

PARTNER TELEBRIEFING TRANSCRIPT

CDC ANNOUNCES FINAL RECOMMENDATIONS FOR ROUTINE HIV SCREENING IN HEALTH CARE SETTINGS

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Moderator: Thank you for participating in the Centers for Disease Control and Prevention call to discuss new HIV testing recommendations. As a reminder, today's call is recorded. Here is your host for today's call, Dr. Fenton. Please go ahead.

Dr. Kevin Fenton: Thank you very much. Good morning everyone. I'm Dr. Kevin Fenton, director of the National Center for HIV, STD and TB Prevention at the Centers for Disease Control and Prevention.

Today I am joined by Dr. Timothy Mastro who is the Acting Director of the Division of HIV and AIDS Prevention and Dr. Bernie Branson, Associate Director for Laboratory Diagnostics in the Division of HIV and AIDS Prevention.

Thank you for joining us today to discuss CDC's revised recommendations for HIV testing in health care settings. The revised recommendations will be published in the September 22nd issue of CDC's *Morbidity and Mortality Weekly Report*, or *MMWR*. The revised recommendations are in fact embargoed until 12:00 p.m. Eastern Standard Time today at which time our Web site with supporting materials will go live. The Web site address is www.cdc.gov/hiv/topics/testing/healthcare.

Now at CDC our goal is to reduce the impact of HIV and AIDS in the United States and we pursue this goal in a number of ways. We provide funding and support to help departments and community-based organizations to implement proven HIV prevention programs for people at risk and people already infected with HIV.

We worked with our constituent communities in both the public and private sectors to create recommendations that reflect best practices in HIV prevention. We carefully monitor the epidemic to identify populations at greater threat for infection and we researched new behavioral and biomedical strategies to prevent HIV transmission.]

Now, key to the success of our prevention program is our ability to ensure that people know whether or not they're infected with HIV so those that are HIV positive can access life-extending treatments and protect their partners.

The recommendations we are discussing today are an important step in addressing one of the nation's most important public health challenges. Of the more than 1 million people estimated to be living with HIV in the United States, approximately one quarter, and that means 250,000 people living in the United States do not realize that they are HIV infected.

Increasing the number of people who are aware of their HIV infection is an essential step towards improved HIV treatment and prevention efforts in the United States. Today, nearly 40 percent of individuals diagnosed with HIV are diagnosed within one year of developing AIDS for an average of approximately 10 years after they've become HIV infected.

For many it may be too late to full benefit from available treatment. At the same time, data suggests that persons who do not know their HIV status account for between 50 and 70 percent of new sexually transmitted HIV infections in the United States. But when people learn that they are HIV infected, research shows that most take steps to protect others from infection.

These recommendations respond to an urgent need for new approaches to reach a quarter of a million persons in the United States who have HIV but do not realize they are infected. These individuals have the right to know they are infected so they too can seek treatment and take steps to protect themselves and their partners.

For many people with HIV, health care settings provide the best opportunity for an early diagnosis, yet HIV screening rates remain low in many of these facilities. The CDC's revised recommendations are designed to overcome several key barriers to testing in busy health care settings and to make HIV screening a routine part of medical care for all patients between the ages of 13 and 64.

They also recommend additional steps to enhance routine screening for pregnant women in order to advance the dramatic progress already made in reducing mother to child transmission of HIV in the United States.

These recommendations are the culmination of an extensive process that began in 2003 to increase early diagnoses of HIV. Many of you were part of this process. While these recommendations are only one part of our efforts to increase opportunities for HIV testing through multiple venues and approaches, they represent a significant step forward towards improving diagnosis in health care settings.

Now Dr. Timothy Mastro will describe the specific recommendations and I'll then talk about some of the next steps we're taking with partners to ensure the recommendations are effectively implemented. Dr. Mastro?

Dr. Timothy Mastro: Thank you very much, Kevin, and good morning.

The revised recommendations we're discussing today replaced CDC's 1993 recommendation for HIV testing in acute care hospital settings and update portions of CDC's 2001 guidelines for HIV counseling, testing and referral and recommendations for HIV screening of pregnant women.

It is important to note that the revised recommendations address HIV testing in health care settings only. For those of you on the phone who work in non-clinical settings, we want you to know that these recommendations do not alter current CDC guidelines for HIV counseling and testing in non-clinical settings such as community centers or outreach programs. CDC currently is working to revise those guidelines and you will hear more about them in the near future.

CDC's previous HIV testing recommendations for health care settings called for routine testing for those at high risk and for everyone in high prevalence areas, defined as settings with HIV prevalence above one percent. But these were never fully implemented and HIV screening rates in high prevalence health care settings remain low.

Several key barriers have hindered implementation of the prior recommendations in health care settings. First, many facilities report that they do not have information about HIV prevalence in their facilities or do not have sufficient time to conduct this assessment and second physicians

report that the processes related to separate, written consent and intensive pre-test prevention counseling are often not feasible in busy medical settings.

For example, one recent study found that even for patients infected with other sexually transmitted diseases, HIV testing is rarely provided. In that study, 76 percent of emergency department professionals said they never or rarely encouraged HIV testing for these patients. Among the main reasons reported were the time consuming processes associated with HIV testing and lack of certification perceived to be necessary for counseling.

So there continues to be major missed opportunities for diagnosis in health care settings and it is simply not acceptable for HIV infected individuals to visit a health care facility without having the opportunity to learn that they have a life threatening illness. Given the dramatic advances in HIV treatment and the clear benefits of reaching individuals early in infection, we simply must improve early diagnosis.

The goal of the revised recommendations is therefore to ensure everyone who receives medical care also has the opportunity to learn if they are infected with HIV. I'll reiterate that these recommendations are intended only for health care settings, not for non-clinical settings.

I will now briefly explain the most significant components of the CDC's recommendations. First, HIV screening for all patients, regardless of risk.

Evidence shows that many patients with unrecognized HIV infections access health care but are never tested for HIV. To normalize HIV screening as a routine part of medical care, the revised recommendations by screening all patients aged 13 to 64 years. Studies have shown that when HIV testing is presented as routine, more patients accept testing and learn their HIV infection status.

Further, this approach will help reach infected individuals who do not recognize the risks. We also believe that universal screening that is not tied to risk assessment will help reduce the stigma associated with HIV testing.

Second, voluntary opt out screening. We are recommending an opt out approach to screening in health care settings. Patients should be specifically informed that HIV testing is part of the routine care they'll receive, that they will have the opportunity to decline testing.

Before making this decision, patients should be provided basic information about HIV and the meanings of positive and negative test results and should have the opportunity to ask questions. It is very important to know that the recommendations continue to emphasize that HIV testing must be and I'll repeat, must be voluntary and be undertaken only with the patient's knowledge.

Third, simplified procedures. The recommendation also advised removing two previous requirements for HIV screening that are proven to be significant barriers in many health care settings.

Prevention counseling. The revised recommendations advise that prevention counseling should not be required before an HIV test in a health care setting. The recommendations do underscore the need to ensure that patients who test positive for HIV receive prevention counseling and ongoing care and prevention services.

In addition, the CDC continues to encourage prevention counseling for high risk uninfected patients where feasible, especially when the health care visit is related to substance abuse, sexual health, family planning or comprehensive health assessment.

Separate written consent. The recommendations also advise that separate written consent for HIV testing should not be required. Instead, as it is done for most diagnostic tests, consent for HIV testing can be incorporated into general consent for medical care.

Again, our goal is twofold. To diagnose more people who are HIV infected and to normal HIV tests as a routine and important part of everyone's health care.

Recent survey data suggests that two thirds of Americans agree that separate procedures for HIV testing are unnecessary and we have learned from our experiences with prenatal testing that patients are more comfortable when HIV testing is treated like other routine diagnostics. They report less anxiety since they do not feel singled out as having high risk behavior.

This opt out approach to HIV testing without separate written consent has already proven highly successful in increasing diagnosis among pregnant women and has led to significant declines in mother to child HIV transmission in the U.S.

The estimated number of infants born with HIV declined from a peak of approximately 1,650 cases in 1991 to fewer than 240 cases earlier – each year today.

We believe the revised recommendations which reinforce and expand upon an earlier screening recommendation in pregnant women will help reduce this number even further.

Now I'll say a few words about our process for developing the recommendations. As Dr. Fenton mentioned, these recommendations are the culmination of a three year process. The CDC has worked closely with national, state and local partners to identify the best ways to achieve the goal of making HIV testing a routine part of medical care.

In 2003, CDC issued interim guidance for states and local efforts to develop programs for routine testing and health care spending and implemented several demonstration projects to evaluate potential approaches for expanding HIV screening.

In 2004 and 2005, CDC convened three consultations with health care providers, public health experts, insurers, community-based organizations and advocates to elicit further input. Based on lessons learned from these efforts, we developed draft recommendations and distributed them earlier this year to a diverse group of professional, scientific, community-based organizations around the country for review and comment. The draft was also submitted for scientific and peer review.

We have since worked to clarify and strengthen the recommendation based on comments received and we believe these final recommendations will be a critical step forward toward improved diagnosis, treatment and prevention in the United States.

I'll now turn the call back over to Dr. Fenton.

Dr. Kevin Fenton: Thank you very much.

It is important to note that CDC's revised recommendations are one of the many steps that CDC in conjunction with private and public sector partners is taking to ensure that individuals in health care and other settings have the opportunity to learn whether they are infected with HIV.

CDC is committed to supporting health care providers in implementing those recommendations and will issue additional guidance in early 2007. This guidance will provide examples and practical tools for implementing the recommendations in various types of health care settings. It is most important to recognize that while knowledge of HIV infection status is critical, testing efforts must be part of a comprehensive program of prevention and care to ensure that newly diagnosed individuals have access to necessary treatment and ongoing prevention services. CDC will continue to collaborate with the Health Resources and Services Administration, HRSA, and other government and private organizations. CDC is also conducting demonstration projects in several states to improve linkages from emergency departments to primary care for people newly diagnosed with HIV.

I'd like to thank you again for participating in this morning's briefing. We are extremely excited to take this next step to reduce the impact of HIV in this country and welcome your questions. I realize due to the volume of callers to this partner telebriefing that we may not have time for all listeners to ask their questions. Therefore, you may find further information on CDC's revised recommendations at www.cdc.gov/hiv/topics/testing/healthcare after 12:00 noon today.

I'd like to now ask the operator to open the call for questions.

Moderator: Ladies and gentlemen, if you wish to ask a question, please press star, one on your touchtone phone. You will hear a tone indicating that you have been placed in queue. If you wish to remove yourself from queue at any time please press the pound key. If you are using a speakerphone, please pick up the handset before pressing numbers.

Once again, ladies and gentlemen, if you have a question please press star one. One moment please.

Your first question comes from Michael Weinstein with AIDS Health Care Foundation. Please go ahead.

Michael Weinstein, AIDS Health Care Foundation: My question is how will the CDC coordinate with the states in terms of their legal structure or in terms of their legal structure and in terms of their requirements for testing and counseling in these settings?

And secondly, where will the funding come from for these additional tests in these settings?

Dr. Kevin Fenton: We're going to ask Dr. Branson to respond to your question.

Dr. Bernard Branson: I think it's important to note that in more than half the states right now it is possible to proceed with the recommendations as they are. We recognize that certain states have regulations that may conflict with one part or another part of the recommendations. We had the same experience when the prenatal testing recommendations were introduced for pregnant women and we found that many states began to respond to the recommendations by revising some of their state legislation and we anticipate supporting states in their efforts to do that if they find it not feasible to implement these recommendations under their current parameters.

With respect to funding I think it's important to recognize that these recommendations are intended for health care settings and funding in health care settings comes from a variety of sources. We expect that there will be insurance reimbursement for a portion of this testing. We insurance (ph) that Medicaid may cover testing for certain individuals and we recognize that some public funding will be necessary in order to support these efforts and anticipate them under the president's proposal and funding that has been appropriated by Congress, we will be able to supplement some of the activities that are going on.

Dr. Kevin Fenton: Next question?

Moderator: All right. The next comes from the line of Frank Oldham, Jr., from the National Association of People with Aids. Please go ahead.

Frank Oldham, Jr., National Association of People with Aids: It's a multiple clarification. When you say voluntary HIV testing and counseling, so it's going to be in medical settings CDC is going to work with in terms of the authorization to ensure that there is still informed consent?

Dr. Timothy Mastro: Well, thank you for that question. Our goal is really to ensure that everyone has lifesaving information about whether or not they're infected with HIV. We believe very strongly that all testing must be voluntary, so as part of our implementation guidance, we will work to elaborate the specifics on how to make sure information is transmitted to patients before a test is offered and then to allow people to ask questions and to set up mechanisms where people really have an opportunity to decline testing if they choose not to. It's very important that testing be voluntary with information and the opportunity to decline.

Dr. Branson?

Dr. Bernard Branson: Yes, Frank, this is Bernie. We actually have a couple of prototypes for this. For example, for almost 10 years, in Texas STD clinics, they have been doing opt-out testing, and they find very high acceptance rates. But, on the other hand, there still is a consistent 5 to 6 percent of people who do decline testing and don't see any difficulty with declining on that. I mean, our goal is to ensure that everybody has lifesaving information on whether or not they are HIV infected and to continue to support the kinds of voluntary approaches that we've been using.

We are convening several consultations with providers to address specifically the issues you are talking about with respect to making sure that in the process of implementing these efforts, to make sure the quarter of a million Americans who are unaware of their infection have access to testing, that at the same time their autonomy and their privacy is respected in this process to make sure that testing remains voluntary.

Frank Oldham: Well, I very much appreciate that. That's very important to the National Association of People with AIDS. So this is very good to hear.

Dr. Kevin Fenton: Thank you, Frank. Next question.

Moderator: Okay, your next question comes from Daniel Kuritzkes from Harvard Medical School. Please go ahead. Daniel Kuritzkes, your line is open.

Daniel Kuritzkes, Harvard Medical School: I'm sorry. I had the mute button on. My mistake. I had a quick question about a point you made when you emphasized that these recommendations apply only to healthcare settings, and I think this gets to the consent issue.

By targeting the recommendations specifically to the healthcare setting, presumably this does not give license to other groups, like insurance companies and others to surreptitiously test for HIV. I think that might go a long way towards reassuring people.

Dr. Bernard Branson: Yes, Dan, this is Bernie again. One of the reasons that we are really targeting these to healthcare settings is this what healthcare settings do. They screen for different kinds of conditions, especially things that are asymptomatic, with the interest of making sure that there's benefit to patients. As you point out, there are other people who might be interested in screening for other reasons that are not necessarily supportive of our goal, to, number one, remove the barriers in healthcare settings. But, number two, to make sure that everybody has this information. And, of course, this is only one of many steps that CDC is taking in order to do this.

But I appreciate your opportunity to emphasize that these don't apply to other settings where people might do testing. Healthcare settings obtain consent in their process for every activity that they do, and so we feel much more confident that there won't be abuse of this system in the healthcare setting environment.

Daniel Kuritzkes: Right, thanks very much.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: It comes from the line of Dr. Kees Rietmeijer from Denver Public Health. Please go ahead.

Kees Rietmeijer, Denver Public Health: Yes, this is Kees Rietmeijer in Denver. Another barrier in testing is the requirement to complete lengthy data forms, the infamous PEMS forms. Could you brief us a little bit about where CDC is at with the development of the PEMS recommendations?

Dr. Timothy Mastro: Okay, thank you. This is Tim Mastro. That's an issue that's very much on the front burner with us, to actually look at information requirements related to HIV testing, and we're anticipating a streamlined, simplified information collection for CDC-supported testing in healthcare settings. And that will be rolled out very soon, as we look at comprehensively how the PEMS system would be working. So stay tuned for guidance soon on reporting requirements for HIV testing that's done with CDC support in medical settings, including STD clinics.

Dr. Kevin Fenton: Next question.

Moderator: Okay, your next question comes from the line of Diana Bruce from AIDS Alliance for Children, Youth and Families. Please go ahead.

Diana Bruce, AIDS Alliance for Children, Youth and Families: Hi there. Thank you. And I apologize, there's someone drilling above me, so I apologize if that gets started. I have two questions, one related to pregnant women and one related to adolescents. Regarding pregnant women, I know much of the reduction in mother-to-child transmission has involved HIV testing that also includes written informed consent. So I would like it if Dr. Mastro could walk us through why that change was made, given the enormous reduction that we have experienced using written informed consent for pregnant women.

And the second question, regarding teens, is, for example, the 13-year-old who goes into the pediatrician's office for sort of their routine checkup is offered an HIV test or is told that they will receive an HIV test, yet it's still supposed to be voluntary. If the parent is there, whose voluntary decision is it? Is it the adolescent's voluntary decision, or if the parent wants it and the teen doesn't, whose decision is supposed to be taken?

And the, also, around teens and privacy, how would the HIV test be reimbursed and where would their privacy be maintained if the health insurance is billed for the HIV test?

Dr. Timothy Mastro: Those are two very important areas. I'm going to ask Dr. Bernie Branson to answer those for us.

Dr. Bernard Branson: Yes, thanks, Diana. First of all, with respect to pregnant women, we agree that we have achieved very substantial increases in testing. However, our data from numerous sites shows that testing increases considerably further when you use an opt-out approach for women, and our goal is to make sure that we accomplish universal testing. Even though we have had dramatic improvement in the amount of transmission, there still remain a persistent number of cases from women who have gone untested.

We recognize this as one of many strategies and people may take different approaches in order to do the implementation. Our goal is to accomplish universal testing, and we see that while we've made considerable progress with methods that we've used before, we still have some work left to be done, and we think that this will help us move in that direction.

With respect to adolescents, we have actually had some extensive discussions with the American Academy of Pediatrics about exactly how to approach this. And the academy, of course, supports very much that adolescents need to be very much involved in the decision making with respect to their own healthcare. And our concern is to try to balance two things.

One is that it's obviously important for parents to be involved in the health of their children. On the other hand, when you're dealing with sensitive issues like sexual activity or not, there are times when the adolescent may be hesitant to have a frank discussion with the parent, where they may have a different relationship with the provider. And, in fact, one of the professional standards for adolescent medicine by the American Academy of Pediatrics is to ensure that the provider establish an independent relationship with that adolescent.

And so we think that the adolescent has to be the primary person making the determination about their HIV status, hopefully with the support of their parents. But if they perceive that that will somehow interfere with their healthcare, we'd like the pediatric provider to have sufficient flexibility in order to be able to work with the adolescent to build in good health-promotion behaviors.

The obvious intention here is to create a norm where people entering sexual activity perceive that HIV testing is a good idea and preferably perceive that it's a good idea before they engage in sexual activity with a new partner, rather than closing the barn door after the horse has gotten out. And so the idea here is to help people also perceive the benefit of being HIV negative and creating a norm where they'll ask their partners if they've been HIV tested in order to determine exactly what precaution they need to take to prevent from acquiring HIV.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: Your next question comes from the line of Margaret Friedrich from the University of South Florida. Please go ahead.

Margaret Friedrich, University of South Florida: I just want to clarify, does prevalence have nothing to do with this anymore?

Dr. Timothy Mastro: Yes, we're actually recommending now that HIV screening proceed, and regardless of prevailing prevalence in that jurisdiction or in that healthcare facility and people should go and proceed with HIV screening. We do have a provision in the recommendations that if a facility has proceeded with testing and has clearly documented that, in their patient population, the prevalence of HIV is less than one per 1,000 – and you have to do more than 1,000 tests to comfortably determine this – you can consider discontinuing routine screening in that population. However, you'd want to keep alert for other epidemiologic phenomena in your area to determine if perhaps HIV has changed in the future.

Dr. Bernard Branson: Margaret, one of the things is that the Institute of Medicine strongly encouraged federal agencies like CDC to consider cost-effectiveness considerations in making their decisions about prevention efforts. There were two very compelling and very consistent cost-effectiveness analyses that were published last year that show screening was cost effective down to a prevalence of 0.1 percent, especially when you take into consideration the ability to influence or to reduce future transmissions.

Given that U.S. general population prevalence is around 0.4 percent, we think there will be very few healthcare settings that fall below this threshold of 0.1 percent that has been identified to be cost effective. I think the second difficulty that we really confronted is that unless you do screening, you don't know what the prevalence is in your setting. And so it has proven to us to be impractical to make a recommendation based on prevalence, when people don't know what their prevalence is. And so the orientation of these recommendations is to encourage screening, as we do for other conditions, where you screen everyone who is coming through the healthcare setting so that you're not stuck with some people making, perhaps, inappropriate decisions on what they think the prevalence might be or what they think the risks of their patients might be.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: And your next question comes from the line of Rob Lunn from Vermont Department of Health. Please go ahead.

Rob Lunn, Vermont Department of Health: Yes, our question has to do with you could give us some more information on the demonstration project that you've got planned as to where, when, if there's any specific criteria to be participating?

Dr. Timothy Mastro: The demonstration projects that we referred to so far have to do primarily with the ones that had been conducted in healthcare settings. Many of those, which were conducted in settings requiring separate written informed consent or pretest counseling demonstrated quite clearly that only a fraction of the people who were eligible for HIV testing could be offered the services, simply because of how time consuming the processes were.

What we're seeking to do in the future is really going to depend very much on what some of the outcomes are of federal appropriations about exactly what the extent of the projects that we're going to be able to initiate on that and we don't have full information on that yet, because we haven't found out yet exactly how much funding we will have available to commit to those.

Dr. Kevin Fenton: Okay, next question?

Moderator: Okay, your next question comes from the line of Tammy Wells of Excel Health, Incorporated. Please go ahead.

Tammy Wells, Excel Health Incorporated: Good morning. Actually, my question was already answered. My question was about the funding, the additional funding, for additional test kits, but it has been already addressed. Thank you.

Dr. Kevin Fenton: All right. Thank you very much, Tammy. Next question.

Moderator: Okay, your next question comes from the line of Richard J. Gardner from HIV/AIDS Prevention and (inaudible), Des Moines Department of Public Health. Please go ahead.

Richard Gardner, Des Moines Department of Public Health: Thank you, and I just wanted to mention to Dr. Fenton that Chicago really enjoyed your visit here.

Dr. Kevin Fenton: Thank you.

Richard Gardner: My question had pertained to the definition of healthcare setting. Even with our Perinatal Act that we passed in Illinois, we still have a problem with mothers refusing to have their infant testing, even though we don't know their HIV status. And so healthcare settings, are we just clinics, hospitals, or how do we define that?

Dr. Timothy Mastro: Richard, our definition of healthcare settings is basically any place that conducts routine diagnostic or screening testing. And so we recognize that that may be different in different jurisdictions and that this has been a little bit tough. In the recommendations itself, it sort of has a list that includes a variety of kinds of places that range from public clinics, private healthcare settings, correctional health facilities. But as a general rule of thumb, we are saying that any place that obtains blood in order to do other diagnostics or screening testing would be considered a healthcare setting.

Richard Gardner: Thank you.

Dr. Kevin Fenton: Great. Next question?

Moderator: All right. Once again, ladies and gentlemen, if you have a question, please press star, one at this time. Your next question comes from the line of Scott Sanders from UTHPAS. Please go ahead.

Unknown: Hello, thank you. This is Israel (ph) from UTHPAS. The question that we had is we've been doing a lot of work, health departments and community planning groups, around implementing paid testing and testing in general. You talked about new tools. How are you going to work with the jurisdiction and the community-planning groups to implement these new tools?

Dr. Timothy Mastro: Izzy (ph), thanks for getting up early. I think you're in San Francisco, right?

Unknown: I'm actually in Florida, and we have a whole room, so you're on speaker.

Dr. Timothy Mastro: At least you're in the same time zone. One of the things we learned during the consultations is that many of the people working with CBOs recognized that they were going to need to establish new relationships with healthcare settings, where they had not previously been involved in doing that. Similarly, we are hoping with FDA approval of two additional rapid tests in May that there is going to start to be more price competition and we're going to be able to make – or it's going to be easier for different jurisdictions to be able to afford implementing some of the newer tools that are going on.

Right now, what we anticipate doing is trying to forge relationships between some of the provider organizations and some of the healthcare facilities with the community-based organizations in their area so that we can get the sort of best of both worlds in order to proceed with this implementation, recognizing that a lot of the experience with providing support and the follow-on services that people need reside in the CBOs that have experience in doing these.

Unknown: Right, and so we just want to again enforce that we are a resource. We have been doing this work for a long time, and I think that CDC needs to continue working with community planning groups to implement this. The other question that I have is some real clarity on your community clinics, because there is some clarity that needs to happen around funding. Because you've talked about some public funding, but you haven't talked about who's funding that sum, whether you're expecting that the local jurisdictions ante up on their community clinics, their public health clinics, their STD clinics that a lot of times don't do this billing and testing everyone that goes through an STD clinic and who is going to pay for that. And I know you talked about some public health funding, but who's the sum? Who's that coming from?

Dr. Timothy Mastro: This is going to be context specific, because different jurisdictions have different packages that they put together. For example, a lot of HIV testing that's being done opt out in Texas is completely supported by the state as a part of their state initiative in that area. We worked with HRSA and the Bureau of Primary Care Services, where they will be providing some funding for the clinics over which they have jurisdiction.

So I think we're looking at a variety of sources and it really depends on where you are to figure out exactly what that package is going to look like.

Unknown: Thank you.

Dr. Kevin Fenton: Thanks, Israel. Next question?

Moderator: All right, your next question comes from the line of Michael Pates from American Bar Association. Please go ahead. Michael Pates, your line is open.

Michael Pates, American Bar Association: Thank you, good morning. Three quick questions, if I may. First, it was suggested that where this has been tried, it's been very successful in identifying people who otherwise would not have been identified. I'm just wondering if there is any data on what has happened to those folks after they received their positive test result in terms of preserving their confidentiality, any employment discrimination they may encounter, housing discrimination, that kind of thing?

Secondly, wondering what the status of the 2001 legal services guideline might be in the new recommendations?

And, third, regarding informed consent, I'm wondering why the CDC now things that general consent with optional pretest counseling is tantamount to informed consent when it never did before. Thank you very much.

Dr. Bernard Branson: Michael, this is Bernie Branson. There are a couple of things. First of all, what we have been able to track from the demonstration project so far, is that of the people who get identified as part of routine screening, 80 percent of them are enrolled in continuing primary care services. We have been attempting to solicit information on the experiences that they have had with respect to encountering discrimination in other circumstances, and, while we have not identified that, I don't think that is a sufficient guarantee for us that it doesn't exist. And so we're looking very much forward to continuing to work with ABA and the AIDS Coordinating Committee in order to track to see whether there are unanticipated problems that come forward with this.

The, I think, legal services guideline that you're referring to from the 2001 guidelines, where part of the counseling messages therein pretty much sees recommendation focused on testing and do not go into the content of various counseling messages. We anticipate that the recommendation for referring people, as needed, to legal services, will be part of the implementation guidance that CDC will be issuing. And, again, we think that's going to be context specific. It very much depends on where a person ends up getting tested to see exactly what the nature of their counseling message is.

I think that the final question that you're raising, with respect to the separate consent versus inclusion in the general informed consent has a great deal to do with evolution in thinking. We have been subjected somewhat to lobbying, if I should put it, by a lot of private providers who say that this has created a significant barrier for them and for their patients. And I think that most compelling is the recent Kaiser Family Foundation survey that said that two-thirds of people in the United States feel that no separate signed permission is necessary.

And so this is not a conclusion that CDC came to on its own, out of thin air, but rather from a great deal of supportive evidence. Similarly, there are several states that already had these provisions within their laws and testing has been conducted in this regard. They specifically state that consent is required for HIV testing, but testing can be conducted without a separate form while a general consent for medical care is in effect. And, noting that that has been successful in those jurisdictions, we feel that it's a model that other locations can adopt.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: Okay. Your next question comes from the line of Vincent Delgado from Borinquen Health Care. Please go ahead.

Vincent Delgado, Borinquen Health Care Center: Hello, first of all, I want to make it clear it's not Puerto Rico Healthcare, it's Borinquen Health Care Center in Miami.

Dr. Kevin Fenton: Okay, thank you.

Vincent Delgado: Okay, my question is this. I just went to the HRSA conference. It's a big thing now to make HIV testing as a routine testing. But we have a situation right now, we have in the community health center, we have been doing testing with previous funding that we have from the health department, we identify at least five new diagnosed individuals every week. We provide care here. But we have funding for care for Ryan White Title I and Title III. We don't

have any more funding right now conducting testing because our funding from the department of health ended June 30th and was not renewed.

But we still are conducting testing and now with this campaign, now, we want to help the public, if we continue conducting testing, how we are going to provide care for those individuals that we diagnose? Because we don't get more funding. And, actually, Ryan White was cut. Title I was cut, Title II was cut. For the amount of money that we receive right now, it's not sufficient for all the numbers of individuals being diagnosed every week.

Dr. Timothy Mastro: Thanks for that question. That's clearly important. We feel very strongly that linkages to care and support services are essential and that all people identified as HIV infected really need to have linkages of care, treatment and prevention services so they both can have life-extending treatment as well as prevention services to learn how not to transmit HIV infection to others.

We've been working with HRSA and the National Association of Community Health Centers to help ensure that newly diagnosed individuals do have access to care. As your question points out, there's still a fair bit to do, and we're eager to actually work with you and our partners, both federal and private partners, to learn better ways to move forward and optimize the way we can identify funding sources to both do screening, identify individuals and make sure that people can get linked to care. But, clearly, there's more work to be done.

Bernie, did you have any additional...

Dr. Bernard Branson: You're raising what's a bit of a dilemma for us compared to an earlier question with respect to CDC collecting data on this kind of thing. What we need to be able to do is take evidence to places like HRSA, and, frankly, to Congress, to say this is the size of the demand, in order to be able to help generate some additional funds.

And so your experience of conducting more screening and identifying more patients is one that is not an uncommon experience. And we feel that we need to start somewhere here, and we need to demonstrate that the demand exists in order to make sure that we can justify the additional funds necessary to make sure that we can provide the important care that is the only justification for this whole process.

Obviously, screening people and not getting them into care does not accomplish what our ultimate goal is, is to make sure that people have lifesaving information and they have the opportunity to enter care to realize the benefits of this program.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: All right, your next question comes from the line of Jenny McFarlane from Texas State Health Services. Please go ahead.

Jenny McFarlane, Texas State Health Services: It's actually quite ironic that my question was directly related to the previous question from Miami, because I believe we did have this discussion during the consultation, and I just would like to follow up, with reauthorization, what type of input has been given to the legislatures with the impact of these guidelines and the identifications of more individuals living with HIV?

Dr. Timothy Mastro: Jenny, this has been sort of thorny, as you know, because there have been many iterations of the reauthorization with Ryan White. CDC continues to provide

information and we continue to provide estimates on what we see that the potential impact of this might be for identifying additional patients. Until we get started and we see what the yield is going to be from some of the screening, it's hard to come up with some additional figures.

We're working with HRSA on this. We're working with CMS on this, in order to develop some projections and to come up with a package. I don't want to pretend that we have the answer and that we have all of this solved. I mean, this is one of many steps that CDC is trying to take, but in this particular regard, with respect funding for care, we really have to rely on our partners in order to shoulder part of the burden.

Dr. Bernard Branson: Yes, these recommendations are really just one step and one part of the whole puzzle of trying to achieve our goal, which really is to make sure everyone has access to testing and therefore care and services. And we would encourage our partners to help carry those messages forward, that there really is a need for traditional services.

Dr. Kevin Fenton: Thank you. Next question.

Moderator: Okay, your next question comes from the line of Gina Arius, from Gay Men's Health Crisis. Please go ahead.

Gina Arius, Gay Men's Health Crisis: Yes, you mentioned that you anticipate supporting states in their efforts to change legislation in order to be able to implement these guidelines, specifically the piece around discarding written informed consent. Could you elaborate on what form that support may take?

Dr. Timothy Mastro: I think that what we anticipate doing is providing prototypes and examples, and I think our best example of that, which was something that was developed by the American College of Obstetrics and Gynecology, which was a legislative tool kit. And it laid out several different options and several different approaches.

In the specifics with respect to New York, we've been invited to come up and have a discussion with their AIDS Advisory Council as they consider some of the proposals that have been made in order to change legislation. I think what we plan to do is to provide examples and to provide the scientific evidence in order to help states and help their legislatures make informed decisions with respect to what course of action makes the most sense for their constituents.

Dr. Kevin Fenton: Okay, thank you, Gina. Next question.

Moderator: Okay, your next question comes from the line of Judy Levison from Baylor College of Maine, please go ahead.

Judy Levison, Baylor College: Hi. My question is, once we do initial screening, how often are you recommending that we repeat screening?

Dr. Bernard Branson: Judy, we actually carefully avoided making that recommendation in these first revised recommendations, simply because we think that the answer to that question has to be based on evidence. For people with known risk factors, and many providers are going to be familiar, because of their relationship with patients, that they have risk factors, we're recommending repeat screening at least annually.

With respect to other individuals who don't have any specific or known risk factors, we're not making an explicit recommendation on re-screening. The cost effectiveness, that is upon which

some of these recommendations are based suggests that in low-prevalence populations, what we really only need to do is one-time screening.

We were careful to state in the recommendations that on the basis of the information that we gain as a result of this screening, we will come out with additional recommendations to talk about things like frequency of re-screening or levels, for example, of prevalence for retesting of pregnant women.

We don't pretend to have all of the answers at this time. We're hoping we remove some of the barriers to testing in healthcare settings, and then we will gain information from this implementation that will help guide future activities.

Judy Levison: Great. Thank you, Bernie.

Dr. Timothy Mastro: Just to emphasize what Bernie was saying, we do recommend at least annual testing for people at high risk, defined as injection drug users and their partners, the sex partners of HIV-infected individuals, people who exchange sex for money or drugs or men who have sex with men, or heterosexuals who have greater than one sex partner since their last test.

Judy Levison: Thank you.

Dr. Kevin Fenton: Wonderful. Thank you. Next question.

Moderator: Okay, your next question comes from the line of Pamela Wrenn from Midwest AIDS Training. Please go ahead.

Pamela Wrenn, Midwest AIDS Training: Yes, it sounds like the responsibility of medical providers is great. What is your strategy of your plan in working with HRSA to ensure that medical providers are adequately providing this service?

Dr. Bernard Branson: Pamela, I think that we're not just working with HRSA. I think that our first initiative is to work with a lot of the professional organizations representing medical providers in order to get their insights, to get their input and to develop several strategies. CDC has actually scheduled an initial meeting with the medical providers on October 16th. A group of individuals from Johns Hopkins and Brown University have scheduled another two-day forum in order to look at mechanisms for implementing these recommendations that will be at the end of November. And then we're going to count on participation from both the professional associations and from HRSA in order to monitor this implementation.

Similarly, the National Center for Health Statistics conducts ambulatory medical care surveys, and one of the questions there is how many HIV serology tests are being conducted? So we plan to rely on several different partners to initiate the implementation and several different mechanisms to monitor whether the implementation is successful.

Dr. Kevin Fenton: Thanks. Next question.

Moderator: All right. Your next question comes from the line of Yvette Rivero from the University of Miami. Please go ahead.

Yvette Rivero University of Miami: Hello, can you hear me?

Dr. Kevin Fenton: Yes, we can.

Yvette Rivero: Okay, my job in Florida was to implement rapid testing in all the O.B. Florida hospitals, and the greatest hurdle that I found was that rapid testing (inaudible) was only a recommendation from CDC and the department of health, and it was not mandated for the hospitals to have the ability to have rapid testing like they do in the state of Illinois. So my question to you is, can CDC do anything to help the health department move this forward, where the hospitals must at least have rapid testing available in labor and delivery to capture these women that are missed opportunities?

Dr. Timothy Mastro: You know, Yvette, CDC doesn't really have regulatory authority, so that we can't put out an edict that says everybody has to do this. And so we will obviously be using the bully pulpit, but I think that the more important consideration with respect to the particular issue you raised, rapid testing in labor and delivery, the American College of Obstetrics and Gynecology came out with an opinion piece which ends up making something standard of care in many environments. And so I think that it's going to require a sort of multidisciplinary effort in order to move forward on this.

We have a recommendation. As you know, CDC conducted a series of regional workshops in order to assist hospitals in putting together a strategic and logistic plan for implementing rapid testing. We still need to cooperate on the voluntary participation of providers.

One thing that we do anticipate, though, is that with this expanded screening, a message that we heard from many facilities is that if they were doing this in both the labor and delivery and in the emergency department, it would be a lot easier to justify, it would be a lot easier to do the training. And so part of this whole strategy is to remove some of the barriers, because if you only have a test that you do once a shift, for example, in labor and delivery, the hospital is not going to be very enthusiastic.

But if this is part of a larger screening program that's going on in urgent care and the emergency department, it makes it much easier to justify in labor and delivery. And so we think that this combination of ingredients is going to probably help to forward this.

Our commitment is to make sure, whether it's pregnant women in labor or other people accessing healthcare settings that we reduce these missed opportunities of people who are not being diagnosed. And too much for our evidence shows that people come through healthcare facilities multiple times with HIV infections before they ever get an HIV test.

Yvette Rivero: Right, and most of the hospitals, I mean, they will protect us (ph) to this, and all the those things I did with them, but then you have those hospitals that always stated, is this mandated? Are they going to make me do this? Are they making the hospital do this? And I always said, no, it's just recommended, and then I would go on with this stuff, but I thought that maybe if someone can – I wonder by in the state of Illinois it's mandated by the health department and it's not by us.

Dr. Timothy Mastro: All I can say, Yvette, is it sounds like you certainly have job security in continuing to pursue this.

Dr. Kevin Fenton: Thank you so much for that question. We have time for only one more question and then we'll wrap up the call this morning. Next question.

Moderator: Okay. Your next question comes from Sean Barry from CHAMP. Please go ahead.

Sean Barry: Bernie, you said earlier that many of the concerns that partner organizations expressed about the guidelines were more related to the implementation guidance you're planning to develop. As you know, there was frustration on the part of many organizations with the opportunity for input in designing these guidelines. How are you planning to improve the process for feedback in developing the implementation guidance?

Dr. Bernard Branson: One of the things that actually will be coming out with these recommendations is the response to many of the organizations who had provided questions to us with an invitation to participate in the implementation guidance and which in fact there's going to be a specific contact person, e-mail address in order to coordinate the input from organizations that are seeking to be part of this process, recognizing that the implementation guidance is going to be context specific.

And so we seek participation from many different partners. You heard Michael Pates, earlier from the American Bar Association, with their specific concerns. We certainly recognize the interest that CHAMP has in making sure that this implementation occurs in a way that protects autonomy and the respect for individuals in those environments.

If you have any suggestions on how we can better coordinate, I'd really appreciate it if you would let me go. Because, obviously, we don't have all the answers and are seeking the kind of assistance from organizations like yours in moving forward.

Sean Barry: And I know you're planning a modular release for the implementation guidance. Do you have that segmented out yet for which settings will be released at which time, (inaudible).

Dr. Bernard Branson: So far, some of our initial progress is in places where we have the most experience, like for emergency departments, and we already had done, of course, before, labor and delivery. And we don't have a greater schedule than that. It really depends on exactly how active other partners get in moving forward, because we expect a lot of this burden will be shouldered by partners, rather than the CDC developing it on its own.

Dr. Kevin Fenton: Great, thank you very much. So I'd like to again thank you all for participating in this morning's briefing. We are extremely excited to take this next step to reduce the impact of HIV in the United States. And just to reiterate, our goal is to ensure that everyone has lifesaving information on whether they're infected or not. The new recommendations will help answer a need for new approaches to reach the more than a quarter of a million HIV-positive Americans who are unaware of their diagnosis.

And the recommendations really remove some of the barriers to testing in healthcare settings, and the recommendations are in fact one of many steps to reach everyone with an opportunity to learn about their HIV status. I know that due to the volume of callers in this partner telebriefing, some of you may not have had time to ask your questions. Therefore, you may find further information on the revised recommendations at www.cdc.gov/hiv/topics/testing/healthcare after 12:00 noon today.

Thank you very much and have a good morning, everyone.