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## The CDC Revised Recommendations for HIV Testing: Reactions of Women Attending Community Health Clinics

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### Abstract

**Purpose**—To examine reactions to the CDC revised recommendations for HIV testing by women attending community health clinics.

**Methods**—Thirty women attending three community clinics completed semi-structured individual interviews containing three questions about the recommendations. Thematic content analysis of responses was conducted.

**Findings**—All agreed with the recommendation for universal testing. Most viewed opt-out screening as an acceptable approach to HIV testing. Many emphasized the importance of provision of explicit verbal informed consent. The majority strongly opposed the elimination of the requirement for pre-test prevention counseling and spontaneously talked about the ongoing importance of post-test counseling.

**Conclusions**—There was strong support for universal testing of all persons 13-64 years old, but scant support for the elimination of pre-test prevention counseling. In general, respondents believed that verbal informed consent for testing as well as provision of HIV-related information before and after testing were crucial.

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## Keywords

Revised Recommendations for HIV Testing; HIV; Women; Qualitative; Interviews

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The purpose of this paper is to present the findings of a study that examined the reactions of women attending community health clinics to the Centers for Disease Control and Prevention's (CDC) revised recommendations for HIV testing (CDC, 2006). The background of the new recommendations and a summary of literature pertinent to this study are presented. The study methodology, findings, and conclusions are presented as well as associated clinical considerations.

## Background

The U. S. Public Health Service first issued its guidelines for HIV testing in 1987. The CDC extended those guidelines in 1993 to include hospitalized patients and persons obtaining health care as outpatients in acute-care settings. These guidelines addressed HIV counseling and testing as a priority prevention strategy for at-risk persons regardless of the health care setting. The CDC revised these guidelines in 1994, 1995, 2001, and 2003 based on advances in testing technology and an ever evolving knowledge of HIV and transmission factors (CDC, 1993, 2001a, 2001b). In 2004, the revision process was begun again, resulting in the most recent 2006 version.

The 2006 revisions, originally conceived to expand HIV testing with a focus on high-volume, high-prevalence, acute-care settings, were based on "a review of literature regarding HIV testing in health care settings, published evidence and lessons learned from CDC demonstration projects," (p.3) as well as on invited input from constituent agencies and consumer advocates involved in HIV testing and care provision (CDC, 2006). The revisions allow a broader testing base because there is no longer a focus on testing persons with clinical presentations or behavioral risk histories (Lifson & Rybicki, 2007). Also, the changes are viewed as a method to increase early detection of HIV infection, as well as decreasing HIV stigma, by not focusing on behavioral risk groups (Valdiserri, 2007).

The most recent recommendations for HIV testing in primary care settings, released in December, 2006, are in various stages of implementation across the United States. However, according to the CDC, the revisions do not include changes to voluntary testing in other community settings, such as community-based AIDS service organizations. The major revisions include:

- In all health care settings, screening for HIV infection should be performed routinely for all patients ages 13-64 years.
- HIV screening is recommended for patients in all health care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening). As a result, separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health care settings.
- Persons at high risk for HIV infection should be screened for HIV at least annually. (CDC, 2006)

Data on which the recommendations were based were primarily derived from epidemiological analyses and from studies addressing barriers and facilitators to HIV testing from the

perspective of the health care system and health care providers. For example, a study of health care providers' perceptions of HIV testing in primary care settings cited eight barriers to HIV testing in health care facilities: insufficient time, burdensome consent process, lack of knowledge/training, lack of patient acceptance, pretest counseling requirements, competing priorities, and inadequate reimbursement (Burk et al., 2007). However, little if any evidence is provided from the perspective of the patient/consumer who would be subject to the recommendations.

## Review of the Literature

### Universal Testing

Universal testing is based on the premise that the most effective approach to testing is to offer an HIV test to everyone; patients then have the option to refuse the test. Targeted testing, on the other hand, is based on the premise that those who are at increased risk of being HIV infected should be the focus of testing efforts (Valdiserri, 2007). In addition to data used by the CDC to revise the testing guidelines, other data reports added to the debate about which method, if any, was the best.

For example, Holtgrave (2007) conducted a scenario and cost-effectiveness analysis over a one-year time period. For the same cost, targeted counseling and testing services, based on a 1% HIV seropositivity rate, would diagnose 188,170 new HIV infections as compared to 56,940 new infections using opt-out testing methods (Holtgrave; Holtgrave, McGuire, & Milan, 2007). Holtgrave found that even when HIV seropositivity rates were as low as 0.3%, targeted counseling and testing performed better than opt-out testing. Holtgrave also noted that the opt-out approach may not address racial/ethnic health disparities because HIV disproportionately affects communities of color, such as the African American community. More specifically, David, Mercado, Becker, Edmundo, and Mugisha (2007) addressed the needs of those living in slums and similar situations in urban areas, noting that these individuals needed to be provided with opportunities equal to those of the rest of the population to access proven interventions. Even with these newer data, Valdiserri (2007) cautioned that prevention efforts should not be limited to only opt-out and targeted testing methods.

### Opt-Out Screening

The requirement for written informed consent has been a significant barrier to testing in health care settings. In an effort to overcome that barrier, written consent is no longer recommended (CDC, 2006). However, it should be noted that some states have legislated requirements for written informed consent and pretest prevention counseling (Kaiser Family Foundation, 2006, 2007). Zeotola, Klausner, Haller, Basso, and Katz (2007) reported a significant increase in HIV testing after the San Francisco Department of Public Health Medical Care System's requirement for a separate written informed consent was eliminated; they noted that because the data were observational, other events may have contributed to the results. Others, however, reported no significant increase in testing rates when requirements for consent and counseling were lifted at another agency within the system. This other study (Girardi, Puro, De Carli, Orchi, & Ippolito, 2007) also found that more persons tested without pretest counseling had a lower HIV positivity rate when compared to those tested after such counseling. Finally, there are concerns in some communities about dropping the requirement for written consent. In Massachusetts, for instance, officials were concerned that high-risk individuals would avoid health care if they perceived that an HIV test could be conducted without their consent (Kaiser Family Foundation, 2007).

## Pretest counseling

The elimination of the requirement for pretest prevention counseling could lead one to believe that this strategy is not effective. A randomized, controlled trial sponsored by the CDC in the late 1990s demonstrated that interactive client-centered counseling could reduce risk behaviors and the incidence of new sexually transmitted infections (Kamb et al., 1998). Further, the impact of counseling and testing was likely to be greatest for HIV-infected individuals because it was thought that those individuals would use information gained in counseling to avoid transmitting HIV to others (Wohlfeiler & Ellen, 2007). Valdiserri (2007) noted that one of the scenarios posed in Holtgrave's analysis addressed the revised recommendation of not requiring pretest prevention counseling in health care agencies and actually indicated that there could be an increase in HIV incidence as an outcome of high-risk individuals interpreting negative test results as validating that their risky behaviors were safe.

Obermeyer and Osborn (2007) pointed out that, while provider-initiated testing and counseling has tended to lead to positive outcomes in terms of acceptance of testing and access to service, unanswered questions remained about the use of counseling in the testing process and its "gradual erosion." In other words, "how much is necessary, who will provide it and under which conditions?" (Obermeyer & Osborn, 2007, p.9). Finally, the use of a one-size-fits-all approach may be ineffective. Local meaning (i.e. perceptions about HIV infection and HIV testing) and the social context of testing should be taken into account during testing. The opportunity to do this usually occurs during pretest counseling (Obermeyer & Osborn, 2007). One study suggested that an ethical dilemma could exist concerning who would be offered counseling when HIV care practitioners anticipated poor outcomes, a compromised patient/provider relationship, and/or failure of the patients to change their risk behaviors (Grodensky et al., 2007). Thus, an ethical dilemma could exist in health care agencies regarding who should be offered pretest counseling.

The literature indicates three areas of concern in regard to the new recommendations: (a) universal testing of all individuals 13-64 years of age who present for health care, (b) incorporation of consent for HIV testing into the general informed consent for medical care (i.e., opt-out screening), and (c) streamlining pretest counseling.

The present study addresses three of the four CDC-recommended changes to the way in which voluntary HIV testing is approached in health care settings: universal testing, opt-out screening, and streamlined pretest prevention counseling. These three areas were selected for study on the basis of a literature review that indicated the need for further assessment and a lack of data from patients in clinical settings in the context of the recommended changes.

## Purpose of the Study

This study was conducted as part of a larger research effort to develop and test interventions to encourage women to get tested for HIV and to consider participation in HIV-related clinical trials. Since the CDC indicated that its revised guidelines were developed to decrease barriers to HIV testing, it was reasonable to assess patients' perceptions of the recommendations as part of the larger study. Thus, an additional research question, "What are the reactions of women in community health clinics to the CDC revised recommendations for HIV testing?" was developed to address this issue and subsequently framed data collection and analysis.

## Methods

### Setting

Participants in this study were adult women seeking clinical services at one of three urban community health clinics located in Indianapolis (population approximately 800,000). All

three recruitment sites were full-service health clinics administered by one university-based medical group. The clinics offered a full range of diagnostic and treatment services. An average of 3,300 women visited these clinics each year. A purposive sampling method was used to ensure diverse ethnicity (Patton, 2002). Participants were recruited from clinic waiting rooms to complete in-depth, in-person semi-structured individual interviews. Participants received gift cards with a value of \$25, redeemable at a local retail store for their participation. Written informed consent was obtained from each participant and the study was approved by the University's Institutional Review Board.

## Sample

Thirty women completed the interviews. Ten women identified themselves as Latinas, 10 as non-Latina White, and 10 as non-Latina Black. They were 22-67 years of age (*Mdn* = 30).

## Data Collection

A semi-structured interview protocol was used to guide the digitally recorded interviews that were conducted by trained research assistants at the clinics. The interviews took about 30 minutes to complete. The research assistants transcribed their own recorded interviews for use in data analysis. A research assistant fluent in Spanish translated the interview guide for Spanish-speaking participants prior to data collection. She interviewed the Spanish-speaking participants and transcribed and translated those interviews.

The interview guide included three questions about the revised recommendations. The women were asked to share their perceptions of: (a) universal testing of all individuals 13-64 years of age presenting for health care, (b) incorporation of consent for HIV testing into the general informed consent for medical care (i.e., opt-out screening), and (c) no pretest requirement for prevention counseling. All of the women were asked the same questions, posed in the same order. The following introduction and questions used in the semi-structured interview guide were developed by members of the research team with expertise in HIV testing. Probing questions or prompts were used by interviewers to clarify or augment responses:

- **Introductory Statement:** “Recently, health officials changed the guidelines for how doctors and clinics should do HIV testing. I want to describe these changes to you, and then hear your opinions about them.”
- **Interview Question 1:** “In the past, HIV testing was mainly offered to people who were considered at “high risk” for HIV infection due to sexual behaviors or injection drug use. Now, health officials recommend that all Americans who go to a clinic or doctor’s office for medical care and are between the ages of 13 and 64 should be tested for HIV, unless they clearly say they don’t want to be tested. What do you think about this change?” [PROBE as needed]
- **Interview Question 2:** “In the past, a clinic would not give you an HIV test unless you signed a separate permission form saying you wanted HIV testing. Now, health officials recommend that once you have agreed to receive medical care at a clinic, you are simply told you will receive an HIV test, and then are tested, unless you clearly say you don’t want to be tested. Although this clinic does not use this approach to HIV testing, we want to know what you think about this change.” [PROBE as needed]
- **Interview Question 3:** “In the past, clinics had to give patients counseling on HIV prevention before giving them an HIV test. Now, clinics are not required to give HIV prevention counseling to patients prior to HIV testing. What do you think about this change?” [PROBE as needed]

Health care communication experts assisted in the development and refinement of the questions. Co-investigators served as experts in the review of the questions. Prior to data collection, the questions were piloted in each of the three clinics and revised for clarity.

## Analysis

Thematic content analysis was initiated by conducting a line-by-line analysis of the interview transcripts. Transcripts were checked against the audiotape by the interviewer and corrected as necessary. Pattern recognition was performed by reviewing the sentences and phrases for patterns or core meanings. The patterns were refined and synthesized into descriptive statements of the data provided by the participants.

The portions of the interview guide specific to the research question served as a structure for the organization of the data. Independent coders were used in the coding process. Interviews were coded independently, and any disagreements were resolved through discussion. Finally, trustworthiness, credibility, transferability, dependability, and confirmability of the data were ensured by data verification ascertained by both research team members and participants.

An iterative process of comparison was used to further analyze the data, moving between individual elements of the text specific to participant responses to each of the three questions in the structured interview guide. Several cycles of comparison were accomplished: across all accounts to identify particular themes, subthemes, categories, and classes; within each individual account to identify meanings that were implicit rather than explicit in the text; and of one whole account with another to identify overall patterns of meaning (Tesch, 1990).

## Findings

Initial review of participant responses about the CDC's revised recommendations for HIV testing in primary care settings showed that all respondents agreed with the recommendation for universal testing. Twenty-four of the 30 participants viewed opt-out screening as an acceptable approach to HIV testing, whereas six women had concerns about the elimination of written consent. Seventeen of the 30 women were strongly opposed to the elimination of the requirement for pretest prevention counseling, seven were unsure, and six agreed with the recommendation to not require pretest counseling.

## Theme

Participants were very responsive to the central theme of "change" explicit in our questions about the revised CDC recommendations and readily expressed their opinions about the proposed changes. The three major changes addressed by our questions elicited rather strong opinions from the participants. Some of the changes were clearly characterized as good, others as both good and bad, and still others as definitely problematic.

### Changes Characterized as "Good"

Some changes (principally universal testing) were perceived as good, in part because the participants indicated that the changes would provide them and others with better protection from infection with HIV directly or indirectly because the new recommendations focused on testing everyone as opposed to only those in risk groups.

In terms of risk groups, some women indicated that the change would help identify even more infected individuals in vulnerable groups, such as adolescents and older adults who were sexually active and perceived themselves as being not susceptible to infection. Finally, participants indicated that the changes would help identify those who were asymptotically infected due to tainted blood transfusions and thus protect others from being infected by them.



Because the more people they get tested, the more they have it, the less, I think, it's likely to get spread. At least people will come and sense they don't want to spread it. If you know you have it you're more liable to prevent spreading it. I think it should be mandatory. I don't think you should have a choice. It's because it can save lives. 'Cuz some people could have it and not know they're passing it.

I think that is OK that you get tested, and the people that don't want to be tested they are wrong because it's nothing wrong to be tested, it is only to make sure that they are healthy because you can get contagious from anything, can't you? And overall, it is good for the young people because now they are crazy, they don't care with who they sleep, and they don't take care of their self.

I think that it is good because the young people are now experimenting a lot with what sexuality is, and a lot of them don't protect them self, you know, at school, in the clinics, at stores is very common to see condoms, but they don't use them, because they don't like them, and the thing is to be protected.

I think it's excellent, but it doesn't have to be only until 65 years old, it should be until 75-80, you are going to think that I am crazy, but no, I am not crazy, there is a population in Florida where the majority of the people retire and most of them are widowed, and they start having sex after many years. Because usually they widowed, and in 5 or 6 years they find someone to spend their lives, and is a generation that has never been informed about the virus or anything else, and they should get tested. Now there are hundreds of people that have the virus and not know it because they are having a single's life now after many years. You may have people that who is older that might have had a blood transfusion or something. You know, back in the day [mumbles] they wasn't screening the blood right or whatever. So I mean the change is good.

The revised recommendations were also perceived by some participants as "good" in terms of reducing barriers to HIV testing. Barriers to testing such as paperwork, redundant information provided in pretest counseling, and stigma were perceived as obstacles to testing due to the time required for signing consents and participating in pretest counseling, which some women believed were not needed.

From having to write it, and then just request to have it, I think it's a good change.

They only don't do it 'cuz maybe they're afraid of being sued or something. 'Cuz I think if other clinic groups do it, then they should do it.

I think it is better this way because before when you had to sign, one felt obligated to do it, and now they just ask, I think it is better this way because one get scared when you have to sign something, adding the fear of get tested or if you are infected you might say no, but now it is easier.

Makes it, the idea of being tested more acceptable and open to people.

I think that now we are more informed.

### **Changes Perceived as Both "Good and Bad"**

Women who indicated that changes were "good and bad" noted concerns about trusting the health care system in terms of confidentiality, since the thrust of the revised recommendations is that all people would be tested as opposed to only individuals identified as at-risk.

I think it's good, but the only drawback that I could see against it is who's compiling this information, and can the people be discriminated against or whatever like that.

Some seemed concerned that people might be coerced into being tested because HIV testing consent forms might not be available for signature.

They must tell you what they are going to do, and can choose to do it or not.

My thing is it right? ... I want an HIV test, BUT if you're getting medical treatment, they should not assume that you want one. You need to be asked. You see what I'm saying?

Finally, some indicated concern that the changes might be misinterpreted by providers in a more rigid way and not be flexible to meet the situational needs of patients, such as assessing knowledge levels of patients and providing counseling prior to testing if needed or desired.

Uh, middle. Middle. I'm sort of on both sides of that, whether they should be talked to before or after, I don't know.

It depends on the person, on his temperament, if he is an optimistic person, he is going to be OK, but if he is a selfish person, he is going to worry a lot, and he is only going to be thinking about that, so I think that kind of person should need counseling.

### Changes Perceived as Problematic

Some women perceived changes as “problematic” or did not believe them to be beneficial in that universal testing may not always be appropriate. There was some overlap in ideas about the changes between these women and those who perceived the changes as “good and bad.” Specifically, this was a concern about confidentiality and that people might be coerced into being tested under the guise of opt-out testing. The notion of lack of trust of health care providers and the health care system in the context of patient rights about having a choice to have a test or not emerged in women's responses to the recommendations that there would no longer be clear and specific written informed consent prior to testing.

I think I'd of stuck with getting the written consent because that way they could have proof in case somebody were to come back and try to go after the person saying that they never authorized them to—or they never give them the consent to test them.

I don't think that's right. I think, like I said, it's really the discretion of the patient. If they don't feel comfortable with it, I wouldn't force them.

That is wrong because you have to ask for the permission of the person and let them know in writing that they know and they want to be tested. I don't like if they do something and they don't ask me first.

As noted earlier, most women disagreed with the change in the recommendations surrounding pretest counseling. An ethical concern emerged in the responses about the necessity of education to explain the test and procedure in enough detail so that patients would have as much information as they needed to make a truly informed decision about the choice to be tested.

I think it's kind of wrong because I think if they're at the age to where they're being promiscuous then they need that counseling. They need to know.

I would probably have to disagree with that one. I would rather have the counseling because not only if they get affected by the HIV virus or whatever, they need to know how they got it. How to prevent it. Or if they don't have it, how to prevent it. So I would not agree to that. I would have some kind of counseling.

As previously noted, only six women objected to the elimination of a separate written consent for HIV testing. However, the women's responses about their perceptions of the change related to eliminating mandatory pretest counseling further informed their responses about the



necessity of informed consent prior to testing. They felt that without adequate counseling, making informed choices about testing options would be difficult.

I think that they have to give counseling to the patients, to let them know how is the disease, how it attacks the body, for me it is not OK, that the person just come and be tested and they don't receive any information, they don't know what to expect.

I think that before was better because they explain everything to you, if you would be positive you know what it is. Now the doctor says to you, "If you are HIV positive this can happen." I think before was better. Receive counseling and explain everything with details, yes, that is the reason why now are more diseases.

The perception that the changes were "problematic" in the context of pretest counseling also reflected concerns that not routinely providing pretest counseling was clearly a missed opportunity to provide education about prevention of HIV transmission, particularly to youth.

## Conclusions

Although there was strong support for universal testing of all persons 13-64 years of age, there was scant support for the elimination of pretest prevention counseling. In general, respondents believed that at least verbal informed consent for testing and provision of HIV-related information before and after testing were crucial. These preliminary results suggest that as the revised HIV testing recommendations are implemented, it will be important to address patients' concerns about counseling and consent and to continue to have pretest counseling services available.

Participants' perceptions of the changes in the HIV testing recommendations provide valuable information with which to influence clinical practices in the context of HIV testing, care, and prevention. The changes were not viewed in a dichotomous fashion. The overlapping aspects of testing found in the data lend support to the complexity of the issues involved in decision-making and willingness to participate in HIV testing.

The findings give crucial information for health providers on which to base their approaches to HIV screening, treatment, and prevention. In order to meet the needs of clients, health care staff must understand the complexity of universal testing and possess the necessary skills, education, and resources. Further, there must be an awareness of local statutes regulating HIV testing consent. Finally, ethics, advocacy, and inherent patient rights must be in the forefront of health screening interventions for all clients in the context of HIV infection.

## Clinical Considerations

- All health care staff must have a clear understanding of what universal testing for HIV involves for them and their patients.
- All health care staff must have the necessary skills, education, and resources to address patient/family questions, prevention counseling, if indicated or requested, and ongoing care and referral in order to meet patient needs.
- Local statutes governing confidentiality and the HIV testing consent and reporting process should be consulted and followed according to law.
- Regardless of whether the institution's policy is opt-out or opt-in testing, patients must be given a clear and distinct choice of whether to be tested (or not), as well as receive enough information on which to make a truly informed decision.

- Ethical considerations should include a patient's choice to participate in prevention counseling as needed or desired and to have this information provided by qualified and knowledgeable individuals.
- For settings that are new to the process of universal testing, it will be essential to develop standard operating procedures and the infrastructure for delivering test results, conducting post-test counseling, performing confirmatory testing, and making referrals for appropriate follow-up services for those who test positive.

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