Harm of not permitting personal HIV screening in developing countries

In their recent review, Schopper and Vercauteren [1] addressed issues and controversies concerning personal screening tests for potential infection with HIV. While the authors were careful in their appraisal and cautious in their conclusions, they did not mention the enormity of the world-wide HIV problem that testing attempts to address, or the devasting impact on HIV discordant couples in much of the world where testing is not accessible or acceptable. By the year 2000, UNAIDS officials estimate that 40 million men, women and children will have become HIV-infected, with nearly as many women as men harboring the virus [2]. It is likely that 90% or more of those living with HIV will not realize they are infected, and thus will do little to avoid transmitting the virus to their spouse or offspring. When faced with this reality, the technical and social concerns expressed by Schopper and Vercauteren pale in comparison.

Four years earlier, Carter and Hinman [3] of the US Centers for Disease Control and Prevention tried to bring realism to a similar epidemiological debate. Being prevention specialists, they were deeply concerned with the belief held by some that preventive techniques must be perfectly effective before being recommended or valued. They concluded with the observation, “We do not live in a perfect world, and our quest for solutions must recognize that fact.” The same holds true today when addressing the reluctance of many to support personal screening with home HIV tests as a means for early viral detection [4].

Fear of easier access to testing must be overcome if we are ever to halt the movement of the virus. HIV testing has been very successful in many settings. For example, such testing continues to safeguard the blood supply in much of the world. Where zidovudine is available and affordable, antenatal HIV testing has contributed to a substantial reduction of HIV-infected infants [5]. Self and partner testing should have similar benefits for couples planning or experiencing marriage, and is especially important for the majority of women who are intimate only with their husband. The choice to buy and use such tests should be left to the individual, who after, all cares more about his or her health and the well-being of family members. When given the opportunity and both access and cost are acceptable, people are more likely to buy HIV screening tests. If health officials deny people such opportunities, either by preventing the sale of simple tests or imposing excessive regulatory or administrative burdens, then testing will remain limited and few will benefit from knowing their HIV status.

Among the many questions Schopper and Vercauteren asked is whether home HIV tests are allowed for public use [1], two should be addressed before licensing is approved (i.e., accuracy and reliability), whereas the where should be researched after the tests are in wider use. Clearly, the accuracy of tests should be assessed in laboratory-based studies as a prerequisite for licensing, but preferable in countries or regions where the test is to be used. The studies need not be large, but should use standard external designs [6]. Such evaluation studies will provide research opportunities for local scientists, and for manufacturers reduce the high development costs that are incurred in wealthier societies such as the United States. The reliability of such tests when used by lay personnel should also be assessed before licensing, but again determined by local researchers. Accompanying brochures should be simple, using both pictures and words to explain how the product is to be used and interpreted.

The other questions cited by Schopper and Vercauteren are a mixture of research and marketing interest. Some address demand, while others address cost, and still others focus on consequences. It seems clear that studies should be conducted of the acceptance and use of home HIV tests, and education programs should be initiated to stimulate proper follow-up of test findings to promote care and avoid further...
transmission. Rarely, however, is such research per¬
formed in a comprehensive manner before a product is
available in the marketplace, especially in developing
countries. Consumer acceptance is measured by sales,
whereas use is determined by interest, education and
related factors.
One recommendation of Schopper and Verscaetens is
to be especially troublesome, and would limit availability of
home HIV test in economically deprived countries to
only the wealthy [1]. Specifically, they state that, "No
test should be marketed in another country before hav¬
ing been approved by the regulatory body of the coun¬
ytry of production". If this advice had been followed
with the first home-based HIV test licensed in the
United States, people would need to pay US$ 35–50 per
test, priced high by the manufacturer to recoup the
7 years it took to become licensed and the many
requirements imposed by the US Food and Drug
Administration [7]. With only local research to support
licensing applications, the cost in developing countries is
likely to be reduced to under US$ 2 per test.
If public health officials accept the need for early detec¬
tion, and recognize that only testing can provide such
information, then we need to develop mechanisms to
increase the use of HIV tests. In high prevalence
regions, people should screen each other before mar¬
riage and at regular intervals during marriage. Such
screening tests should be purchased for home use in the
private sector, and should be viewed as indicators of the
need for confirmatory testing, rather than tests of HIV infec¬
tion per se [8]. Such personal screening tests should be
simple to use, inexpensive, accurate, widely accessi¬
ble and acceptable to the public. People will remain
willing to support HIV prevention programs that build
on the foundations of the past, but we must offer new
means to leap of infection, foster individual responsi¬
bility, and take personal action. The central question
not addressed by Schopper and Verscaetens [1] is
whether those entrusted to preserve the health of the
public will allow people access to such life-saving mea¬
sures. Unfortunately, this important public health ques¬
tion remains to be answered in much of the developing
world.
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A placebo-controlled clinical Phase I trial with combined anti-HIV-1 and anti-interferon-0 immunization

Immunization with HIV-1 or gp160 [1,2] or gag
lar immune response in HIV-1-uninfected humans. By
contrast, such an immunization in HIV-1-infected
immune deficient patients does not generate a specific
cellular response, nor does it restore the impaired cellu¬
lar immune reaction to recall antigens. This HIV-
induced immune suppression is associated to a cytokine
dysregulation, including in particular to overproduc¬
tion of interferon (IFN-0 [4]. To counteract the
effects of IFN-0 in HIV infection, we have designed a
new AIDE vaccine combining both an anti-HIV and
an anti-IFN-0 immunogen. The safety of this multi-
component vaccine has been previously reported [5].
In the present Phase I randomized study, the safety of
the full vaccine was assessed by comparison with the
adjuvant alone. The vaccinal preparation combined recombinant IFN-0 inactivated by formalin treatment;
HIV-1 particles depleted from their RNA and
stabilized with formaldehyde [7], four synthetic HIV-
derived peptides embedded in proteosomes [8], and
adjuvant composed of P40 (Protein 40, Corynebacterium
eosinophil extract) [9], and calcium phosphate as a gel,
produced by Superfos (Bioscoret, Vedbaek, Denmark).
Twenty-five asymptomatic HIV-1-infected persons,
with a mean CD4 cell count of 485 x 10^9 and with¬
out previous antiretroviral drug treatment were ran¬
donently assigned to the full vaccine or adjuvant groups.
Treatment was administered four times at days 0, 30,
60 and 150. Patients were followed at days 10, 30, 40,
60, 70, 90, 150, 260 and 180. Clinical side-effects were
all under grade 2 (WHO grade, moderate). Fever was
more frequent in the full vaccine group (seven out of
12 versus two out of 13 in adjuvant group; P = 0.03).
For other side-effects (pain due to injection and
transient fatigue) there was no significant difference
between the two groups. However, grade 3 or 4 tran¬
sient increase of creatinine phosphokinase (CPK) were
observed in three patients receiving the full vaccine.
There was no clinical progression to AIDS-related
complex or AIDS over the 18 months of follow-up.