Iatrogenic Harm Following "HIV" Testing

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ABSTRACT

A large proportion of asymptomatic human immunodeficiency virus (HIV) "positive" individuals—50% or more—are likely never to progress to illness if left untreated. That follows from official estimates of numbers of undiagnosed "HIV positives," numbers of known HIV/AIDS cases, numbers of AIDS deaths over the years, and from the high frequency of false positive tests that result from screening low-risk populations.

Nonetheless, antiretroviral treatment (ART) is, increasingly, being initiated purely on the basis of laboratory tests for HIV and CD4 cell counts, in the absence of symptoms. Perhaps half or more of HIV-positive patients are needlessly taking drugs with highly debilitating side effects. At highest risk of iatrogenic harm are pregnant women, Africans, and persons of recent African ancestry.

The rationale for population-wide screening for human immunodeficiency virus (HIV) is timely initiation of treatment to prevent progression to symptomatic immune deficiency and early death, and also to prevent transmission, especially vertical transmission from mother to infant. Optimal decisions depend on characteristics of the test, the illness, and the treatment.

HIV Testing

"Positive" tests for "HIV" do not necessarily signify infection by human immunodeficiency virus (HIV), as summarized previously.[1] A substantial number of people hold that this is because HIV does not even exist—or that it has never been isolated and proven to exist—but the argument here is independent of whether or not those claims are true: Even if HIV exists, and even if HIV tests diagnose its presence with high *overall* specificity, it remains a statistical fact—true for all such diagnostic tests[2]—that low-risk populations are bound to have a high proportion of false positives.

Even if some people have been properly designated "HIV positive," cofactors may be required before HIV can damage the immune system. Lemaître suggested a mycoplasma as a necessary co-factor[3] while Gallo called HTLV-I and -II "*the only known specific co-factors* for AIDS" (emphasis in the original).[4] Healthy immune systems can ward off HIV after exposure so that a positive antibody test may signify immunity rather than infection, according to Luc Montagnier,[5] who received the 2009 Nobel Prize for discovering HIV. Individuals with such healthy immune systems, together with those diagnosed on the basis of false-positive test results, presumably constitute the cohorts of "long-term nonprogressors" or "elite controllers" who have remained healthy for upwards of two decades while HIV positive.

However, the common practice is for clinical laboratories to designate test results as "positive," "indeterminate," or "negative." Physicians interpret "positive" as referring to inevitably fatal HIV infection, and patients are treated accordingly. An HIV-positive test, together with a low count of CD4 cells, is usually regarded as reason to begin antiretroviral treatment (ART);[6] CD4 $<200/mm^3$ is a common criterion, but some recommendations have the cutoff at 350 or even higher.

Because of the toxicity of the drugs, which patients may be asked to take for the rest of their lives, it is important to discover how many people designated HIV positive under present criteria would not progress to HIV-caused illness without treatment.

To estimate the proportion of people receiving ART who should not, one must assess (1) the rate of false-positive diagnoses, and (2) the proportion of nonprogressors among actually HIV-positive individuals.

In all low-risk populations, even highly specific tests deliver many false positives, for purely statistical reasons. Specifically for HIV, if the tests have a reported sensitivity and specificity each at 99.5%, *five out of six "positive" HIV-test results would be false positives in a population where the actual prevalence of HIV is 0.1%,*[7, p 149] In the United States as a whole, the HIV prevalence is approximately 0.5%. This means that with 99.5% specificity, 50% of all positive tests would be false positives. But outside the high-risk groups of chiefly tuberculosis patients, drug abusers, and gay men, the prevalence is ≤0.1%,[8, Fig. 22] and the specificity of the tests is often stated as 99% rather than 99.5%. Therefore, positive tests outside the high-risk groups in the United States are likely to be overwhelmingly false positives. The same conclusion follows for almost every country outside southern Africa and the Caribbean.

Unfortunately, and with the consequences described below, the very high probability that a positive HIV test is a false positive in a person who is not in high-risk group is not generally known. It is not part of the public conventional wisdom, and indeed, official statements seem as if designed to prevent this essential information from becoming widely recognized.

Materials intended for practicing physicians as well as for the general public offer advice about HIV and information about tests without mentioning the numerous and common reasons for false-positive HIV test results, and without appropriate emphasis that people in low-risk groups are highly prone to misleadingly positive HIV test results.

For example, AIDSinfo, "a service of the U.S. Department of Health and Human Services," has a fact sheet about "HIV Testing and Pregnancy,"[9] which nowhere mentions that pregnancy itself is a potential reason for testing HIV positive, at the same time that it states that "the U.S. Public Health Service recommends that all pregnant women be tested." Benefits of being tested are said to be that "[b]y knowing your HIV status, you and your doctor can decide on the best treatment for you and your baby and can take steps to

prevent *mother-to-child transmission* of HIV" (emphasis in original, which states that it was reviewed in May 2009).

The Centers for Disease Control and Prevention makes no mention of false positives in its testing recommendations for adults, adolescents, and pregnant women.[10]

The San Francisco AIDS Foundation, in existence since 1982, receives funds from federal, state, and city governments, and is evidently an authoritative resource. Its document, "AIDS 101: HIV Testing,"[11] almost makes it seem that *not* being infected is rather unusual (emphasis in original):

> **Interpretation of Test Results**
>
> A **positive (reactive)** result means:
> - You are HIV-positive (carrying the virus that causes AIDS).
> - You can infect others who come into contact with your blood, semen or vaginal fluid. You should take necessary precautions to avoid transmitting HIV to others.
>
> A **positive** result does *NOT* mean:
> - You have AIDS.
> - You will necessarily get AIDS.
> - You are immune to AIDS, even though you have antibodies.
>
> A **negative (non-reactive)** result means:
> - No HIV antibodies were found in your blood at this time.
>
> A **negative** result does *NOT* mean:
> - You are not infected with HIV (you may still be in the "window period").
> - You are immune to HIV.
> - You have a "resistance" to infection.
> - You will never get HIV.
>
> An **indeterminate** result (which is rare) means:
> - The Western Blot (WB) result is unclear. The entire HIV test must be repeated with a new blood sample, usually several weeks after the first blood test.
> - Indeterminate results usually occur if the test is performed just as the person begins to seroconvert.[11]

Although the possibility of a false positive is acknowledged, it is in a way that makes it seem highly unlikely to be of concern (emphasis in original):

> **Accuracy of Antibody Tests**
>
> Antibody tests are extremely accurate, whether receiving a rapid test or a more traditional ELISA. Rapid tests, for example, have an accuracy rate exceeding 99%. However, positive results from a rapid or ELISA test must be confirmed by another test to ensure that a person is HIV-positive.
>
> The accuracy of a medical test is a combination of two factors: *sensitivity and specificity*. The ELISA is extremely *sensitive* (about 99.5%), which means it will detect very small quantities of HIV antibody. This high sensitivity reduces the odds of reporting a "false negative" when HIV antibodies are present. Assuming you are being tested beyond the "window period" and have not engaged in activities that put you at risk for HIV, *if the ELISA is "negative," there is virtually no chance you have HIV*.
>
> The high sensitivity of the test creates a slightly lower *specificity*. This means the result could (infrequently) be "false positive." To compensate for this, confirmatory tests are *automatically* performed after a positive ELISA. The WB and IFA are highly *specific* for HIV antibodies, so they rule out false positive ELISAs nearly every time.
>
> **The CDC states that the *combined accuracy* of the ELISA plus either the WB or IFA is greater than 99%.**
>
> The CDC recommends re-testing any positive (reactive) ELISA twice; if either retest is positive (reactive), then a confirmatory test is performed. Only when the confirmatory test is also reactive is the result reported as HIV positive. Again, reputable test sites automatically follow this procedure, so results reported to you as positive can be relied upon completely. It is also important to note that if you test positive through the use of a rapid HIV test (with results provided in 20 minutes or less), your result is still *preliminary*. A confirmatory test must be performed to verify whether you are infected with HIV and these results will take several days.[11]

These statements from the San Francisco AIDS Foundation are in direct contradiction to the authoritative technical literature, which points out that no combination of tests alone suffices to prove infection, and that so-called "confirmatory" tests should rather be called "supplemental" because they merely provide additional information, not confirmation of infection.[7] Moreover, the calculation of "accuracy" may be quite misleading because of differences between the populations in which it is measured and those in which it is applied, for example, in prevalence of disease.[2]

AIDS InfoNet, established in 1998, is another putatively authoritative resource for the medical profession and the general public, being partly funded by the National Library of Medicine and maintained by the AIDS Education and Training Center at the University of New Mexico Health Sciences Center. It asserts that "HIV testing tells you if you are infected with the Human Immunodeficiency Virus (HIV) which causes AIDS,"[12] another statement that is in direct contradiction to the facts that positive tests do not necessarily indicate infection and that the tests have not been approved for the purpose of detecting infection. AIDS InfoNet does acknowledge that "one" of the rapid tests has had a higher rate of false positives, and that some "special cases" can give false positives, for example, babies who still carry their mother's HIV antibodies; but it goes on to assert that other tests, such as viral load, can be used instead, as though these other tests could diagnose infection.

Commendably, AIDS InfoNet acknowledges also that "[p]regnant women may have false or unclear test results due to changes in their immune system," but this falls short of acknowledging that pregnancy itself is the *likely* cause of a positive HIV test in someone who has no known AIDS risks. Furthermore, all these caveats are likely to be overlooked given the statement that "Antibody test results for HIV are accurate more than 99.5% of the time," which misuses the term "accurate," and lacks the crucial explanation that in low-risk groups (≤0.1% HIV prevalence) five out of six positives are false positives. It also fails to point out that antibody positive does not necessarily mean infection.

Altogether, then, the clear impression is given by seemingly authoritative sources, in information intended for medical professionals as well as for general consumption, that HIV testing is highly accurate and can be relied upon to detect infection. This is not in keeping with the technical literature, which makes plain that testing can be no more than an adjunct to clinical judgment in inferring whether a person might actually be infected with HIV.[7]

Dissemination of these unqualified and thereby misleading assertions that HIV testing is 99.5% accurate misinforms practicing physicians and thereby represents a clear danger to the psychological and physical health of the general public, particularly of low-risk individuals.

Doctors have to deal with so many different illnesses that they cannot keep current with the specialist technical literature on every ailment, and they are likely to rely on official advice in "fact sheets" from sources such as the National Institutes of Health, the Food and Drug Administration, and the World Health Organization. Few doctors, if any, would think that they need to read a highly technical monograph like *AIDS and Other Manifestations of HIV Infection* to check on official sources. Journalists and members of the public who are adept at doing internet searches are also being misled, even though this book is not the only source describing the unreliability of HIV tests. For example, Gigerenzer et al.[13] pointed out a decade ago that in "heterosexual men with low-risk behaviour," a positive HIV test has a 50% likelihood of being a false positive. It is precisely people in low-risk groups who are also least likely to have read anything that differs from the official conventional wisdom about HIV/AIDS, and thus unlikely to know of the likelihood that their "positive HIV test" is a false positive.

One person affected by a false positive is Karri Stokely.[14] Two examples that came to my attention through personal communications are a low-risk woman who tested positive after an operation for uterine cancer, and a healthy married heterosexual man who was refused life insurance as a result of testing HIV positive shortly after he received a tetanus immunization.

Women who are currently pregnant or who have had multiple pregnancies are perhaps at the highest risk, because HIV testing in pregnancy is so highly touted by official sources,[9] even as pregnancy itself is a reason for false positives. When a pregnant woman is told that she is HIV positive without the caution that this is at least 80% likely to be wrong if she knows herself to be at low risk, she naturally blames her partner for deceiving her. Ruined relationships and psychological and perhaps physical harm to the woman herself are possible consequences.[8, p 247]

Long-Term Nonprogressors

The phenomenon of long-term nonprogression seems not to have been recognized officially before the mid-1990s. Personal testimonies from many healthy HIV-positive people have been published by Maggiore.[15] Bruce Walker recalls asking an audience of several hundred doctors in the late 1990s whether they had encountered the phenomenon: at least half of those present raised their hand. Walker estimated recently that perhaps only 1 in 200–300, or perhaps 5,000 of the million HIV-positive Americans, are long-term nonprogressors,[16] which seems low if more than half the queried doctors had encountered such an instance.

Because of the very fact that long-term nonprogressors are healthy, there is no way to determine definitively what proportion of all potential HIV positives they might constitute, since not every healthy person has been tested. However, one piece of empirical evidence shows that Walker's estimate is indeed far too low: Members of the United States armed services are typically HIV tested biennially, and 8.4% of the HIV positives are nonprogressors who have been observed for up to 20 years.[17]

Another approach to the question also suggests a much higher proportion. About 1 million Americans have been HIV positive at least since the mid-1980s.[8, pp 1-2,108] Although it cannot be known how many were positive before testing began, it was surely some substantial number; it could not have become 1 million overnight around 1985. According to the CDC, about one third[18] or one quarter[19] of HIV-positive people do not know that they are HIV positive. So, at least since the mid-1980s, there have been 250,000–333,000 HIV-positive Americans who did not know they were positive, and who therefore were also not known to the authorities to be positive, and who were consequently not receiving ART. How many of those have been long-term nonprogressors?

A recent estimate gives an annual incidence of about 55,000 new HIV-positive cases in the U.S.,[20] generated by transmission from about 1 million HIV-positive individuals. The 1 million HIV positives in 1985 and later will then have been augmented annually by a similar amount, for a total of no fewer than 1.1 million additional positives by 2007 (55,000 annually for two decades).

On the other hand, AIDS deaths have been recorded as 583,000 through 2007.[21] So the 1 million HIV-positive individuals in 1985 should have grown by 2007 to $\geq$ 1.52 million (2.1 million minus 583,000). Instead, the CDC reports 264,000 "living with HIV infection" and 469,000 "living with AIDS" at the end of 2007, [21, Table 14] a total of 733,000. The difference between the expected $\geq$ 1.52 million and the actual 733,000, namely $\geq$ 787,000, arguably represents the number of people who, at one time or another would have been HIV positive, but have never been tested, and have not become ill from anything that would occasion an HIV test: in other words, long-term nonprogressors.

Therefore today, there are plausibly on the order of $\geq$ 787,000 nonprogressors, rather more than the 733,000 currently believed to be living with HIV/AIDS. Thus more than half of all those who would test positive currently—if there were universal testing in the United States—seem to be at no risk for progressing to illness as a result of being HIV positive. This would be in keeping with the early report, some months after the first HIV test (by Abbott Laboratories) had been approved for blood screening, that 44% of samples from blood donors that were positive for HIV antibody contained no virus detectable by culture.[22]

Antiretroviral Treatment (ART) Is Not Benign

Treatment Guidelines[6] acknowledge that adverse non-AIDS events are more common than AIDS events among people on ART. These include cardiovascular diseases, liver-related events, renal disease, and certain non-AIDS malignancies. In persons on ART with CD4 T-cell counts >200 cells/mm^3, the risk of these complications is greater than the risk for AIDS.[6, p 21]

The Dec 1, 2009, version of these Treatment Guidelines has more than 10 pages listing the serious and sometimes fatal adverse effects of the various components of ART: bleeding events, bone-marrow suppression, cardiovascular effects (including myocardial infarction and cerebrovascular accidents), central-nervous-system effects, gastrointestinal intolerance, hypersensitivity with hepatic failure, hepatotoxicity, hyperlipidemia, hypersensitivity reaction, diabetes mellitus, lactic acidosis, hepatic steatosis, severe mitochondrial toxicities, lipodystrophy, nephrolithiasis, nephrotoxicity, neuromuscular weakness syndrome, osteonecrosis, osteopenia, pancreatitis, peripheral neuropathy, Stevens-Johnson syndrome, and toxic epidermal necrosis.

Some personal testimonies, albeit anecdotal, can be quite telling, for instance Karri Stokely's account,[14] which is underscored by photographs showing how she lost weight and hair while on ART and then recovered rapidly after going off the treatment.[23] Another known case is that of Audrey Serrano, who was awarded $2.5 million in damages after being wrongly treated for HIV infection for years, during which time she suffered "depression, chronic fatigue, loss of weight and appetite, and inflammation of the intestine."[24]

According to some official reports, 40% of continuing prescriptions for antiretroviral drugs are never filled,[25] presumably because the side effects are so severe. That the protease inhibitors in typical "cocktails" used in modern highly active antiretroviral treatment (HAART) produce lipodystrophy and life-threatening organ damage has long been known: It was mentioned as early as 1997[26] and 1998,[27,28] just a few years after the introduction of protease inhibitors. Significant numbers of middle-aged people on HAART show such signs of premature aging as bone weakness and dementia.[29]

These observations do not exclude the possibility that ART might nevertheless prolong the lives of individuals who would actually have proceeded to AIDS without treatment, but they do mean that people with false-positive HIV tests, and actually HIV-positive individuals who are potential long-term non-progressors, should not be exposed to ART, since that could not benefit them but is very likely to harm them.

HIV Tests Are Racially Biased

None of the HIV tests are definitive because all later tests were approved if they reproduced positives and negatives in the same manner as the initial Abbott enzyme-linked immunosorbent assay (ELISA). The latter depends on measurement of color intensity with a particular cutoff value for what constitutes a positive.[7] To determine the proper cutoff requires a control group of people known beyond any doubt to be uninfected. No such group exists, of course, but repeat blood donors are used as the closest approximation. Weiss and Cowan remark that some of those people may well be infected, however, so not all HIV-positive tests among them are false positives, and disparate testing methodologies should be used to minimize the consequent uncertainty.[7, p 161] Still, there is no way to make the cutoff value completely objective and definitive.

Weiss and Cowan also note that in Africa, several potential sources of false positives are particularly prevalent that "may, in effect, systematically shift the standardization curve for African sera as compared to U.S. and European sera,"[7, p 159] for example "sticky sera" or hypergammaglobulinemia (see their Table 8.2, p 152). In other words, HIV tests should be calibrated differently for use in Africa than in Europe. However, no region- or race-specific test kits exist. What effect might it have that genetic, hereditary, racial, or regional differences are not taken into account in the calibration of HIV tests?

Since repeat blood donors constitute the control group of putatively uninfected individuals by which tests are calibrated, the rate of HIV positivity among repeat donors is an obvious way of looking for possible racial bias. Using the present versions of HIV tests, black American repeat donors test positive about 14 times more often than white American donors,[8, Table 8] and black South African repeat donors test positive 23 times more frequently than white South African donors.[30] Asian-American donors test positive much less often than white American donors.[31]

Under present circumstances, however, in absence of racially adjusted calibration of the tests, the undisputed fact that Africans and black Americans test HIV positive far more often than others is ascribed to a higher degree of irresponsible behavior, primarily promiscuous sexual activity, even in the face of actual studies that find no indications of such behavior.[8, pp77-78]

To interpret relative rates of testing HIV positive as reflecting high promiscuity among Africans and black Americans is not just unwarranted, but demonstrably harmful to social interactions and social policies, and places Africans and black Americans at particularly high risk of unnecessary exposure to toxic medications. Additionally, the fact that pregnancy itself is a possible cause of false-positive HIV test results goes a long way to explaining why American black women have come to be regarded as a high-risk group. The potential unwarranted destruction of loving relationships is likely to affect black Americans more than others, assisted as it is by the shibboleth of the "living on the down-low" phenomenon that alleges relatively common covert bisexual behavior by black men.[8, pp 246-247] The evidence is, however, that higher rates of testing HIV positive occur among black Americans because the tests are racially biased as a result of calibration with non-black repeat-donor "controls."

Informed Consent for Testing

In view of the uncertainties associated with HIV tests and the toxicity of ART, fully informed consent should be solicited before anyone is subjected to an HIV test.[7, p 148] "Informed" surely must include knowing that a positive test does not prove infection; that nevertheless "positive" is routinely presumed to mean infection; and that this may lead to the prescribing of highly toxic drugs that may be of no benefit, and whose side effects are so debilitating that a high proportion of those for whom they are prescribed fail to take them.

In many situations, such properly informed consent is not obtained. For example, HIV-positive pregnant women are urged or required to take antiretroviral drugs, and those are routinely administered to HIV-positive babies, even though "[o]nly a fraction of initially seropositive newborns are actually HIV-infected."[7, p 148]

Large numbers of people may have been suffering and may continue to suffer iatrogenic harm from unnecessary ART, most particularly black Americans, Africans, pregnant women, and gay

men. An additional danger for Africans is the recent recommendation, based purely on computer modeling, that every HIV-positive African, irrespective of CD4 counts or health condition, be treated immediately with antiretroviral drugs in order to curtail the spread of HIV,[32] a recommendation that has been extended to "high-risk" groups—black Americans and gay men—in the United States.[33,34]

Conclusion

Despite the claimed high sensitivity and specificity of HIV testing, widespread testing of low-risk populations carries a substantial risk of iatrogenic harm, even if the currently accepted theories on HIV and AIDS are correct. In addition to the stigma and the social and psychological injuries from the diagnosis of HIV, ART has significant, frequently intolerable toxicity. These harms are not offset by the prospect of *any* benefit in patients who have false-positive tests, or by commensurate benefits in a poorly understood but probably large group of nonprogressors. Disproportionate harm from aggressive testing and treatment will be experienced by pregnant women and persons of black African ancestry.

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Disclosure: I am the author of the cited book, *The Origin, Persistence and Failings of HIV/AIDS Theory*, which claims to show that HIV is not the cause of AIDS, that what HIV tests measure is not an infectious agent, and that the very existence of HIV has not been proven.

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