

FINAL DRAFT OF THE MEETING REPORT:
PROVIDER-INITIATED HIV TESTING AND COUNSELLING IN CLINICAL SETTINGS:
OPERATIONAL RECOMMENDATIONS
WHO/UNAIDS Meeting- 3 July 2006

INTRODUCTION:

The availability of improved technologies and expanding access to HIV prevention, treatment and care has led to reconsideration of the services for HIV testing. The client-initiated model of voluntary counselling and testing is effective but has been observed to be limited in reach; infection continues to spread largely through asymptomatic individuals, who likely do not recognize some of their behaviours as exposing them to risk. With increasing opportunities for care, treatment and prevention, it is essential that more people be aware of their HIV infection status. One of the ways to expand this awareness is to ensure that health providers have the responsibility to provide the high quality confidential HIV testing and counselling the public increasingly expects them to provide. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) emphasized health provider initiated testing and counselling alongside Voluntary Counselling and Testing as part of their 2004 Testing and Counselling Policy. However, the operational recommendations on provider-initiated testing and counselling have not been published. This two-day consultation gathered participants from 24 countries in Chavannes de Bogis, Switzerland to discuss the operational recommendations for Provider-Initiated HIV Testing and Counselling in clinical settings (PITC).

OBJECTIVES OF THE MEETING

The meeting started with introductory words by Dr Purnima Mane (UNAIDS) and Dr Kevin Decock (WHO) and a round of self introductions by participants.

In their opening remarks Dr Purnima Mane and Dr Kevin Decock stressed the importance of providing feedback and comments on the draft guidelines on Provider Initiated HIV Testing and Counselling (PITC) in clinical settings at this meeting. Dr Mane emphasized that testing is seen by the UNAIDS programme as part of a continuum of services including VCT and is a useful tool in controlling the spread of HIV. Protecting human rights and public health are complementary and strengthen each other. The right to a test is part of the broader right to health. PITC has been part of the UNAIDS/WHO testing policy since 2004 and this consultation has been called to address the need for operational guidance. Dr Mane pointed out that PITC in clinical settings complements the voluntary counselling and testing (VCT) approach, adding that this meeting should provide practical suggestions on how to implement PITC in resource constraint settings. The draft guidelines have been elaborated in a changed context; the political commitment to HIV has

increased¹; funding is higher, advances have been made on the treatment front and in many places, stigma and discrimination has come down and awareness about HIV/AIDS has increased. She further elaborated that implementing PITC could be possible in settings where ART was not yet available, if other treatment and care are available. An inherent and essential feature of PITC is the right to decline HIV testing. She asked the group to think of the basic set of services and what measures can be taken to address stigma and discrimination, and build the capacity of health care providers to deliver these services.

Dr Kevin Decock pointed out that WHO's mandate is to set international health policy and standards. WHO is the lead agency in the UNAIDS programme for addressing HIV in the health sector. He reminded participants that the consultation was about Health and life saving interventions.

WHO has five priorities in health sector in the context of Universal Access to treatment:

- i) Scaling up knowledge of HIV status through confidential HIV testing and counselling
- ii) Strengthening Prevention
- iii) Accelerating the Scale Up of Treatment and Care
- iv) Strengthening and Expanding Health systems
- v) Strategic information to guide a more effective response

Dr Decock stressed that this consultation is about moving towards universal access, it is about health and particularly about HIV testing in health care settings. He pointed out that the discussion should be evidence based, perhaps assisted by anecdotes but not based on opinions. The final document does not need to be perfect but practical. He pointed out that with or without a test, HIV will declare itself. The current status quo is not acceptable and in order to achieve universal access a massive scale up of testing is required. Funding has increased, but the global community needs to deliver. He mentioned the example from Botswana which had decreed routine testing in health care settings. Similarly, the Centers for Disease Control and Prevention (CDC) in the United States is coming out with policies that set the stage of routine HIV testing in health care settings; WHO and the UNAIDS partnership are already behind the curve. He further elaborated that there has been a shift in understanding of stigma and discrimination in many places and that stigma comes from both inside and outside a person and may be based on fear.

Any testing must respect the autonomy and rights of each person but must consider the fear and internal stigma which may prevent a person from undergoing HIV testing. This presents a typical public health dilemma, a trade off. He provided an example that many children in Africa die before the age of two years because appropriate diagnosis, treatment and care were not available.

¹ The '3 by 5' call to action on scaling up treatment access, the Declaration of commitment on HIV/AIDS at the 2006 UN Assembly, and the commitment by G8 countries to expand Universal Access to prevention, care and treatment

Dr Decock pointed out that this meeting may not reach consensus especially in light of the heterogeneity of contexts and backgrounds from which participants come. WHO expected to receive advice on draft guidelines, more comments which will be followed by Regional consultation and adaptations. Ultimately, the countries will have the final say. He also asked the group for ideas about how to distribute this document more widely for further comment after this meeting.

Following these introductory remarks, the participants were briefed on the agenda of the meeting for which a number of key questions to be answered and expected outcomes were listed (see Annex). The participants then went through an exercise to list and agree on ground rules for the discussions.

PITC IN GENERALIZED EPIDEMICS

Three presentations were given by representatives from each of Cote d'Ivoire, Kenya and Botswana. Each described their experience with implementation of PITC in settings such as antenatal clinic (ANC), sexually transmitted infections (STI) and tuberculosis (TB) clinics, and highlighted challenges and successes.

COTE D'IVOIRE -Dr E Boni-Outtara, Elizabeth Glaser Pediatric AIDS Foundation

This presentation described the challenges of implementing PITC in a setting in which prevention of mother-to-child transmission of HIV services are expanding. Some of the challenges faced in rolling out the program;

- mentoring and training for health care providers
- adequate equipment
- management supply of commodities and drugs
- task shifting
- re-training on the importance of confidentiality; further highlighted by observed interruptions of counselling sessions,
- need to arrange patient flow

It was reported that Cote d'Ivoire will hold a meeting on 13 July 2006 to revise and integrate PITC in their prevention of mother-to-child HIV transmission (PMTCT) guidelines.

KENYA - Dr I K Tanui, CDC/KEMRI, Kenya

In Kenya, new guidelines for HIV testing in clinical settings were developed in 2004. Between March and October 2005, 1941 patients in medical wards were offered PITC resulting in 97% uptake (n=1883) and 1038 individuals (55%) testing HIV-positive. 87% of those HIV-positive persons were enrolled for care and 45% initiated ART.

The representative from Kenya described results of a recent health care worker (HCW) survey that showed many health workers to be willing to manage HIV patients if they had the right training and tools. Additionally, major findings included low uptake of testing and counselling amongst HCWs, inadequate training and existing stigma associated with HIV.

Furthermore, nearly 37% of the HCW surveyed have HIV patients in their homes. Challenges for implementation include record keeping (confidentiality and linking data), maintaining test kit supplies and training. Kenya was reported to be developing data collection tools, preparing training roll out and reviewing the management of quality assurance for PITC and subsequent care interventions, with the objective of ensuring that every clinically trained HCW should have the capacity to initiate HIV testing and counselling.

Recommendations to WHO and UNAIDS on expanding PITC included:

- Keep PITC guidelines short, simple, yet broad and flexible
- Disseminate guidelines widely and to all levels
- Encourage testing and counselling at point-of-care
- Develop and support short, generic training material

BOTSWANA - T Steen, Dept. of HIV/AIDS Prevention and Care, Ministry of Health

The speaker from Botswana reported that the wider implementation of PITC was done in an environment where wide consultation with stakeholders took place, and where there was high level political commitment, PMTCT and ART treatment services were available in clinics facilitating uptake and acceptance, and rapid test were introduced and their use decentralized. These criteria were deemed critical to enable the scale up of testing and counselling and it was believed (though not proven) that PITC increased not only the uptake of testing in the clinical settings, but also uptake of VCT services. PITC in Botswana was reported to have high acceptance with no formal complaints made to the Ministry of Health (MoH).

The presenters collectively highlighted the need for certain minimum standards including consent (written or verbal), personnel/staff capacities, quality of lab services, communication /counselling, and addressing standards in confidentiality and disclosure. Some of the challenges were record keeping of test results as each clinical setting keeps records unlinked to other services, confidentiality versus anonymous testing, maintenance of separate forms, and establishing links between healthcare services.

Discussion:

Following the country presentations, participants gave comments and recommendations including on the draft guidelines. Some of the issues raised were around couples counselling, adherence, partner counselling in PMTCT /ANC settings, the challenge of referrals from testing and counselling in home-based care (HBC), and partner disclosure and the possibility of violent outcomes.

In response to questions on the extent of partner testing where PMTCT services are offered, all three presenters reported low numbers of male partners coming in for HIV testing. The Botswana representative explained that only 20% of ANC clients report themselves as married or having a partner, making it a challenge to ask that a partner be brought in for testing and counselling. In Cote d'Ivoire there was reported to be limited

documentation on couple counselling and from this information, less than 10% of partners had been counselled.

Confidentiality/shared confidentiality:

One main concern was how to manage sharing of information between different health providers/services who need it for good clinical management while maintaining confidentiality. A participant pointed out that in other disease programmes "take home records" are standard such as in ANC clinics/TB records/child immunization card (the 'passport to health'). Kenya is reviewing how to ensure confidential counselling in the ward with use of screens or moving patients to another room.

Opt-out / opt-in:

Participants found this terminology unclear and stated that it would be useful to have more evidence on the implementation of the different approaches. They questioned how "informed" consent actually works and asked what evidence exists for reasons why people refuse to get tested. The amount of information that HCW's must give a patient was also queried with the Kenyan presenter emphasizing that any patient coming in for care should be informed of risks and benefits of an HIV test. A recommendation was made for the need for standards to be established for health care providers to be clear about the line between encouragement to access testing and the danger of a drift into mandatory testing. Several participants pointed out that the language in the document needs to be more specific, simplified and clearer on this aspect.

Counselling:

The discussion began with a description of the delivery of counselling services in different countries. In the Ukraine, only physicians can counsel and not nurses; in Cote d'Ivoire nurses provide the counselling. Kenya aspires to every health care worker being able to provide testing and counselling services given that a simple HIV test can be done by general health workers, avoiding the need to refer a patient outside to a VCT centre. Health workers are also being encouraged to know their HIV status. In Botswana, lay counsellors who get 6 weeks of training may deliver the counselling; if a client tests positive, a more experienced counsellor (nurse or social worker) provides further counselling. A number of participants expressed reservations about the sufficiency of information rather than full counselling sessions accompanying provision of an HIV test.

The discussions identified other concerns that participants felt should be addressed in the guidelines or for which there should be more consultation, including:

- quality/monitoring/supervision - the quality for HIV testing is easier to gauge; how can counselling quality be assured?

- age of consent and informed consent - there are disparities between the age of consent (and the age at which informed consent can be sought without the presence of a parent or guardian) and the age of sexual debut, how to resolve this?

- patient flow - a number of comments pointed to the need to develop tools to help manage patient flow in countries where there is great pressure on health services; tools are needed to guide the development of referral networks and strengthening links to other services.

PITC IN CONCENTRATED AND LOW EPIDEMICS

In this session, presentations were given describing conditions on how HIV testing is conducted in the Asia-Pacific region, India and the United States.

ASIA-PACIFIC REGION - Dr K Casey, Family Health International, Asia-Pacific region

The first presentation highlighted some of the regional aspects of the HIV epidemic, including:

- Diversity of the epidemic
- Testing strategies; in some areas, test results are available after 2 months. Cost of testing is high given the long distances from services and labs, as well as the routine use of the Western blot test.
- Routine testing in health care settings is often implemented as mandatory testing, and in some settings, all patients are tested, often without their knowledge, for the sake of protecting health care workers who are afraid of infection, there is no official provision of post-exposure prophylaxis (PEP), there are stigma issues, etc.
- Access to ART often not assured; often there is no co-trimoxazole available.
- Age of consent is often higher than the age of first sex; if no consent, no access to treatment and care.
- Consent for street children is taken without any guardian support
- People stop going to the settings where routine testing is offered.
- Stigma and discrimination in many places is still very high.
- Since health insurance is often funded by the employer, an HIV positive test result may lead to job loss

Dr Casey pointed out that with the routine testing strategy, the emphasis tends to shift away from prevention and that after a negative result is delivered, people may not be as attentive during post-test counselling and the prevention aspect may be lost. Providers should be trained in communication skills for delivering results. She also echoed the need to improve client flow and drew attention to the issue of quality assurance for HIV testing and counselling in PITC.

INDIA - Dr G Alexander, ASHA Foundation, India

The public sector in India was reported to provide free treatment for HIV/AIDS and is more structured in its organization than the private sector. The private for-profit health

care sector supplies nearly 80% of the out-patient health services to the Indian population. Mandatory HIV testing is common and providers bear high stigma and discrimination towards patients. A large number of Indian women go to private sector clinics for antenatal care believing safer and more efficient services including PMTCT services to be available here than in the public sector. Dr Alexander reported that her organization had developed a 'prevention of parents to child HIV transmission' (PPTCT)??? (a word is missing) and faces challenges in implementation given high turnover of medical staff, maintenance of confidentiality in limited facilities, and little follow-up of post-partum patients. This speaker also reiterated that in countries with low HIV prevalence, it is necessary when strengthening PITC to ensure a prevention component - counselling is important.

Other recommendations to improve these services were:

- Husband friendly clinics
- Data monitoring:
- Counsellor meetings every month to share experiences
- Evaluations, exit client interviews.

UNITED STATES OF AMERICA - Dr B Branson, CDC, Atlanta, GA

In the US, HIV prevalence is not uniform in the population; it is concentrated in mostly white men who have sex with men (MSM) and black men and women. About 1.1 million people are believed to be HIV infected but up to 27% are unaware of their infection. Only 6% of HIV testing occurs in VCT clinics; the greater part of testing occurs in health care settings. Most people test late when they already have clinical signs/symptoms of HIV i.e. the first test is at time of AIDS diagnosis. Most people don't perceive themselves to be at risk or won't acknowledge being part of a high risk group; people get tested because they are sick.

HIV screening has been a routine part of medical care at Cook County Hospital (Chicago, Illinois) and rapid testing has been utilized since October 2002. There has been a 62% acceptance rate of testing and 98% of those accepting to be tested receive results. Several other pilot projects have been undertaken in a number of US cities. Among the lessons learned are that it is difficult to obtain separate written consent and provide counselling, yet still screen the large numbers of patients in health care settings. It was also observed that sustainability depends on development of streamlined systems, additional staff, or both.

The Centres for Disease Control and Prevention will soon release new guidelines on HIV testing in an attempt to normalise testing and make it a routine part of general medical care. The following criteria are said to justify screening for a disease:

- Serious health disorder that can be detected before symptoms develop
- Reliable, inexpensive, acceptable screening test
- Treatment is more beneficial when begun before symptoms develop

- Facilities for diagnosis and treatment should be available
- Costs of screening are reasonable in relation to anticipated benefits

The new CTC guidelines will likely recommend that HIV testing be routinely offered in areas with a prevalence of over 1%, and that targeted counselling & testing will be provided based on risk assessment. HIV testing will be routine in STI clinics. CDC may propose the following recommendations to expand testing and counselling services:

- Routine, voluntary HIV screening for all persons aged 13-64 years in health care settings, not based on risk or prevalence
- Opt-out HIV testing with the opportunity to ask questions to the provider, and the option to decline
- Include HIV consent with general consent for care; separate signed informed consent is not required
- Prevention counseling in conjunction with HIV screening in health care settings is not required
- Communicate test results in same manner as other diagnostic/screening tests
- Provide clinical HIV care or establish reliable referral to qualified providers
- Repeat HIV screening of persons with known risk at least annually
- Recommendations are intended for all health care settings, including inpatient services, emergency departments, urgent care clinics, STD clinics, TB clinics, public health clinics, community clinics, substance abuse treatment centers, correctional health facilities, primary care settings
- In low prevalence settings, screening should be initiated although, if HIV prevalence is shown to be <0.1%, screening is no longer warranted

The criteria for developing routine HIV screening was drawn from the WHO Public Health Paper (Principles and Practice of Screening for Disease, WHO Public Health Paper, 1968)

A study in the US published results comparing high-risk sexual behaviours in HIV positive people who were aware of their HIV status versus those unaware of their status. They found a 68% reduction in unprotected anal or vaginal sex with their HIV-negative partners in HIV-positive people aware of their status. The authors of a study called for increased testing and counselling to reduce HIV exposure from people unaware of their status, and increased prevention interventions for those aware of their status and still engaged in high-risk behaviour. The presenter also reported that routine voluntary HIV testing for all pregnant women in the U.S. has resulted in a 95% reduction in HIV transmission to infants.

Discussion:

The discussions again focused on various challenges of scaling up HIV testing drawing on the information brought up during the presentations. Several participants raised concerns which ranged from operational issues to human rights issues. A certain amount of time was devoted to debate about the terminology; several participants requested that the recommendation should refer to a 'routine offer' not 'routine testing'. It was pointed out that in principle every medical procedure is offered to a patient, so the word offer in

'routine offer' is redundant. The problem is that routine is often confused with mandatory, hence in the context of testing, the mention of 'offer' is an important distinction.

A number of participants from the Asian countries brought up concerns about the language of the WHO documents, their interpretation at the national level, and apprehension that recommendations would be applied in way that would lead to mandatory testing for HIV. In Asia, the epidemic is largely driven by injecting drug users and men who have sex with men (MSM). Although the example of the 100% condom campaign in Thailand was to be commended, it was pointed out that the campaign did not fully address injecting-drug users (IDUs) or male sex workers.

Other recommendations that came out of the discussions were:

- the proposal to create a Stigma Index
- agreement on the importance and relevance of clear standards for expanded PITC
- addressing the concerns about the environment in which this would be introduced
- what safeguards could ensure success, and the formation of strong partnerships to ensure this success through shared resources bearing in mind that in some countries, government have an uneasy relation with non-governmental organizations (NGO) and are reluctant to empower them.

A systematic review of social and behavioural evidence on testing and counselling

Presenter - Dr C Makhoul Obermeyer, WHO, Geneva

This review of articles published from research work focuses on the process of HIV testing and counselling. Some of the findings were:

- There is a large gap between acceptance and actual test results received; in some settings, one third to one half of clients do not return for their test results
- HIV testing not simply about information - it's about relationships, life plans and partners. There is a context in which results are taken and 'lived' that is additionally influenced by the local meaning of HIV.
- There tends to be a contradiction between information and attitudes - often counselling provides abstract information and results that fail to recognize the individual as being at risk. Risk has to be personalized
- Gender-specific messages about HIV testing have been successful in encouraging testing uptake;
- Need to distinguish the consequences (violence...) that directly result from HIV testing from those that reflect wider gender inequalities and pre-existing behaviours and hence would require broader measures, not just related to testing itself
- The effects of stigma are difficult to measure, although it is one of the biggest obstacle to testing

Discussion:

A meeting participant from Brazil mentioned that despite a mature program in which treatment has long been available to those who need it, nearly 50% of those tested do not return for their results and asked colleagues what had been observed to be effective ways to follow up patients for their receiving results. A representative from Haiti described a program Health in Haiti where a network of healthcare workers has involved the community in reaching to patients; nearly 100% of those testing get their results. Other participants pointed out a higher success rate of using rapid tests, the use of which averted the need to return for results.

Out of this review there were some questions for which operational research is needed, including

- to what extent the results of well-designed, well-funded programs apply to resource-poor settings
- the effect of treatment availability on increasing demand for HIV testing and counselling
- does the routinization and expansion of HIV testing reduce stigma
- which aspects of stigma are amenable to change through health services
- how much information/ counselling is needed
- what information about context is needed to adapt services, and how it can be quickly obtained.

Events following Disclosure of HIV status to partners. Findings from Literature Review
Presenter - E Pegurri, UNAIDS, Geneva

In general, disclosure is low, particularly among casual sexual partners and is also often delayed, representing a considerable risk to the sexual partner. In Sub-Saharan Africa and South East Asia it was found that disclosure is lower for women tested in ANC as opposed to VCT. In general people who disclose are in a stable, supportive relationship, with good communication between partners, and typically already know someone with HIV or AIDS. Fear of external reactions, in some cases linked to personal and partners' attitudes towards HIV were among the reasons for non-disclosure.

The effects of disclosure on prevention are not well established: self-disclosure is not consistently associated with safer sex. It is more disclosure accompanied by open discussion about safer sex that leads to changes in sexual behaviour. Studies suggest that for the majority of women and men, disclosure leads to support (for more than 80% of women and men in Sub-Saharan Africa/South East Asia, the US and for men who have sex with men in the Latino community in the US) and that experience of violence may not be attributable to HIV status (studies with of pregnant women in the US) but linked to a previous history of violent behaviour. However, in a minority of cases disclosure to partners does lead to negative events. From 0 to 14,6% of women reported negative events including violent reaction from partner in Sub-Saharan Africa/South East Asia. Also, women may be blamed for bringing HIV into the relationship. In general, HIV positive women in discordant couples reported the higher rates of abandonment/break-ups. In

Thailand, as reported by the Network of people living with HIV, men were more likely than women to be abandoned by the spouse (9% versus 5%).

More consideration is needed on how to ensure positive outcomes from disclosure.

Positive and adverse effects of PITC for infants and children

Presenter - Dr. C Luo, United Nations Children's Fund (UNICEF), New York

The UNICEF campaign, "Unite for children-United against AIDS" aims to draw attention to the paucity of literature available on testing and counselling for children. The presenter highlighted the fact that HIV in children in Western countries is nearly a "thing of the past". HIV in children is particularly aggressive and there is a very small window of opportunity in which to act. Children do better than adults on treatment and currently 660,000 children need treatment. PITC should be carried out within the three continuums of optimizing testing in pregnancy, the need for the child to be protected and the mother being able to access care.

- Testing children early (before 18 months) is important
- Staging of symptomatic children needs to be further strengthened.
- Where should routine offer for children be offered?

Both these presentations were followed by discussion in which participants pointed to the need to train HCW to be more sensitive around the matter of disclosure even as patients were strongly encouraged to disclose to their sexual partner. At the same time, in referring to the situation in Malawi for which data indicates that up to 60% of couples are discordant for HIV, there needs to be recommendations on how to ensure that partner notification is done as early as possible.

WORKING GROUP SESSIONS TO REVIEW GUIDELINES AND GIVE ADDITIONAL GUIDANCE AND TOOLS FOR PITC

The second day of the meeting began with a presentation on the draft guidelines (version dated 27 June 2006), followed by discussion to try and come to concurrence on the language around initiation of the HIV test. The ensuing paragraph was proposed as an example of dialogue from the provider to a client:

"In this clinic HIV testing is available to every patient so we can provide the best possible care. Patients always have the right to decline a test. I will tell you your result after the test. Unless you tell me not to, I will perform an HIV test for you today"

Discussions about language and statement:

Several suggestions for improvement were made including:

- Include a definition for confidentiality
- Include the phrase "I will explain the test result"
- Current language-"unless you tell me not to" does not include an empowered way to say no.
- It should be made clear that getting access to care is not contingent on going through with the HIV test.
- The "onus" is a fundamental issue- onus is on the patient to decline.
- The recommendations should flag the need to consider religious and cultural aspects of the factors surrounding HIV testing.
- Following the statement ask the question ". . . would you like to discuss having a test further today"?

It was recommended that we move away from a set script, which can be confusing and can cause further confusion during translation. Counselling and confidentiality are important and would need to be included in the statement. However, a participant suggested identifying "elements" or concepts which express the spirit of PITC. Still others among the participants felt that the issue was beyond language, and about standards and protocols. There is need for full understanding of the guiding principles underpinning the offer to test/key points on which the client needs to be informed to make a decision.

A point was raised about the term 'clinical settings' as not all health care facilities are clinics. In some parts of the world, NGOs are the only providers of these services so the suggestion was made to change to 'guidelines in health sector/health settings'. Other points were raised were on testing in prisons and correctional settings; given the power imbalance, how could informed consent be assured?

Routine offer or routine test?

Participants argued that there is an obligation to maximize the individuals' right to health and the right to treatment. Therefore, the operational guidance has to maximize beneficial outcomes from testing. The key is that health care workers must understand the principles. In PITC, the onus is on the provider to initiate the HIV test and provide

information in such a way that the patient can decide. Sufficient information needs to be given to the client in order for them to make an informed decision i.e. what happens after the test, what is available and what is not.

A participant with field experience from Malawi reiterated that it is important not to lose the historical perspective; from an absolute risk, HIV is now a manageable risk. HIV testing provides a gateway to benefits. Experience in the field suggests that if testing is made available, people take it up. There appears to be a lack of confidence in our 'product' of HIV testing services.

GROUP WORK

Participants worked in groups collected around issue pertinent to HIV testing for the rest of the day. The following listing includes suggestions made towards the guidelines, other factors to consider as the guidelines are finalized and further guidance or tools to operationalize PITC.

Group 1: PITC for adults

- Definitions should be placed at the front of the document
- Rename document: health settings and guidelines
- Consider the cut off age for accessing testing (legal age of a minor versus onset of sexual activity)
- Employer provided health care -implications of disclosing to the employer?
- Need for global tools on 3 C's and pre-test information
- Use of PITC for Medical surveillance?
- Special need to focus on health care workers
- Post Exposure Prophylaxis access
- Include the elderly - not just reproductive age
- Operational aspects to be influenced by regional context (epidemiology and resources); WHO/UNAIDS to support development of local operational tools
- Others to be involved: Ministries of Health /National coordinating organizations (AIDS Control of AIDS Councils), regulatory bodies, health councils, medical associations, NGOs; need for advocacy and communication from WHO/UNAIDS/CDC

Group 2: PITC for infants and children

General comments

- Standard Operating Procedures to be developed
- Greater detail regarding package of services associated with T&C services (care, counselling, treatment, etc.)
- Accountability and obligations of health care providers
- Provide reference to Human Rights documents & other relevant declarations/documents
- No reference to lab based testing which may be appropriate for in patients (document currently only refers to rapid testing)

- National AIDS Coordinator to have oversight
- Operation research issues

Children-specific

- Start with rationale for PITC in children
- Ensure onus on provider to ensure and document consent even if inferred; not on client to "opt in" or "opt out"
- Counselling for children and care givers
- What is the best interest of the child?
- Address & briefly explain "child friendly", remove other terms (non-judgmental, etc.). Include select examples, with reference to operational & policy guidance included elsewhere.
- statement regarding detection of exposure at any age can be detected by Ab test is incorrect
- a document that addresses national policy requirements specific to HIV testing of infants and children is needed - a draft already exists.
- Specific tools to support PITC in children
 - o Counselling (children and caregivers)
 - o Eliciting consent
 - o Informing and disclosing
 - o Psychosocial support
 - o How to determine best interest of child
- ART and diagnostic recommendations need to be in place at national level for PITC in children to be operationalized
- Highlight responsibilities and obligations of providers, address accountability of providers;
- Identify national mechanisms for oversight of PITC implementation (utilizing existing mechanisms e.g. national coordinating organizations)

Operational Research

- Cost-benefit/cost effectiveness analysis of - "routinely recommended HIV testing" (not diagnostic testing) for children in well child clinics (high prevalence)
- Parents' understanding of risks/benefits of testing of children
- HCW reluctance to testing of children
- Stigma for children testing positive
- Service configuration to optimize PITC for children and entry into care (e.g. Best Practices)
- Models for testing and service provision for unattached minors (e.g. orphans)

Next Steps (children)

- Need further consultative process urgently to review children section within the framework, review & endorse draft policy guidance, and identify operational tools required (WHO, UNAIDS, UNICEF to organize)
- Children and adolescents should be included in the development and final review of recommendations.

Group 3: PITC for adolescents

- In pre-test information, include the risks of testing (benefits are already included); Sequencing needs to be made explicit: initial text, then information, then offer.
- Referral to detailed counselling for people who require more support
- Informed consent depends on the level of health and HIV knowledge, thus the need to address community education and capacity building of health professionals
- Non-diagnostic testing in those who are unable to give consent
- Need for specific reference to existing agreed international norms, including human rights, medical treatment and ethics
- Needs more attention to the issue of confidentiality of test results and safety.
- Guiding principles should be grouped and consolidated, include 3C's as well a human rights and ethical imperatives, need to link to the context outside the health care setting (prevention, care and support).
- Where helping an individual to identify barriers to his or her decision not to test (p.14) need detailed guidance to increase sensibility of provider and reduce risk of coercion/badgering.
- What if policy / legal framework is not in place, should PITC still be implemented?
- Define who is the "provider" in light of insurance issues

Adolescent specific

- Opt out situations: power imbalances and marginalized groups
- If the necessary legal and policy framework is not in place, then can PICT be offered?
- How to take into account the evolving capacity of children (age 0 to 18)? Guidance from the Convention on the Rights of the Child.
- If PICT is not offered to all adolescents, how to avoid selective application and stigmatization.
- In the case of adolescents, the requirement for full pre-test counselling should be maintained.
- Information needs to be provided in a youth-appropriate manner.
- Encourage client to have someone with them for the test
- Consent - legislation for consent - which children can consent

Operationalization

- PITC will require adaptation to regional and country contexts: epidemiological, social and cultural, economic and legal contexts.
- Roll out process will take time and the following steps need to be planned:
 - Identification of key providers and settings (e.g. prisons, military)
 - Design of materials and training programmes to suit different provider settings
 - Sensitization and training of providers in these different settings
 - Development and incorporation of supportive supervision, monitoring and reporting that promotes quality service rather than numbers tested
 - Links with other parts of the AIDS response e.g. HIV education and communication, policy and legal analysis and reform.

- Monitoring of positive and adverse events and refinement accordingly.

Further consultation

- Regional WHO and UNAIDS consultations to develop the core document.
- Consultation with adolescent groups and adolescent service providers and with people who have experienced PITC.

Group 4: PITC for women during pregnancy / labour

- Routine offer of HIV testing with right to decline is preferred
- Institutionalizing HIV testing as routine standard practice in ANC settings
- Draw from the 2004 policy document on what is the minimum for pre information; add to last bullet point: support for disclosure and benefits to partner, availability of couple counselling, availability of peer support groups
- Insert: "Where mothers refuse testing, programmes considering mandatory testing of babies after delivery should take into account the type of regimen to be offered to the baby for PMTCT and the operational issues including infant feeding counselling and support"
- Consider repeat testing in high-incidence settings or for women at high risk

Some suggestions for research

- Effectiveness of different testing models (endpoints: uptake of testing, uptake of PMTCT interventions)
- Assessment of mothers' understanding of PMTCT issues
- Determinants for uptake of services
- Impact of routine offer of testing on stigma
- Approaches to male engagement in PMTCT services
- Impact of routine offer of testing on health facilities' workload and quality of services

Group 5: Most At-risk Populations

- What needs to be in place for PITC?
- Grounding the document in the political, cultural and social environments of communities of vulnerable populations
- Strong language and tools to sensitize service providers to the impact of stigma and discrimination
- Mechanisms for redress discrimination or similar injustices are crucial
- Shared ownership of PITC - role of civil society, private providers, etc.
- Redefining clinical settings - move PITC closer to communities
 - Validate HIV testing in other settings
 - Eligibility of many other people to implement PITC
- Choices of testing - anonymous, availability of PITC sites, VCT
- Offer testing for people to have the opportunity to say yes - build relationships, prepare people and communities, link pre test information

- Networks required to enable the scale up of PITC: with communities of vulnerable populations; government - civil society; intra-civil society; strong connected networks; links between all groups -example given of MSM in England
- At page 3, among the aims of the guidelines, add: to support member states to ensure that PITC is available, accessible, and acceptable to all without discrimination

Offering Testing

- Routinely offering testing for people to have the opportunity to say yes
- To build relationships with communities of vulnerable populations
- Preparing people and communities for testing
- Linking pre-test information to counselling

Selected Issues

- Monitoring and Evaluation: incorporate the role of civil society p. 32
- User fees for testing should be covered
- Scale-up of rapid testing as the best and preferred option for PITC should be emphasized
- PITC is one option among others (e.g. VCT)
- Leave out the language "source client" and expand the last bullet on the prevention of violence and family disruption.

Prisoners

- To address prisoners, refer to 'HIV/AIDS Prevention, Care, Treatment, and Support in Prison Settings. A Framework for an Effective National Response' (UNODC, UNAIDS, WHO)

Supplements for Most at Risk Section

- Tools for the reduction of stigma
- Recommendations for involving civil society
- Outlining rights of communities of vulnerable populations
- Tools for redress

Legal and Policy Framework

- Establishing or making accessible mechanisms for redress
- Removing barriers to accessing prevention, care, treatment and support

Partner Notification

- Insert text from UN International guidelines on HIV/AIDS and human rights : Guideline 3 28 g
- Public health legislation should authorize but not require.....(focus on encouraging)
- Support regarding the disclosure process
- The dual goals of prevention and psycho-social support

And when people do not return for their results

- A simple and respectful follow up informed by community members is recommended.
- For those identified as HIV positive, health care providers should provide referrals to peer support networks for PHA's.

Regional Consultations with.....

- Positive men who are willing to disclose
- Private sector and Faith Based organizations

- Community-based organizations
- PLHIV groups in different regions
- Health care workers

Group 6: Programmatic issues

- Need to clarify the intention of the guidelines (what services they cover, what they do not): do they cover prisons? What about services offered by NGOs? What about marginalized populations (might the health sector have limited reach towards the vulnerable?)
- Make clearer distinction between high prevalence and low prevalence settings.
- Stress the need for linkages with existing HIV services
- In Asia VCT is integrated into hospitals. Acknowledge this and help clarify how to link VCT services inside hospitals and routine offer
- Include flow charts that speak to specific circumstances and tools (who should do what)
- Use 'health care settings' instead of 'clinical' settings. In Eastern Europe clinical settings would only include specialized hospitals
- The document is biased towards public sector. In India private sector is prominent - how to motivate private practitioners?
- Take into account the huge human resources implications - training alone is not enough. Need for task shifting - reconstitute/expand clinical teams, not persons
- Take into accounts needs of lab systems
- Clarify the content/meaning of pre-test counselling and informed consent
- Involve health workers - need for social dialogue; how to address testing of health workers? (problems of confidentiality)
- Make sure PITC will be part of National AIDS plan - the '3 ones'
- Need for community preparedness and enabling legal environment
- Lay counsellors need training and supervision - not always 'cheaper' than social workers
- Include stigma index and human rights in M&E
- Foresee operational research to address cost, human resources implications and human rights issues

Group 7: 3 Cs and other beneficial outcomes

- Introduction to the document was too long and difficult to understand - shorten, make things more clear
- Keep the "V" for voluntary present despite the advocacy for scaling up provider-initiated testing
- Counselling, consent and confidentiality apply to all testing - no matter who initiates
- Formal process to engage the governments
- Intro should reflect the aims of PITC. Duty to treat, positive outcome of early diagnosis etc., access to care support, prevention, and behaviour change.
- Reflect some undesired outcomes - coercive, etc
- Drop distinction of diagnostic and routine testing

- Mention of training of health workers needed
- Community mobilization, M&E, research
- Reference to legal framework is weak
- Concept of 3 Cs should be programmatic approaches
- Counselling: information versus counselling before testing
- Offer for individual counselling or dialogue
- Risk assessment in certain settings
- Quality control for people who are not health professionals
- Consent - recorded or not recorded in writing?
- Build in monitoring component
- Training needs strengthening
- It should be clear when and how informed consent is given, especially if counselling in group session or video session
- Provision of meaningful information
- Record keeping, etc for confidentiality

GENERAL DISCUSSION

A suggestion was made that healthcare workers should be consulted and made part of the process of developing guidelines that they will be implementing. Developers of the guidelines document should make specific reference to existing and agreed on international norms and other guidelines.

Other issues for which recommendations should be made in the document were:

- Pre test information should be adapted to specific groups.
 - Group counselling is acceptable only in combination with individual counselling later.
 - For counselling, communication skills are critical and should be included in medical school curricula.
 - For repeat testing, what is the recommended time interval?
 - Health care workers must be encouraged to test.
 - Recommendations are needed for pregnant women in both low and concentrated settings
 - Further specification of table number 2 (Recommendations for provision of routine HIV testing and counselling with the right to decline in clinical services based on type of HIV epidemic)
 - Add algorithms for ELISA testing
 - Five conditions on disclosure - voluntary participation, confidentiality, accessibility, quality assurance and do no harm (taken from Chapter 11, Partner Management. Control of Sexually Transmitted Diseases Section II: Case Management of STD. Authors: Kathleen E. Toomey, Ahmed S. Latif, Richard C. Steen. Family Health International)
 - Who can give consent (relative to children)
 - When and how to disclose to HIV positive children
 - Further consultations early in the process of scaling up PITC should be undertaken with health care workers
-

- Increased guidance for PITC in the private sector is needed where routine testing could become or be interpreted as mandatory. Furthermore, doctors in the private sector often have less support for counselling, etc.
 - Country level strategies and adaptations are needed.
-

CONCLUDING REMARKS

Dr Decock expressed gratitude for the active participation and discussions, and acknowledged that in order to have greater diversity of opinion, it would have been ideal to include more participants, especially health care workers, but that funding limited the numbers who could be invited. In the draft document, there was the attempt to address "settings where people go when they need special services", and granted that it is a narrow definition. In asking for further recommendations, he pleaded for specificity, adding that other consultations may be required for additional important issues. The decision to implement PITC on a wider scale would be influenced by factors as a heterogeneous epidemiology, what HIV prevalence threshold will be high enough to make scale up cost-effective, the need to avail the intervention to pregnant women, among others. The challenge for the development of these guidelines is at three layers - global policy - regional adaptation - and country specific implementation. He promised that prior to finalizing the strategy, WHO will seek more opinions, to infuse into the document and provide more clarity, and more brevity.

Dr P Mane of UNAIDS described the meeting as having highlighted rich discussions-frank, forthright, intense, concerned, heated. She stressed that passion is what we need in fighting the epidemic. The recommendations from this meeting provide an enriched understanding. Scaling up HIV testing is extremely important, as are scaling up prevention, treatment and reducing stigma and discrimination in the context of human rights. She suggested that the document include adapted, refined and differentiated recommendations for specific populations.

ACRONYMS

WHO - World Health Organization

UNAIDS - The Joint United Nations Programme on HIV/AIDS

PITC - Provider-initiated HIV testing and counselling in clinical settings

VCT - Voluntary counselling and testing

ART - antiretroviral treatment

CDC - Centers for Disease Control and Prevention

ANC - antenatal clinic

STI - sexually transmitted infections

TB - tuberculosis

PMTCT - prevention of mother-to-child HIV transmission

HCW - health care worker

HBC - home-based care

PPTCT - prevention of parents to child HIV transmission

MSM - men who have sex with men

IDUs - injecting-drug users

NGO - non-governmental organizations

UNICEF - United Nations Children's Fund

MoH - Ministry of Health

ANNEX

Provider-Initiated HIV Testing and Counselling in Clinical Settings: Operational Recommendations

Hotel Chavannes-de-Bogis Chavannes-de-Bogis, Switzerland

3-4 July 2006

Of the estimated 40 million people currently infected with HIV worldwide, 90% do not know their HIV status. The increasing availability of prevention, care and treatment for those infected by HIV, and the low-cost and easy access to rapid HIV testing is changing the landscape of HIV testing and counselling. The traditional client-initiated Voluntary Counselling Testing (VCT) now needs to be viewed as only one approach to the provision of HIV testing and counselling services. Another recommended approach is provider-initiated HIV testing and counselling (PITC) in clinical settings. This two day expert meeting aims to review current and ongoing experience with PITC at the country level and give input into draft WHO/UNAIDS operational recommendations on PITC in clinical settings.

Key questions to be addressed:

- How can health care providers initiate PITC in a manner which respects the principles of confidentiality, informed consent and counselling?
- How can PITC result in ensured linkages to available care, treatment, support and protection against discrimination?
- What are the basic components required for effective operationalization of PITC?
- What are considerations for PITC in low-level and concentrated and in generalized epidemics?
- How can most-at-risk groups in both generalized and concentrated epidemics best be served by PITC?
- How should the special needs of adolescents best be addressed in PITC?
- What are appropriate models for PITC for infants and children?
- How can adverse consequences of PITC be tracked and minimized?
- What operational research is required to inform PITC?

The intended outcomes of the meeting include:

- Better understanding of current and ongoing experiences in countries on implementing PITC
- Feedback on draft operational recommendations for PITC, including identification of where additional guidance or operational tools are required
- Identification of areas of research that is required to inform expansion of PITC programming
- Identification of ways to best ensure beneficial outcomes of PITC

DRAFT AGENDA

Provider-Initiated HIV Testing and Counselling in Clinical Settings: Operational Recommendations

July 3, 2006

- 08:30 Registration
- 09:00 Introductions
- 09:15 Welcoming Remarks *Purnima Mane- UNAIDS, Kevin De Cock- WHO*
- 09:30 Overview of agenda, key questions and intended outcomes of meeting
- 09:45 Discussion
- 10:00 Presentations- PITC in generalized epidemics (*15 minutes are given for each presentation as well as 5 minutes for clarification*)
- *Edith Flore Boni - Côte d'Ivoire*
 - *Isaiah Tanui - Kenya*
 - *Tore Steen - Botswana*
- 11:00 Coffee Break
- 11:15 Discussion
- 12:30 Lunch
- 13:30 Provider-initiated testing and counseling in concentrated and low prevalence settings
- *Kathleen Casey - Thailand*
 - *Gloria Alexander - India*
 - *Bernie Branson - United States*
- 14:30 Discussion
- 15:30 Coffee Break
- 15:45 Review of experience and literature on positive and adverse events related to HIV testing services and disclosure
- WHO, UNAIDS, UNICEF*
- 16:00 Discussion
- 16:30 Preparing the health workforce for PITC

Ethiopia: Challenges of rolling out PITC Eyerusalem Kedebe, Sandy Gove

Swaziland: Review of health workers attitudes in Swaziland Rejoice

Nkambule

17:00 Discussion

17:30 Close of meeting

July 4, 2006

08:30 Plenary Review of Progress to Date

**09:00 Presentation of WHO/UNAIDS Draft Guidelines on Provider-Initiated
HIV Testing and Counseling in Health Care Settings**

**09:30 Breakout groups to comment on guidelines and identify additional
guidance and technical tools required**

- *PITC for adults*
- *PITC for infants and children*
- *PITC for adolescents*
- *PITC for women during pregnancy, labor or postpartum period*
- *PITC for most-at-risk populations*
- *Programmatic considerations for implementing PITC (legal framework, qualifications for providers, task-shifting, etc.)*
- *Ensuring the 3 Cs and beneficial outcomes in PITC*

11:00 Coffee Break

11:15 Breakout groups continue

12:30 Lunch

13:30 Presentation and discussion on findings from group work

15:30 Tea Break

16:00 General Discussion

17:00 Next Steps- Implementing PITC at country level

17:30 Close of meeting