

April 23rd 2010

Dear Professor Huntoon,

My detailed comments are inserted below within the MS in bold type. I hesitate to recommend publication of this MS for the following reasons and those listed are not, by any means, all the reasons:

1. Ethical.

The author wrote “The likelihood of false positives has been known chiefly to people who doubt the official view about HIV and AIDS”. That is, the so called dissidents. The dissidents also know that my group are the first and still remain the only individuals who have published scientific evidence showing that:

(a) there is no evidence that HIV has been isolated/purified, neither from fresh tissue nor cultures containing tissues derived from even one patient.

(b) since HIV has not been isolated from anyone there is no gold standard for the antibody tests. That is, there is no proof that a positive test, even in one single individual, proves HIV infection.

It is obvious that the author of this MS is aware of our work. Yet he/she does not give credit where credit is due. Instead, in order to appear original, the author ends up contradicting himself/herself: On the one hand he/she asserts that “HIV has been detected by culture” in 50-80% of ““HIV positive” people”, while on the other hand “There is no gold standard for an HIV test”. This makes nonsense of his argument.

2. Scientific.

Given the title “Iatrogenic harm following “HIV” testing”, one would expect the author would thoroughly document:

(a) well renowned evidence of the side effects of antiretroviral therapies. Instead the author copies a list of side effects documented in the “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents”. This is information all manufacturers are expected to provide. Indeed, they are under a legal obligation to do so.

(b) once the toxicity of the drugs is described the author is open to several courses:

- (i) to complete his paper having merely documented these toxicities without further comment;
- (ii) accept there are the toxicities but argue for their use;
- (iii) argue against their use.

There can be two main arguments in support of the last claim.

Firstly, the benefit/harm ratio is 1 or less. No such evidence exists in this manuscript.

Secondly, the antibody tests do not prove HIV infection because there is no gold standard to prove their specificity. That is, the author provides evidence that HIV has not been isolated. Or that the specificity has been determined but is low and thus the diagnosis of HIV infection is unreliable. No such proof exists in this manuscript.

Instead he claims that doctors prescribe these drugs in ignorance, not being aware of how flawed the tests are because they obtain their information from websites instead of by reading highly-technical (and according to him/her highly reliable) books such as *AIDS and Other Manifestations of HIV Infection*. However, if doctors read this book they will find out that the ELISA, “the first type of test to be licensed in the U.S. to detect infection with HIV”, has a specificity of 99.9% (when the individuals from both low and high risk are included), and when “classic patterns are present [in the Western blot], positivity [infection] is a virtual certainty”. This is a description of a diagnostic test which is as good as any to be found in medical practice. So on what basis does the author question doctors who prescribe these drugs?

Publication of this manuscript as it stands will be of no benefit to the author and, more importantly, to the *Journal*. However, I am willing to provide continuing assistance. If the author can be persuaded to rewrite the manuscript and address the above points, that is, if he proves that:

- (i) the ratio of benefit/risk is at least less than 1;
- (ii) the specificity of the antibody tests has not been proven because HIV has not been isolated;
- (iii) HIV has been isolated but the specificity is low;

I will gladly reappraise the manuscript.

Kind regards,

Eleni Papadopoulos-Eleopoulos

PS. Please let us not repeat what happened with Dr Henry Bauer’s manuscript. I recommended publication but on the *proviso* of some modifications. Dr Bauer did modify the manuscript but not in the manner recommended. For example, I asked him either to discuss the molecular biology of HIV and provide original evidence that HIV has not been isolated or, since we have already done so, make reference to our published work. He did neither. Instead he reproduced a comment from an article by Weiss and Cowen which states: “In the absence of a gold standard, the true sensitivity and specificity for the detection of HIV antibodies remain somewhat imprecise”. However, he omitted to state: (a) that the above authors, like him, accept that HIV has been isolated, that is, there is a gold standard for the test; (b) according to Weiss and Cowen: **“Gold Standard (Reference Standard)”** – A definitive means of categorisation, widely

accepted by experts in the field, for absolutely defining the presence or absence of a condition (such as HIV infection)". **"Confirmatory Test** – A supplementary test that is maximally independent from any other tests that have been utilised. A well performing confirmatory test will be part of a "confirmatory algorithm," the results of which would serve as the basis for optimally **definitive test** result categorisation" (first two emphases in original, last emphasis mine). In fact Weiss and Cowen devote a whole subsection to HIV "ANTIBODY CONFIRMATION ASSAYS" (page 155).

Let me remind you that the title of Bauer's paper is "HIV tests are not HIV tests" and one of his subtitles reads "Isolation is not isolation; Purification is not purification". These controversial statements are based on Weiss and Cohen's paper! This means that the *Journal of American Physicians and Surgeons* has published a paper in which no matter how hard one tries, one will utterly fail to find any scientific proof of Henry Bauer's assertions.

The author of the present manuscript seems to follow Dr Bauer's footsteps. In science one cannot "have his cake and eat it too".

REVIEW BY ELENI PAPADOPULOS-ELEOPULOS

APRIL 23RD 2010

IATROGENIC HARM FOLLOWING “HIV” TESTING

By *****

ABSTRACT

False-positive HIV tests are very likely in low-risk populations. This is made plain in the technical literature, but it is not commonly known. Information for general consumption disseminated by authoritative sources emphasizes that the tests have $\geq 99\%$ “sensitivity” and “specificity,” a statement that is readily and widely but mistakenly interpreted as the tests being *>99% accurate in diagnosing infection*.

Nowhere in this manuscript can one find any evidence for the claim by “authoritative sources” “the tests have $\geq 99\%$ “sensitivity” and “specificity”“ is “mistakenly interpreted as the test being 99% accurate in diagnosing infection”.

More than half of all individuals testing HIV-positive may never become ill as a result of being HIV-positive, be it because of false positives or for some other reason.

This is nothing new. In the HIV/AIDS literature this has been emphasised for over 20 years.

However, antiretroviral treatment is based increasingly on no more than laboratory tests of HIV and CD4 cells rather than on the presence of clinical symptoms of actual illness.

Antiretrovirals are given to prevent the onset of the clinical syndrome. The only way one can claim antiretrovirals should not be given on the basis of a positive antibody test and decreased T4 cell count is to have proof that either (i) a positive test does not prove infection; (ii) there is no relationship between decrease in T4 cells and the clinical syndrome; (iii) both. No such evidence exists in this manuscript.

As a result, some unknown but probably large number of people are needlessly taking antiretroviral drugs whose side effects may be highly debilitating. Particularly at risk of such iatrogenic damage are pregnant women, Africans, and people of recent African ancestry.

INTRODUCTION

“Positive” “HIV” tests do not necessarily signify infection by HIV.¹ For example, HIV was detected by culture in only 50-60% of “HIV-positive” people. There is no gold standard for an HIV test.

The author is contradicting himself/herself. On the one hand he/she claims that no gold standard for the HIV antibody test exists and on the other that HIV has been detected by culture in 50-60%. The author does not say from where he obtained this figure or what, in his view, is meant by “culture”. However, by culture, HIV experts mean “isolation”, and if HIV has been isolated from even one person there is a gold standard for the antibody tests.

Dozens of other conditions than HIV infection can stimulate a positive “HIV” test, even vaccination against flu, and many illnesses like malaria or tuberculosis.² In some cases the “HIV”-positive result may be only temporary, as reported with anti-tetanus shot.^{3,4} Pregnancy can bring on a false-positive HIV test-result,² which explains why so many surveys find pregnant women having a higher rate of testing “HIV-positive.”^{5-7;8,Table 2,Figure 22} This non-specificity and lack of a gold-standard test underlie the disclaimers in HIV test-kits that the tests do not suffice to prove infection and are not approved for diagnosis of infection.⁹

No antibody test is 100% specific and in fact for most of tests there are maybe a dozen or so conditions which will cause a false positive result. Yet antibody tests are a very useful tool in clinical practice. There are HIV antibody tests that are approved to diagnose HIV infection. In the author’s ref. 13 one reads: “The EIA (ELISA) was the first type of test to be licensed in the USA to detect infection with HIV”. page 150.

It is not only that some people might have been designated “HIV-positive” as a result of false-positive tests, it is also that HIV appears to require co-factors before it can damage the immune system;¹⁰ 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,¹¹ who received the 2009 Nobel Prize for discovering HIV. Individuals with such healthy immune systems presumably constitute the “long-term non-progressors” or “elite controllers” who have remained for upwards of two decades healthy while HIV-positive.

The author is misinterpreting Montagnier’s claims in the documentary *House of Numbers*. Montagnier did say that a good immune system gets rid of HIV infection. But there is much more to the immune system than antibodies. Montagnier did not say that a positive antibody test signifies immunity. To the contrary, according to Montagnier a good immune system reverts a positive test to negative. As the authors of ref. 13 pointed out, which the author of the manuscript uses extensively to make his/her claims, the presence of antibodies does not signify immunity. “It is

important to remember that with many viruses, including HIV...the presence of antibodies does not indicate resolution of infection” page 148.

Now, the common practice is for clinical laboratories to designate test results as “positive,” “indeterminate,” or “negative,” and for physicians to interpret those as referring to inevitably fatal HIV infection and to treat patients accordingly: “HIV-positive” together with a low count of CD4 cells is usually regarded as reason to begin antiretroviral treatment (ART);¹² CD4 <200/mm³ is a common criterion, but some recommendations make the cut-off 350 or even higher.

Those treatments comprise highly toxic drugs that are expected to be taken for the patient’s lifetime. After about a decade’s experience with the modern form of these treatments, it is apparent that HIV-positive individuals on ART experience a greater number of life-threatening *non-AIDS* events than they do AIDS events:

In the era of combination antiretroviral therapy, several large observational studies have indicated that the risk of several non-AIDS-defining conditions, including cardiovascular diseases, liver-related events, renal disease, and certain non-AIDS malignancies [14-19] is greater than the risk for AIDS in persons with CD4 T-cell counts >200 cells/mm³; the risk for these events increases progressively as the CD4 T-cell count decreases from 350 to 200 cells/mm³.^{12,p.21}

The most recent version of these Treatment Guidelines (Dec 1, 2009) has more than 10 pages listing for the various components of ART their serious and sometimes fatal adverse effects: 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, toxic epidermal necrosis.

All drugs are toxic to greater or lesser degrees. If the author wants to argue against the use of ART he must present evidence which shows that the risks/benefits ratio with ARTs is at least 1. Is the author suggesting chemotherapy of cancer should be abandoned?

These overall observations do not exclude the possibility that ART might nevertheless prolong the life 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 only harm and not benefit them. Therefore it is important to discover how many people designated “HIV-positive” under present criteria would not proceed to HIV-caused illness without treatment.

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

HOW MANY FALSE POSITIVES?

In an individual judged to be at low risk, a “positive” “HIV” test may be false-positive more than 80% of the time. For example, if the tests have a reported sensitivity and specificity each at 99.5%, 5 out of 6 “positive” HIV-test results would be false positives in a population where the actual prevalence of HIV is 0.1%.^{13,p.149}

The subtitle “HOW MANY FALSE POSITIVES?”, implies that the author will present evidence regarding the specificity of the HIV antibody tests. Instead he accepts that it is 99.5%. On page 149 Weiss and Cowan are referring to the positive predictive value of the HIV antibody test. They show that positive predictive value of the HIV antibody tests in a low risk population is low. This is no different from antibody tests for most infections. Because of this physicians go to great lengths and take in consideration other factors and also perform supplementary tests before declaring a patient is infected.

According to Weiss and Cowan this is the case for the HIV antibody tests as well. “CDC has developed a series of guidelines for counselling, testing, and referral to assist clinicians in the proper interpretation and reporting of test results to patients (25-29).

Although health care professionals who order HIV tests have become increasingly familiar with these tests, it is important for the laboratory report to provide the clinician with considerable guidance concerning the implications and limitations of the test results. Further consultation with the laboratory (or blood bank) director, infectious disease specialist, or other expert may be particularly important in circumstances of an “unexpected” result. Such experts should be able to assist the clinician in employing standard principles of decision theory to apply the battery of tests appropriately and efficiently to a given situation. For example, blood donor screening assays have been developed to maximise sensitivity to meet the specialised needs of safety for the blood supply. This results in decreased specificity identifying the need for confirmatory testing of reactivity”.

Since the author accepts that the specificity of the HIV antibody test is 99.5% then the positive predictive value of the HIV antibody test in a low risk population is at least as good as that of the antibody test for any sexually transmitted agent. Yet nobody will argue such patients must not be treated with antibiotics.

This statistical fact is virtually unknown outside specialist circles, yet the underlying rationale is straightforward. Specificity of 99.5% means that out of 1000 actually negative people who are tested, 5 will falsely test “positive”. If the actual prevalence of HIV is 0.1%, then 1 in 1000 will be a true positive. Thus among every 1000 tests there are on average 5 false and 1 true positive: of 6 apparent positives, 5 are false.

This has an import whose significance can hardly be exaggerated: In the United States, prevalence of $\leq 0.1\%$ characterizes large cohorts of the population,^{8, Fig. 22} especially among white Americans.^{8, chap. 5} When a heterosexual Caucasian American is said to be “HIV-positive,” the chances are $>80\%$ that this does not signify infection with HIV. For the USA overall, the rate of HIV-positive is about 0.5% , so in a random sample of the population about half of all positive tests would be false positives.

(Sensitivity of 99.5% means that of every 1000 HIV-positive samples, 5 will test negative. Such false negatives are of concern in screening blood, but hardly of concern for individuals, because negative tests on high-risk individuals will almost certainly be repeated.)

So are positive tests in low-risk individuals. In addition in these individuals the results are “confirmed” with non-antibody tests i.e. PCR.

No test can be 100% specific and sensitive. In addition to the high probability of false positives in a low-risk population on purely statistical grounds there is the phenomenon of cross-reactions: A large number of physiological conditions other than HIV infection can bring about a positive “HIV” test-result. As already mentioned, these conditions include such common illnesses as tuberculosis and malaria and such common vaccinations as against flu or tetanus. Additional, not already mentioned potential causes of false positives include autoantibodies, cross-reactive proteins, hypergammaglobulinemia, multiple pregnancies and other retroviruses.^{13, Table 8.2} Human endogenous retroviruses are yet another possible source of cross-reaction on HIV tests.¹⁴

Overall, then, for an individual who is not in one of the AIDS-risk groups, the probability is very high indeed, certainly more than 80% , that a positive HIV-test is likely to be a false positive. But this is not generally known, it is not part of the public conventional wisdom, indeed official statements seem as if designed to prevent this essential information from becoming widely recognized.

There is nothing “in addition”. The statistical probability is the result of the “phenomenon of cross-reactions”.

PUBLIC ADVICE ABOUT HIV TESTS

The likelihood of false positives has been known chiefly to people who doubt the official view about HIV and AIDS.

Where do they get their information? Where is the proof that the HIV antibody tests do not prove HIV infection. The author of ref. 1 claims that the specificity of the HIV antibody test has not been proven because there is no gold standard. So does the author of this manuscript under review: “There is no gold standard for an HIV test”. However, the only gold standard for the HIV antibody test is HIV, is HIV isolation. Both authors claim that HIV has been isolated repeatedly. In other words they are contradicting themselves.

Materials intended for practicing physicians as well as for the general public offer advice about HIV and instructions about testing without mention of 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”¹⁵ which nowhere mentions that pregnancy itself is a potential reason for testing “HIV”-positive, at the same time as 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 “By 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 was reviewed in May 2009].

The Centers for Disease Control and Prevention makes no mention of “false positives” in its testing recommendations, “in health-care settings,” for adults, adolescents, and pregnant women.¹⁶

The San Francisco AIDS Foundation has been in existence since 1982 and receives funds from federal, state, and city governments; evidently an authoritative resource. Its document, “AIDS 101: HIV Testing,”¹⁷ almost makes it seem that *not* being infected is rather unusual:

“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.”

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

“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 retesting 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.”

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.¹³

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,”¹⁸ which again is in direct contradiction to the fact 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 “Pregnant 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 sorely lacks the crucial explanation that in low-risk groups ($\leq 0.1\%$ HIV prevalence) this corresponds to 5 out of 6 “positives” being false positives, and it 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 be actually infected with HIV.¹³

The 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, most particularly all low-risk individuals.

As the title of this section says, the information in the cited websites is for the general public, not for physicians. More importantly, he/she seems to confuse specificity (or tries to confuse others) with predictive value.

WHO IS MOST LIKELY TO BE DAMAGED BY FALSE-POSITIVE HIV TESTS?

Doctors have to deal with so many different illnesses that they cannot keep up-to-date with the specialist technical literature relating to every possible ailment, and they are likely to rely on official advice in “fact sheets” from and web-sites of such places as the National Institutes of Health, the Food and Drug Administration, the World Health Organization, etc., like those cited in the previous section. Few doctors, if any, would think that they should read a highly technical work like *AIDS and Other Manifestations of HIV Infection* lest the information broadcast by those authoritative resources might be grossly misleading, as it happens to be about the significance of positive HIV tests.

I am at a loss to understand what makes the author of this manuscript think that only he/she is capable, willing or even competent to obtain his/her information from reading higher technical works, but the physicians, that is the HIV/AIDS specialists who look after the HIV+/AIDS patients get their knowledge from websites. Such a statement does not help his/her credibility whatsoever.

Journalists, too, as well as those members of the general public who have learned to Google as a way of getting second opinions about what their doctors tell them are being misled in the same dangerous fashion.

It is not only in monographs like *AIDS and Other Manifestations of HIV Infection* that the unreliability of HIV tests is described, of course. For example, Gigerenzer et al.¹⁹ pointed out a decade ago that “heterosexual men with low-risk behaviour” are likely to experience a 50% rate of false-positive HIV tests.

**In AIDS and other manifestations of HIV infection one reads:
“The EIA (ELISA) was the first type of test to be licensed in the
US to detect infection with HIV...In the US, the latest generation
of licensed EIA screening test typically has sensitivities of $\geq 99.9\%$
and specificities of $\geq 99.9\%$ ” (page 150,151). In the confirmatory
WB test “When classic patterns are present, positivity is a virtual
certainty (Table 8.4) page 156.
Any medical test, not to mention an antibody test which has a
specificity of 99.9%, under no circumstance can be considered
unreliable.**

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, let alone anything technical, so they are least likely to know that when they are given a “positive” diagnosis it is quite likely to be wrong, based on a false-positive test. That’s what happened to Karri Stokely,²⁰ for example, and also to some quite unknowable number of others. Personal communications to this author have come from a low-risk woman who tested positive after an operation for uterine cancer, and from a healthy married heterosexual man who was refused life insurance as a result of testing “HIV-positive” -- he believes that his reason for testing positive may have been a precautionary anti-tetanus shot after he had cut a finger with a power saw shortly before the life-insurance physical examination.

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 sources¹⁵ 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 $\geq 80\%$ likely to be wrong if she knows herself to be at low risk, that woman naturally blames her partner for deceiving her, and surely some unknowable number of relationships has been unwarrantedly destroyed thereby, on top of the other psychological and perhaps physical harm to the woman herself.^{8,p.247}

HOW MANY LONG-TERM NON-PROGRESSORS ARE THERE?

The proportion of non-progressors, no matter how large, cannot be used “To estimate the proportion of people receiving ART who should not be doing so”. The reason is simple. By definition the non-progressors are individuals who have a positive antibody test but never developed any laboratory (T4 decrease/or clinical abnormality). These individuals are not treated with ART.

The phenomenon of long-term non-progression seems not to have been recognized officially before the mid-1990s. Personal testimonies from many healthy “HIV-positive” people have been published by Maggiore²¹. 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 two or three hundred, perhaps 5000 of the million HIV-positive Americans, are long-term non-progressors,²² which seems low if more than half the queried doctors had encountered such an instance.

By the very fact that long-term non-progressors 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 during the last two decades. 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 non-progressors who have been observed for up to 20 years.²³

Another approach to the question suggests a much higher proportion again. About 1 million Americans have been HIV-positive ever since the mid-1980s at least.^{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 third²⁴ or one quarter²⁵ of HIV-positive people do not know that they are HIV-positive. So at least ever 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 antiretroviral treatment. How many of those have been long-term non-progressors?

A recent estimate gives an annual incidence of about 55,000 new HIV-positive cases in the USA,²⁶ generated by 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 less than 1,100,000 by 2007 (55,000 for two decades). On the other hand, AIDS deaths have been recorded as 583,000 through 2007.²⁷ So the 1,000,000 in 1985 should have grown by 2007 to ≥ 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,^{27,Table14} a total of 733,000. The difference between the expected ≥ 1.52 million and the actual 733,000, namely $\geq 787,000$, represents arguably the number of people who, at one time or another, were "HIV-positive" but have never been tested nor become ill from anything that would occasion an "HIV" test: in other words, long-term non-progressors. Nowadays, then, there are plausibly on the order of $\geq 787,000$ non-progressors, 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 Abbott test 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.²⁸

HOW DEBILITATING IS ANTIRETROVIRAL TREATMENT?

As noted earlier, the Treatment Guidelines acknowledge that adverse *non-AIDS* events are more common than AIDS events among people on antiretroviral treatment. Some personal testimonies, albeit anecdotal, can be quite telling, for instance Karri Stokely's account²⁰ which is underscored by photographs showing how she lost weight and hair while on ART and then recovered rapidly after going off the treatment.²⁹ Another known case is that of Audrey Serrano, who was awarded \$2.5 million in damages after being wrongly treated for HIV infection for 9 years during which time she suffered "depression, chronic fatigue, loss of weight and appetite and inflammation of the intestine."³⁰

Some official reports have it that 40% of continuing prescriptions for anti-retroviral drugs are never filled,³¹ 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 1997³² and 1998,^{33,34} just a few years after the introduction of protease inhibitors. Significant numbers of middle-aged individuals on HAART show such signs of premature aging as bone weakness and dementia.³⁵

ART, like most if not all drugs have side effects. This fact is acknowledged by HIV/AIDS experts. If the author wants to argue against their use, he/she must prove that the ratio of benefit to risk is at least less than 1.

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 ELISA. The latter depends on measurement of a color intensity with a particular cut-off value for what constitutes a “positive.”¹³ To determine the proper cut-off, a control group is needed of people known beyond any doubt to be not infected. 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.^{13,p.161} Still, there is no way to make the establishment of a cut-off value completely objective and definitive.

Weiss and Cowan¹³ 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” (p. 159), for example “sticky sera” or hypergammaglobulinemia (Table 8.2, p. 152). In other words, HIV tests should be calibrated differently for use in Africa than in Europe.

The claim that if the HIV tests are calibrated “differently for use in Africa than in Europe” will lead to an improvement of the test parameters in general and specificity in particular is scientific nonsense. The test parameters, in any group of people, can only be determined by using HIV, that is, HIV isolation as a gold standard. In this regard the author contradicts himself/herself. On the one hand repeatedly claims that HIV has been isolated from many people and on the other that “there is no way to make the establishment of a cut-off value completely objective and definite”.

However, no region- or race-specific test-kits are in existence. 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-positive” among repeat blood donors is an obvious way of looking for possible racial bias. Using the present versions of HIV tests, black American

repeat donors test positive ~14 times more often for than white American donors,^{8,Table8} and black South African repeat donors test positive 23 times more frequently than white South African donors.³⁶ (Asian American donors test positive much less often than white American donors.)³⁷

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,chap.7}

The interpretation of relative rates of testing “HIV-positive” as reflecting high promiscuity among Africans and black Americans is not just unwarranted, it is demonstrably harmful to social interactions and social policies and it places Africans and black Americans at particularly high risk of unnecessary exposure to toxic medications. Additionally, the fact that pregnancy is in itself a possible cause of false-positive “HIV” test-results goes a long way to explaining why nowadays black women in the USA 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 “down-low” phenomenon that alleges relatively common covert bisexual behavior by black men.^{8,pp.246-7} 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.”

The higher rates of testing “HIV-positive” among black Americans cannot be “because the tests are racially biased as a result of calibration with non-black-donor “controls”“. The author seems to be ignorant of a simple fact. At least in America, continental Europe, Australia and according to the South African HIV/AIDS experts present at 2000 President Mbeki’s AIDS Advisory Panel meeting, all the ELISA tests are confirmed with a WB test. The latter does not depend “on measurement of a colour intensity with a particular cut-off value for what constitutes a “positive”. Although for the WB different criteria are used by different laboratories in America, the criteria are not racially based.

CONSENT TO BE TESTED

In view of the uncertainties associated with HIV tests and the toxicity of antiretroviral treatment, fully informed consent should be solicited before anyone is subjected to an HIV test.^{13,p.148} “Informed” surely must include knowing that a positive test does not prove infection, that nevertheless “positive” is 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 prescribed them fail to take them.

But in many situations 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 “Only a fraction of initially seropositive newborns are actually HIV-infected.”^{13,p.148}

Indications are that quite large numbers of people have been suffering and continue to suffer iatrogenic harm from unnecessary antiretroviral treatment, most particularly black Americans, Africans, pregnant women, and also 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.³⁸

POTENTIAL CONFLICT OF INTEREST

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