse, compared with 33 of 233 women (14.2%) who received individual HTC. The OR was 1.29, not statistically significant (95% CI 0.67–2.49). Similarly, no significant differences were found for separation/divorce (OR 0.94, 95% CI 0.94–2.31) or strength of relationship among HIV-positive women (OR 2.07, 95% CI 0.24–17.72) (35,49).

The values and preferences report did not specifically address CHTC in ANC settings. However, the same

¹ The background report, *Concerns about intimate partner violence (IPV) following CHTC*, can be found in Annex 11 on the WHO website at <http://www.who.int/hiv/topics/vct/en/index.html>.

general points hold: CHTC should not be mandatory, and most potential concerns with CHTC could be minimized with good counselling and programme planning. Budgets and other resources were considered to be generally adequate to provide CHTC in ANC settings where individual HTC is already provided, although additional training on issues specific to couples may be necessary. In one cost-effectiveness study measuring infant HIV infection as an outcome (56), CHTC was associated with averting 91 infant HIV infections and saving 2861 disability-adjusted life years (DALY) per 10 000 pregnant women. By comparison, individual HTC was associated with 88 infections averted and 2772 DALYs saved per 10 000 pregnant women. In summary, the Guidelines Group concluded, CHTC is feasible in ANC settings where HIV testing is regularly provided, as long as adequate training for counsellors on couple-specific issues is provided and efforts are made to encourage men to come and to accommodate men's schedules.

2.1.3 Individual HCT with support for mutual disclosure

Sometimes, individuals who are in partnerships test for HIV as individuals, without their partners. These individuals then know their own HIV status, but their partners do not know theirs. Four studies found more condom use across a variety of measures when partners then also were tested and mutual disclosure took place (57,58,59,60). On this basis the Guidelines Group recommended offering CHTC with support for mutual disclosure to individuals with known HIV status and their partners (Recommendation 3). For individuals who test HIV-positive, voluntary testing for partners was recommended regardless of epidemic setting, given the potential benefits of identifying HIV infection in partners and high rates of serodiscordance within couples in which one partner is known to be HIV-positive. For individuals who test HIV-negative, this recommendation was conditional, based on country-specific HIV prevalence. Offering couple and partner testing when one partner has tested HIV-negative as part of routine services was considered feasible and cost-effective only for high-prevalence, generalized epidemic settings, including sub-Saharan Africa.

For this recommendation the values and preferences, costs and feasibility were considered to be similar to those of the other CHTC recommendations.

Although no cost-effectiveness studies were identified for this intervention, participants in the technical consultation felt that it would likely be cost-effective to test the partners of HIV-negative index persons only in high HIV prevalence settings, such as sub-Saharan Africa, or to test partners of those in key populations in low-prevalence areas, such as sex workers, men who have sex with men (MSM) and injecting drug users (IDU).

2.2 ART for prevention in serodiscordant couples

2.2.1 ART for prevention in a serodiscordant partner eligible for ART for treatment

People with HIV should be offered ART for treatment of their own HIV infection when indicated according to clinical and immunological criteria (CD4 count of ≤ 350 cells/ μ L), as recommended in the 2010 WHO treatment guidelines (43). In addition to the needed treatment benefit, persons with low CD4 counts are likely to have higher viral load, which is significantly associated with the risk of HIV transmission, and ART significantly reduces viral replication. There is increasing evidence from basic science (61), interventions for PMTCT (62,63,64), observational studies (65), RCTs (66) and community-based studies (67,68,69,70,71) that ART helps prevent transmission of both HIV and tuberculosis (TB). The GRADE review concluded that there is high-quality evidence from one randomized controlled trial (36) that ART decreases the risk of transmission to an uninfected partner

RECOMMENDATIONS

4. People living with HIV who are in serodiscordant couples and who are started on ART for their own health should be advised that ART is also recommended to reduce HIV transmission to their uninfected partner. *Strong recommendation, high-quality evidence.*
5. Antiretroviral therapy for HIV-positive partners with >350 CD4 cells/ μ L in serodiscordant couples should be offered to reduce HIV transmission to uninfected partners. *Strong recommendation, high-quality evidence.*

in a serodiscordant relationship. The ratio of rates of linked HIV transmissions in this trial was 0.04 (95% CI 0.00–0.27)—that is, treatment reduced HIV transmission within discordant couples by 96%. Supporting these findings is moderate-quality evidence, from six of seven observational studies, that ART is associated with a decreased likelihood of transmission to an uninfected partner in a serodiscordant relationship, with an estimated effect of 0.34 (95% CI 0.13–0.92) in combined data from the seven studies, which is the pooled odds ratio equivalent to 66% decreased odds of infection (72).

Because of this evidence health workers should discuss with patients the potential additional benefit of decreased infectiousness for people on ART, to reinforce the importance of adherence to treatment. Also, this additional HIV prevention benefit may be an important for people to consider when deciding whether to start ART. ART for HIV prevention should be used whenever possible in combination with other proven methods of sexual risk reduction, such as use of male or female condoms, partner reduction and male circumcision (73). Decreased infectiousness due to ART may also be an important topic during conception counselling for serodiscordant couples.

The HIV preventive benefit of ART further increases the importance of promoting CHTC for those testing positive and starting ART, as a significant number of additional HIV-positive people can be identified through CHTC and offered treatment, if eligible, while also identifying negative partners and increasing the potential for prevention of transmission within serodiscordant couples.

In the studies, noted above, that demonstrated the effectiveness of ART in preventing HIV transmission in serodiscordant couples, couples were also urged to use condoms. Therefore, the Guidelines Group considered it important to emphasize recommending consistent use of male or female condoms to serodiscordant couples in which the index person was receiving ART for both treatment and to prevent HIV transmission. HIV transmission can occur in the period soon after initiating ART, before viral suppression has been achieved. Therefore, condom use should be particularly emphasized in the three months following initiation of treatment.

2.2.2 ART for prevention in a serodiscordant partner with CD4 >350 cells/μL and without clinical indications for treatment

Viral load is strongly associated with the risk of transmitting HIV and would be the best available marker to determine risk of infection to an uninfected partner. However, ART eligibility criteria and most studies rely on CD4 count as a surrogate marker for an individual's immune status. Furthermore, in low-income and middle-income countries viral load testing is not yet widely available. In general, a lower CD4 count correlates with higher viral load and thus infectiousness, but the biological evidence suggests discrepancies between CD4 count and viral load and that a significant proportion of HIV transmission events occur at CD4 counts above 350 cells/μL.

There were no studies on HIV preventive effects of ART that looked at viral load. One randomized controlled trial (36) and two observational studies (64,74) provided data on the risk of transmission in couples where the infected partner had ≥ 350 CD4 cells/μL and started ART. (Current WHO guidelines (2010) recommend ART if a person's CD4 count is ≤ 350 cells/μL or if he or she is in WHO clinical stage 3 or 4.) The quality of this evidence is high. The RCT found a 96% reduction in HIV transmission in serodiscordant couples where the partner with HIV with a CD4 count between 350 and 550 cells/μL had started ART.

Of the 1763 couples in this RTC, only 37 were MSM couples (36). A WHO and US National Institutes of Health (NIH) working group meeting held in October 2011 concluded that it is biologically plausible that similar prevention benefits would be observed in same-sex couples as in heterosexual couples; the magnitude of the effect is unknown. An additional randomized clinical trial in this community is not warranted, the meeting concluded (75). In developing these guidelines, the Guidelines Group have not reviewed the current evidence on the

The HPTN 052 randomized controlled trial found a 96% reduction in HIV transmission in serodiscordant couples where the partner with HIV with a CD4 count between 350 and 500 cells/μL had started ART early.

prevention effect of ART in populations other than heterosexual couples.

The discussion of values and preferences regarding the advisability of providing ART for people with HIV with CD4 counts >350 cells/ μ L weighed the scientific evidence and other information. Some members of the Guidelines Group stated that there are insufficient published data on potential long-term risks, such as adverse events associated with early initiation of ART (i.e. at >350 CD4 cells/ μ L), including unknown effects of longer-term ART and the potential for earlier development of antiretroviral resistance, particularly given poor adherence and intermittent stock-outs (reported in several countries), which could result in a need to change regimens earlier. Although some answers are likely to emerge from the ongoing follow-up in HPTN 052, there are no randomized controlled clinical trial data yet available that explore the impact of ART provided at CD4 levels above 350 cells/ μ L on development of drug resistance, on acquisition of primary drug-resistant HIV among previously uninfected partners or on the quality of life of the person taking ART. From the trials to date, there are few data on adverse events and side-effects of ART, HIV-related morbidity and HIV-related mortality for those initiating treatment at >350 CD4 cells/ μ L.

Careful monitoring and evaluation of implementation and implementation research are recommended to countries that chose this intervention. Questions to address include whether earlier treatment of asymptomatic infected patients results in a greater burden of medication-related adverse events or earlier development of antiretroviral resistance, balanced against whether earlier initiation of ART leads to significant beneficial long-term clinical outcomes. Full assessment of the risks and benefits of earlier therapy will depend on the eventual collection and review of these data.

The purpose of the recommendation to offer ART to people with >350 CD4 cells/ μ L in serodiscordant couples is to prevent transmission to their partners. Current WHO guidelines do not recommend the initiation of ART for people with >350 CD4 cells/ μ L for the treatment of their own HIV infection. The Guidelines Group advised that people with >350 CD4 cells/ μ L who are offered ART to prevent HIV transmission to their partners should be told why

The Guidelines Group advised that people with >350 CD4 cells/ μ L who are offered ART as an option to prevent HIV transmission to their partners should be told why they are being offered ART and that, once started, ART should be continued for life.

they are being offered ART and that ART, once started, should be continued for life.

The Guidelines Group also recommended that, for safer conception, ART for prevention should be specifically offered to people with CD4 counts of >350 cells/ μ L in serodiscordant relationships. The Group emphasized that ART for HIV prevention should be recommended for serodiscordant couples who wish to conceive, thereby minimizing the risk of transmission to the partner and also to the child. This approach should be taken only in consultation with a health care provider, and the treated partner should remain on ART for life once therapy is started.

This recommendation has important implications for PMTCT interventions, both for CHCT and ART for serodiscordant couples and for the broader strategies of PMTCT prophylaxis and treatment. The current WHO PMTCT ARV guidelines (2010) (43) recommend ART for HIV-infected pregnant women eligible for treatment (and that eligible pregnant women be prioritized for treatment) and that women not eligible for treatment be provided with prophylaxis—either an AZT monotherapy-based option (Option A) or a triple ARV-based option (Option B)—for themselves and the infant to reduce the risk of mother-to-child transmission throughout the risk period of pregnancy, delivery and breastfeeding. Recently, Malawi has proposed and has begun implementing “Option B+” (76), in which all HIV-infected pregnant women, regardless of CD4 count, are begun and maintained on lifelong ART. In effect, the Option B approach would provide prevention benefit to serodiscordant partners during the period that prophylaxis is provided (typically, for 12 months or longer during breastfeeding), even if CHTC has not been done and the seronegative partner has not been identified. Option B+ was proposed to simplify and harmonize PMTCT and ART interventions, to provide effective interventions where CD4 testing

is not available and to avoid repeatedly stopping and starting ARVs with repeat pregnancies. This new option also would provide potentially significant ongoing prevention benefit for sexual transmission and for a longer period of time. It will be important to assess the impact of this Option B+ approach, as well as the impact of a targeted approach for serodiscordant couples, and also to promote CHTC in this setting, for both male and female partners, in order to obtain the full benefits underlying all five of these recommendations.

Currently, data on the effectiveness of ART for HIV prevention in serodiscordant couples are limited to the provision of ART to people with HIV whose CD4 count is ≤ 550 CD4 cells/ μ L. It is unlikely that there will be another RCT examining this question at CD4 counts of >550 cells/ μ L. In this light, although it is likely that there will be an HIV prevention benefit for those starting ART at >550 CD4 cells/ μ L, it will be largely an operational decision whether to offer ART for HIV prevention to everyone with a CD4 count >350 cells/ μ L or to limit the offer to those with CD4 counts of ≤ 550 cells/ μ L (thus requiring CD4 testing capability). Currently, few people present for HTC with CD4 counts of >550 cells/ μ L. Programmatically, making a decision to offer ART for HIV prevention to all people with HIV in a serodiscordant relationship may be substantially easier than requiring repeated follow-up of the small number of people who present for CHTC with >550 CD4 cells/ μ L, waiting for their CD4 counts to fall below this level.

The choice of antiretroviral regimens and ART monitoring requirements are not considered in these guidelines; choice of regimens should be based on first-line regimens in countries, as recommended by the current WHO ART treatment guidelines (43,77) and future revisions. Countries will need to consider, in the context of their local epidemiological, health and community systems, the costs of additional drugs and diagnostics, as well as of service delivery and other related costs,

before designing and implementing treatment as HIV prevention for serodiscordant couples.

The strong HIV prevention benefits seen in the HPTN 052 RCT and supported by the cohort studies were all described in serodiscordant couples. The Guidelines Group noted, however, that the provision of ART was just one component of the tested intervention, which also included pre- and post-test counselling of couples and mutual disclosure and support to use condoms to prevent transmission, as supported by Recommendations 1–3 of these Guidelines. These components of CHTC should continue to be supported and emphasized even where ART is available to these couples.

Some members of the Guidelines Group raised concerns about the additional financial costs of ART for HIV prevention. Some also expressed concerns about the potential for significant implementation and ethical difficulties if ART for HIV prevention were to be preferentially offered to people with >350 CD4 cells/ μ L in serodiscordant relationships when the rest of the population is eligible for ART only according to WHO or national treatment guidelines that specify lower CD4 counts. Additional equity concerns were raised about offering earlier ART to serodiscordant couples (i.e. by expanding treatment indications) when in many places large numbers of patients that meet clinical criteria for treatment are currently untreated. When making a global recommendation on a health intervention, there is always the understanding that there will be issues of cost and feasibility that vary with context. Countries and programmes will often have to make difficult choices when resources are limited. In situations of limited or inadequate resources, individuals who require ART for their own health should always be given priority.

In situations of limited or inadequate resources, individuals who require ART for their own health should always be given priority.

3. GUIDING PRINCIPLES FOR IMPLEMENTATION

Human rights principles, as set forth in a number of international agreements (78,79), inform these guidelines.

Stigma and discrimination remain significant problems for people with HIV. For couples receiving HTC jointly and sharing their results with each other, and for those considering early initiation of ART for the HIV-infected partner, there are the potential negative consequences of relationship difficulties and gender-based violence. Therefore, it is essential that, like all other HIV counselling, testing and care, CHTC and the offer of earlier ART for prevention in serodiscordant couples adhere to basic tenets of self-determination, privacy, informed decision-making and protection.

3.1 Voluntary utilization of testing services

Mandatory or coerced testing is never appropriate, whether that coercion comes from a health care provider or from a partner or family member. It is particularly important in CHTC that health workers are sensitive to potential gender-based power imbalances in relationships; they must be able to assess whether, and to assure that, both partners are freely able to make independent decisions about testing and disclosure, and they must be prepared to suggest deferring the process until a later date if necessary to address any concerns about the couple's readiness.

3.2 Five Cs—consent, confidentiality, counselling, correct test results, link to care

The following are key principles of all HTC and apply to CHTC in all circumstances:

- Persons receiving CHTC must give informed consent to be tested and counselled. Couples and partners should be informed of the process for CHTC. They should understand that they will be tested and counselled together and will receive their results together, and they both must agree to this.
- CHTC services are confidential, meaning that what the HTC provider and the couple discuss will not be disclosed to anyone else without

the expressed consent of both partners in the couple. Before receiving CHTC, couples/partners should agree to shared confidentiality—that is, although each partner in the couple will know the other's HIV status, they agree not to share these results with anyone else unless they both agree to do so. Decisions concerning to whom to disclose their results should be made together. While confidentiality must be respected, it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should raise the issue of whom else the couple may wish to inform, how they would like this to be done, etc.

- CHTC services must be accompanied by appropriate and high-quality pre-test information and post-test counselling. This includes the provision of effective referrals to appropriate follow-up services as indicated, including long-term prevention and treatment support. Quality assurance mechanisms and supportive supervision systems should be in place to ensure the provision of high-quality counselling to couples and partners.
- CHTC providers should strive to provide high-quality testing services, and quality assurance mechanisms should be in place to ensure the provision of correct test results to partners and couples. Quality assurance may include both internal and external measures and should include support from the National Reference Laboratory as needed.

3.3 Access to justice

Many people with HIV have experienced discrimination and stigma following diagnosis, whether they have been tested as individuals or as couples. Emotional, sexual and physical violence are sometimes also significant issues, particularly for women with HIV. CHTC providers must receive training on human rights and protection issues and be aware of all relevant support services for timely and appropriate referrals. When planning and developing CHTC and ART for HIV prevention services, explicit description of human rights and gender-based violence issues and related programmatic elements must be included in proposals and documentation of funding needs. For their part, donors in their requests for proposals should require such descriptions. Additionally, there

will continue to be a need for strong leadership to mobilize communities and for advocacy to reduce stigma and discrimination and to ensure provision of services.

3.4 Human rights

Adherence to fundamental principles of human rights is foremost among all considerations when establishing CHTC services. Most importantly:

- CHTC should always be voluntary for both partners.
- People should not be turned away from services if they cannot or do not want to bring their partner.
- If a couple does not want to test together, they should still be offered individual HTC.

3.5 Provision of earlier treatment

The HIV prevention benefit of ART constitutes a strong argument for promoting universal access to treatment for key populations. However, Recommendation 5, based on the findings of HPTN 052 (36) and other studies, focuses more narrowly on the situation of HIV-positive individuals in serodiscordant relationships whose CD4 levels are above 350 cells/ μ L and who are offered and choose to initiate treatment for the purpose of preventing HIV transmission.

It is important, as countries consider Recommendation 5, that those faced with difficult financial and programmatic choices ensure access to ART for all people with HIV who are eligible for treatment to protect their own health, prioritized over offering earlier treatment to some people for the purposes of preventing HIV transmission to others. Achieving universal access to ART for all who need it for their own health will have significant preventive benefit in itself. If countries have the resources available to offer earlier therapy to HIV-positive partners in serodiscordant couples

to prevent HIV transmission, the preventive public health benefit will be enhanced. In such countries close evaluation of these services through operational research is essential to gain knowledge and to document the impact of the intervention at the individual, couple, family, programme and population levels.

For an individual or couple, initiating lifelong treatment, such as ART for HIV prevention, when it is not yet needed for one's own health, is a complex issue. When considering earlier initiation of ART primarily for HIV prevention, health workers and individuals/couples must understand that this option is primarily for HIV prevention purposes, not for treatment of the partner with HIV, and the provider must verify that the couple understand this.

Deciding for or against this option requires full consideration of its potential benefits, adverse consequences and implications. The individual or couple making such a choice should consider in particular the potential adverse effects of medication, the implications of a commitment to lifelong adherence and the possibility of the development of drug resistance through non-adherence. Counselling should assure that the couple fully considers these issues and that together they make an informed choice.

In addition, an HIV-positive person in a serodiscordant couple considering ART for HIV prevention should review with his or her partner and health care provider all the options for reducing the risk of HIV transmission. In addition to early initiation of ART, options for prevention of HIV transmission include consistent and correct use of male or female condoms, circumcision of the male HIV-negative partner, harm-reduction interventions if one or both partners inject drugs, and behavioural interventions tailored to the needs and preferences of the couple.

It is important to ensure that people do not feel coerced (either by their partner or by their health care provider) into initiating ART for prevention, and they should be fully supported regardless of their decision.

4. OPERATIONAL ISSUES IN IMPLEMENTATION OF CHTC AND THE PROVISION OF EARLY TREATMENT FOR HIV PREVENTION IN SERODISCORDANT COUPLES

CHTC is an opportunity to increase the impact of efforts to prevent HIV transmission and to increase access to HIV care and treatment through services that are currently used largely by individuals (see Table 1 in section 1.1). At present, however, there are no global operational standards for CHTC in any health service delivery setting nor is there global guidance on use of ART for HIV prevention by people who are not eligible for treatment under current criteria. These guidelines seek to start filling these gaps with an overview of potential programmatic issues concerning CHTC and ART for HIV prevention.

CHTC is an opportunity to strengthen the impact of efforts to prevent HIV transmission and to increase access to HIV care and treatment.

4.1 Overarching issues

CHTC can be offered in a variety of clinical and community settings. A number of issues and conditions are common to all settings. These include promotion and advocacy as well as various staffing issues.

4.1.1 Promotion and advocacy

It will be important to offer CHTC services widely and to promote them globally and within regions and countries. Internationally, advocacy should raise awareness among bi-lateral donors and international research and financial institutions. In countries information, education and communication (IEC) for the public and health care consumers will need to be tailored to specific local needs and HIV epidemic profiles. To the extent possible, CHTC should be integrated into existing policies and programmes for client- and provider-initiated testing and counselling. While this may prove easier than starting an entirely novel service, CHTC will still need promotion—to health policy-makers, programme managers, and providers, to assure availability, and to the public and especially to the clients of existing services, to encourage demand. At the community level intensive efforts to increase awareness must be shaped by a good understanding of existing health systems, people's actual health-seeking practices and cultural norms that may influence the acceptability, practicability and uptake of services. In communities where there has been

little access to HTC, the preparatory phrase may be more extensive and include community and staff orientation. A broad approach, addressing both the communities of potential clients for CHTC and its providers, will ensure that sufficient emphasis goes to advocating the benefits of CHTC and its increased availability.

Introducing ART for prevention will especially require education and communication. While in many countries and settings policy-makers and programme managers and staff understand clearly the benefits of ART for treatment and the associated logistic and implementation issues, the provision of ART for HIV prevention in serodiscordant couples is a recently proposed intervention and less widely understood. A range of communication activities directed to health workers will be needed to address training and service delivery issues as will communication to inform the wider community of the benefits of ART for HIV prevention for serodiscordant couples.

Promotion of CHTC will require innovative thinking and flexible programming. To encourage men's participation in CHTC, for example, it will be useful to engage influential political leaders at all levels, peers, community leaders, role models and celebrities to promote the intervention. Services can be provided in a variety of settings including the community (e.g. home-based and workplace HTC) as well as health facilities (80). At the level of service delivery, to help promote CHTC, appropriate incentives for clients, such as reimbursement for transport, distribution of bed nets or prioritization of couples in queues for services, could be considered. These activities must be explored fully and undertaken in a sustainable way.

4.1.2 Staffing

Health workers currently providing individual HTC would be the primary source for CHTC staffing. Existing training curricula for HTC focus on individual HTC; modifications and new materials will be needed to address the special issues and skills needed to deliver CHTC services. Similarly, if ART for prevention is going to be proposed to the HIV-positive person in a serodiscordant couple, counsellors and ART providers will need updated information and training on the benefits and cautions associated with this intervention. Also, they will need the skills to communicate this information to the couple and to assess whether

Supporting effective linkages from HTC to ART services and retention on ART for life are significant challenges for ART for both treatment and for HIV prevention.

both partners clearly understand the choices and the implications of their decisions.

Health workers will also need training in promoting treatment adherence. Adherence counselling for ART for prevention will be essentially the same as adherence counselling for patients taking ART for treatment. Still, some differences may need consideration, as the motivation for adherence will be different.

As HTC and ART are often provided by different health workers in different settings, appropriate and consistent referrals and linkages must be ensured. Supporting effective linkages from HTC to ART services and retention on ART for life are significant challenges for ART for both treatment and for HIV prevention.

In most countries the pool of health workers with training in HTC is still insufficient to meet current needs, and health system budgets are not increasing. Creativity and flexibility as well as some additional funding may be needed if the offer of CHTC requires an increase in staff time.

Lay staff

In many settings lay counsellors and peer educators have supported the work of professional staff (81). In particular, lay counsellors living with HIV have played a unique role in supporting people through the HTC process and, if they test positive, especially in post-test care. Lay counsellors may be able to offer such support to CHTC. For example, as CHTC services in ANC settings expand, more men will need to be recruited and trained to work in this setting.

For people taking ART for HIV prevention, support for follow-up is likely to be more straightforward than for people with clinical symptoms, who, particularly at the initiation of ART, may require significant clinical contact. Lay providers may be well placed to provide follow-up counselling and support in the community for asymptomatic people taking ART primarily for HIV prevention.

For lay counsellors to take on more responsibility and expand their role in services, ministries of health may need to change employment regulations. At the same time, increasing the lay workforce to provide new services will require more task-shifting, innovative recruitment and fair compensation.

Training

A first step in developing training will be to assess providers' needs for information about HIV serodiscordance and related service delivery issues. This guidance provides a basis for creating training materials and job aids that meet these needs. (WHO is currently working with the United States Centers for Disease Control (CDC) to update their CHTC training materials, which will support a 2-day training on CHTC for health workers.) When developed at the international level, training materials and practical tools should be generic and applicable to a wide range of settings, while amenable to the necessary local adaptation. All resources should be field-tested and pilot-tested to ensure that they are appropriate and effective.

In the preparation of providers to offer CHTC, it is important to avoid over-specialized training. All providers should be trained in basic HTC skills according to existing national guidelines, and then further training can address the additional skills required for specific services such as CHTC. In general, to provide CHTC, health workers will need to know how to involve men in services that have conventionally addressed or appealed more to women, such as ANC and maternal and child health (MCH) services. For their part, male circumcision providers will need the skills to encourage women's involvement. All CHTC providers will need the ability to assess a couple's readiness to engage in the counselling and decision-making process jointly. Training providers how to address conflict when it arises in the context of the counselling session is an important priority. Furthermore, all counsellors should receive training on human rights and protection issues; they must be able to recognize women or men who may be vulnerable to abuse following CHTC, including verbal or emotional abuse, intimate partner violence, relationship dissolution, and stigma-related abuse. They will also need to know how to address or prevent such abuse.

Training must help health workers to understand why it is important to counsel couples on the

benefits of ART for the health of the HIV-positive partner/s (for those who are clinically eligible) and the benefits and cautions of ART for HIV prevention for individuals with CD4 >350 in serodiscordant couples. At the same time, providers should appreciate that starting ART early is a personal and couple choice; many people may not want to initiate ART early and may prefer to rely only on other preventive measures, such as condom use, to avoid transmission to their partner. Health workers need to respect the decision of the couple who decide against early ART, whatever their reason. HIV prevention counselling and supplies of condoms should always be available for all couples and individuals.

Attitudes of health workers

Providers' support for CHTC, for ART for HIV prevention and for treatment adherence in serodiscordant couples will be critical to the success of such services, and providers' attitudes and views must be considered when planning orientation and training. The qualitative report prepared as background for developing these guideline¹ and other studies reveal clients' common experiences with unhelpful or judgmental health workers (82,83). Such attitudes can stem from any of a range of causes, including fear of exposure to HIV (84) and fear of "stigma by association" with HIV-positive clients (85). In some cases ANC providers may be uncomfortable having men attend their clinics. Exploring and addressing health workers' attitudes and beliefs during training and support activities will be key to making services acceptable and appropriate and to averting harm.

Involvement of people with HIV

There are many programmatic examples of people with HIV playing important roles in designing, developing and implementing HIV services (86,87). The greater involvement of people with HIV (GIPA) should not be tokenistic. Reflecting this distinction, the term MIPA ("meaningful involvement of people with HIV") is preferable.

Health staff themselves may be HIV-positive. These staff members have important insights and personal experiences that enhance their skills and effectiveness with clients, especially during pre- and post-test counselling and support. It will

be crucial to ensure that health staff members with HIV can carry out their responsibilities in a supportive environment and have access to care and treatment as necessary.

People with HIV need to be involved in developing and planning CHTC services so that these services will be as effective and acceptable as possible and provide counsellor-assisted mutual disclosure in a safe and supported environment. Furthermore, to the extent possible, individuals or couples with HIV should be available to share their experiences with and offer emotional support to couples deciding on and in the course of CHTC.

4.1.3 Services

Follow-up and linkages to prevention, care and treatment services

Unless services are available after testing, the benefit of knowing one's HIV status is limited, particularly for an HIV-positive person. For couples participating in CHTC, as with individuals receiving HTC, a range of linkages should be available to prevention, care, treatment and support services. These linked services include:

- male circumcision for men who test HIV-negative
- male and female condoms
- ongoing counselling, psycho-social and spiritual support through lay counsellors, peer support groups and faith-based organizations as needed
- re-testing for negative partners in serodiscordant relationships
- clinical care for those with HIV, including ART screening and cotrimoxazole prophylaxis
- TB screening and care as clinically indicated (88), including isoniazid preventive therapy
- support and referral to protective services for domestic abuse/gender violence
- counselling on alcohol and other substance use as required
- reproductive health services, including family planning, with access to effective contraceptives, conception counselling for

¹ This report can be found in Annex 9, on the WHO web site at <http://www.who.int/hiv/topics/vct/en/index.html>

serodiscordant couples and antenatal care and follow-up

- PMTCT for pregnant women
- ART for prevention in serodiscordant couples.

For couples mutual disclosure can take place in any of a number of processes, such as simultaneous joint disclosure or pre-arranged disclosure after individual HTC. These processes usually will need ongoing support from a counsellor specially trained and skilled to structure the process and guide discussions and decision-making. Similarly, support for HIV prevention for serodiscordant couples will require more than a single post-test session, as is often the norm for individual HTC, and follow-up HTC will be required for the HIV-negative individual in a serodiscordant relationship, who should be offered re-testing on an annual basis. Also, marital and family relationships can be complex and may require longer-term support following CHTC.

In many countries health services are under-funded, and health workers are already over-burdened. Offering adequate ongoing and possibly longer-term counselling and support to couples will require alternatives to placing still more responsibility on the shoulders of current providers. Lay counsellors or community health workers may be well placed to offer this ongoing support, and peer support groups for couples have proved to be a useful approach.

Support groups

There are many examples of groups that successfully offer peer support and access to follow-up services for people, including couples, following HTC (89,90). For example, some programmes employ community members such as mothers with HIV, who work alongside doctors and nurses to educate pregnant women and new mothers, to give them support for PMTCT and treatment and to serve as role models in the longer term (91). Similarly, programmes should, where possible, identify serodiscordant couples to participate in these support groups as peer counsellors; there is no substitute for the empathy and practical advice that comes from shared experience.

Retention and adherence issues for serodiscordant couples who choose early ART for prevention

Serodiscordant couples who opt for early ART for

prevention will require adherence counselling and support, and long-term monitoring and follow-up, as do those who receive ART for treatment. Most likely, long-term needs will vary from one person to the next, and counsellors' responses will best be individually tailored. On one hand, a person whose treatment is not for direct personal benefit may be less conscientious about taking medications. On the other hand, people starting on treatment earlier, when they are asymptomatic, may have better clinical outcomes and retention in care. Furthermore, someone who has a partner to support him/her in accessing and remaining on treatment may require less intense follow-up by programme staff.

4.1.4 Facilities

Managers of programs that now offer HTC will need to consider whether existing infrastructure will need modification to accommodate CHTC services. Simple steps, incurring little or no extra cost, may suffice—for example, offering a separate entrance for couples or reserving certain service hours for couples, in case men are uncomfortable coming to services with other women present. As with individual HTC, areas for CHTC must provide the couple and counsellor with visual and auditory privacy. If demand for CHTC services increases, facilities may need to consider renovations to add space or acquiring new space when feasible.

4.1.5 Test kits, ART monitoring supplies, ARVs and other supplies

Supplies are procured at levels based on projections according to current utilization rates. These projections and the assumptions underlying them will need to be revisited to accommodate potential requirements for more ARVs, test kits and other supplies, including condoms, if demand for CHTC and ART for prevention in serodiscordant couples increases.

4.1.6 Cost issues

Current budget allocations for HTC may be partially re-allocated to CHTC, as their objectives are virtually identical and the impact and savings with CHTC are potentially greater than with individual HTC. Cost savings can be achieved when providing services for two people at the same time, although in some cases there may be complex issues to address that will increase the time needed for counselling.

At the same time, however, additional investments will be needed, especially at first, to take full

In the long run initial cost increases should be counter-balanced by future savings brought about by reduced HIV transmission.

advantage of the potential of CHTC and ART for prevention. Potential costs include specialized training for counsellors, compensation for additional lay counsellors and peer educators, and possibly longer-term monitoring and support as well as promotional activities and the anticipated increase in uptake.

Providing ART for prevention will increase certain costs beyond those of serving the current population of clinically eligible patients. The additional costs of drugs and staff and costs associated with clinical monitoring will need to be estimated and additional funding budgeted. In the long run initial cost increases should be counter-balanced by future savings brought about by reduced HIV transmission.

4.1.7 Monitoring and evaluation

Monitoring the quality of CHTC services

In new programmes, before developing and implementing a service, formative research could be considered to explore the views of service providers and end users as to the acceptability of services and their optimal delivery.

CHTC services require the same basic elements of counselling and testing services as individual HTC, and the availability and quality of each of these needs to be monitored. Some basic service elements that need to be in place are listed in Box 1.

Monitoring the provision of ART for prevention in serodiscordant couples

A checklist for ART for treatment services appears in Box 2.

Targets, programme evaluation and indicators

It is important for countries and programmes to set targets for CHTC, to develop relevant and measurable indicators, to monitor progress, and to conduct operational analysis to determine whether and what adjustments are needed to improve ongoing programmes.

Recently developed WHO monitoring and evaluation (M&E) guidelines for HTC include useful indicators

Box 1 Checklist for CHTC services

- Appropriate and safe space for counselling, where conversation can be confidential
- Adequate, trained workforce, including:
 - counsellors
 - health care providers
 - peer/lay counsellors including people living with HIV
- Quality improvement measures to support and maintain the quality of counselling
- HIV testing capacity, including:
 - adequate lab capacity
 - sufficient stocks of test kits and supplies, especially for same-day testing
 - effective supply chain management system and capacity, including medical waste management
 - participation in an external quality assurance system
- Links with prevention, care and treatment services, including pre-ART, ART and TB services
- Links with services for male circumcision, male and female condoms, sexually transmitted infection (STI), family planning, MCH and other services as appropriate.

Box 2 Checklist for ART for prevention services

- Appropriate space for ART provision
- Adequate, trained workforce, including:
 - Health care staff to provide ART
 - Peer/lay counsellors, including people living with HIV, to support retention and adherence
- Quality improvement measures to support and maintain the quality of ART services
- ART monitoring
 - Adequate lab capacity
 - Sufficient stocks of ART monitoring tests used in the ART programme and supplies (including transportation systems if central laboratory services are used)
 - Participation in an external quality assurance system.

that can be modified to capture conditions and measure services specific to CHTC (92). If indicators are being used for the first time, they should be pilot-tested first and refinements made if needed.

To monitor and evaluate CHTC, data on the following areas could be collected, analysed and reviewed to support service development and improvement:

- **Uptake of services.** It will be important to record the number and proportion of clients testing together as couples and to establish systems to clearly record re-testing of negative partners in serodiscordant couples. Programmes may also wish to disaggregate the number of couples testing together by test result, to monitor the proportions of serodiscordant couples, seroconcordant infected couples, and seroconcordant uninfected couples.
- **Acceptability of services**
- **Linkages.** Monitoring the uptake of referrals and linkages will be needed to ensure that couples are receiving appropriate follow-up care and support (see section 4.1.3). These data will help identify critical service gaps and inform advocacy, partnerships and policy for establishing additional support and protective services as required.

At this time little is known about the acceptability and long-term outcomes of early initiation of ART for HIV prevention. Therefore, it is particularly important to monitor these programmes carefully for adverse treatment events, ART drug resistance and rates of HIV transmission to negative partners.

To monitor and evaluate the ART for HIV prevention intervention, the follow areas could be considered:

- **Uptake of ART**
 1. number of serodiscordant couples with CD4 \leq 350 offered ART (disaggregated by M/F index case)
 2. number of these accepting ART
 3. number of serodiscordant couples with CD4 $>$ 350 offered ART (disaggregated by M/F index case)
 4. number of these accepting ART.
- **Acceptability of services**

- **Impact of earlier ART on**
 1. morbidity and mortality
 2. drug resistance
- **Retention in care** at 6, 12, 24, 60 months, etc.
- **Adherence.** In many settings people who receive ART primarily for HIV prevention will be registered at the same facilities/services as people who receive ART primarily for treatment. It will be important that the monitoring of retention and adherence in ART for HIV prevention is consistent with monitoring of ART for treatment, to prevent overburdening health services with multiple monitoring and reporting systems.
- **Monitoring for adverse effects.** No significant increase in adverse effects has been reported with CHTC when compared with individual HTC (35). However, HIV infection has been associated with gender-based violence in some other studies (93,94) (although not in a recent review of data from 10 countries (34)). It is important for service providers to monitor for adverse consequences of CHTC and to seek to mitigate them. Also, providers should alert programme managers to any potential problems so that services can be reviewed and modified if needed.

If ART for HIV prevention in serodiscordant couples is offered, adverse treatment effects and the possible emergence of ART drug resistance will need to be monitored.

4.2 Antenatal, perinatal and postnatal care

Routine provider-initiated HTC is the standard of care in most ANC settings as one of multiple tests used to protect a woman's pregnancy. These services present the most immediate and obvious opportunity for integration of CHTC (see section 2.1.2). While women are the primary users of ANC services, such services are widely recognized as offering a key opportunity to include men in discussions about and services for sexual and reproductive health, HIV prevention, HIV treatment and care and child and family health.

In many cultural contexts gender inequities create power imbalances in relationships. As a result,

women are often reluctant or anxious about making decisions regarding HTC, PMTCT and infant feeding options without the knowledge and support of their male partners. In general, however, men do not attend ANC clinics with their partners, and often women must assume the responsibility of very heavy decisions alone. The availability of CHTC would help to make the participation of men more routine and acceptable, could relieve many women of the burden of deciding alone and could build support for PMTCT interventions. Also, support for mutual disclosure in ANC services would relieve some women of the burden of disclosing a positive HIV test result to their partner and thus perhaps help to reduce the risk of violence.

ANC and MCH services would provide multiple entry points for HIV information and support through CHTC, along the full continuum of ANC services, including:

- pre-conception
- antenatal care and support
- prevention of vertical transmission (PMTCT)
- labour and delivery
- post-delivery support
- home-based services
- postpartum contraceptive services.

ART for HIV prevention in serodiscordant couples may be offered and initiated in ANC, labour and delivery and other related MCH services, as well. While work to integrate ANC and ART services is ongoing in countries, currently longer-term ART provision and follow-up occur primarily in standard ART programmes. Therefore, to minimize the real risk of significant loss to follow-up, strong links and referral mechanisms must be assured to support the transition from ANC to ART services.

4.2.1 Pre-conception counselling and ANC services

Uninfected women in serodiscordant relationships are at increased risk of becoming infected with HIV around the time of conception and during pregnancy. At the time of conception this is unavoidable—a relaxing of safer sex practices to

conceive (95). Increased risk of infection during pregnancy may be due to changes in maternal immunity. Men also are more prone to HIV infection during this time (96); an infected pregnant woman's increased viral load and vaginal shedding of HIV may increase her partner's exposure.

This increased vulnerability—whether for behavioural or biological reasons—highlights the importance of including male partners in pre-conception and antenatal HIV prevention activities. CHTC may be men's point of entry to these activities. Because of the significant risk of incident HIV infection, current WHO guidelines recommend re-testing HIV-negative pregnant women in high prevalence generalized epidemics in the third trimester, so that women who seroconvert can benefit from antiretroviral prophylaxis to prevent vertical transmission (97). CHTC prior to conception and in early pregnancy could help to prevent both horizontal and vertical transmission by supporting HIV prevention interventions (condoms and PMTCT post-conception) and by giving ART to the HIV-positive partner.

CHTC could enhance the effectiveness and impact of ANC and PMTCT services at every level—access and uptake of PMTCT services, use of safer infant feeding options and prevention of HIV transmission to partners. Early counselling could emphasize the importance of HIV testing and prevention, the implications of serodiscordance, the risk of transmitting HIV to infants and the benefits of PMTCT interventions, and the benefits and risks of mutual disclosure. CHTC can be offered along with support for mutual disclosure, enrolment in PMTCT services for HIV-positive women and referral for appropriate support services.

4.2.2 PMTCT/labour and delivery

CHTC linked to PMTCT/labour and delivery services would emphasize the importance of physical and emotional support for the pregnant woman and the vital supportive role of her partner. Following delivery, by making both parents aware of their own and each other's HIV status, CHTC can facilitate access and adherence to treatment for either or

CHTC could enhance the effectiveness and impact of ANC and PMTCT services at every level.

Checklist: Considerations for implementing CHTC services

Commitments

- Who are the stakeholder groups? Who are their leaders? How can they be engaged to endorse and promote CHTC?
- How will stakeholders' representatives be brought together for commitment and strategy planning?
- What gate-keepers must approve CHTC? Who can reach them? What arguments will convince them?

Planning the roll-out

- What health services could offer CHTC?
- How will CHTC phase in—into which health services first and where?
- What additional budget will be needed? Where will funds come from?
- Is the budget secured?

Staffing

- What additional training do CHTC counsellors, providers and supervisors need? How and when will it take place?
- Will new staff need to be recruited? What more can lay counsellors do, including people living with HIV?
- What training materials and counselling aids will CHTC providers need?

Communication

- Who will take overall responsibility for advocacy with stakeholders? political leaders? health staff? the news media?
- How will CHTC services be promoted:
 - to the community and the public?
 - to clients of services offering CHTC?
- Who will be ongoing champions of CHTC in the community and in health services?
- How can the full commitment of all health care providers be won and sustained?

Supplies and facilities

- Will purchasing forecasts and logistics need adjustment?
- How can facilities and services be more "couple-friendly"?

Linkages and referrals

- Are linkages and referral systems for CHTC clients adequate?
- How can services be consolidated or integrated, so as to minimize drop-out?

Follow-up

- How should record-keeping be modified to track couples as well as individuals?
- How will annual retesting of HIV-negative partners be assured?
- Are support groups thriving? If not, how can they be supported?
- Are couples who tested together being recruited into support groups and as peer counsellors and community advocates?

Monitoring and evaluation

- How will the effects on clients of CHTC be monitored, including behaviour change, transmission, intimate partner violence or abuse, and stigma?
- How will the effects on patients of early ART for prevention be monitored, including transmission, adherence, behaviour change, side-effects, adverse events, and drug resistance?
- How will programme activities be monitored, particularly:
 - Client numbers and characteristics, including trends? What services are offered to clients, with what uptake?
 - Sufficiency of staff and training?
 - Staff performance? In particular, how well do counsellors help couples with disclosure, discussion and decision-making? How well do they manage difficult situations?
 - Other service quality issues—equity, privacy, confidentiality, accurate test results, friendly atmosphere?
 - Clients' and the public's perceptions of CHTC services?
 - Adequacy of supply? Any stock-outs?
 - Community outreach and results?
 - Continued functioning of linkages and referrals; follow-up rate?

Knowledge sharing

- How will M&E findings be regularly analysed and used to improve services?
- How will staff members, facilities and services share experience, and knowledge?

both parents and safe infant feeding choices. CHTC also can promote early infant diagnosis and follow-up and appropriate care for exposed infants.

A study in Uganda recognized labour and delivery as an important opportunity to offer partner testing, as more men attended deliveries than ANC visits (98). Men who accompanied their partners through labour and delivery readily accepted the offer of testing and counselling. In fact, 51% of all women tested in labour and delivery were counselled together with their partners, compared with only 5% in ANC. In the study setting HTC during labour and delivery enabled approximately an additional one-third of women to know their HIV status; 11% of this one-third were identified as HIV-positive and linked to care.

These findings suggest that CHTC in labour and delivery settings may be a feasible and acceptable way to reach women and their partners who were not tested and counselled earlier, before or during pregnancy. It must be emphasized, however, that, while ANC/MCH services are an important setting for reaching couples, every effort must be made to reach them as early as possible in a woman's pregnancy and even before, to prevent possible transmission to her and her baby if her partner is HIV-positive and she is HIV-negative.

Current operational context

The routine offer of individual HIV testing is generally the approach used to promote uptake of HTC in ANC and perinatal care settings. As services for couples become established and CHTC becomes more routine and acceptable, CHTC could become the norm for testing and counselling in ANC and perinatal care settings, with individual HTC available on request.

In general, men are not encouraged, and in some settings they are not allowed, to attend ANC/MCH services. Even where men are allowed or encouraged to accompany their partners, they seldom do. Public information campaigns will need to introduce the concept of CHTC, including mutual disclosure and joint counselling, as an important and routine aspect of ANC/MCH services.

What is needed going forward

Promotion of couples HTC and greater utilization of ANC, perinatal and postnatal services by couples will require orienting countries and communities to

a novel concept that may challenge existing health infrastructure and systems as well as behavioural conventions. A community sensitization process should accompany the introduction of CHTC into ANC, perinatal, and postpartum services. This sensitization, both specifically for CHTC in these settings and to promote uptake of these services by couples, may involve a variety of approaches:

- **Harnessing political will and donor commitment.** Full implementation of CHTC in ANC/MCH services will require political support—both high-profile public advocacy and policy-level advocacy to explicitly integrate CHTC into national ANC/MCH policies and strategies.
- **Increasing awareness of the benefits of and demand for CHTC in ANC.** This can be achieved through a variety of community mobilization interventions. Interventions should be tailored to the community setting and may include behaviour change communication (BCC), dissemination of IEC materials, and strategic engagement with traditional and faith leaders in the community.
- **Increasing male involvement.** There are a number of ways to ramp up innovative efforts to increase men's involvement in ANC, perinatal and postnatal services—involvement that would also provide opportunities for information-sharing and promotion of CHTC. Programme managers or providers might consider letters inviting partners of ANC clients or men in the community at large to attend clinics. In the case of male circumcision (MC), there is a period of abstinence required following the procedure; optimal timing for MC could be the immediate postnatal period. Testing and counselling to identify HIV-negative male partners who can be referred for MC might be integrated with labour and delivery services in ANC settings.

Workplaces have provided good opportunities for peer educators to communicate with other men about HIV prevention and the benefits of HTC (99,100), although the effectiveness of current workplace HTC programmes may be limited by the types of services and support that they provide (101). Workplace programmes could incorporate information about and promotion of CHTC and emphasize the importance of men's involvement in ANC.

- **Making services male-friendly.** Programme managers should reconsider ANC service delivery models to find ways to make services more comfortable for men. This may involve modifying physical spaces to allow men to accompany their partners without feeling self-conscious or intrusive in spaces that need to remain private for women. Inexpensive changes might include scheduling a couples-only day or preferential hours for couples in the early morning and evening, providing informational videos for men in the waiting area and recruiting male health care workers for ANC/CHTC services.
- **Addressing barriers and constraints to CHTC in ANC services.** Many of the issues that will limit uptake of CHTC in ANC settings already pose challenges to ANC services in general. In most low- and middle-income countries, the level of male involvement is very low, usually due to cultural or community norms. In addition, ANC coverage is often low to begin with, and the rate of loss to follow-up is high. Moreover, in some countries rapid HIV testing with same-day results does not exist, exacerbating loss to follow-up of testing. In fact, CHTC may present opportunities for strengthening demand for and consistent attendance at ANC services by reducing women's anxieties about support from their partners.
- **Providing links between ANC and HIV care and treatment services.** Currently, although there have been impressive increases in the uptake of HTC and PMTCT interventions by pregnant women attending ANC, many women who need ART for their own health are not linked to ongoing ART programmes following delivery. This lack of robust referral systems and clear linkages needs to be addressed for all women (and their partners) who are diagnosed with HIV in the ANC clinic, whether they need ART for treatment of their own infection or they are offered ART for prevention.

4.3 Other clinical settings

TB clinics

People with HIV are an estimated 20 to 37 times more likely to develop tuberculosis than people who do not have HIV infection (88). Thus, TB/HIV co-infection rates are very high. WHO recommends

the integration of HIV and TB services, and HTC has taken place in TB clinics for at least two decades. Couples or the partners of TB patients are not generally served in these settings, however. Directly observed therapy (DOT), the widely practiced protocol for TB treatment, requires clients to visit the health facility regularly for at least six months. This schedule offers multiple opportunities to involve partners of clients and to identify partners who are co-infected with TB and HIV.

HIV care and ART clinics

Like TB clinics, HIV care and ART clinics see clients on a more regular basis than most clinical services. Thus, these settings offer multiple opportunities to involve partners for CHTC, with emphasis on preventing transmission and addressing other issues affecting couples when one or both have HIV. For partners who test HIV-positive, the ART setting makes rapid clinical assessment possible. Especially when a partner tests HIV-negative, it offers multiple opportunities to reinforce adherence counselling—especially crucial if there is a risk of transmitting drug-resistant viruses.

Male circumcision services

Studies have demonstrated that male circumcision (MC) helps prevent HIV transmission from females to their uninfected male partners. Therefore, MC is being promoted as an additional HIV prevention strategy for HIV-negative adult and adolescent males, part of a comprehensive HIV prevention package in areas with generalized HIV epidemics and low prevalence of MC (102).

Potentially, MC services would provide a major opportunity to get men tested and counselled, and they could provide an opportunity for involving partners. Although HTC is already a key component of the MC minimum service package, couples HTC is not currently a routine part of MC programmes, which have been rolled out largely as vertical programmes. CHTC could reinforce linkages and increase the impact of MC programmes.

MC clients should be strongly encouraged to bring partners for testing, counselling and support (and thus female-friendliness should be a consideration for these services). As MC is not fully protective, men who undergo circumcision will need to continue to practise safer sex, including use of condoms, at least outside a relationship with a

Male circumcision services offer an opportunity to get men tested and counselled and could provide an opportunity for involving partners.

seroconcordant partner. CHTC could support and reinforce a couple's communication and decision-making about condom use. A female partner who tests positive can obtain timely ART to further reduce the potential for transmission. A 6-week period of abstinence is recommended following MC; this is another reason for partners to be present, so that they can understand this and have an opportunity to ask questions.

CHTC as part of MC services might mitigate some adverse consequences of HTC and disclosure. In most cultures men are considered the decision-makers, and they could encourage their partner's participation in CHTC with minimal risk of abuse or abandonment. However, it is imperative that both partners agree to participate in CHTC and that coercion is avoided.

Child health services

When children with HIV are identified, providers should encourage parents to come in together for CHTC, as either the mother or both the mother and father will also have HIV infection. This will enable parents to obtain treatment and will provide support in the long term for their affected child. Since a child's infection with HIV means that infection was most likely acquired from his or her mother, CHTC must be handled delicately in these situations.

Family planning services

New data has emerged regarding a potential association between the use of hormonal contraception, particularly progestogen-only injectable contraception, and HIV acquisition in women and transmission from HIV-positive women to male sexual partners (103). Some studies suggest that women using progestogen-only injectable contraception may be at increased risk of HIV acquisition, other studies do not show this association. WHO concluded in February 2012 that women at risk of HIV or living with HIV, may continue to use all existing hormonal contraceptive methods (oral contraceptive pills, contraceptive injectables, patches, rings, and implants) without

restriction, but that a strong clarification (as detailed in the WHO Technical Statement on hormonal contraception and HIV) relating to the use of progestogen-only injectables be added for women at high risk for HIV, to reflect the seriousness of the issue and the complex balance of risks and benefits (103). WHO continues to recommend dual protection (hormonal contraception plus condoms). Women using progestogen-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures. CHTC is a powerful tool to discuss reproductive choices as well as how to prevent HIV. For women in a serodiscordant couple who choose to use injected hormonal contraception, any risk of HIV transmission or acquisition would be minimized by use of ART by the positive partner.

Other services

Many other health services provide opportunities to offer HTC, including CHTC. Routine testing and counselling should be part of the full package of reproductive health services and STI/HIV prevention services, which should also include male and female condom use. In concentrated epidemics, offering CHTC could be considered in harm reduction services for drug users. Also, in countries with generalized HIV epidemics, managers of outpatient services may consider offering CHTC in situations where partners accompany patients.

Hospitalized patients may be offered CHTC routinely in countries with generalized epidemics, and on a case-by-case basis in low-level and concentrated epidemics, as spouses or partners may be visiting frequently. Providers need to exercise sensitivity as to where and when to offer HCT, so as to assure privacy even when suggesting CHTC and to avoid adding to the burdens of patients facing difficult procedures or recoveries.

4.3.1 What is needed going forward

- **Integrate CHTC into existing HIV services.** Guidelines, standards and standard operating procedures should be revised as needed to reflect new guidance on CHTC and to promote its offer as a standard part of the services package.
- **Sensitize providers and public.** Education should address the high prevalence of

serodiscordance and the importance of couple/partner testing.

- **Form private/public partnerships.** Such partnerships—for example, with company clinics, private clinics, faith-based organization clinics—can multiply the impact of CHTC interventions.
- **Make services couple-friendly.**
- **Find CHTC champions.** Each service needs champions for CHTC within its ranks, including charismatic health care providers, staff with HIV and community leaders. People who have been through CHTC themselves may be especially powerful champions in the community.
- **Strengthen linkages.** To maximize impact, linkages with the full range of available prevention and treatment interventions must be reinforced.

4.4 Community programmes and settings

The formal endorsement in 1978 of primary health care (PHC) for all by the year 2000 in the Declaration of Alma-Ata identified community participation as one of the cornerstones of effective PHC. Community-based HTC has been designed to increase access to HTC, in particular for key populations and people without easy access to health care facilities (104). A range of services may be already available in a community, with structures and networks that could host CHTC services and facilitate linkages and referrals following CHTC.

Community-based organizations can play a crucial role in providing CHCT and promoting its uptake. Their services are often more flexible than those of facility-based programmes, and they are run by peers who understand the circumstances and challenges faced by people in the community. Trained community health workers (CHW) can broaden access to and coverage of health services, alleviate the workload of professional health workers, are relatively inexpensive and enhance self-reliance and local participation.

A disadvantage of community-based HTC services, if they are not closely linked to health care facilities,

is that people who test positive are not referred quickly enough to treatment and care. Unless these linkages are strengthened, the benefits of community-based HTC for individuals and couples will be limited. Clearly defined working relationships between CHWs and health care professionals are critical to the success of community-based HTC. Community health services and workers should be integrated agents within existing formal health systems (105).

4.4.1 Community health programmes

Many community health programmes have been offering voluntary HTC and have well-established links with both communities and formal health systems. These can be built upon to extend HTC to couples. In rural areas access to formal health system services is a particular challenge; these community-based programmes can serve as a bridge to link serodiscordant couples with district facilities.

4.4.2 Stand-alone VCT

Stand-alone voluntary counselling and testing (VCT) services often have well-established links with community leaders and referral networks that can be built upon to deliver counselling, support, treatment and care to couples. Many stand-alone programmes have more flexibility in determining the scope of their services than conventional health facilities. They can focus services on reaching men and couples through extended service hours and innovative promotional strategies. At VCT centres counsellors may have more time than health service staff elsewhere to provide in-depth counselling and support to couples.

4.4.3 Home-based HTC

Home-based services offer unique opportunities to engage with couples together at home, particularly those who are not accessing facility-based services.² Health services at home may be a more acceptable way of meeting with health providers, especially where sensitive issues are concerned. In some cases couples that have been together a long time may not have considered the risk of HIV transmission in their relationship; home-based CHTC may bring them a service that they would not have thought to seek out. There may be special considerations in establishing home-based

² See *Planning, implementing and monitoring home-based HIV testing and counselling*. A practical Handbook. Atlanta, Centers for Disease Control/World Health Organization, 2012 (in press).

services—especially maintaining confidentiality and ensuring adequate follow-up. These issues will need to be considered by providers familiar with the community. Finally, there may be security issues for providers of home-based services, which will need to be considered when planning activities. As in other HTC settings, strong referral linkages and support are key for ongoing prevention and treatment.

4.4.4 Faith-based communities

The role of faith communities in family life offers many opportunities for promotion of CHTC through existing forums such as church congregations and religious services and ceremonies. Faith leaders are generally well-respected, trusted and influential members of the community and, as such, may be ideal people to train as counsellors for CHTC.

It will be important for faith leaders to work with other community leaders in crafting consistent messages on CHTC—messages that are evidence-based and that conform to nationally disseminated contents and standards. It will also be important in faith-based settings, as elsewhere, that CHTC is completely voluntary and never coercive.

4.4.5 Outreach HTC

There may be opportunities to introduce and scale up CHTC through outreach services to key populations and through community-based organizations that provide integrated health services. The acceptability of CHTC may be high where such services are well-established. Male involvement can also be encouraged and strengthened through outreach activities in workplaces and social venues.

5. ADAPTING THE GUIDELINES

These guidelines have been developed for a global audience; it is expected that regions and countries will adapt the recommendations to suit their own circumstances. These circumstances include the epidemiology of HIV in the country, social and cultural norms and economic factors. The ultimate goal of these adaptations should be to tailor the development and implementation of CHTC to the various settings where HIV testing is done, recognizing the different priorities, opportunities and challenges of specific settings.

In many countries a national consultation process involving representatives of all stakeholder groups should help to develop a policy and programme environment conducive to implementation. It is important that stakeholder groups endorse the incorporation of CHTC, as an important intervention, into national HIV prevention, treatment and care

The ultimate goal of these adaptations should be to tailor the development and implementation of CHTC to the settings where HIV testing is done.

programmes. Other steps include the development and implementation of national and local advocacy and public information programmes to inform communities, development of CHTC training programmes and standards for health workers and lay counsellors and standardized M&E (see section 4.1.7).¹

Globally, the efficacy and impact of these guidelines will be evaluated through the global HIV reporting system, which will monitor worldwide implementation of CHTC and ART for treatment and prevention in serodiscordant couples. In addition, WHO and ministries of health, along with key stakeholders, will participate in country-level programme reviews to support adaptation and implementation of the guidelines. Feedback from communities and other stakeholders will help to guide revision of the next edition of these guidelines.

¹ For a guide to adapting WHO HIV guidelines, see: *Adapting WHO normative HIV guidelines for national programmes: essential principles and processes*. Geneva, World Health Organization, July 2011. http://whqlibdoc.who.int/publications/2011/9789241501828_eng.pdf

6. RESEARCH GAPS

Review of the evidence for formulating these recommendations exposed important unmet needs for research. The Guidelines Group discussed the priority research gaps that will need to be addressed in order to update these guidelines. The following are the key questions that the Guidelines Group identified. It is important to close these gaps soon.

6.1 Epidemiology of serodiscordance

The studies that document high levels of serodiscordance among stable couples are largely from sub-Saharan Africa. Few data are available from other regions.

6.2 Impact of couples HTC and treatment as prevention

The systematic review revealed a paucity of data for many of the proposed CHTC outcomes, in particular:

- **Impact of CHTC on concurrent partnerships**, including potential reduction in new infections among concordant HIV-negative couples.
- **Uptake of and adherence to PMTCT and ART services and regimens.** Findings suggest that CHTC can increase uptake of PMTCT and ART services and adherence to drug regimens (see section 1.1). To date, studies have examined PMTCT uptake after CHTC, but no couple-specific interventions have been developed expressly to improve PMTCT uptake.
- **Acceptability of and adherence to earlier ART treatment for HIV prevention.**
- **Risk of adverse social and psychological consequences.** Based on long experience with individual HTC and anecdotal evidence from preliminary efforts to provide CHTC, there is consensus that CHTC has significant potential to benefit couples and to enhance HIV prevention efforts. There are very few data, however, on adverse social and psychological outcomes such as those affecting quality of life, marital relationships or the risk of violence, including emotional abuse and gender-based violence.

Research also must address a number of issues to inform planning and implementation of CHTC services:

- **Operational issues**
 - barriers to accessing CHTC
 - ways to generate demand and increase utilization of CHTC
 - the range of acceptable and effective models for CHTC, including models of community-based services
 - acceptability, uptake of and retention on ART for HIV prevention in serodiscordant couples
 - monitoring requirements for people starting ART early for HIV prevention
 - the ideal package of services for serodiscordant couples.
- **Monitoring (targets and indicators for CHTC).** Standard targets and indicators will be needed to measure performance. Key areas to cover include:
 - uptake and coverage of CHTC (disaggregated by sites and serostatus of clients)
 - referral for and uptake of treatment, care, family planning, MC, clinically indicated ART and ART for HIV prevention
 - impact of CHTC on the timing of enrolment in prevention and care protocols.
- **Impact on health systems and health workers.** It will be important to understand the effects that integration of CHTC has on the accessibility, efficiency and equity of health systems. There may also be effects on health workers in terms of professional satisfaction or burn-out that echo or differ from those experienced with provision of individual HTC.
- **Cost and cost-effectiveness.** Long-term studies will be needed to assess the costs (monetary and otherwise) and the cost-effectiveness of CHTC. In addition, cost, cost-effectiveness and cost-comparison studies will need to compare interventions for people above and below CD4 counts of 350 cells/ μ L.
- **Long-term risks/benefits of early treatment.** It is not clear whether earlier treatment of asymptomatic or mildly symptomatic HIV-positive patients results in a greater burden of medication-related adverse events or earlier

development of antiretroviral resistance. Specific concerns include:

- adverse events for individuals with CD4 counts of >350 cells/ μ L when started on treatment
- acquisition of drug-resistant HIV among previously uninfected partners
- HIV-related morbidity, mortality and quality of life in individuals starting ART with CD4 counts of >350 cells/ μ L.

Full assessment of the risks and benefits of earlier treatment will depend on the long-term collection and review of these data.

7. PRE-EXPOSURE PROPHYLAXIS (PrEP)

PrEP is the use of antiretroviral medications by uninfected persons to prevent the acquisition of HIV. The concept was established in the laboratory by animal models (106) and in humans by the prevention of mother-to-child transmission and post-exposure prophylaxis (PEP). The drugs being used in trials of oral PrEP are tenofovir alone or tenofovir combined with emtracitibine, meant to be taken on a daily basis. Topical tenofovir gel has also been developed for coitally-linked vaginal application.

Evidence of the effectiveness of PrEP is growing. Since 2010 four randomized controlled trials of oral PrEP have produced evidence. Two trials were completed as scheduled. The iPrex study tested a daily combination of tenofovir and emtracitibine in high-risk men who have sex with men. In this study the overall HIV transmission rate for the PrEP users was 44% of the rate for the controls, who were not using PrEP. The protective effect was significantly higher for those who were more adherent (107). The TDF2 trial tested a daily combination of tenofovir and emtracitibine in high-risk heterosexuals and reported an overall HIV transmission rate that was 63% of the rate for the controls (108).

Two other trials were stopped prematurely. The first, FemPrEP, among high-risk women, was stopped for futility when it was judged to be impossible to reach a conclusion by the planned end of the trial. The reasons for this failure are still under review. The second study, Partners PrEP, involved serodiscordant couples. It tested the effectiveness of two formulations, tenofovir alone and the combination of tenofovir and emtracitibine. This trial was stopped for effectiveness. Tenofovir alone was 62% effective in this trial in preventing HIV acquisition in the uninfected partner; the combination was 73% effective (109).

Evidence of the effectiveness of topical PrEP is available from the Caprisa 004 trial, a randomized controlled trial of tenofovir gel in women who were to apply the product up to 12 hours before and no more than 12 hours after coitus. Overall, the gel was 39% effective in this study, with higher effectiveness among those who were more adherent (110).

Two additional trials, one of daily oral PrEP and the other of daily oral as well as topical PrEP, are still underway.

While the effectiveness of PrEP has been established in clinical trials, the potential role that PrEP may play in HIV prevention remains unclear. How PrEP can best be delivered, and for whom, to make it as safe, effective and cost-effective as possible are questions that must be addressed in implementation research before normative guidance on PrEP can be developed.

The results of the Partners PrEP study—the only PrEP study to date to involve discordant couples—were not available when the Guidelines Group on CHTC formulated its recommendations. Therefore, the offer of PrEP to the HIV-negative partner in serodiscordant couples—and how this might relate to ART for prevention—was not considered for these guidelines. As an entirely new prevention intervention, the introduction of PrEP presents considerable operational challenges. WHO is currently preparing “rapid advice” as interim guidance for establishing and conducting demonstration projects outside the controlled situation of an RCT. Demonstration projects will aim to evaluate the outcomes and impact of delivering PrEP among men who have sex with men and among serodiscordant couples in a variety of epidemiological contexts.

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