TOWARD IMPROVEMENTS IN HIV EPIDEMIOLOGY

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Abstract ID: 7

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Policies to combat HIV/AIDS epidemics are based on epidemiological data and projections from those data into the future. The presently available data are highly variable in quality and generally unreliable for a number of reasons, therefore projections are presently not good guides to effective public policy.

False-Positive HIV Tests

The possibility of false-positive HIV tests is widely ignored, yet a significant incidence of false positives could vitiate inferences drawn from epidemiological data. An estimate of the frequency of false positives can be made based on the following premises:

- 1. Untreated HIV infection leads inevitably to death after a median period of about a decade. (This is a fundamental tenet of HIV/AIDS theory, an axiom, not an assumption.)
- 2. In the United States, between one quarter and one third of HIV-positive individuals are not aware that they harbor HIV [1].
- 3. There were between 1 and 1.5 million HIV-positive Americans as early as 1986 [2].
- 4.People not known to be HIV-positive would not be receiving antiretroviral treatment and could be expected to have died about a decade after becoming HIV-positive.

Together with published data from the Centers for Disease Control and Prevention of the numbers of deaths, of HIV+ Americans, and of American AIDS patients, the pertinent calculations show that approximately one half of all positive HIV tests are false positives [3].

Though public pronouncements about the desirability of testing do not mention the possibility of false positives, the technical literature makes quite plain that HIV tests are not capable of diagnosing active infection. Weiss and Cowan [4] point out that

- -No gold-standard HIV-test exists
- -Therefore one should never speak of "confirmatory" tests, only additional or supplemental ones.
- -For purely statistical reasons --- for all tests for anything ---, in low-prevalence populations there will be a high proportion of false positives even when tests have high specificity.

HIV Has Never Been Isolated in Pure Form

There is no gold standard for HIV tests because no pure sample of HIV virions is available. All so-called "isolates" of HIV are material sedimenting at a particular rate under ultracentrifugation and containing various types of particles [5, 6].

Luc Montagnier and Robert Gallo have both conceded that their putative isolates of retrovirus were never purified. Gallo has even stated that purification is unnecessary since his cultures produced the virus in such profusion as to make impurities unimportant [7].

What Contemporary HIV Tests Detect

Several independent types of evidence show that present-day HIV tests do not diagnose active infection by HIV [8]. The traditional tests, ELISA and Western Blot, detect antibodies commonly present in AIDS patients, but present also in a large range of other physiological conditions, not necessarily pathogenic ones, for example, pregnancy or effects of some types of vaccination [9]. Viral load tests and culturing rely on identifying sequences of RNA or corresponding DNA supposedly characteristic of HIV; but in absence of any pure samples of HIV virions to serve as gold standard, it cannot be known whether these sequences are indeed characteristic of HIV, let alone unique to it. De Harven [10] has pointed out that the unreliability of HIV tests and the associated conundrums can be understood in terms of human endogenous retroviruses (HERVs) and of circulating DNA in blood.

Paradoxes

That presently available data are seriously misleading is illustrated by the fact that they deliver inexplicable conundrums, for example:

-The magnitude of the HIV epidemic in sub-Saharan Africa can only be explained by an enormous rate of sexual promiscuity with multiple concurrent partners [11]. But the concurrency hypothesis is disproved by actual evidence [12].

-In different regions of the world, one has to assume entirely

different pathways of HIV transmission [13]: in eastern Europe, 90% via infected needles; in Latin America, ~65% via homosexual

activity and only ~5% via infected needles; in

sub-Saharan Africa, ~50% via marital sex! (Fig. 1)

-Persistent racial disparities in incidence and prevalence of HIV: Africans and African Americans test HIV-positive about an order of magnitude more frequently than Caucasians, and the latter test HIV-positive about 50% more frequently than Asians. The genetic basis for these disparities is demonstrated by the fact that in the western United States Hispanics, largely of Mexican ancestry, test comparably to Caucasians whereas Hispanics in the east, largely of African ancestry, test comparably to Africans [14].

-Pregnancy is associated with higher rates of HIV-positive but also with lower rates of risky behavior [15, 16].

-HIV is supposedly transmitted via breast milk, yet exclusive breast-feeding guards against babies becoming HIV-positive [17, 18].

Explaining Conundrums and Paradoxes

Contemporary HIV tests are highly non-specific and subject to false positives. So-called "HIV isolates" are undefined mixtures containing various types of particles and cell debris, including DNA, RNA, antibodies, other proteins, and enzymes. These mixtures naturally differ from one experiment or patient or trial to another, and this can explain the range of paradoxes and inexplicable behavior reported throughout the research literature, for example:

- -The extraordinary number of "strains" and "mutations" and "recombinants" of HIV, whereby "no two virus isolates are identical.... Within a single ... host, HIV-1 population represents a complex mixture, or swarm, of mutant virus variants" [19]. This reflects that the "HIV isolates" are mixtures of not always the same components.
- -The non-specificity of HIV antibody tests presumably has to do with the fact that Western Blot and ELISA respond "positive" to almost any combination of two or three among ten different proteins, at least some of which are normal components of human cells [20].

GLOBAL VARIATION IN THE CRITERIA DEFINING A POSITIVE HIV WESTERN BLOT



A-R-AFRICA. AUS-SAUSTRALIA. FLARUS FOOD AND DRUG ADMINISTRATION. ROX-LIS RED CROSS. DOCLIS CENTER FOR DISFASE CONTROL. CONING CONSCRITUM FOR REITOVIRUS SERGLOOV STANDARDZATION, GER-GERINAY, UK-UNITED KINDOWN FRA-FRANCE, MACS- US MULTICEVIER AUS CO-HORT STUDY 1983-1982. Bands for in electrophorie

-The higher tendency for people of African ancestry to test HIV-positive may be associated with the tendency for people of that ancestry to generate particularly strong antibody response to p24 antigen [21].

-Similarly, pregnancy, vaccinations, etc., which are known to be confounds in HIV testing, may stimulate production of one or more of the supposedly "HIV" antigens. Data are badly needed to determine whether particular conditions are indeed associated with particular bands or groups of bands in "HIV-positive" Western Blots.

Misguided Public Policies

Public policies regarding HIV/AIDS are based on statements from official agencies such as UNAIDS and the Centers for Disease Control and Prevention. Those statements are based on data from contemporary HIV tests and computer models incorporating those data. These are fallible bases for public policy for two reasons, each in itself sufficient to ensure unreliability: 1. The tests are subject to a high proportion of false positives and confounding conditions.

2. The computer models themselves cannot be more reliable than the test data; but in addition,

they include a number of assumptions that are continuingly found to be wrong, leading to successive modifications in which estimates of, for example, AIDS deaths are changed by large factors [22].

Public policies cannot become appropriate and effective unless the deficiencies in HIV testing are corrected.

> HIV epidemiology cannot become reliable in absence of a gold-standard HIV test. Isolation of veritable pure HIV virions is the central need in HIV/AIDS research.



Fig. 1

Casual sex MSM
Sex workers IDU

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