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Price, Performance, and the FDA Approval Process: The Example of Home HIV Testing

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Abstract

The Food and Drug Administration (FDA) is considering approval of an over-the-counter, rapid HIV test for home use. To support its decision, the FDA seeks evidence of the test's performance. It has asked the manufacturer to conduct field studies of the test's sensitivity and specificity when employed by untrained users. In this paper, we argue that additional information should be sought to evaluate the prevalence of undetected HIV in the end-user population. Our analytic framework produces the elementary but counterintuitive finding that the performance of the home HIV test – measured in terms of its ability to correctly detect the presence and absence of HIV infection among the people who purchase it – depends critically on the manufacturer's retail price. This finding has profound implications for the FDA's approval process.

Keywords

HIV testing; FDA; predictive value

Introduction

In November 2005 and again in March 2006, the Food and Drug Administration (FDA) Blood Products Advisory Committee reviewed testimony regarding the approval of an over-the-counter, rapid HIV test for home use [1]. The technology in question is the OraQuick ADVANCE 1/2 (OraQuick [OraSure Technologies, Inc., Bethlehem, PA]), a rapid, point-of-care test that can detect antibodies to both HIV-1 and HIV-2 in 20 minutes, using oral fluid obtained via a simple cheek swab. The OraQuick test is already FDA-approved and waived for use in health care settings under the Clinical Laboratory Improvements Amendments Act of 1988 (CLIA) [2]. It is widely employed in a variety of hospitals, drug treatment facilities, state and local health departments, clinics, community-based organizations, and university health centers throughout the United States [3–8]. Sales of OraQuick during 2007 totaled \$32.7 million, including almost \$20 million in direct sales to the US public health market [9].

The FDA hearings focused on the studies needed to validate an HIV test for home use and to establish that it would be safe and accurate when used by a ordinary consumers rather than by a certified test operator [10,11]. Based on this discussion, the FDA instructed the manufacturer to collect and report on the sensitivity and specificity of the test in the hands of untrained users in real-world settings.

In prior work [12], we have argued that the information currently sought by the FDA is not sufficient to address the true benefit of the HIV test for home use. The attributes of the test itself, its sensitivity and specificity – whether observed under controlled or uncontrolled

circumstances – are only a part of the story. Another part of the story is the target market and, more specifically, the presence of undetected but detectable HIV in the population of individuals who will purchase and use the test.

This paper focuses on the *positive predictive value* (PPV) and the *negative predictive value* (NPV), two widely accepted summary measures that quantify the likelihood that a screening test will produce the correct diagnosis [13]. We propose a formal, analytic framework that modifies the traditional approach to estimating PPV and NPV. Specifically, we draw an explicit link between individual income, HIV risk, and the demand for home HIV testing. We use this relationship to explore the potential impact of retail pricing on the prevalence of undetected HIV in the target population and, by direct consequence, the ultimate performance of the test (as measured by its PPV and NPV). Our findings suggest that if the FDA seeks to understand the performance and validity of an HIV test for home use, it might pay attention to price and market factors in addition to sensitivity and specificity in the end-user population.

Methods

Preliminaries

The positive and negative predictive values measure a diagnostic test's reliability when it is used within a particular population [13]. The positive predictive value (PPV) is defined as the fraction of true positive results obtained from among all positive results (true and false). Its analog, the negative predictive value (NPV), represents the fraction of true negatives obtained from among all negative results. The PPV denotes the probability that a positive result truly indicates the presence of disease; NPV is the probability that a negative test truly indicates the absence of disease. Stated formally, the PPV and NPV are given by:

$$ppv \equiv \frac{\alpha\pi}{\alpha\pi + (1 - \delta)(1 - \pi)} \quad (1)$$

and

$$npv \equiv \frac{\delta(1 - \pi)}{(1 - \alpha)\pi + \delta(1 - \pi)} \quad (2)$$

respectively, where α represents the sensitivity, δ is the specificity, and π is the underlying prevalence within the tested population.

This paper is premised on the view that PPV and NPV – and their interpretation as measures of a test's ability to correctly detect the presence and absence of disease among the people who will actually use it – are key yardsticks by which the FDA might judge the performance of a new diagnostic test. Other criteria, such as overall cost-effectiveness, are also pertinent to FDA decision-making. We confine our attention to predictive values, given the FDA's explicit focus on these test characteristics.

From equations (1) and (2) above, one can see that at least three factors determine the PPV and NPV of a given diagnostic test: its sensitivity (α), its specificity (δ), and the presence of undetected disease in the sub-population that chooses to employ the test (π). (Of course, this parameterization ignores significant variation in PPV and NPV across clinical populations, depending upon specific comorbidities and clinical presentations. Making due allowance for such complexities, public policy and regulatory decision-making are often necessarily based on population averages [14].)

Of particular relevance is the rapid loss of positive predictive value when a test with imperfect specificity is employed by a low-prevalence population. Consider, for example, the positive predictive value of a test with 99.7% sensitivity and 99.8% specificity. When this test is employed in a population with underlying prevalence of disease of 10%, the PPV = 98.2%. PPV falls to 83.4% when the same test is used by a population whose underlying disease prevalence is 1%. When the prevalence is further reduced to 0.1%, PPV falls to 33.3%.

The FDA has noted that the real-world sensitivity and specificity of the home HIV test kit, when purchased and employed by untrained end-users, may differ from the sensitivity and specificity achieved by trained operators using the same kit in healthcare settings or under strict laboratory conditions. Accordingly, the agency has instructed the manufacturer to collect data on the sensitivity and specificity of the test when placed in the hands of ordinary consumers. In contrast to this degree of care and interest with respect to sensitivity and specificity, the FDA seems to treat π , the prevalence of undetected HIV among persons who purchase and use the test, as either unimportant or immutably given. We contend that the manufacturer may exert partial control over parameter π – most notably via the setting of a retail price which may, in turn, affect the composition of the subpopulation who choose to purchase the test, thereby influencing both the prevalence of undetected HIV among end-users and the consequent PPV and NPV of the test – and that π may therefore be deserving of greater FDA attention.

Refining the derivation of PPV and NPV

In this section, we refine parameter π . Our aim is to draw a sequence of explicit links between the manufacturer's retail price for the home test, the prevalence of undetected but detectable HIV among persons who buy the test at that price, and the ultimate performance of the test, as measured by its PPV and NPV. We are motivated by two observations regarding the current state of HIV epidemiology and testing behavior. First, HIV risk and socioeconomic status appear to be inversely related in the United States. While data in developing nations are less conclusive with regard to the relationship between SES and HIV risk [15-17], evidence from the U.S. suggests that race, education level, and income all correlate with HIV risk behaviors, transmission, and prevalence [18-20]. For example, Brown and colleagues examine HIV testing and risk-behaviors among more than 43,000 women age 18-49 who responded to the 2004 Behavioral Risk Factor Surveillance System (BRFSS). These authors find, correcting for age, education, marital status, and other factors, that women with annual incomes less than \$30,000 are significantly more likely to report high-risk behaviors (adjusted odds ratio > 1.5, $p < 0.01$) [21]. Unadjusted income disparities are even larger. Second, the price of most goods influences the socioeconomic distribution of persons who buy those goods. It is a general economic pattern that, all other things being equal, demand for most goods ("normal goods") increases with consumer income [22].

A formal description of our approach is contained in the Technical Appendix. Here, we provide a qualitative outline that captures the essential dynamic that concerns us. Briefly stated, we rely on a few key assumptions:

1. We assume that the income distribution in the target population for home HIV testing is known. For simplicity, we conduct our analysis in terms of income percentiles ranging from 0 to 100.
2. We treat demand for the home HIV test as a function of both the test price and the individual consumer's income. Specifically, we denote the price of the home test by \$q. We assume that everyone with an income at or above some threshold percentile $I(q)$ buys the test; everyone with income below this threshold does not. We further assume that $I(q)$ is an increasing function of q. This means that as the price of the HIV test rises, some individuals with lower incomes will no longer be willing or able to

purchase it. In specifying this form of consumer demand, we do not deny the role played by many variables other than price and income (e.g. access to testing, knowledge about testing, perceptions of risk and perceptions of stigma around testing and HIV) in determining willingness to test. Cost is just one of many considerations driving the decision to purchase a home HIV test. People who perceive themselves to be at lower risk, for example, may be less interested in testing; someone who perceives herself to be at higher risk and sees value in testing may be more likely to test. We merely claim that, all other things being equal, a higher-priced test will elicit weaker demand and that this weaker demand will be linked to consumer income.

3. We suppose that income and HIV risk are inversely related among consumers purchasing the home test kit. Specifically, we assume that every income percentile has an accompanying HIV prevalence π , which declines in $I(q)$. In other words, higher incomes are associated with lower rates of HIV infection. Given that $I(q)$ rises with q , the prevalence of infection $\pi(I(q))$ in persons at the threshold income level will decline as the price of the test rises.

With these assumptions in hand, the analysis proceeds: First, we use the relationship between income and test price to determine the total number (and income distribution) of people affluent enough to purchase the test at any given price. We then use the relationship between income and HIV risk to evaluate $\pi(q)$, the prevalence of HIV in the entire population of individuals who buy the test kit at this price. Relying on assumptions #2 and #3 above, it is readily shown that HIV prevalence within the population of persons who actually buy the test declines as the price of the test rises.

Illustrative results

We ran numerical experiments using baseline sensitivity of 99.7% and specificity of 99.8%. This reasonably matched both published estimates [23-26] and the values reported in the OraQuick package insert [27]. We assumed a prevalence of 1% at the lowest income percentile ($I = 0$) and, further, that prevalence dropped linearly to 0.25% at the highest income percentile ($I = 100$). Our illustrative prevalences are higher than the CDC's estimate that there are approximately 233,000 undetected cases of HIV infection in the United States [28], implying a population prevalence below 0.1%. They are consistent with the prevalences reported for many at-risk US populations [29-34] and reflect our supposition that a home test would attract a population facing moderately higher-than-average HIV risk.

We further assumed that every pertinent consumer is willing to pay at least \$2 for the home test (implying that $I(2) = 0$), but that demand drops linearly with price until only the most affluent consumer is willing to pay \$100 (i.e., $I(100) = 100$). These rough boundaries are consistent with the limited literature on willingness to pay for HIV testing [35] and allow us to illustrate the main point.

Figure 1 depicts the relationship between the price of the test and the prevalence of HIV infection in persons willing to make a purchase at that price. The upper line plots the prevalence in the *marginal* consumer (i.e., the buyer who is willing to pay the specified price, but no more). The lower line shows $\pi(q)$, HIV prevalence among all consumers who are willing to purchase and use the test at the specified price. Under our illustrative assumptions, Figure 1 indicates that when the test is priced at \$2, the average HIV prevalence among buyers is 0.63%; raising the cost of the test to \$50 reduces the HIV prevalence among test buyers to 0.44%.

Figure 2 illustrates the impact of this price change on the positive predictive value: raising the test price from \$2 to \$50 (and, thereby reducing the prevalence of undetected HIV infection in the target population from 0.63% to 0.44%), results in a reduction in PPV from 76% to 69%.

At any specific test price, positive predictive value depends strongly on test specificity; yet as shown in Figure 2, the influence that the price of the test exerts on the prevalence of undetected HIV infection in the target population is equally important. The most specific of the three tests (specificity = 0.998), if offered at \$90, has a lower PPV than one could achieve by offering the least accurate test (specificity = 0.996) at a price of \$15. The same test has lower PPV than could be achieved by offering a test with a specificity of 0.997 for \$54.

Discussion

Sheila Weiss Smith has noted that the FDA drug-approval process is

“...typically based on a narrow interpretation of benefits and risks. Benefits are defined according to the intended effect and intended population, as proposed by the sponsor. These factors are measured in efficacy studies performed in a modest number of carefully selected patients, who may or may not reflect the characteristics of the broader population likely to receive the drug...Should the benefit–risk balance be constructed on the basis of the approved (labeled) indication or the actual use?” [36]

Our analysis highlights the importance of this basic question. We have demonstrated that the “actual-use” benefit of a home HIV test – its power to correctly detect the presence or absence of HIV infection among those who purchase the test – depends on the prevalence of undetected HIV in that population. This, in turn, may partly depend on the manufacturer’s retail price and other market factors. Our analysis suggests that a cheaper test may have higher positive predictive value – the home HIV test product might actually work better at a lower price.

The economic and behavioral assumptions behind our analysis are plausible. They are also, we hasten to add, empirically untested. One should scrutinize our concern that home testing will attract a predominantly affluent clientele, including many HIV-uninfected, “worried well” persons for whom a home test provides an attractive alternative to public or private testing systems, and who may be least sensitive to price [12]. The target population for the manufacturer is “whoever will be willing to buy it.” Cost is just one of many factors, including convenience, privacy, and recent behavior. Individuals may have very different pre-test probabilities of disease. There is not one uniform population of persons undergoing testing with a home test kit, but rather a spectrum of subpopulations with varying prevalence of disease.

We acknowledge that a home testing pricing policy consistent with our analysis is not the only route to HIV testing. The decision to obtain an HIV test is a complicated one. The criteria extend well beyond the retail price of the test. If cost were the only criterion, we would expect that most of the persons with low income at high risk for HIV disease would already have been tested. Free (or very low-cost) HIV tests are available at many public health facilities across the country. Persons could access these tests for the cost of transportation and time. Alternatively, insurers might opt to cover the cost of a home HIV test. Additional field studies can be conducted by the manufacturer to verify or refute our main contentions and to estimate $\pi(q)$, the relationship between price and prevalence.

We also acknowledge that home-based HIV tests are no less accurate than many other tests for diseases, conditions, and health states performed in the privacy of one’s home. Many home-based tests—most prominently pregnancy tests—have imperfect positive predictive value and must be confirmed by a trained provider in a healthcare setting. Presumably the unique nature and history of HIV testing lead FDA regulators to apply particularly stringent standards on test performance. For most consumers, the performance of the home HIV test will be very satisfactory. This is because NPV is likely to be of greater importance to most consumers than PPV. With a general prevalence of undetected HIV in the order of 1% or less, most consumers will obtain negative test results. Moreover, given high test sensitivity, the NPV will be

extremely high. In our simulations based on data in the package insert, NPV remained above 0.9999696 at all test prices.) Thus, consumers who obtain negative test results will have a high degree of confidence that those results are correct.

In previous work [37], we have argued the cost-effectiveness of routine HIV testing, even in settings where the positive predictive values would be lower than those illustrated in Figure 2. We have no reason to doubt that the cost-effectiveness of home HIV testing, as described here, would compare favorably to a host of widely available, commonly accepted screening tests for chronic disease. However, a comparative assessment of economic worth is beyond the scope of the present study. Our purpose here is merely to comment on regulatory approval and to highlight an inconsistency in the FDA's attention to the details of how the performance of screening tests should be measured. In our view, the FDA should pay more attention to whatever factors may significantly influence a person's decision to purchase a test. Price may be one of many such factors.

Looking beyond the home HIV test approval decision, this paper raises issues about the evidence used by the FDA to support its decision making:

1. Should the FDA approve drugs and technologies for use in specific sub-populations? The FDA already approves drugs for use in specific populations, typically based solely on clinical indications. Yet the agency could explore more carefully the market context which shapes the population likely to buy a particular product. This question is especially intriguing in situations such as home HIV testing, where market price influences the population of consumers and therefore population test performance.
2. Should the FDA consider price an explicit criterion for approval? The FDA has long pursued an approval process for new drugs and technologies based exclusively on their safety and efficacy. The agency does not take price into consideration, leaving it to the reimbursement process to handle questions of value. In this paper, we suggest that price may be a critical determinant of the efficacy of at least one technology on the FDA's docket. HIV testing is particularly interesting given the inverse relationship between socioeconomic status and HIV prevalence. In most situations, the people at the highest risk are likely to be the ones with the highest willingness to pay for an effective intervention. In the case of HIV, however, there is a more complicated relationship between risk and willingness/ability to pay. The most vulnerable populations in greatest need of a more convenient, more accessible HIV test may be the least able and willing to pay for it.
3. Is this evidence of a need for a post-approval subsidy and/or multi-tiered price schedule? Multi-tiered pricing or explicit subsidies might improve the PPV of a proposed home test. Other approaches such as targeted marketing to high-incidence/undetected prevalence groups might also prove beneficial.

Overall, our analysis underscores the insight that policymakers and regulators must consider how – and on whom – diagnostic tests, medications, procedures, and devices are actually used. One cannot make sound product approval or regulator policy without understanding the population of patients who will actually use these products or interventions.

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Technical Appendix

Suppose demand for a test is a binary variable. The price of a test is some \$q, Everyone with an income over the threshold $I(q)$ buys the test, and everyone with incomes below q does not. We suppose that the HIV test has sensitivity α and specificity δ .

We suppose that income is distributed across the population in accordance with some probability density $f(I)$ and accompanying cumulative distribution function $F(I)$. We also suppose that every income level I has an accompanying HIV prevalence $\pi(I)$. Normalizing population to one, the total number of kits sold is

$$\int_{I(q)}^{\infty} f(I) dI = 1 - F[I(q)] \quad (1)$$

To find HIV prevalence among the full population of test users, one integrates over the population of people affluent enough to buy the test, hence:

$$\pi(q) \equiv \frac{\int_{I(q)}^{\infty} \Pi(I) f(I) dI}{1 - F[I(q)]} \quad (2)$$

If π is a declining function of income,

$$\pi(q) \leq \frac{\Pi(I(q)) \int_{I(q)}^{\infty} f(I) dI}{1 - F[I(q)]} = \Pi(I(q)) \quad (3)$$

In general,

$$\begin{aligned} \pi'(q) &\equiv \frac{-I'(q)\Pi(I(q))f(I(q))}{1-F[I(q)]} + \frac{I'(q)f\left(I(q)\int_{I(q)}^{\infty}\Pi(I)f(I)dI\right)}{(1-F[I(q)])^2} \\ &= -\left(\frac{I'(q)f(I(q))}{1-F[I(q)]}\right)[\Pi(I(q)) - \pi(q)] \leq 0 \end{aligned} \quad (4)$$

So prevalence within the tested population moves inversely with the price of the test.

We have not parameterized prevalence $\pi(I)$ or the threshold $I(q)$. So without loss of generality we can transform income to be uniformly distributed on the interval $[0,1]$. This is equivalent to writing $I(q)$ as an income percentile between 0 and 100% of its maximum value.

Moreover, suppose prevalence declines with price. We examine one special case, in which prevalence declines linearly with income percentiles, and in which test demand is linear in $I(q)$:

$$\begin{aligned} \Pi(I(q)) &= A - \alpha q, \\ I(q) &= I_0 + cq < 1 \end{aligned} \quad (5)$$

So $q = (I - I_0)/c$

$$\begin{aligned}
 \pi(q) &\equiv \frac{\int_I^1 (A - \alpha(I - I_0)) dI}{1 - I} \\
 &= \frac{\int_I^1 (A - \alpha(I - I_0)) dI}{1 - I} = A - \frac{\alpha \left(\frac{1 - I^2}{2} \right)}{1 - I} + \alpha I_0 \\
 &= A - \alpha \left[\left(\frac{1 + I}{2} \right) - I_0 \right] = \Pi \left[\frac{1 + I}{2} \right]
 \end{aligned}
 \tag{6}$$

If everyone in income percentile $I(q)$ or above buys the test, HIV prevalence among test-takers is given by the prevalence in the income category halfway between $I(q)$ and the maximum income.

Indeed for any income distribution, the test's positive predictive value is given by the number of "true positive" test results divided by the total number of positive results. By the definition of sensitivity and specificity, this implies that

$$ppv(q) \equiv \frac{\int_{I(q)}^{\infty} \alpha \Pi(I) f(I) dI}{\int_{I(q)}^{\infty} [\alpha \Pi(I) + (1 - \delta)(1 - \Pi(I))] f(I) dI}
 \tag{7}$$

One can readily calculate that PPV(q) declines in price as long as $\pi(q)$ does.

One can perform analogous calculations for negative predictive value.

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FIGURE 1. Relationship of prevalence and price

The figure depicts the relationship between the price of home HIV test and the prevalence of HIV infection in persons willing to make a purchase at that price. The upper line denotes prevalence in the *marginal* consumer; the lower line represents prevalence in the *average* consumer. Under our linearity assumptions, the marginal consumer line has exactly half the slope of the average consumer line, reflecting the fact that the average test purchaser has substantially higher income than the consumer who is just willing to pay the specified price.

FIGURE 2. Positive predictive value for three different specificities

The figure illustrates the relationship between price and positive predictive value for a home HIV test with three possible levels of test specificity (99.6%, 99.7% and 99.8%). Each retains sensitivity= 99.7%.