

# Communicating Indeterminate HIV Western Blot Test Results to Clients: An Observational Study of Three Community Testing Sites

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## ABSTRACT

This study examined HIV test counselors' beliefs and practices regarding communicating indeterminate HIV test results to clients. There are many reasons for an indeterminate HIV antibody/Western blot assay including early HIV infection, infection with other contagious diseases, autoimmune diseases, and second or subsequent pregnancies in women. Field observations of three community HIV testing sites and semistructured interviews with 16 HIV test counselors were conducted from August 2002 through June 2003. Counselors defined an indeterminate test result in different ways. They also presented several different theories of causation, yet failed to mention two potential causes of an indeterminate result, association with large animals and infection with other (non-HIV-1) HIV strains. Counselors' understanding of the meaning of an indeterminate HIV test result varied a great deal. Some counselors believed that an indeterminate result truly was ambiguous while others believed it was indicative of being either HIV-positive or HIV-negative. Counselors' primary advice to clients who received an indeterminate result was to retest immediately without a waiting period. Counselors reported that communicating indeterminate test results to clients was a challenging task because clients who received such a result were confused, angry, and/or mistrustful. Results highlight the need for further research to provide reliable estimates of the extensiveness of indeterminate HIV test results and to further assess the nature of counselor and client responses to indeterminate test results.

## INTRODUCTION

**M**ANY INDIVIDUALS get tested for HIV in order to reduce uncertainty.<sup>1</sup> What if getting tested turns out to increase uncertainty? That is precisely the situation presented when an indeterminate test result occurs. This may be in addition to the uncertainty related to the window period (some persons may have been exposed to HIV infection but have not had time to develop detectable antibody).

Approximately one of every three adults in the United States has been tested for HIV.<sup>2,3</sup> Approximately 24.6 million HIV tests are conducted annually in the United States.<sup>4</sup> In 2003 the Centers for Disease Control and Prevention (CDC) initiated a new strategy to advance HIV prevention by facilitating early HIV testing. The new CDC prevention strategy is designed to increase the number of at-risk persons who are tested by making testing a standard part of medical care. The aim of the CDC policy is,

"... to ensure that all health care providers include HIV testing, when indicated, as part of routine medical care on the same voluntary basis as other diagnostic and screening tests."<sup>5</sup> The CDC policy also funds various projects to provide more HIV testing in nonmedical settings, such as correctional facilities. This new prevention strategy is likely to increase the number of HIV tests performed each year in the United States significantly.

After getting tested for HIV, there are three possible test results: HIV negative (no HIV antibodies were detected), HIV positive (HIV antibodies were detected by the enzyme-linked immunosorbent assay (ELISA) test and confirmed by the Western blot test), or indeterminate (HIV antibodies were detected by the ELISA but were not definitively confirmed by the Western blot). As more people are tested for HIV in the United States, it is likely that the number of indeterminate test results will increase.

Rich et al.,<sup>6</sup> citing studies published in 1988, 1994, and 1995, state, "Rates of seroconversion for individuals who receive indeterminate Western blot test results are <1% for blood donors and other low-risk individuals." The rate of HIV seroconversion after an indeterminate result may be greater in high-risk populations. Rich et al.<sup>6</sup> studied Rhode Island prison inmates who received mandatory HIV testing and found that 74% ( $n = 23$ ) of prisoners who had an indeterminate HIV Western blot result seroconverted. They describe this finding as, "the highest rate of seroconversion ever reported for persons with indeterminate WB test results." However, it is not known how many people who test for HIV receive an indeterminate result in the first place. A MEDLINE search was undertaken, but we were unable to find overall population estimates of the number/percent of indeterminate Western blot results given in the United States.

There are three reasons why a person's HIV test may come back indeterminate. One is that the person was very recently infected with HIV and is in the process of developing antibodies.<sup>7</sup> Another possibility is that the person may be infected by particular HIV-1 or HIV-2 variants that are not detected by some HIV antibody screening assays.<sup>8</sup> Third, the indeterminate test

result may be a false-positive and not be associated at all with HIV infection.<sup>9</sup> Possible reasons for a false-positive HIV test result include: (1) prior blood transfusions, (2) prior or current infection with syphilis, (3) prior or current infection with malaria parasites,<sup>10,11</sup> (4) autoimmune disease such as diabetes, (5) association with large animals, for example through veterinary work,<sup>12-14</sup> and (6) second or subsequent pregnancies in women.<sup>12</sup> Indeterminate results from multiple blood transfusions, syphilis, autoimmune diseases, and multiparity may be caused by autoantibodies, particularly anti-major histocompatibility complex (MHC) antibodies that may cross-react with glycoproteins or HIV proteins.

The CDC recommends that persons who receive an indeterminate HIV test result get tested again 1 month later (most persons infected with HIV-1 will develop antibodies within 1 month).<sup>15</sup> Some persons who receive an indeterminate result opt for more specialized laboratory tests that measure viral load. Although they have been used by blood banks and for some public testing purposes in North Carolina, nucleic acid amplification tests are not approved for diagnosing HIV and thus are not typically recommended for persons receiving an indeterminate test result.<sup>16</sup> The CDC recommends that unless a recent HIV exposure occurred, persons who continue to test indeterminate after 1 month should be counseled as though they were HIV-negative.<sup>15</sup>

Rapid HIV tests, those in which clients can receive results in less than 60 minutes, are becoming more readily available across the United States. Wurcel et al.<sup>17</sup> found a client acceptance rate of 60% for the rapid HIV test for inpatients and outpatients at a Boston hospital, a rate significantly higher than that found for the standard HIV test. One study found that public concern regarding the accuracy of the rapid HIV test may pose a barrier to acceptance of this form of testing.<sup>18</sup> On one hand, concern with the accuracy of the rapid HIV test is inconsistent with the scientific literature that shows that rapid tests are just as accurate as standard tests.<sup>19</sup> On the other hand, recent press reports have revealed an abnormally high number of false-positives with the rapid oral test in San Francisco, California, and New York

City.<sup>20</sup> This has led the CDC to recommend that someone who tests positive with a rapid oral test be given a rapid finger-prick test (a blood test) and then followed up with the standard confirmatory Western blot. The high number of false positives with the rapid oral test may increase public concern regarding the accuracy of all rapid tests and complicate the problem of educating consumers regarding their sensitivity and specificity. It will be necessary to inform the public that these problems occurred only with the rapid oral test and that no accuracy problems have been found so far with the rapid finger-prick blood test.

Rapid HIV tests use only the first part of the two-part traditional testing process, the ELISA. A positive result must then be confirmed with either a Western blot or an immunofluorescent assay (IFA). This confirmation process can take some time—clients do not receive the final result right away after receiving the preliminary positive. Ultimately, clients who test positive for antibodies during a rapid test may be negative, positive, or indeterminate (in the latter case when the Western blot or IFA does not definitely confirm the ELISA findings). In regard to indeterminate test results using the OraQuick rapid test (Abbott Diagnostics, Abbott Park, IL), "Although no false-positive results were found in the clinical trial, statistical analysis of the data show that a very small number of people who are not infected with HIV-1 will have reactive test results (that is, tests that show HIV infection)."<sup>21</sup>

Under traditional, nonrapid HIV testing conditions, clients are notified of their result after both parts of the testing process are conducted. Under rapid testing conditions, clients are notified of the result of the first part of the testing process immediately and are counseled that a positive result is "preliminary" until follow-up testing is performed. For clients whose ultimate result is in fact indeterminate, the CDC recommends that persons who had given blood specimens for rapid testing return for another test in 1 month. For clients who had given oral fluid specimens the CDC recommends that the Western blot or IFA be repeated using a blood specimen because results from blood specimens are slightly more accurate.<sup>22</sup> We were unable to locate any previous research on how

HIV test counselors communicate with their clients regarding HIV indeterminate test results. This is unfortunate because such communication may be an integral part of how clients react to the news and what steps they take to resolve their ambiguous result. An appropriate follow-up to an indeterminate test result is important in order to help clients who are HIV-positive link to appropriate medical care and help ease the minds of those who are false-positives.

The purpose of this study was to examine HIV test counselors' beliefs and practices regarding communicating indeterminate HIV test results to clients.

## MATERIALS AND METHODS

An ethnographic observation-based methodological approach was used because we were interested in observing the HIV testing process in its natural context. This approach is particularly useful in developing theory about settings and phenomena about which little is known. By participating in the daily lives of those under study field researchers watch what happens, listen to what is said, and ask questions. The aim is to understand and document the phenomena from the "insider's point of view."<sup>23</sup>

### *Testing sites*

This study was part of a larger project involving six intensive observational studies of HIV testing sites in Los Angeles County, California. This convenience sample consisted of three traditional medical sites and three alternative sites. No sites were using rapid testing technologies that permit results to be obtained in less than an hour.

Three alternative testing sites were studied from August 2002 through June 2003: a free clinic, a thrift shop, and a mobile testing van. The free clinic advertises itself as providing "free and nonjudgmental health care for those who cannot pay" and serves a racially/ethnically diverse group of low-income persons. The thrift shop is run by a large private-not-for-profit HIV/AIDS community-based organization that caters to young Caucasian and Latino

men who have sex with men. The mobile testing van, also operated by the HIV/AIDS organization, visits public and commercial venues and targets high-risk populations from all racial/ethnic groups.

Additional information about the sites studied, including the average number of clients tested monthly for HIV, the number of staff, and the average percent monthly of clients tested anonymously can be found in Grusky et al.<sup>24</sup>

#### *Data collection*

Three trained ethnographers (one for each site) collected the data. The number of days/nights of observation ranged from 25 to 39 over 3 to 8 months (Table 1). The ethnographers took extensive field notes by hand each day/night they were at the HIV testing sites. The number of hours the ethnographers spent at the sites varied, but ranged from at least 1 to 8 hours per visit with more hours during the initial time of data collection and fewer hours toward the end. Field notes included descriptions of the HIV testing environments, observations of staff members and clients, and descriptions of informal conversations with staff members and clients. Field notes were typed into electronic files. In all, hundreds of pages of field notes were recorded.

Additionally, semistructured interviews were conducted with four to seven HIV counselors from each site. Counselor interviews were conducted face-to-face at a convenient private spot such as an unoccupied examination room or a coffee shop. The interviews lasted between 30 to 60 minutes. All interviews were audiotaped and transcribed. Counselors were asked about their understanding of the

meaning of an indeterminate HIV test result and the procedures they used when giving clients an indeterminate HIV result. They also were asked to describe specific illustrative instances.

Participants gave written informed consent for being observed and interviewed in accordance with Institutional Review Board requirements. Potential participants were offered the choice of either having the research staff person read aloud the consent form while the participant read along with a printed copy or reading the consent form themselves. They were then asked questions to ensure their comprehension of the study goals and if they had any questions before making a decision about participation.

#### *Data analysis*

Transcripts and field notes were loaded into the Ethnograph (Qualis Research Associates, Colorado Springs, CO), a software program for computer-based text search and retrieval. Multiple readings of the data were performed to identify major themes. A line-by-line review of the transcripts and fieldnotes was performed and first-level codes (descriptors of important components of the interviews) were noted in the margins. All codes were then tagged to associated text segments in Ethnograph. Data corresponding to each of the first-level codes were printed and reviewed, and subcodes were established to divide the first-level codes into smaller categories. The results correspond to the emergent categories and quotations are drawn from the transcripts and field notes. Respondent validation was obtained by sharing the emerging categories and hypotheses with key informants of the stakeholding groups from which data was originally collected in the interest of assessing and establishing credibility.<sup>25,26</sup>

## RESULTS

Three themes were found regarding counselors' beliefs about indeterminate HIV test results: definitions, causes, and the true meaning of an indeterminate test result. Three themes

TABLE 1. DESCRIPTIVE INFORMATION ON THREE COMMUNITY TESTING SITES

	<i>Free clinic</i>	<i>Thrift store</i>	<i>Mobile testing unit</i>
Number of staff interviewed	7	5	4
Days/night of observation	39	25	34
Period of observation (in months)	7	3	8

also were found regarding counselors' interactions with clients who receive an indeterminate test result: the language used to explain the result; the advice given to the client; and clients' reactions to indeterminate test results.

#### *Definitions of an indeterminate HIV test result*

Counselors' definitions of an indeterminate result focused on two steps in the testing process with ELISA being the first step and Western blot the second. Counselors agreed that a positive result on the ELISA test was the first step. However, counselors differed on how many bands (each band refers to a specific antigen) on the Western blot result had to be visible for a result to be deemed indeterminate. Some counselors believed that a reaction on just one band constituted an indeterminate result. Others believed that a result is defined as indeterminate if from three to five bands of the Western blot are visible. A counselor from the thrift shop claimed that, "When they have more than five, more than three, especially DP120 . . . DP24, those are the ones that indicate" that a person would be considered to have an indeterminate result.

In addition to counselors, manufacturers also appear to be conflicted about how many and what type of bands constitute a true-positive Western blot. There are a number of approved Western blot kits available in the United States and in Europe and their definitions of true-positive Western blot's are not always the same, even though more than one band is always required.

#### *Theories of causation*

Because medical training was not required for counselors and their experience varied considerably, it is not surprising that they varied in their understanding of the technical reasons for an indeterminate test result. Counselors gave a number of different reasons why a client may receive an indeterminate test result. One frequently cited theory was that the person was newly infected with HIV and his/her body had not yet begun to produce antibodies. A counselor from the mobile van said, "You're on the road, baby, you're there. You got a rash anywhere? Feel like you got the flu or something?"

Similarly, a counselor from the thrift store said an indeterminate result "indicates . . . conversion for HIV." On the other hand, perhaps because it is rare, no counselor mentioned the possibility that an indeterminate result may be because the person is infected with a different strain of HIV such as HIV-2. Similarly, no counselor mentioned association with large animals as a potential cause of an indeterminate HIV test result.

Counselors presented a number of theories that were not related to HIV, including infection with another disease, smoking, pregnancy, lab error, and specimen error:

An indeterminate . . . something is causing it . . . if a person is infected with TB, their body tends to produce antibodies too." (mobile van counselor)  
Being sick can affect it. (thrift store counselor)

All I know is there could be other things happening within that person's immune system than can make it indeterminate. (free clinic provider)

[Smoking too quickly before] can affect it. (thrift store counselor)

Could be a pregnant mother. (free clinic provider)

There could've been an error in the specimen. There could be an error with the lab. (mobile van counselor)

#### *The true meaning of an indeterminate result*

Many counselors believed that an indeterminate result was an ambiguous result because it indicated neither an HIV-positive nor HIV-negative result. A counselor from the free clinic stated, "It could mean that you're negative and it could mean positive."

In contrast, other counselors asserted that an indeterminate result suggested being HIV positive. Other counselors suggested it meant being HIV negative. A counselor from the thrift store said, "In my experience all those who are minimally reactive have turned out later to be positive . . . This is probably an indication of a positive." Similarly, a counselor from the mobile van said, "If they show up reactive on one band of the Western blot, they're positive." On the other hand, a counselor from the free clinic asserted that an indeterminate result typically indicated a negative, "If you want to know the average, the majority of the time the person ends up being negative."

*The language of an indeterminate test result*

Counselors used a variety of different terms when discussing an indeterminate HIV test result with clients including "indetermined," "inconclusive," and "minimally reactive." One term a counselor insisted that she specifically avoided was "seroconversion." She said, "I don't use the word 'seroconversion' to them. I just say . . . 'You need further testing because the test isn't showing what we need to be 100% sure.'"

Some counselors opted to explain the specifics of how one part of the client's test had come back positive and another had not when communicating with the client. A counselor at the free clinic stated, "I tell them . . . there's something about it that triggered one part of the testing process to positive and another to negative." Other counselors did not go into such specifics, focusing instead on the unknown nature of the result. A counselor from the mobile van said, "Indeterminate means the specimen didn't work . . . they just weren't able to tell whether it was negative or positive." Similarly, a counselor from the thrift shop said: "The test was not clear." A frequent part of the discussion that counselors had with clients was to offer an apology that the client's test had returned indeterminate. A counselor from the mobile van said, "We have to retest you, we're sorry."

*Advice to client: "Best to retest"*

Not surprisingly, the advice that counselors gave most often to clients who tested indeterminate for HIV was to retest. Sometimes counselors stated that they would test the client again right away. None of the counselors discussed giving clients a specific amount of time to wait before getting another HIV test. Instead they simply advised clients that it was, in the words of a counselor from the free clinic, "always best to retest."

In addition to retesting, some counselors were aware of other options such as a more sophisticated laboratory test:

E. explained to me that you could get another test done to find out, it's called the PCR, and it rather than testing for the antibodies it actually tests for the viral load, how that this is an expensive test and

. . . the cheapest place to get it done right now is X [a clinic] for eighty dollars, and that the good part is that the viral loads will show up in terms of about seventeen days as opposed to the three month waiting period for the antibodies.

Hence, some counselors were aware of less standard and more specialized methods of detecting HIV even though these methods are not routinely used for diagnostic purposes.

Some counselors advised clients who received an indeterminate test result to seek medical care/advice. A counselor from the free clinic said, "Basically what I tell them is to go see a doctor . . . there's something going on in the body . . . I highly recommend seeing a general doctor, maybe getting a physical or something." Such advice is particularly appropriate for persons whose indeterminate test result may be related to medical conditions other than HIV of which clients may or may not be aware.

*Clients' reactions*

Counselors reported that giving clients an indeterminate test result is very difficult and, in some cases, even harder to give than positive results. The problem is uncertainty. Clients come in expecting to learn definitively whether or not they are infected with HIV but with an indeterminate result they do not receive the expected definitive answer. A counselor from the thrift store said, "That [an indeterminate] is the hardest . . . because you can't give them a straight answer." Some clients may become confused by the news. A counselor at the free clinic said:

The client is really confused. They don't understand. They want you to explain. You explain. Then you explain again, explain again. They still don't understand. You have to explain it a couple of times and it usually gets to the point where they just want to retest again. That's usually what they do.

In addition to confusion, some clients react with anger. A counselor from the thrift store said:

They do get angry because . . . they think it's either the OraSure [HIV test] that this is not working or they think it's us. That . . . we made some sort of mistake that made the result come back that way. And that's where the anger comes from. Counselors

sympathized with clients' feelings of anger. They affirmed that they could easily understand how anxiety-arousing it is for someone to get an indeterminate result.

Sometimes clients did not trust the result of the oral HIV test; that is, they believed that the oral test was not accurate and that this was the cause of the indeterminate result. Clients who felt this way sometimes told counselors that they wanted to get retested again using a blood sample (as opposed to oral fluids).

A less frequent client reaction was empathic understanding. One counselor from the mobile van stated that clients to whom he had given indeterminate test results usually realized that "mistakes happen . . . It's still humans touching specimens and mistakes still happen." This counselor believed that although clients naturally would prefer to receive a definitive result, occasionally some clients take an indeterminate result quite calmly in the vein of "life is not always easy or fair" and move on to the next step.

## DISCUSSION

To the best of our knowledge, this is the first study to examine HIV test counselors' beliefs and practices regarding communicating indeterminate HIV test results to clients. We found that counselors generally had a fairly good albeit incomplete understanding of the definition/meaning of an indeterminate test result. They were aware that an indeterminate result means that the two basic parts of the testing process did not completely coincide with one other. Laboratory technicians are called on to interpret the result of a Western blot HIV test and they make the final call regarding indeterminate results based on their interpretation of the visibility of bands corresponding to each HIV antibody.<sup>12</sup> Unfortunately, follow-up data that would enable assessment of how many indeterminate Western blots were true-positives were unavailable.

Counselors were aware of some, although not all the reasons for an indeterminate test result. Counselors discussed early HIV infection, other diseases, pregnancy, laboratory error, and specimen error. However, they omitted as-

sociation with large animals and infection with other (non-HIV-1) strains of HIV. HIV test counselors may benefit from education targeted at better understanding of the numerous potential causes of indeterminate test results. Such education would help counselors provide clients with a more complete explanation for such a result.

The most common advice counselors gave clients who received an indeterminate HIV test result was to retest. The CDC recommends that persons who test indeterminate wait one month to be retested primarily because this may allow the bodies of newly infected individuals sufficient time to produce antibodies.<sup>15</sup> Contrary to the CDC recommendation, no counselor suggested a waiting period before the client retested. This may be because other possible reasons for an indeterminate result such as laboratory error or specimen error do not require a waiting period. Retesting again immediately may help fill the counselors' psychological need to do something right away for the client. The counselors often mentioned how difficult it was to not give the client straight answers.

One of the questions that might be raised by this study is whether or not interventions are needed to assist counselors who give and clients who receive an indeterminate test result. We believe that two kinds of studies should be undertaken next: research that provides reliable estimates of the extensiveness of indeterminate HIV test results and studies that further assess the nature of counselor and client responses to indeterminate test results.

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