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Centers for Disease Control and Prevention (CDC)
Division of HIV/AIDS Prevention
National Center for HIV, STD and TB Prevention
1600 Clifton Road
Atlanta, GA 30333

Re: Comments on the Revised Recommendations for HIV Testing of Adults, Adolescents,
and Pregnant Women in Health Care Settings

The American Academy of HIV Medicine (AAHIVM) is an independent organization of HIV Specialists and others dedicated to promoting excellence in HIV/AIDS care. Through advocacy and education, the Academy is committed to supporting health care providers in HIV medicine and to ensuring better care for those living with AIDS and HIV disease. AAHIVM members provide direct care to more than 340,000 HIV patients. This is more than two thirds of the patients in active treatment for HIV disease.

AAHIVM appreciates the opportunity to offer comments on the proposed revisions to HIV testing in clinical settings and we hope to continue to work with the CDC in the development of these and other recommendations around HIV prevention, counseling, and testing. We play a unique role in evaluating the revised recommendations because we are health care providers who actively care for people with and at risk for HIV. Our constituency includes providers who address primary care, hospitalizations, testing and counseling, education and training, research and development, and are actively involved with the development of standards-of-care. This experience and insight enable us to evaluate this draft in a broad clinical context. We hope our recommendations will be useful, while we acknowledge that many of the issues we raise are complex.

If we may offer immediate assistance or answer any questions or concerns you may have regarding our comments, please contact Greg Smiley, Director of Public Policy for AAHIVM, at (202) 659-0699 or through greg@aahivm.org.

We begin by stating that AAHIVM strongly supports the CDC's stated goal of increasing routine HIV screening in health care settings, fostering the early detection of HIV infection, identifying

people at risk and linking them to clinical and preventive services and reducing perinatal transmission in the United States even further. We do, however, have several concerns, which are outlined below in roughly the order they are presented in the revised recommendations.

While the majority of our comments relate to content, we do have a recommendation on the format. We would suggest that the specific recommendations themselves be moved much closer to the beginning of the document. As currently structured, the recommendations themselves are buried on the seventh page, dampening their impact.

I. Risk Assessment and Prevention Counseling in the Clinical and Non-Clinical Settings

(Summary): We would recommend that the introductory paragraph to the summary include a statement similar to those on page 7, end of paragraph 1 and page 15, bullet 1 explaining that:

“The guidelines only address HIV testing in health care settings; they do not modify existing guidelines on HIV counseling, testing, and referral for high risk persons who seek or receive HIV testing in nonclinical settings (for example, at community based organizations, in outreach settings, or in mobile vans).”

While this distinction may appear obvious, we have heard a great deal of confusion from people who believe that CDC is advocating eliminating or minimizing risk assessment and risk reduction counseling in all settings. We feel it is important that CDC emphasize that this is *not* its recommendation.

The statement on page 9 about this issue: *“Prevention counseling is strongly encouraged for persons at high risk for HIV in settings where risk behaviors are routinely ascertained.....”* also should emphasize that risk assessment and risk reduction are indeed important, and ideally both would be available. We assume the only reason this is not what CDC is advocating is because it would not be feasible. There is internal inconsistency in the statement on page 12 about recommending retesting and referral for those at high risk given the emphasis on eschewing risk assessments: *“Persons known to be at high risk for HIV infection should be advised of the need for periodic retesting and offered or referred for prevention counseling.”* CDC needs to clarify this recommendation, given that the overall recommendations emphasize not needing to do a risk assessment with HIV testing.

AAHIVM also feels that there is a missed opportunity here to stop the spread of other diseases. Given similar transmission routes and associated morbidity and public health issues, we think that CDC should recommend including other screening that is logically linked to HIV screening including tests for hepatitis B and C infection and various sexually transmitted infections.

II. General Consent: We know that informed consent in many settings does not need to be written to be adequate. Written informed consent may, in fact, be inadequate, especially when provided without any real verbal communication. We support an opt-out approach but only assuming that the informational elements outlined in these guidelines are addressed. We have several concerns, however:

- We fear that the CDC’s recommendations will lead to clinicians simply telling the patient he or she will receive a test, without explaining the test, possible results, or the opt-out provision. The CDC’s recommendations that all patients should be told about the test, what the results mean and do not mean and very specifically be told that they are able to “opt out” need to be significantly strengthened.

- CDC needs to better define the components of consent by a patient, both informed consent as applied to HIV testing, and the general medical consent that is now supposed to be enough.
- We are concerned about the intersection with state laws around the legal definition of informed consent. As we understand it, a general consent to care does not meet the legal standard of informed consent for agreeing to have an HIV test in most instances. Therefore, we advise CDC that any recommendation to relax the definition of informed consent to a level below what is legal under state law and regulations be more explicit so that each state might actively evaluate its legality and whether to change its laws or regulations regarding consent for HIV testing.
- We have concerns regarding legal protections for clinicians without written consent. There is now a long history of needing to get written informed consent from patients with HIV testing and to do pre and post-test counseling. We also know that patients do not understand, in many cases, the difference between various HIV test technologies and the process of testing. A possible scenario: A patient is told he will be tested and agrees. He receives a rapid test that is positive. The clinician spends time talking with him about what will happen next, that this is a screening test and that a Western Blot confirmatory test will be done; that he is not necessarily HIV positive. The patient, in shock from the result does not really understand but fails to admit to this. He goes home and commits suicide. One week later the Western blot returns negative. We have concerns that the general consent does not fully protect the medical provider from litigation in such a scenario.

Currently New York State is considering legislation proposed by New York City Health Commissioner Thomas Frieden which states in part:

“In order for there to be informed consent, the person ordering the test shall at a minimum advise the protected individual that an HIV test is being performed.”

This may be the first example of an official moving for change in law based on the discussions at CDC as well as his own opinion. Language such as Dr. Frieden uses demonstrates that the CDC recommendations may be poorly interpreted and may lead to such a relaxation of “informed consent” to be rendered meaningless or non-existent. Therefore, we encourage CDC to better define general consent for medical care and informed consent for HIV testing.

III. Prevention Counseling (Summary of Major Revisions): The statement on page 9 (top paragraph) beginning: *“Prevention counseling is not recommended as a part of HIV screening in health care settings”* seems unnecessary and should be eliminated from the document. While we do support not *requiring* prevention counseling in this setting, we do not support *not recommending* prevention counseling in this setting. In an ideal world, prevention counseling would be available in conjunction with ALL screening procedures (e.g., nutrition and exercise counseling with cancer screening). We are concerned about the message this point sends. It could be easily misinterpreted and we do not feel it is necessary. Please highlight this AAHIVM recommendation under your request for comments marked **“Omissions that may warrant consideration.”**

IV. CDC Paragraph on “Purpose”: While we agree with all of these goals, we feel it is important to acknowledge that these recommendations really only address half of the HIV prevention equation. That the identification and referral of high-risk HIV-negative individuals is

sacrificed in order to increase the detection of those with HIV infection should be explicitly acknowledged and not brushed aside. As they stand, the revised recommendations present a missed opportunity for providing prevention services to at-risk HIV-negative individuals. Feasibility issues, not data, appear to be driving CDC's revised recommendations. As stated on page 5, paragraph 3, "In a randomized controlled trial with carefully controlled, theory-based prevention counseling in STD clinics, HIV-negative participants demonstrated significant reductions in risk behavior." Clinical setting can be effective venues for providing risk-reduction counseling. The revised recommendations minimize both the effectiveness of clinical settings as venues for risk reduction interventions and the needs of at-risk HIV-negative individuals.

The importance of linkages and referrals to existing HIV prevention services for HIV-negative individuals really needs to be reinforced both in the Purpose section and throughout the document. This does present a dilemma, because it suggests that post-test risk assessment of HIV uninfected individuals is important, and we would suggest that it is. Because it is difficult to do and because it is currently not being done in most settings does not necessarily justify *not* doing it. While it may take time and resources to implement such services, we feel this should still be considered the goal and not just a barrier.

V. "Opt-out screening" (Background Definitions): This is an inadequate definition that could be dangerous if taken out of context. It does not include the important educational pieces and chance to ask questions as discussed in other areas of the document. We strongly recommend that this definition be more comprehensive and explicit with regard to the necessary elements of informed consent and the *importance of ensuring the individuals know they can decline*. The poster from the Texas department of health shown in Denver at the Conference on Retroviruses and Opportunistic Infections (CROI) is a great example of a message that implies that the patient has no choice about testing and this should not be condoned or allowed. Patients need to have a real, meaningful chance to opt out of testing.

Informed consent does not have to be written nor does it need a patient's signature, but it does need to be "real." Meaningful informed consent can still allow for an opt-out provision, but as currently written, this definition does not meet any legal standard of informed consent—what a reasonable person would want to know prior to consenting. We urge CDC to revisit this definition and explicitly indicate what elements should be included in true standard of informed consent, including an explicit assurance to the patient that they may decline or defer testing.

VI. Informed Consent (Background Definitions): The word "may" is concerning here. The guidance needs to be more definitive.

VII. Screening v. Diagnostic Testing (Background Definitions):

We believe there are significant challenges to setting two different legal standards for HIV testing: diagnostic testing versus screening. Further, significant inconsistencies in the use of these two terms exist in the current draft.

VII. Screening for HIV Infection (Background): AAHIVM agrees with the goal of routinizing screening as for "other treatable conditions." We would recommend that CDC consider and comment upon what is required for other similar screening tests for diagnoses of similar medical and emotional magnitude, including PSA, pap smears, mammograms, and occult blood testing. Specifically, CDC should consider what type of information constitutes adequate informed consent, how results are delivered, and the types of follow-up services and mechanisms for referral that are required.

Given similar transmission routes and associated morbidity and public health issues, we would also recommend that CDC consider any other screening or prevention services that might logically be linked to HIV screening, such as screening for hepatitis C (HCV) infection, sexually transmitted infections, and immunization against hepatitis B infection. HCV screening seems especially important to consider at this time.

VIII. Acute HIV (Rationale): While it is extremely important to screen for acute HIV infection, the complexity of appropriate acute HIV screening cannot be under-emphasized. Even HIV specialists probably do not always understand the test characteristics of the currently available HIV RNA tests, and the issues of pre-test probability and specificity. To ask non-HIV specialists to make this judgment without clear and appropriate guidelines that include expert consultation seems very unwise.

The AAHIVM recommends that CDC invest in the widespread implementation of pooled HIV RNA testing strategies in conjunction with routine HIV antibody screening, as is currently implemented in North Carolina (Pilcher, et al JAMA; 2002 Jul 10;288(2):216-21). In addition, we recommend that a clear discussion of the specificity, positive predictive value and consultative issues be included in this document with any mention of acute HIV screening. This is clearly an area where additional guidance materials should be developed.

IX. The Provider-Patient Relationship (Recommendations):

In the introduction to the recommendations (top of page 7) CDC states:

“These recommendations encourage diagnostic HIV testing and opt-out HIV screening as part of routine clinical care in all health care settings, preserving the patient’s option to decline HIV testing and ensuring a provider-patient relationship conducive to optimal clinical and preventive care (emphasis added).”

AAHIVM recommends that CDC explicitly define what this means and what the necessary components of this relationship are in the settings described. The uncoupling of testing from counseling, the removal of informed consent and other recommendations are being done in the interest of encouraging more testing. Part of that equation for providers is saving them time. In point of fact, the current recommendations may make this a *less* conducive environment in which to conduct clinical and preventive care.

X. Consent and Pre-test Information (Recommendations): AAHIVM recommends that this section also include an explicit discussion of the next steps in each scenario of a negative or a positive test result. For example:

- “If your test is negative, we will provide you with referrals to services where you can receive additional information and support to help you stay negative.” AAHIVM is concerned that those at risk of HIV who receive a negative screening test will perhaps under-appreciate their risk even more if they do not receive appropriate risk assessment and risk reduction counseling. The unintended consequence could be an increase in new HIV infections.
- “If your test is positive, we will refer you to care services where you will be able to receive treatments that help prevent people with HIV infection from getting ill, etc... You will also receive counseling on how you can prevent spreading HIV to others.” AAHIVM believes that CDC should develop materials for use in these settings that emphasizes that

HIV is no longer a death sentence, which is how it still is commonly perceived by the general public. Unfortunately, this may even be how it is perceived by many of those who will be conducting this screening and providing results.

XI. Provision of Results and Test Results (Recommendations):

AAHIVM recognizes that the provision of results of screening tests is complex, and that ideal procedures are often compromised for feasibility reasons. For example, results of cancer screening tests should ideally be provided in person, not by telephone. However, return visits in a primary care setting to review the results of these screening tests are rarely scheduled. While point-of-care testing or rapid testing would obviate the need for follow up appointments, utilization of this diagnostic tool is not universal.

This dilemma is clear in the current draft recommendations on page 12 and 13, where it is stated that negative results do not need to be provided in person and can be delivered by phone, but positive results should be done in person. We urge CDC to recommend how such a system would be implemented. This proposed system is compromised by the fact that a call to return to the provider's office means the test came back positive. Many patients, correctly inferring the results, unfortunately would not return for appropriate management and follow-up.

Wherever possible, all results should be delivered in person. However, one of the most productive areas to diagnose more people is in city public hospitals in the urgent care settings and inpatient services where the requirement of scheduling a follow up appointment with someone who does not have a primary care provider and/or a provider that would order a the test but who may not have a clinic to schedule a follow up are major obstacles to testing. Given those obstacles many people are not offered HIV testing in a setting where the HIV prevalence is often greater than 1%. Unfortunately, this is still very much unresolved and we urge you to work with AAHIVM and others to better define the provision of test results.

In addition, AAHIVM recommends that CDC consider further guidance about providing results in different settings when rapid testing is not used, or for confirmation of preliminary positive rapid test results. For example, in primary care, STD clinic and TB clinics, an appointment should be made, with back-up contact information available. We would like guidance on how CDC would envision this working in emergency department and urgent care settings; similarly, for inpatients who are discharged prior to receiving their test result. We further ask CDC to delineate their plans for increasing utilization of rapid testing to minimize these issues at least for those who screen negative.

XII. Clinical Care for HIV-infected Individuals (Additional Considerations for HIV Screening):

One of CDC's stated purposes in this effort is to get more people with HIV into care at an early stage of disease. *AAHIVM strongly believes that direct, dependable linkages to care are absolutely critical to any screening and testing program.* We believe that referrals for clinical care specifically by an HIV specialist should be in place before testing is done. In rural areas without specialists, a clinician who has such specialist consultation services available would be adequate.

XIII. Prevention Counseling (Additional Considerations for HIV Screening): *Prevention counseling resources must be in place prior to the institution of testing.* AAHIVM requests

specific guidance from CDC on how to ensure that such collaborations are in place prior to testing.

XIV. HIV/AIDS Reporting (Additional Considerations for HIV Screening): AAHIVM believes that CDC must address this issue in the context of the definition of informed consent, both in these recommendations as well as in further guidance.

Conclusion

Finally, the request for comments asked for recommendations on items to be included in the Implementation Guide, which will accompany the revised recommendations. AAHIVM is currently funded by CDC, through a cooperative agreement that ends in August 2006, to work with clinicians to incorporate HIV counseling and testing into clinical encounters. In working in this area, we have found that there is a significant lack of information available. This includes both 1) training and capacity building resources targeting providers that are designed to help them implement HIV counseling and testing into routine health care; and 2) patient-oriented materials that are designed specifically for this scenario where pre- and post-test counseling will at most, be minimal. Because of this lack of materials, the question is much larger than what should be included in the implementation guide.

AAHIVM believes that significant technical assistance will be required to effectively implement the recommendations. This includes the development and/or dissemination of protocols and best practices, designed for the various clinical venues covered by the recommendations, which can be utilized by providers. Clinicians may also require training on how to counsel and refer HIV-infected patients and how to build effective linkages with community-based counseling and treatment providers. AAHIVM is well positioned to assist CDC in developing resources and training clinicians, both HIV specialists and non-specialists, as the revised recommendations are implemented.

In addition, the issue of reimbursement for HIV prevention-related services remains a significant and unresolved barrier to the provision of HIV prevention services in clinical settings. While the revised recommendations minimized the role of counseling in the testing process, it is inevitable that some patients, both HIV-positive and HIV-negative, may seek answers to their HIV-related questions during a clinical encounter. Referring these individuals to a community-based organization for counseling or giving them a brochure may work for some, but not for all. Addressing the reimbursement issue so that clinicians are compensated for prevention counseling will not mean that counseling is provided to every patient seen by a clinician. It simply provides an additional opportunity to address the HIV prevention-related needs of patients.

Finally, we would like to comment on the inadequate time period with which we had to offer comments. HIV counseling and testing is both extremely important but also quite complex. In many of our comments, we make requests of CDC for further clarification or guidance. Given more time, we would have suggested specifically how we might have made clarifications or suggestions to further guide the CDC in its efforts. Regretfully, we were not able to fully explore all of the potential positions and clarifications we would have liked to. We hope that you will call upon our constituency to enhance and improve these recommendations before they are finally released.

Again, we thank you for your time and your consideration.

