A Health Technology Assessment of HIV Counseling and Testing Technologies: Evidence of Effectiveness, Cost-Effectiveness and the Consumer Perspective

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LIST OF ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ACER	Average cost-effectiveness ratio
ART	Antiretroviral therapy
ATC	AIDS testing center
BH	Bath house
CAT	Computed axial tomography
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
CEA	Cost-effectiveness Analysis
ELISA	Enzyme-linked immunoassay
ER/UCC	Emergency room/ urgent care center
HTA	Health technology assessment
ES	Effect Size
HIV	Human Immunodeficiency Virus
HIV CT	HIV counseling and testing
ICER	Incremental cost-effectiveness ratio
KKK	Ku Klux Klan
NE	Needle exchange
OR	Odds ratio
OTA	Office of Technology Assessment
PCEHM	Panel on Cost Effectiveness in Health and Medicine

QALY	Quality-adjusted life year
RCT	Randomized controlled trial
SAFE	Serostatus approach to fighting the epidemic
STD	Sexually transmitted disease

LIST OF DEFINITIONS

1. HIV counseling and testing - the process of getting tested for HIV includes pre-test counseling, informed consent, HIV testing and post-test counseling.
2. Risk-based testing - an approach to testing in which patients are offered testing based on their HIV risk factors. This approach is often considered the current practice in most settings.
3. Routine testing - an approach to testing in which patients in a specified population considered to be at high risk are routinely offered testing. As with all other types of testing being evaluated in this dissertation, this approach is voluntary.
4. Rapid testing - a testing procedure or modality in which test results are available the same day, typically within hours.
5. Enzyme-linked immunoassay (ELISA) testing, also called enzyme linked immunoassay (ELISA) - a type of HIV test in which patients must return to the testing site, typically in 2 weeks time, for test results. It is frequently the standard of care.
6. Seroprevelance - the number of existing cases (measure by a positive blood test) in a population at a given time.
7. Sensitivity - a measure of accuracy of a screening test, it is the probability of testing positive if the disease is truly present.
8. Specificity - the probability of testing negative if the disease is truly absent.

A HEALTH TECHNOLOGY ASSESSMENT OF HIV COUNSELING AND TESTING TECHNOLOGIES: EVIDENCE OF EFFECTIVENESS, COST-EFFECTIVENESS AND THE CONSUMER PERSPECTIVE

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ABSTRACT

Background: Alternatives to conventional (enzyme-linked immunoassay [ELISA]) HIV counseling and testing (HIV CT) have been used to improve return rates for HIV test results. I conducted a health technology assessment (HTA) to determine the effectiveness, cost-effectiveness and consumer preferences for HIV CT methods.

Methods: I conducted meta-analysis to determine the effectiveness of the alternatives compared to conventional testing. I conducted cost-effectiveness analysis of HIV CT strategies in the emergency room/urgent care center setting (ER/UCC). I used qualitative analysis of focus group data to assess the consumer perspective of alternative HIV CT methods.

Results: Seventeen effect sizes from 13 studies were included (N=23,899) in the meta-analysis. Alternative HIV CT methods included: rapid testing, oral fluid testing, home testing, routine testing, anonymous registration, telephone post-test counseling or combinations of methods. Alternative HIV CT methods were extremely effective in improving return rates compared to conventional testing among all clients tested (odds ratio [OR], 6.1; 95% CI, 2.95-12.61; $p<.001$) and HIV-infected clients (OR, 5.1; 95% CI, 1.22-21.69; $p<.05$). Rapid testing was most effective (OR, 22.1; 95% CI, 7.76-63.01). In stratified analysis, there was evidence for effectiveness in the ER/UCC setting, HIV testing centers and STD clinics. Results of the cost-effectiveness analysis depended on the outcome assessed. Routine rapid testing was the most cost-effective strategy for all clients receiving their HIV test result; however, routine ELISA testing was more cost-effective for HIV-infected clients. Conventional testing was least cost-effective. These results were most sensitive to participation rates by serostatus. Consumers preferred rapid testing to conventional testing, though they were concerns about accuracy. Routine testing was also accepted, but there were concerns about cost and privacy. There was misinformation about the testing process and a lack of trust in HIV/ AIDS information.

Conclusion: By providing comparative information on effectiveness, cost-effectiveness and the consumer perspective, this study shows how the HTA framework adds important elements for public health decision-making.

INTRODUCTION

As the HIV/AIDS pandemic enters its third decade, prevention efforts have been newly focused on diagnosing those with HIV and linking them to treatment so that patients can benefit from earlier treatment and prevent the transmission of HIV to others. The focus on identifying individuals who are HIV-infected has resulted in the use of HIV counseling and testing (HIV CT) methods that make it more likely that people undergo testing and receive their HIV test results and therefore learn their HIV status. Examples of such HIV CT methods include routinely offering testing to high-risk populations and rapid testing with which clients receive test results within hours thus eliminating the need for a return visit. Evaluation of these methods; however, is needed to determine how they compare to standard HIV CT methods. Traditional approaches to evaluating health interventions are based on the assessment of efficacy and do not provide all of the information necessary for policy decision-making. The health technology assessment (HTA) approach, however, is focused on providing evidence for policy decision-making. It incorporates different types of evidence, such as evidence of effectiveness, economic efficiency, the consumer perspective, organizational impact and analysis of practice patterns. Using an HTA framework, this dissertation includes a multi-method approach to evaluate HIV CT technologies to assess the evidence of effectiveness, cost-effectiveness and the consumer perspective.

This dissertation uses the "essay style" and includes 4 independent essays (or papers), where each essay is a separate study and therefore includes its own literature review, methods, results and discussion sections. The Introduction includes the literature review and the study objectives. Essays 1 to 3 include the findings of the three separate

studies used to evaluate HIV CT interventions: essay 1) meta-analysis, essay 2) cost-effectiveness analysis and essay 3) qualitative analysis of focus group data. The final essay discusses the value of the HTA framework in evaluating HIV CT. The references materials that follow include appendices and biographical sketch.

Background and Significance

HIV/AIDS is one of the most significant public health problems in the world today. The consequences of this global pandemic are far reaching. In addition to morbidity and mortality, the HIV/AIDS pandemic has devastated countries socially and economically. While there have been great improvements in the treatment of AIDS worldwide, there is still much to be accomplished in the area of prevention. There were an estimated 42 million people living with HIV or AIDS at the end of 2002, 50% percent more than projected a decade earlier (UNAIDS, 2002). The incidence of HIV in the United States, over 40,000 new cases per year, is increasing rapidly among segments of the population such as racial and ethnic minorities and women (Centers for Disease Control and Prevention [CDC], 2001a). Accordingly, additional approaches to prevention are necessary to control this pandemic.

Lack of knowledge of HIV status is considered a critical barrier to the prevention of the HIV/AIDS. Worldwide an estimated nine-tenths of people who are HIV positive do not know they are infected (UNAIDS, 2001). In the United States, about one-third of those infected are unaware of their HIV status (CDC, 2001b). Since only those who are infected can transmit HIV, HIV prevention strategies that are successful in facilitating knowledge of HIV status are essential to the prevention of HIV. Accordingly, the CDC has set a goal of increasing the proportion of HIV-infected people in the United States

who know they are infected by 25% and developed a new strategy for HIV prevention, the Serostatus Approach to Fighting the Epidemic (SAFE) (CDC, 2001b; Janssen et al., 2001). The SAFE approach is a reassessment of the CDC's approach to HIV prevention. Unlike the prevention programs centered on risk reduction that dominated the first 20 years of the pandemic, SAFE targets individuals already infected with HIV who may not be aware of their serostatus. SAFE outlines steps focused on diagnosing HIV-infected individuals and linking them to treatment and prevention services.

HIV Counseling and Testing

HIV counseling and testing is one of the most important strategies in the prevention of HIV/AIDS. For those who are HIV-negative, the process of testing provides an opportunity for counseling that may translate into risk-related behavior change. Identifying HIV positive individuals who are unaware of their infection can decrease the risk of HIV transmission and institute treatment. Through the timely referral of appropriate therapy, early counseling and testing can delay the onset of AIDS, potentially mitigate disease progression and reduce HIV related morbidity and mortality. Current therapy, combination antiretroviral therapy (ART), has the potential to reduce the duration and degree of transmission by reducing viral load (Janssen, 2001). With ART, the benefits of secondary prevention (prevention of disease progression) are greater than ever before. In fact, these combination therapies are so effective at prolonging life that HIV/AIDS can now be considered a chronic illness (Palella et al., 1998). Given advances in the prevention and treatment of HIV/AIDS, the CDC has recently revised its guidelines for HIV Counseling, Testing and Referral (CDC, 2001c). These new guidelines underscore the importance of early knowledge of HIV status and include

recommendations for more efficiently targeting high-risk groups and updated recommendations for HIV screening of pregnant women.

In developing HIV prevention interventions, reducing barriers to CT is a primary consideration. Barriers to HIV CT may be patient related and/or provider related. For example, many patients do not recognize they are at risk for HIV; additionally, they may refuse testing because of convenience factors or HIV-related stigma. Provider-related barriers to offering HIV CT include discomfort obtaining a sex or drug use history, time constraints, and denial of risk factors by patients at high risk (Boekeloo, et al., 1991; Irwin, 1996). Additionally, clinicians may not discuss HIV testing even in high-risk populations (Kellock & Rogstad, 1998). Thus, clinicians employing an individual risk-based approach to testing may be missing opportunities to diagnose HIV infection.

An additional problem with HIV CT is that patients get tested, but do not learn their HIV status because they fail to return for test results. Return rates vary by population and testing site. A national survey revealed that only 52% to 73% of clients at publicly funded clinics return for test results (Valdiserri, Holtgrave & West, 1999; Keenan & Keenan, 2001). Another study demonstrated lower return rates for African Americans and those who were likely to have been exposed though high-risk behaviors compared to other clients (Molitor, Bell, Truaz, Ruiz & Sun, 1999). Data from another national survey in 1995 reveal similar results in which only 78% of clients received results (Tao, Branson, Kassler & Cohen, 1999). The unfortunate consequences of failing to return for HIV test results are the spread of HIV and missed opportunities to prevent disease transmission and institute appropriate therapy (Phillips & Coates, 1995).

Advances in HIV CT have been introduced that may address some of these

barriers to testing. New technologies such as rapid testing and home testing enable patients to get results back faster and make testing more convenient. Other technologies are less invasive than serum testing, such as oral fluid (saliva) and urine testing (Summers, Spielberg, Collins & Coates, 2000). Rapid testing has the potential to reduce and even eliminate the barrier of waiting time and/or a return visit for the test results, because it allows patients to get test results back in the same day (typically within two hours) compared to the ELISA test, which takes several days to weeks. However, patients who test positive must return to the test site for confirmatory testing (e.g., the Western Blot test). Several studies conducted in the United States have concluded that the first FDA approved rapid test (the Single Use Diagnostic System [SUDS]) is feasible, practical, and cost-effective for the diagnosis of HIV infection (Farnham, Gorsky, Holtgrave, Jones & Guinan, 1996; Kassler, Dillon, Haley, Jones & Goldman, 1997; Kelen, Shahan & Quinn, 1999). Similar results have been obtained with the recently approved OraQuick Rapid HIV-1 Antibody Test that uses a finger stick serum specimen and can provide results in less than 20 minutes (CDC, 2002).

Voluntary routine testing of patients in hospital settings is a population-based approach and an alternative to conventional, risk-based HIV CT. Using this strategy, HIV testing is routinely recommended in entire clinical populations (generally within the ages of 15-65) where HIV is highly prevalent. An advantage of the routine approach is that it has the potential of reducing and possibly eliminating the barrier of patients not recognizing their own risk for HIV by promoting testing for all patients. This approach is based on CDC recommendations that hospitals and clinics with a seroprevelance greater than 1% routinely recommend HIV testing to patients aged 15 to 54 (CDC, 1993). In a

study of the patterns of HIV infection in 20 U.S. hospitals, Janssen et al. characterized the hospitals that are most likely to benefit from routine testing (Janssen et al., 1992). They found that hospitals in urban areas with a high percentage of Medicaid recipients and those with teaching programs were likely to have a high seroprevelance regardless of risk factors. Additionally, routine testing may reduce the stigma associated with getting tested for HIV, since clients will not be "singled out" for testing. There are some concerns, however, that routine screening may compromise patient confidentiality and informed consent (Quinn, 1992).

HIV CT interventions that can be effectively integrated into clinical practice also offer promise of success for high prevalence populations (Lehman, Hecht, Wortley & Fleming, 1999; Janssen et al., 1992; UNAIDS, 2001). Since those at risk for HIV are often at risk for other health problems, one potential strategy is to integrate HIV CT interventions with other health services, thus making it easier to receive testing. Examples of such settings include inpatient (hospital) settings, primary care clinics, emergency rooms and urgent care centers (walk-in immediate care centers that generally serve patients that are non-emergent) (ER/UCC). These are considered alternative settings for HIV CT which is often conducted at sexually transmitted disease (STD) clinics or local health departments

These new technologies and approaches to HIV CT have the potential to impact the AIDS pandemic by increasing the proportion of clients who are aware of their HIV status and linking infected patients to treatment and counseling services. However, they need to be fully evaluated from a number of perspectives for clinicians and policy makers to make informed decisions about their use.

Evaluation of Health Interventions and the HTA Approach

The traditional medical model of evaluating health interventions relies on efficacy (studies done in a controlled research setting) with clinical endpoints (morbidity and mortality). While efficacy is important, there is much more evidence to consider before policy makers can determine the merits of a particular health intervention. Policy making around HIV prevention has often used a program evaluation framework (Holtgrave, Resier & Di Franceisco, 1997). For example, formative evaluation can be conducted to identify the target audience and service needs. Impact evaluation can be used to assess long-term consequences and economic evaluation. Process evaluation can then be conducted to determine who was served, when, where, and how. These are important questions that should be answered for prevention interventions; however, additional information is necessary for policy making. It is necessary to first consider the evidence of efficacy, effectiveness and safety. The HIV CT intervention then needs to be considered from the consumer perspective to assess acceptability, preferences, ethical and social implications. It is also necessary to understand the economic implications; for example, how costs and outcomes compare to current HIV CT interventions. These are the central questions that comprise an additional framework for health policy decision-making – health technology assessment.

Health technology assessment represents a shift from the evaluation of the clinical consequences of medical care to include ethical, economic and other social implications of the diffusion and use of a procedure, technique or medical practice (Banta & Perry, 1997). Within the context of HTA, the term "health technology" refers to any intervention used to promote health and prevent and/or treat disease. Thus, it may be a

specific preventive, diagnostic, or therapeutic procedure. HTA is concerned with the impact of health technology on health and quality of life as well as the social, ethical and economic implications for society as a whole. The goal of HTA, therefore, is to provide evidence for clinical and policy decision-making for the purpose of improving health of individuals and populations. Accordingly, HTA necessitates the use of multiple methods and has a focus on synthesis of the research evidence. For example, in addition to considering the evidence on efficacy and effectiveness, a typical HTA approach will consider economic evidence, the consumer perspective (e.g., patient preferences, informed decision-making), information on practice patterns (e.g., diffusion of medical innovation and practice variation) and ethical implications. Though there are some similarities between health technology assessment and program evaluation, program evaluation generally has a more limited focus on an intervention or program implemented at a particular place and time (Shadish, Cook & Leviton, 1995).

While HIV prevention interventions have been evaluated from a number of perspectives that encompass HTA (e.g., clinical, behavioral and economic), these evaluations have not previously been considered through the lens of health technology assessment. Given that public health officials have refocused HIV prevention efforts, additional approaches to evaluating these prevention interventions should be considered. This dissertation, therefore, uses a health technology assessment framework as a new approach to the evaluation of HIV prevention interventions. Incorporating elements of HTA, this dissertation employs a multi-method approach to evaluating HIV counseling and testing. These methods were chosen as they represent the core, necessary elements of health technology assessment: efficacy and effectiveness, cost-effectiveness, and the

consumer perspective.

Objective

The objective of this dissertation is to determine the effectiveness, cost-effectiveness and consumer perspective of technologies used in HIV CT and to assess the utility of the health technology assessment framework in informing policy decision-making for the prevention of HIV/AIDS. The specific aims are as follows:

1. Determine the effectiveness and efficacy of HIV CT methods and approaches used as alternatives (e.g., rapid testing, routine testing, non-invasive testing) to conventional testing in high-risk populations.
2. Determine the consumer perspective of HIV CT in the ER/UCC setting.
3. Determine the cost-effectiveness of routine HIV testing and rapid testing to promote receipt of HIV test results in a high-risk population in the ER/UCC setting.
4. Explore the use of an HTA framework for making policy decisions about HIV CT.

Literature Review

History of Health Technology Assessment

While conducting assessment and evaluation of medical interventions is not new, the field of HTA is only approximately 30 years old. HTA has its roots in the Office of Technology Assessment (OTA), as agency established to serve congress in 1972 which developed a health program in 1975 (Banta & Perry, 1997). This office produced many influential reports, including a report that demonstrated that the computed axial tomography (CAT) scanner diffused rapidly without being carefully assessed,

subsequently increasing health care costs. Many countries based policy decisions about CAT scanners on this report. Although Congress abolished the OTA in 1995, its legacy includes setting the stage for HTA by demonstrating the inadequacy of information on which decisions are based, identifying strengths and weaknesses of methods used to evaluate technology, and promoting the consideration of economic tradeoffs in decision-making (Houghton, 1995). Based on the OTA model, national and regional agencies of health technology assessment have flourished, particularly in Australia, Canada, Italy, the Netherlands, Sweden, and the United Kingdom. In these countries, HTA efforts are closely linked to policy making (Banta & Perry, 1997).

In the United States, however, HTA-related activities have become decentralized and diffused to many organizations, such as the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention (CDC). The "prevention effectiveness approach," which involves the scientific assessment of the impact of public health policies, programs and practices on health outcomes, has its roots in the assessment of medical technologies (Teutsch, 1992). Like HTA, the prevention effectiveness approach involves assessing the efficacy, effectiveness and the economic impact of health care, although it is specific to prevention and public health programs.

The emerging field of HTA was bolstered by the seminal work of Archie Cochrane, *Effectiveness and Efficiency: Random Reflections on Health Services*, in which he showed that decisions about allocating scare resources in health care should be driven by evidence for effectiveness (Cochrane, 1972). Accordingly, he advocated a coordinated effort to conduct the systematic reviews of randomized controlled trials to determine effectiveness and efficacy in health care. In 1992, the Cochrane Collaboration,

an international collaboration of researchers, was founded to promote informed decision making by preparing, maintaining, and disseminating systematic reviews on the effects of health care. Members of the collaboration are in the process of conducting reviews on virtually all important areas of health care (Cochrane Collaboration, 2001). Not surprisingly, the growth of the Cochrane Collaboration is linked to growth in HTA.

Elements of Health Technology Assessment

Health technologies vary by type (drugs, devices, procedures, informatics, educational interventions), stage of development or evolution, the level of the diffusion, and use of the technology (e.g., preventative or treatment); therefore, there are no set of processes that are considered a standard health technology assessment. However, Liberati et al. (1997) have identified some key elements of HTA (Liberati, Sheldon & Banta, 1997). These include:

- Description of the technology, including its state of development and diffusion and alternative technologies

The stage of development and diffusion of a technology provides context for the HTA. Accordingly, many HTAs include analyses of practice patterns and diffusion related to the technology and alternatives. Along with assessing practice patterns, it is also important to determine what factors determine use, such as patient factors (e.g., patient demand), provider factors (e.g., education), health system factors (e.g., formularies, reimbursement), and policy factors (e.g., laws and regulations).

- Evidence on efficacy, safety and effectiveness

Systematically reviewing the research on efficacy, safety and effectiveness is considered the core activity of HTA. Typically, this includes meta-analysis, in which

individual studies are pooled statistically. "Meta-analysis" is a term used to describe quantitative methods for the statistical combination of data from multiple studies (Glass, 1976). The purpose of meta-analysis is to synthesize existing research to make conclusions about a particular body of research, such as determining a summary estimate of the effects of an intervention and exploring reasons for differences in study findings. An assumption of meta-analysis is that each study provides a different estimate of the underlying relationship within the population. Thus, meta-analysis can be considered an analysis of summary statistics from primary studies to obtain an estimate of the effect in the population. In addition to determining effectiveness, an additional objective in conducting meta-analyses is to account for heterogeneity or variation among studies that influences the effect size. Potential sources of heterogeneity, also known as moderators or covariates include study design and characteristics, differences in treatment or control group, as well as differences in study settings or subjects and study quality.

Since HTA is designed to inform policy decisions, performance in routine practice should be established. Therefore, an important distinction is the difference between efficacy (performance in a controlled research setting) and effectiveness (performance in a non-controlled setting). Typically, health technologies have more favorable performance in a controlled research setting, where effect modifiers (e.g., resource constraints, provider differences, patient compliance) are minimized.

- Economic evaluation

Since there are limits on resources available for health interventions, they need to be considered in terms of their costs and consequences. Methods for economic evaluation include cost-benefit analysis, cost-effectiveness analysis and cost-utility

analysis. In cost-benefit analysis, the cost of an intervention is compared to improvement in health and other interventions and is measured in dollars. Cost-effectiveness analysis compares the cost of an intervention with improvement in health expressed in natural units (e.g., cost per case of HIV detected). Cost-utility analysis is a type of cost-effectiveness analysis where health improvements are expressed as life years saved, adjusted to reflect quality of life. Several excellent resources for conducting economic evaluation standards have been developed, including one specific to HIV prevention programs (Drummond, O'Brien, Stoddart & Torrance, 1997; Gold, Siegel, Russell & Weinstein,1996; Haddix, Teutsch & Corso, 2003; Holtgrave, 1998).

- Consumer Perspective

Health technologies should also be evaluated for their effect on psychological outcomes, such as quality of life, quality of well-being, consistency with consumer preferences and satisfaction. Social outcomes include changes in social relationships; for example, a technology that affects functional status may enable a patient to fulfill a care-giver role. Other social effects potentially include equity issues related to access and availability of the technology; for example, expensive technologies may only be available to those with personal resources.

- Effects on the organization of health services

Health technologies may affect the delivery of health services. Likewise, organizational factors may affect the delivery of health technologies. For example, a health technology may require changes in organizational structure (e.g., may affect clinical practice), personnel (e.g., the type of provider administering the health service or

training /in-service requirements) and other organizational aspects such as equipment needs and reimbursement.

- Ethical issues

Many types of ethical issues arise with health technologies. Among these are properly informing patients about risks and benefits of a technology (e.g., confidentiality issues), issues related to conflicts of interest (when the provider benefits from using the technology) and issues of who has access to the technology. Accordingly, HTA should describe ethical issues related to use of a health technology.

- Consider the perspectives of experts, users and others in reaching of judgments on the implications of the findings.

Finally, the value of a health technology can vary greatly from the perspectives of different stakeholders, including consumers, experts and providers. Accordingly, the HTA should consider these varying perspectives. In addition, issues relative to the utilization and diffusion of the technology (e.g., legal issues) should be considered.

The findings of this dissertation have the potential to provide a different lens through which HIV prevention interventions and possibly other public health interventions can be evaluated. In addition, it will illustrate the importance of multi-disciplinary evaluation for policy decision-making. While these methods are not new or specific to HTA, together they provide the multidimensional information necessary for policy decision-making.

Previous Research Using Elements of HTA to Assess HIV CT

Meta-Analyses in HIV/AIDS. A search for meta-analyses conducted October, 2001 in AIDSLINE illustrates that the majority of published meta-analyses of HIV

interventions have been focused on treatment interventions and behavioral risk reduction interventions. Of the 139 articles identified using the search terms meta, meta-analysis, testing, counseling, and HIV, there was only one meta-analysis of HIV counseling and testing interventions (Weinhardt, Carey, Johnson & Bickman, 1999). This study of 27 articles that included 13,243 participants in the primary analysis is widely cited in the HIV CT literature. However, it does have one major shortcoming. It inappropriately pooled data that were determined to be heterogeneous using a fixed-effects model. This meta-analysis, which used studies published between 1985 and 1997, only included sexual behavior related outcome (e.g., unprotected intercourse, condom use and number of sexual partners).

The HIV review group of the Cochrane Collaboration has recently published a protocol of their ongoing meta-analysis of HIV CT interventions. Like the Weinhardt meta-analysis, the objective of this meta-analysis is to review the effectiveness of HIV CT at lowering HIV risk behavior (Sweat, 2002). In addition, it does not include receipt of HIV test results or knowledge of serostatus among the study outcomes. Thus, there is a paucity of research syntheses around HIV CT. Furthermore, it is likely that there are no meta-analytic data on the effectiveness of HIV CT on the important outcome of knowledge of HIV status and there is no indication that those data are forthcoming. The fact that receipt of HIV test results has not been included as an endpoint in meta-analysis of HIV CT studies is, in itself, an important finding, as knowledge of HIV status along with behavior change are the goals of HIV CT (Phillips, Bayer, and Chen, 2003). Additionally, it implies that those data either do not exist in the primary studies or perhaps that patients who undergo HIV CT do in fact learn their HIV status, which is not

consistent with research on return rates for HIV test results (Molitor et al., 1999 and Tao et al., 1999). Accordingly, an objective of this dissertation is to fill this research gap and contribute to the evidence base on which the SAFE approach is premised.

Consumer Perspective. Consumer preferences for HIV CT programs influence on the decision to undergo HIV counseling and testing. Additionally, there are numerous settings and patient populations in which HIV CT interventions are conducted, as well as numerous HIV testing technologies that may be important in determining the acceptance and utilization of HIV CT interventions. Accordingly, consumer preferences should be assessed in the settings and populations in which they are to be implemented.

Though consumer preferences for HIV CT have been evaluated in some populations, no studies directly address preferences for innovative HIV CT interventions in an urban urgent care center serving a low-income population. Only a few published studies assess patient acceptability of the rapid testing procedure. In a recent study that elicited preferences for HIV test types among an at risk population in Philadelphia, PA, the two tests most preferred were not licensed in the U.S. for commercial use at the time of the study, the rapid saliva test and rapid finger stick test; while the serum test (most commonly available) was the least preferred (Eroglu, Lauby, Bond, Latesta & Peterman, 2000). Another study measured preferences for innovative HIV testing methods, including the rapid test, but was limited to an adolescent population (Peralta, Niel, Deeds, Lee & Kareem, 2001). Another study evaluated patient acceptability of a voluntary HIV screening program at a teaching hospital and found that patients generally held favorable attitudes towards the program (Harris, Boisaubin, Salyer & Semands, 1990). It is important to note, however, that there may be wide variations in preferences

in populations and within populations based on a number of different factors (e.g., education, gender, socio-economic status, religious beliefs); thus, it is important to elicit preferences in the population for which the intervention is to be applied. While some studies have explored patient acceptance of rapid testing in the emergency care setting, I am not aware of an in-depth qualitative study of HIV CT with routine and rapid testing in in the ER/UCC setting.

While it is important to assess consumer preferences and attitudes for the purpose of gaining insight into decision-making about HIV CT, it is important to note that preferences are only part of the decision-making process. Approaches to decision-making that are based in risk communication and address information identified to be important to decision-makers, such as the mental models approach, provide a more complete assessment of the complex process of decision-making (Morgan, Fishoff, Bostrom & Atman, 1997).

Economic Evaluation. There is a rich literature of economic evaluation of HIV prevention programs; however, there is great variation in the type of intervention (e.g., testing and counseling, behavioral), setting (e.g., acute care, drug treatment center), patient population (pregnant women, intravenous drug users) and method used for the economic evaluation. There are also several published reviews of this literature that evaluate the types of evaluations done, address the quality of the published studies and summarize cost and quality of life estimates for use in economic evaluation of HIV prevention programs (Holtgrave, Qualls, & Graham, 1996; Holtgrave & Pinkerton, 1997; Holtgrave 1998; Schrappe & Lauterback, 1998 and Tengs & Ting, 2002).

An important consideration of economic efficiency of an intervention is the circumstances surrounding the program, in particular the goals of the program, the prevalence of the disease in the population and the effectiveness of treatment interventions. In a review of 43 articles and chapters on HIV CT interventions, Farnham outlines the implication of program goals of HIV CT interventions on economic analyses (Farnham, 1998). For example, if primary prevention is the goal, high-risk uninfected persons should be targeted; however, if an intervention is intended to get patients into treatment early, then infected persons should be targeted. Likewise, there are differences between interventions in who receives the benefits from HIV CT. These range from people receiving CT, their partners (sexual or needle sharing), children (if female), health care providers, and society.

Though there are a large number of economic evaluations of HIV CT interventions, only a few directly relate to the use of innovative HIV CT strategies aimed at increasing knowledge of HIV status. The first study to evaluate the cost-effectiveness of rapid HIV testing used decision-analytic modeling to estimate the cost-effectiveness of rapid testing in publicly funded clinics and test sites (Farnham, Gorsky, Holtgrave, Jones & Guinan, 1996). The authors compared two different outcome measures: the overall number of people who correctly learned their serostatus and the HIV-infected clients who correctly learned their serostatus. They found that rapid testing was more cost-effective than the standard procedure when both HIV-positive and negative patients were correctly informed of their serostatus. In addition, they found that when test-positive patients were given their preliminary positive results during the clinic visit, the rapid test was more cost effective. However, when test-positive patients were given results after returning for

confirmatory testing, the rapid test was not more cost-effective. These authors raise the important issue of how to value an initial positive test in decision analysis. An additional study compared the cost of testing and cost per person receiving results for rapid testing and conventional testing in anonymous testing clinics and sexually transmitted disease clinics (Kassler, Dillon, Haley, Jones & Goldman, 1997). For both clinical settings, the cost per person receiving test results was lower for the rapid test than the conventional test. However, when only the provider perspective was considered, rapid testing was less cost-effective than conventional testing in the anonymous clinics.

There are also a few studies on routine, voluntary HIV screening in acute care settings and high prevalence populations. One such study prospectively looked at the cost and effectiveness of routine, rapid testing in an inner-city emergency department based HIV CT program (Kelen, Shahan & Quinn, 1999). The program cost per positive patient was about twice as much for rapid testing as for routine testing. However, the authors estimate that the program would detect an additional 200 infections per year and conclude that emergency department testing was well accepted among patients. An important aspect of this study is that the authors offered incentives to clients for returning for their test results that may affect the generalizability of these findings.

Two studies were identified that evaluated routine testing in hospital patients. Lurie et al. (1994) used decision-analytic modeling to evaluate the cost effectiveness of routine testing. The authors found that routine testing is generally more cost-effective in hospitals with relatively high HIV seroprevalence. For example, the annual cost per detection of HIV infection dropped 50% as the seroprevalence increased from 1% to 10% (Lurie et al., 1994). An additional study looked at the effect of routine testing in an acute

care hospital setting on downstream outcomes, length and quality of life. This study used a decision analytic approach with Markov modeling to determine costs and benefits over time as a cohort of patients move through different health states: asymptomatic infection, symptomatic infection, and AIDS (Owens, Nease & Harris, 1996). The authors found that voluntary screening in acute care settings in which the prevalence was greater than 1% was within the acceptable range of cost-effectiveness. However, cost-effectiveness was substantially affected by quality of life and by the degree to which persons identified as having HIV reduce risk behavior. This was the case because the screening program identified infected patients earlier than without the voluntary screening program; thus, the decrease in quality of life also occurs earlier.

HTA Methods Used to Assess HIV CT

Consistent with the HTA framework, this dissertation includes a multi-method approach used to evaluate new approaches to HIV CT. The elements of HTA employed include meta-analysis, cost-effectiveness analysis and qualitative assessment of the consumer perspective.

Meta-Analysis

I conducted meta-analyses to synthesize the current evidence on the efficacy and effectiveness of HIV CT interventions including newer approaches (e.g., rapid-testing or routine testing) in high-risk groups. The primary outcome of interest, receipt of HIV test results, has been previously unaddressed in published meta-analysis of HIV CT interventions. The meta-analysis includes both randomized controlled trials (RCTs) and non-randomized trials identified by a systematic search of the literature and by contacting experts in HIV CT. The primary effect measure is the reported receipt of HIV test results

and the secondary effect measure is the reported receipt of HIV test results for HIV positive measured in odds ratios. I statistically pooled the data using a random-effects model to account for heterogeneity (between-study differences that account for differences in the effect size).

Cost-Effectiveness Analyses

I conducted cost-effectiveness analyses to compare real policy options for HIV CT in the hospital emergency room/urgent care center (ER/UCC) setting using a decision-analytic model. The CEA is an incremental analysis of three HIV CT policy options: (1) conventional, risk-based ELISA testing, (2) routine testing using the ELISA test, and (3) routine testing using the rapid test. I evaluated two outcomes, the cost per client who received HIV test results and the cost per HIV positive client who received HIV test results. I used data from the following sources for parameters in my decision-analytic model: meta-analyses, single studies reported in the literature and unpublished data (e.g., final report of CDC funded study) of an HIV CT study in the UCC setting. For cost data obtained from the literature, I only included studies conducted in the US.

Qualitative Analysis of Focus Group Data

To obtain the consumer perspective on HIV CT in an urgent care setting, I used structured focus group interviews conducted during the pilot phase of a clinical trial of HIV CT in an urgent care center. The urgent care center was located in an urban public hospital serving a predominately low-income African American population in Atlanta, Georgia. There were six focus groups. For each gender there was a group of participants that (1) accepted routine rapid testing, (2) accepted routine ELISA testing and (3) who refused testing. I used iterative content analysis to analyze the data with three other

content analysts.

Using the results of the above methodologies, I have assessed the value of an HTA framework in informing policy decision-making for HIV prevention interventions. In doing so, I examine linkages among the three methods (meta-analysis, CEA and focus groups) and how each contributes to assessing HIV CT from a policy perspective. The findings of this study have the potential to provide a different lens though which public health interventions can be evaluated.

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ESSAY 1: A META-ANALYSIS OF THE EFFECTIVENESS OF ALTERNATIVE HIV COUNSELING AND TESTING INTERVENTIONS ON RECEIPT OF HIV TEST RESULTS

HIV prevention strategies that facilitate knowledge of serostatus are essential to HIV/AIDS prevention. HIV-infected individuals who are aware of their infection can undergo counseling to decrease the risk of HIV transmission and prevent the spread of HIV to uninfected individuals. Once identified, HIV-infected individuals can be referred for treatment such as combination antiretroviral therapy (ART) that can reduce transmission and HIV related morbidity and mortality (Janssen et al., 2001). HIV counseling and testing (HIV CT), therefore, is a critical first step toward prevention and early detection of HIV.

A significant issue in HIV CT is the fact that many clients undergo HIV CT, but do not receive their HIV test results. National surveys revealed that up to half of clients tested for HIV at publicly funded clinics do not return to the testing center for test results (Valdiserri, Holtgrave & West, 1999 and Tao, Branson, Kassler, & Cohen, 1999). Low return rates are common at sexually transmitted disease (STD) clinics and in some minority populations, and they vary among testing sites and populations tested (Keenan & Keenan, 2001).

Almost one-third of HIV-infected people do not know their HIV serostatus in the United States (CDC, 2001b). Accordingly, the CDC has set a goal of increasing the percentage of HIV-infected people who are aware of their status to 95%. The CDC's Serostatus Approach to Fighting the Epidemic (SAFE) emphasizes the need to promote testing and knowledge of serostatus and link HIV-infected clients to treatment and prevention services (Janssen et al., 2001). Therefore, evaluating the extent to which

different HIV CT strategies increase the rate at which clients receive HIV test results and post-test counseling may be critical to HIV/AIDS prevention.

There have been advances in HIV CT that address barriers to receiving HIV test results. These include new testing technologies and counseling protocols that are considered alternatives to conventional testing: confidential serum testing using enzyme-linked immunoassay (ELISA) and two-visit counseling (pre- and post-test) for individuals who have risk factors for HIV (risk-based testing). With conventional testing, clients must make a return visit to the testing center one to two weeks later for HIV test results. One such technology, rapid HIV testing, allows clients to get test results back in the same day, typically within two hours. Accordingly, the rapid testing approach has the potential to reduce and even eliminate the barrier of wait time and/or a return visit for test results and post-testing counseling. However, clients who test positive must return to the test site for confirmatory testing (e.g., the Western Blot test).

Other technologies such as oral fluid and urine testing are less invasive than serum testing and have been shown to increase client acceptability of testing (Summers Spielberg, Collins & Coates, 2000). The oral fluid test has been particularly useful in outreach settings such as bars, anonymous sex venues and needle exchange programs and may be reaching populations that would otherwise not be tested (Summers et al., 2000). Home testing, approved by the Food and Drug Administration (FDA) in 1996, allows clients to be tested anonymously in the privacy of their own homes. Home testing uses a dried blood (via finger stick) spot or oral fluid specimen; clients return the specimen to the testing laboratory by mail and receive results through telephone post-test counseling. It also reaches high-risk populations that would not otherwise be tested and is useful for

frequent testing of high-risk groups, though the lack of face-to-face counseling is a concern (Branson, 1998; Spielberg et al., 2000). Anonymous registration, though not new, is an HIV CT approach that addresses stigma and discrimination as barriers to HIV testing. There is evidence that clients seek out anonymous testing earlier than they would with traditional, confidential programs (Bindman et al., 1998). Alternative methods of post-test counseling, such as telephone post-test counseling have the potential to increase receipt of HIV test results because they eliminate the need for a return visit, though concern about the quality of post-test counseling remains.

There are also alternative approaches to testing that are designed to increase the number of high-risk people who get tested. For example, routine voluntary testing of persons at high risk is a population-based approach and an alternative to traditional individual, risk-based HIV CT. The routine approach reduces the barrier of clients who do not recognize their own risk for HIV by promoting testing. This approach is based on CDC recommendations that hospitals and clinics with a seroprevalence greater than 1% routinely recommend HIV testing to clients age 15 to 54 (CDC, 1993). While these recommendations have not been widely adopted by hospitals, routine testing has been frequently used in the emergency room setting, where risk-based testing is often not possible due to time constraints (del Rio et al., 2001, Kelen, Shahan, Quinn & the Project Educate Work Group,1999, Kroc et al., 2002).

Since people at risk for HIV are often at risk for other health problems, an additional strategy is to integrate HIV CT interventions with other health services, thus making it easier to receive testing. Examples of such settings include inpatient (hospital) settings, primary care clinics, emergency rooms and urgent care centers. These settings

are considered alternative settings for HIV CT which is usually conducted at sexually transmitted disease (STD) clinics or local health departments.

While these alternative approaches and methods of HIV CT are diffusing into practice, there is a need to assess their impact on clients' receipt of their HIV test results. Although empirical work on the subject has emerged in the past several years, there has been no comprehensive evaluation of this research. Meta-analyses have been conducted infrequently in HIV intervention research when compared to other areas of research (e.g., oncology) and only one meta-analysis was found on HIV counseling and testing interventions (Weinhardt, Carey, Johnson, & Bickman,1999). While this study produced important findings about the effectiveness of HIV CT in reducing HIV risk behaviors, it did not evaluate receipt of HIV test results. In fact, there are few comparative studies that evaluate this outcome. I, therefore, conducted meta-analyses to synthesize the existing research and determine summary estimates of the effectiveness (conducted outside a controlled trial) and efficacy (conducted in a controlled research setting) of HIV CT interventions at informing clients of their HIV serostatus and to explore reasons for differences in study findings.

Method

Systematic Review

I conducted a systematic search of the HIV counseling and testing (HIV CT) literature to identify articles for review. I searched the following databases from 1990 to September, 2002: AIDSline®, Medline®, Embase®, PsycINFO®, CINAHL®, and Sociological Abstracts®. I also conducted a hand search of the following journals: *AIDS*, *Journal of Acquired Immune Deficiency Syndrome*, and the *American Journal of*

Public Health from 1990 to Oct., 2002. In addition, I examined references of retrieved articles and searched abstracts of the *International AIDS* conference. I used the following eligibility criteria.

Inclusion Criteria:

1. Primary studies of voluntary HIV CT interventions must include the outcome of return for HIV test results.
2. Treatment group must include: routine, rapid, oral fluid, urine, home, anonymous testing or any testing approach or modality used as an alternative to serum ELISA testing with 2 visit pre and post-test counseling.
3. Studies must be randomized controlled trials (RCTs) or quasi-experimental designs with a control or comparison group. [The term "control group" is used to refer to the other study group in an experimental study, while the "comparison group" refers to the other study group in a non-experimental study ("control group" will be used to refer to control or comparison group)].
4. Published articles and abstracts must provide sufficient detail to calculate an effect size and included a description of the client population and study setting
5. Unpublished articles identified by experts in the field (e.g., CDC HIV researchers) are eligible for inclusion.

Exclusion Criteria:

1. Studies must not include non-voluntary HIV CT interventions, studies conducted in the peri-natal setting (related to pregnancy) and those related to infection of health care providers.
2. Studies must not be published in non-English language journals.

For the primary effect measure, I used the reported receipt of HIV test results that could also be measured as return for post-test counseling and HIV test results. For the secondary effect measure, I used the reported receipt of HIV test results for HIV-infected clients. I abstracted and coded eligible articles using a standard data abstraction form developed for this study (see Appendix A). I systematically collected the following data from each study: study design, outcome variables, a description of how the authors defined "receipt of HIV test results" (e.g., return for post-test counseling), a population description, the HIV prevalence rate, a description of the experimental and control groups, sample size, study setting, geographic location, data source, journal, publication date, study date, and additional items identified during the review. Since one article (citation) may present more than one study, I used the following criteria to clarify what is meant by an article and a study. If an article reported data from different populations in aggregate, I treated it as one study. If an article reported data separately for different populations and study settings, I considered it separate, independent studies. I used a Reference Manager® database to manage the citations and literature search. I used Excel® and STATA® for data analysis.

Meta-Analytic Methods

Estimation of Effect Size. The term "effect size" (ES) refers to the magnitude and direction of the intervention effect. Because these studies reported binary outcomes, the proportions of clients receiving their HIV test results, I used odds ratios (ORs) as the effect size measure. To calculate odds ratios, I entered data into 2x2 contingency tables consisting of the following cells: the number of clients in the (a), treatment group who returned for HIV test results (b), control group who did not return (c), control group who

did return for results and (d) treatment group who did not return, (OR) = [(ad)/(bc)]. If a 2x2 contingency table contained a value of zero, .5 was added to each cell so that an odds ratio could be calculated, as is standard practice in meta-analysis (Cooper and Hedges, 1994). An advantage of using odds ratios is that they are easily interpretable by most consumers of health and epidemiologic data. An odds ratio less than 1 indicates that clients in the intervention group were less likely to receive their HIV test results than the control group. An odds ratio of greater than 1 indicates that they were more likely to receive their results.

I used a DerSimonian and Laird random-effects model to calculate the pooled effect size (all studies together). In random effects models, the variance component for estimation of the effect size is composed of between-study and within-study differences. Random effects models are indicated when heterogeneity (between-study differences that account for differences in the ES) is suspected or known to be present. The formula for the DerSimonian and Laird method random effects model is:

$$\log_e OR_{dl} = \frac{\sum (w^*_i \times \log_e OR_i)}{\sum w^*_i}$$

where $\log_e OR_{dl}$ is the summary estimate of the odds ratio, w^*_i is the weighting factor for the ith study, ($w^*_i = 1/ 1/ \sigma^2_i$) and $\log_e OR$ is the log odds ratio from the ith study (Petitti, 2000).

Assessment of Heterogeneity. I used the Q statistic to test for heterogeneity, or between-study variation that is not attributable to sampling error variance. It tests the hypothesis that the true treatment effects are the same in all of the studies (homogeneity). Otherwise stated, it tests the assumption that all the studies to be combined are estimating

a single underlying population parameter. Under the null hypothesis, Q has a chi-square distribution with k-1 degrees of freedom, where k = the number of effect sizes. The null hypothesis is rejected when the p value exceeds alpha. A significant Q statistic indicates the presence of an effect moderator; however, it does not identify the moderator. Moderators are variables that influence the effect size. For example, study design characteristics can influence the effect size, but is not often a control variable. When there is evidence of heterogeneity, subgroup analysis (stratification) and meta-regression (both of which are described below) are conducted to further evaluate heterogeneity and identify moderators.

Subgroup Analysis. I used two methods to identify effect moderators and determine the robustness of the meta-analytic results. First subgroup analysis or stratification involves conducting the meta-analysis on sub-groups of studies and assessing differences in the pooled effect size in the subgroups. Subgroup analysis can also be used as a form of sensitivity analysis to test the robustness of the results. For example, the study with the largest effect size can be removed from the analysis to see if there is still a combined effect.

I used several moderator variables for subgroup analysis. Since the included studies were conducted in several study settings and return rates can differ by study setting, I used study setting as a moderator variable. The study settings included STD clinics and HIV testing sites that are typical settings for HIV CT. I also included alternative study settings such as the emergency room/ urgent care center (ER/UCC) setting or outreach settings. By outreach setting, I am referring to settings in which high-risk behavior might be practiced such as bath houses and needle exchanges.

I also used the type of HIV CT strategy as a moderator variable since they have different attributes that can differentially influence return rates. For example, rapid testing, telephone post-test counseling and home testing make testing more convenient and frequently eliminate a return visit to the testing center. Routine rapid testing increases the likelihood that a client is offered testing in addition to the added convenience of the rapid test. Oral fluid testing is less invasive than serum based testing and is considered more attractive to individuals who have a fear of needles.

I also included study design (RCT or non-experimental designs) as it can impact the effect size. It is widely held that it is more difficult to find an effect in an RCT than with other designs. There may, however, be differences in how interventions are delivered between designs, which can also systematically influence the effect. For example, if an intervention is not executed properly in a non-experimental study, there may be less of an effect.

Meta-regression. I used regression analysis (meta-regression) to examine the impact of the moderator variables on the pooled effect size. In meta-regression, the characteristics of the studies are used as explanatory variables in a linear or logistic regression model and the effect size is the dependent variable (Greenland, 1987). The unit of observation is the effect size. I used a random effects approach that incorporates both within-study and between-study variability (Berkey, Hoaglin, Mosteller & Colditz, 1995).

I conducted the analysis in STATA® using the "metareg command". Metareg is a weighted logistic regression with weights equal to two additive components of variance: variance between studies and variance within studies (Sharpe, 1997). The

method for estimating heterogeneity variance (τ^2) was restricted maximum likelihood (reml), the preferred method for estimating τ^2 (Thompson and Sharpe, 1999). The tau squared statistic measures the magnitude of between-study variance and can be considered an effect size for the Q statistic (Mullen, Ramirez, Strouse et al., 2002). Since the number of data points corresponds to the number of effect sizes (k) in meta-regression, there is a danger in over fitting the model if too many covariates are included in small meta-analyses (e.g., k=10) (Berkey, Hoaglin, Mosteller & Colditz,1995). Accordingly, I limited my meta-regression to a few key variables. I ran regressions with and without the covariates to determine the degree to which the different covariates reduce heterogeneity.

Sensitivity Analysis. I did a file-drawer analysis to evaluate publication bias, the tendency for studies with insignificant results not to be published. The file drawer analysis is conducted to estimate the number (also called the "fail-safe N") of studies with negative results that would undermine the conclusion (Rosenthal, 1979). I used the formula by Hedges and Olkin, $k_o=k(d^*d_c)/d_c$ where k is the number of studies included, d* is the effect size, and d_c is the effect size small enough to be considered negligible (Hedges and Olkin, 1985). The value for d_c was chosen to be .10 as consistent with other the recommendations of Hedges and Olkin. In general, a large fail-safe N gives credence to the results in the face of publication bias (Cooper & Hedges, 1994). I used a funnel plot, which plots treatment effect against their standard errors, to visually inspect for publication bias. If the plot reveals asymmetry around the treatment effect, particularly in the area of small studies with no effect, publication bias is suspected (Egger, Smith, Schneider & Minder, 1997).

Results

Systematic Review

The initial search generated 1,155 citations of studies of HIV counseling and testing interventions that included the innovative testing methods as described above and were published in 1990 or later. I also obtained a draft manuscript from an expert in HIV counseling and testing technologies. The majority of the studies were excluded because it was evident, after reviewing the titles and abstracts, that they not report return rates for HIV CT or include a control or comparison group. I identified twenty-two studies that reported return rates and conducted data abstraction. I excluded nine of these studies because they did not include a control group. Ten articles or abstracts met the inclusion criteria with a combined sample size of N=23,899.

These 10 articles included 13 different studies and 17 separate effect sizes (k), because they were conducted in different client populations and some studies included more than one comparison group. Table 1 includes a description of the included studies and Table 2, their effect sizes and study impact (effect size *weight) – the impact of a single study on the pooled analysis. These studies included data on HIV CT interventions conducted in two countries (USA & Uganda) in 5 different testing sites: emergency/urgent care centers (ER/UCC), sexually transmitted disease clinics, HIV information and testing centers and needle exchange programs and bath houses (needle exchanges and bath houses are referred to as outreach centers).

Table 1. Characteristics of Included Studies

Study	HIV CT Intervention	Setting	Demographic Characteristics	n	Study Design
1. Kassler et al., 1998	anon. rapid vs. anon. ELISA	AIDS Info Center , Uganda	African	6654	cohort
2. Kassler et al., 1997	anon. rapid vs. anon, ELISA	Anonymous Testing Center Dallas	not reported	1902	cohort
3. Kassler et al., 1997	rapid vs. ELISA	STD Clinic Dallas	not reported	2653	cohort
4. Kelen et al.,1999	routine rapid vs. routine ELISA	ER/UCC Baltimore	49% male 36% white 49% black	1449	RCT
5. Kroc et al., 2002	routine rapid vs. routine ELISA	ER/UCC Chicago	not reported	1500	cohort
6. del Rio et al., 01	routine rapid vs. routine ELISA	ER/UCC Atlanta	97% black	1839	cohort
7. Metcalf et al., 02	rapid vs. ELISA	STD Clinic Long Beach Denver Newark	54% male 51% black 22% white 18% Hispanic	3297	RCT
8. Spielberg A, (unpublished)	rapid vs. ELISA	STD Clinic Seattle	65% male 61% white 23% black 9% Hispanic	644	RCT
9. Spielberg B, (unpublished)	rapid vs. ELISA oral fluid vs. ELISA written coun./	Bath House Seattle	100% male 82% white 3% black 6% Hispanic	437	RCT
10. Spielberg C, (unpublished)	rapid vs. ELISA oral fluid vs. ELISA	Needle Exchange Seattle	71% male 71% white 11% black	324	RCT
11. Berger et al., 1999	anonymous vs. confidential ELISA	HIV Testing Center St. Louis	100% male 75% white 23% black	251	cohort
12. Schulter et al., 1996	telephone post test vs. ELISA	STD Clinic Denver	58% male 40% white 35% black	2491	cohort
13. Wickrema et al., 2002	home collection vs. "traditional C&T"	Needle Exchange Philadelphia	not reported	458	RCT

Table 2: Effect Sizes of Included Studies Ordered by Study Impact

Author	Setting/Intervention	LnOR(95%CI)	OR(95%CI)	Impact
Kassler et al., 1997	STD clinic, rapid	3.08(2.86-3.30)	21.76 (17.51-27.03)	1
Kelen et al., 1999	ER/UCC, routine rapid	1.67(1.42-1.91)	5.30 (4.15-6.77)	2
Schulter et al., 1996	STD clinic, telephone post-test	.56(.40-.72)	1.75 (1.49-2.05)	3
Metcalf et al., 2002	STD clinic, rapid	3.87(3.35-4.39)	48.04 (28.60-80.69)	4
del Rio et al., 2001	ER/UCC, routine rapid	.29(.08-.49)	1.33 (1.08-1.64)	5
Spielberg A (unpublished)	STD, clinic rapid	3.29(2.44-4.13)	26.71 (11.52-61.91)	6
Kassler et al., 1997	ATC, rapid	2.16(1.43-2.80)	8.68 (4.17-18.07)	7
Kroc et al., 2002	ER/UCC, routine rapid	9.09(6.29-11.88)	8,830 (537-145,038)	8
Spielberg, C1 (unpublished)	NE, rapid	1.30(.49-2.11)	3.67 (1.63-8.22)	9
Kassler et al., 1998	Uganda ATC, rapid	7.31(4.53-10.08)	1,489 (93-23,826)	10
Wickrema et al., 2002	NE, home-testing	.12(-.25-.49)	1.13 (.78-1.64)	11
Berger et al., 1999	ATC, anonymous	.24(-.44-.91)	1.27 (.65-2.49)	12
Spielberg, B1 (unpublished)	BH rapid	3.56(1.55-5.57)	35.16 (4.72-262)	13
Spielberg, C2 (unpublished)	NE oral fluid	.20(-.48-.87)	1.22 (.62-2.38)	14
Spielberg, B3 (unpublished)	BH, written pre-test	.07(-.55-.69)	1.08 (.58-2.00)	15
Spielberg, B2 (unpublished)	BH, oral fluid	-.09(-.67-.49)	.92 (.51-1.63)	16
Spielberg, C3 (unpublished)	NE, written pre-test	.90 (-1.65--.16)	.41 (.19-.86)	17

Ten studies examined rapid testing, two each used oral fluid testing, optional written materials for counseling and there was one study each on home testing, anonymous registration, and telephone post- test counseling (see table 2). Because two of the studies had more than one experimental arm, 17 effect sizes are included ($\underline{k}$=17). All of the studies had a control group consisting of ELISA testing; however, there were some differences in the approaches to counseling in the control group. The three studies conducted in the ER/UCC setting used routine testing in the experimental and control groups (the treatment group used routine rapid testing) (delRio et al., 2001; Kelen et al., 1999; Kroc et al., 2002). These are the only studies that reported using routine testing. Two studies reported using anonymous registration in both the experimental and control groups because it was the standard of care in the testing center (Kassler, Dillon, Haley, Jones & Goldman, 1997; Kassler et al., 1998). Three studies used telephone post-test counseling in the experimental and control groups, as it was the standard of care in these settings (needle exchange, bath house and STD clinic) (Spielberg, unpublished). The Spielberg article included three studies mentioned above: one in the STD setting (study A), one at a bath house (study B) and one at a needle exchange (study C). Two of the studies (B and C) reported different effect sizes for three separate interventions (rapid testing, oral fluid testing and optional written pre-test counseling) compared to one control group. Since the same control group was used for all three interventions within the study, the study weights were divided by 3, so that the overall weight of the study was not increased.

There were also differences in how the author measured the dependent variable, receipt of HIV test results, in the studies that described how this variable was measured.

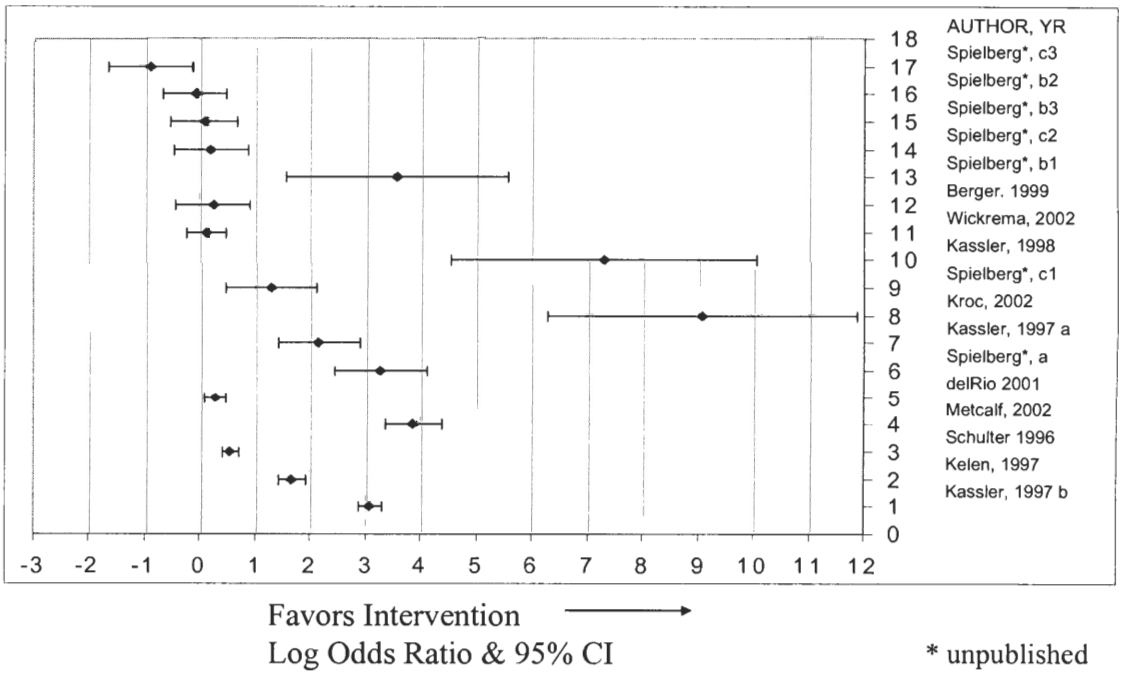
If a study reported that the client returned for HIV test results, I assumed that the client actually received their test results. One study used several methods to confirm receipt of results: medical record, testing log or CD4 test within 2 months (del Rio et al., 2001). Similarly, an additional study used medical records and a HIV testing logbook to document receipt of results within 45 days (Schulter et al., 1996). Others reported a time frame for measuring receipt of test results but did not describe how it was measured (Spielberg, unpublished; Schulter et al., 1996) and one study asked clients if they understood their HIV test results (Kassler et al., 1998).

These studies generally provided more detail on procedures for HIV testing than on HIV counseling. In most cases studies reported very brief information on pre- and post-test counseling. However, Berger Hong, Eldridge, Conner and Veddr (1999); Kassler (1997) and Metcalf et al., (2002) did provide detail on counseling procedures. Metcalf et al. (2002) used rigorous quality assurance to assess the counseling component of HIV CT, as the effect of counseling was the focus of the study. It is important to note, however, that three studies were only reported in abstract form or published conference presentations, so it is not surprising that these details were not reported (Kroc et al., 2002; Metcalf et al., 2002; Wickrema, et al., 2002). Information from the Metcalf study was supplemented by the study website, Project RESPECT (CDC, 2002b).

The individual effect sizes ranged from .41 to 8683 and are reported in Table 2 in odds ratios and log odds ratios and graphically in Figure 1 using odds ratios reported on a log scale. Looking at the individual effect sizes, rapid testing, routine rapid testing and telephone post-test counseling were most effective. There was also evidence for effectiveness for home-testing and anonymous testing. The evidence for oral fluid testing

and written pre-test counseling, which were used in outreach settings, was mixed and in some cases decreased return rates. Two studies that had 100% of clients in the treatment

Figure 1: Meta-Analytic Findings for Receipt of HIV Test Results Studies Ordered by Impact (LogOR*weight)



[1]Because of the large size of the ORs and CIs, data are reported on a $\log_e$ scale

group returning for HIV test results were outliers with results as follows: OR, 1489; 95% CI, 93.05-23,848.7 (Kassler, 1998) and OR, 8683; CI, 528.79-142,582 (Kroc et al., 2002). These odds ratios, which are difficult to interpret because of their magnitude, are not surprising given that there were no responses in one cell because all clients returned for their HIV test result in the treatment group and only 79% (Kassler et al., 1998) and 24% (Kroc et al., 2002) returned in the control group. The effect sizes were much larger

for rapid testing and studies conducted in the STD setting. The ER/UCC studies that used routine rapid testing also had relatively large effect sizes.

Meta-analytic Findings Outcome I: all clients

Table 3 includes the meta-analytic results for both the summary effect size and the subgroup analysis. Based on 12 studies and 16 effect sizes from a total sample of 23,648, the pooled odds ratios (OR) for receipt of HIV test results, in the intervention groups compared to control groups, was large in magnitude and significant

Table 3: Meta-Analytic Results

Studies	k[1]	N	OR (95% CI[2])	Q	τ^2	Study#[4]
Combined: All studies	16	23,648	6.10 (2.95-12.61)†	Q=677.48†	1.77	1-10, 12,13
Outliers Excluded	14	15,494	3.72 (1.79-7.74)†	Q=628.95†	1.64	2-45-10 12,13
Randomized Controlled Trail	10	6,151	6.62(2.22-19.77)**	Q=148.52†	1.93	4,5,7-10
Rapid Testing	10	20,278	22.11(7.76-63.01)†	Q=459.19†	2.27	1-10
HIV + clients	6	2,903	5.15(1.22-21.69)*	Q=27.43†	2.25	1-4,6,11
Stratified by Setting						
STD Clinic	3	15,739	14.67 (2.50-85.90)**	Q=431.16†	3.18	3,7,8,12
ATC	3	2,491	15.34 (1.48-159.28)*	Q=32.70†	3.67	1,2,11
ER / Urgent Care	3	4,788	10.32 (2.35-45.26)**	Q=104.6†	1.35	4,5,6
Outreach	7	1,470	1.12(.78-1.58)	Q=65.44†	.39	9,10,13

Significant at p<.05*, p<.01**,p<.001†

[1] k= the number of effect sizes

[2] CI, Confidence Interval

[3] τ^2, the tau statistic measures the magnitude of between study heterogenity and equals zero when studies are homogeneous.

[4] Study# - Study reference number in Table 1

(OR, 6.10; 95% CI, 2.95-12.61, p<.001)(Table 2, Figure 1). This effect size indicates that for alternative HIV CT methods, the odds of receiving HIV test results were 6 times as high as for those who received standard of care (typically ELISA with 2 visit counseling). There was highly significant evidence of heterogeneity (Q=677.48; p=<.0001), indicating considerable heterogeneity among the studies that should be evaluated with additional methods.

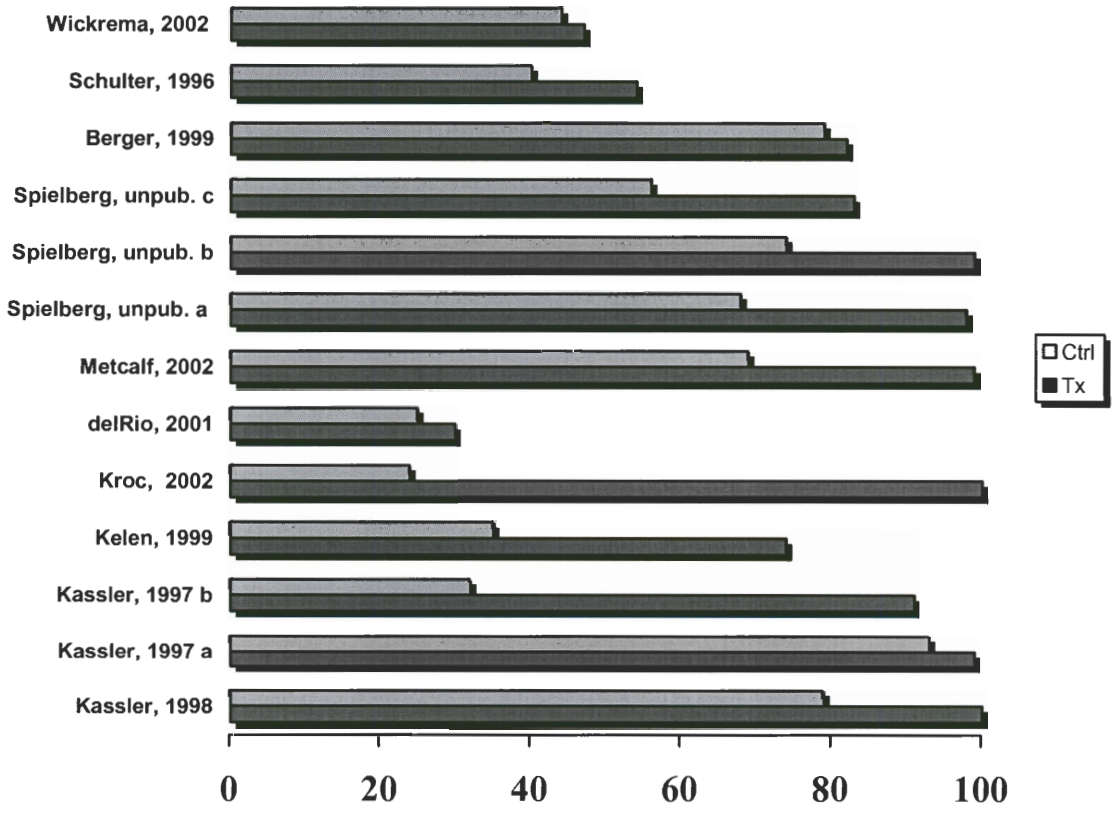
When looking at the average proportion of clients receiving their HIV test results for the included studies, 80% of clients received their results in the intervention group compared to only 54% in the control or comparison group and 89% of HIV-infected clients received their results in the intervention group compared to 68% in the control or comparison group (Figure 2).

Meta-analytic Findings Outcome II: HIV-infected clients

The effect was slightly smaller among the 6 studies that reported return rates for HIV-infected clients, OR, 5.15; 95% CI, 1.22-21.69; p<.05 (N=2,903). The Kassler et al., study (1998), conducted at an HIV testing center in Uganda with 100% of clients returning for HIV test results, had the largest effect size for HIV-infected clients: OR, 369.68; 95% CI, 23 - 5942.86 (Kassler, 1998).

The three studies conducted in the ER/UCC setting also reported outcomes for seeking treatment (e.g., first clinic visit) for HIV-infected clients. In the Kelen study, clients tested with routine rapid testing (55%) were no more likely to seek treatment than those in the control group (64%). Kroc et al. (2002) and del Rio et al. (2001) did find evidence clients in the treatment group were more likely to enter into care (83%

Figure 2: Percent Receiving HIV Test Results

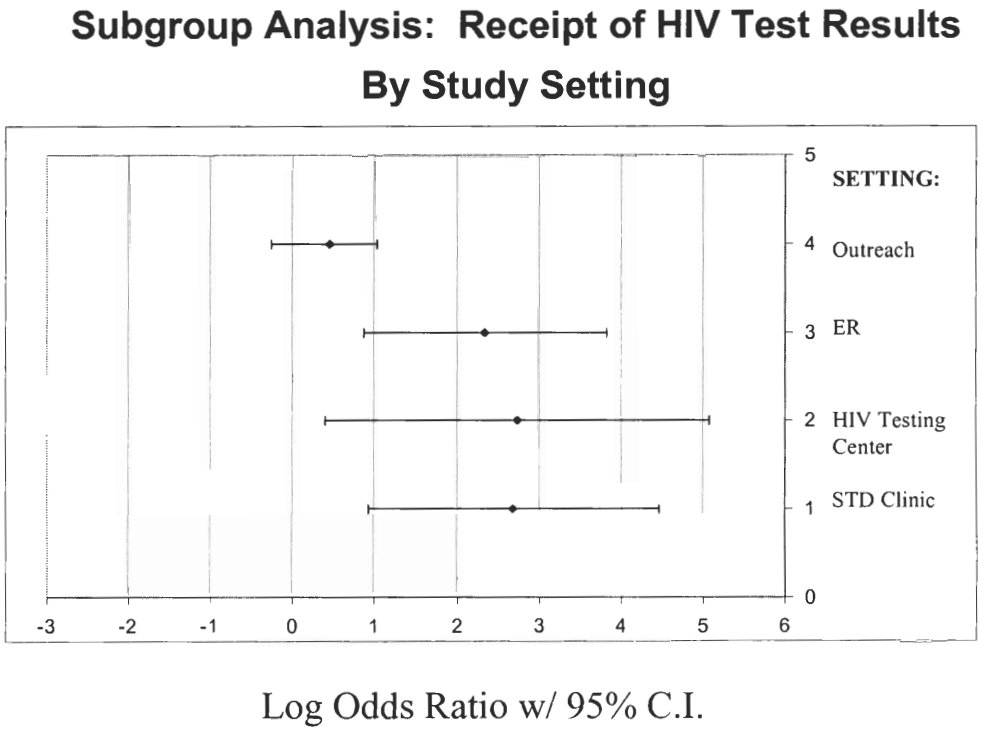


versus 77% and 67% versus 45%, respectively). Since there was variation in how the outcome was measured and it is possible that HIV-infected clients received care in a setting other than the study setting, I did not use entry into care as an outcome.

Subgroup Analysis

I conducted subgroup analysis to identify sources of heterogeneity. Studies conducted in the HIV testing (OR, 15.34; 95% CI, 1.48-159.28), STD setting (OR, 14.67; 95% CI, 2.50-85.90), and ER/UCC setting (OR, 10.31; 95% CI, 2.35-45.26) showed a stronger effect than those conducted in the outreach settings (OR, 1.12; 95% CI, .78-1.58) (Figure 3).

Figure 3: Subgroup Analysis – Receipt of HIV Test Results by Study Setting



The strongest effect was among the studies that used the rapid test (OR, 22.11; 95% CI, 7.76-63.01), indicating that the odds of clients receiving their HIV test results are 22 times higher using the rapid test compared to ELISA testing. I did not conduct subgroup analyses on demographic variables and other variables important to HIV CT (e.g., HIV risk group, acceptance of testing, content of HIV counseling) because these were not consistently reported across studies and were confounded by intervention and setting.

Meta-regression

I conducted the meta-regression to obtain a pooled estimate of the outcome and parcel out the heterogeneity associated with different covariates. The meta-regression measures the degree to which covariates explain between-study variance (τ^2). I tested

several meta-regression models and rejected them because they did not adequately explain between-study variance and were subject to confounding. These include a model that used study setting as a covariate that was confounded with the type of HIV test (e.g., all studies in the ER setting used the rapid test). The final model that explained most of the variance included one covariate, a dummy variable for the rapid HIV test that therefore yielded the same result for the subgroup analysis for the rapid test. It showed that after allowing for additive residual heterogeneity, the odds of receiving HIV test results were 22.03 times as high in studies that used the rapid test as those that did not (OR, 22.03 95% C.I., 1.41-4.77). In addition, τ^2 was reduced by over one half (from 5.4 to 2.5), when adjusting for the rapid test, so the rapid test explained approximately half of the between-study variation. However, adjusting for the rapid test did not account for all of the heterogeneity, as τ^2 was not zero, indicating remaining heterogeneity. The Q statistic in the subgroup analysis for the studies that used rapid testing was significant, also indicating heterogeneity. Given that there were four different study settings (ER/UCC, STD clinic, AIDS testing center, bath house) that used rapid testing, one would expect remaining heterogeneity among these studies.

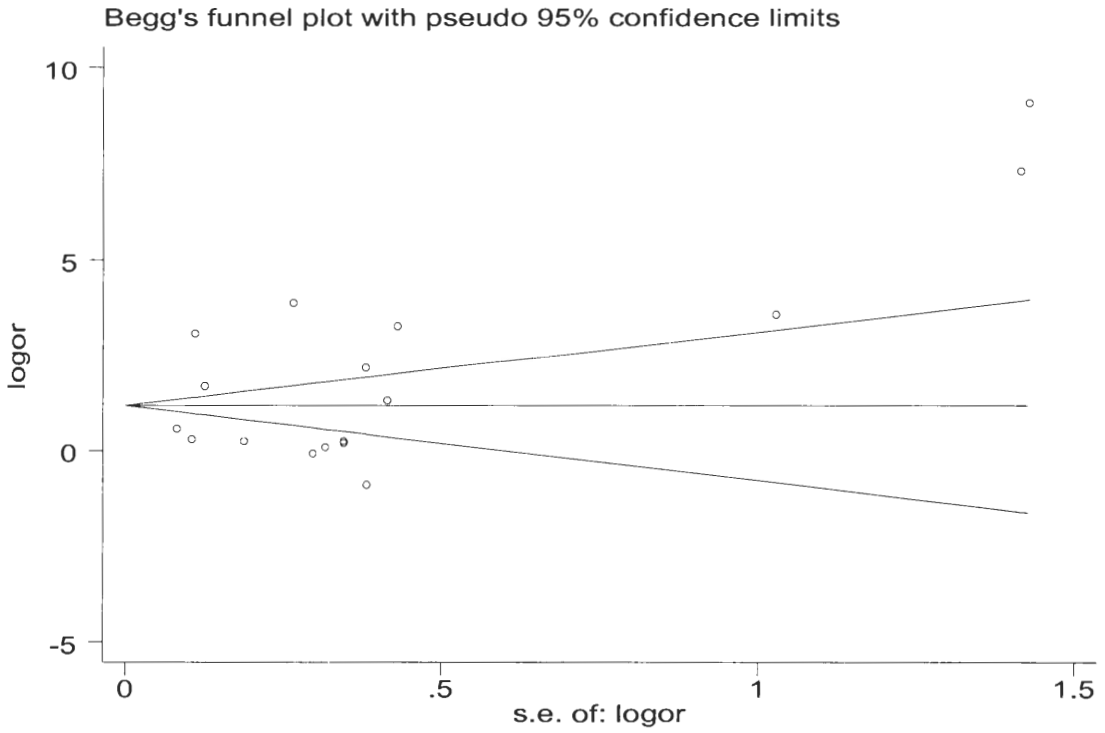
Sensitivity Analysis: Study Design

I conducted sensitivity analysis to test the effect of the two outliers by removing them from the analysis. The pooled OR was reduced by approximately one half, but still strongly in favor of the intervention (OR, 3.72; 95% CI, 1.79-7.74) (N=23,648) (Table 2). I also used sensitivity analysis to test the effect of study design. The pooled results for the RCTs were similar to the full model that included randomized and non-randomized studies (OR, 6.62; 95% CI, 2.22-19.77) (k=10; N=6,151).

Publication Bias

It is unlikely that these findings are due to publication bias as evident by the funnel plot of the effect size and their standard errors (figure 4). If publication bias were

Figure 4: Assessment of Publication Bias



present, one would expect to see more of a void in the right section of the funnel — the area low effect and high variance, where small studies with no effect would be found. This funnel plot is generally symmetrical in shape except for the outliers. Additionally, since the overall effect estimates are above zero, the effect of publication bias would likely be to inflate the effect size rather than lead to an incorrect about the existence of an effect (Steichen, 2001). The file drawer analysis also shows no evidence of publication bias. The Fail-Safe-N indicates that 2,408 studies with negative results would be

required to negate these findings.

Limitations

This meta-analysis, particularly the assessment of heterogeneity, was limited by variations and omissions in reporting key variables. Variation in reporting included important determinants of the effectiveness. For example HIV prevalence ranged from 1% (Metcalf et al., 2002) to 5.4% (Kelen et al., 1999) in the U.S. and was 24% in the Uganda study (Kassler et al., 1998) but was not consistently reported such that it could be used as a moderator variable. Some studies reported baseline prevalence and other reported prevalence for the study period and still others reported separate rates for the different HIV CT interventions (e.g., one for rapid testing and one for ELISA testing). The studies conducted in the ER/UCC setting were the only ones that consistently reported seroprevelance which averaged 3.71%; therefore it was not possible to make conclusions about an overall effect of seroprevalence of receipt of HIV test results (del Rio et al., 2001, Kelen, and Kroc et al., 2002). There were also differences in how studies reported acceptance of HIV testing. Some reported the percentage of clients who were offered testing and accepted testing, other studies reported the percent of clients that were eligible for the study and accepted and others reported the number of clients who completed testing. Additionally, similar to the meta-analysis conducted by Weinhardt et al.(1999) this group of studies generally did not report detail on counseling procedures and content, thus limiting my ability to more thoroughly investigate the impact of the counseling component. Since this analysis investigated the intermediate outcome of receipt of HIV test results, this omission is less important than if the goal were to investigate longer term, behavioral outcomes. Lack of consistency in reporting key

variables also adversely impacted the meta-regression since studies with missing covariates had to be dropped from the analysis.

This study is also limited by differences in incentives to return for HIV test results and how studies handled clients who do not initially return for post-test counseling and HIV test results. Many studies reported that HIV-infected clients who did not return were called and encouraged to return to the testing site; however, all of the studies did not report on this variable (Kassler et al., 1997; Kelen et al., 1999; del Rio et al., 2001; Metcalf et al., 2002). Two studies used more extensive methods to track down HIV-infected clients: one sent reminder letters and placed phone calls (Metcalf et al., 2002), while another reported field follow-up for HIV-infected clients (Kassler et al., 1997). The Kelen et al. (1999), study provided an economic incentive for returning for HIV test results — a $5 voucher at a local fast food outlet. It is the only study that reported an economic incentive for returning for HIV test results. All of the studies that reported whether or not clients had to pay for HIV tests offered the test for free as part of the study.

The characteristics of this population of studies have implications on generalizability. With the exception of the study conducted in Uganda, these studies were all conducted in metropolitan areas of the United States. Since all of the reported HIV prevalence rates were above 1%, the populations in which these studies were conducted can be considered at high risk for HIV infection. Accordingly, caution should be used when applying these findings to rural areas with low prevalence of HIV.

Discussion

This study is the first known meta-analysis of the effectiveness of alternative HIV CT that evaluates receipt of HIV test results. These results clearly demonstrate that alternative methods for HIV CT, particularly the rapid test, can lead to significant increases in the proportion of clients receiving their HIV test results. The size and significance of the pooled odds ratios were impressive even when outliers and non-randomized trials were excluded. This outcome was observed in many different HIV CT settings: STD clinics, emergency departments, HIV CT settings and in outreach settings (needle exchanges and bath houses) that used rapid testing. These results also demonstrated a significant effect of these technologies at increasing receipt of test results among HIV-infected clients. This is extremely important because a previous meta-analysis found that HIV CT is an effective means of secondary prevention for HIV-infected individuals who reduced their HIV risk behaviors and thus the probability of secondary transmission after receiving HIV CT (Weinhardt Carey, Johnson & Bickman, 1999).

Heterogeneity was also evident and significant in the pooled analyses and all of the subgroup analyses, indicating that the relationship between HIV CT and receipt of HIV test result is complex and may be determined by multiple factors. As is often the case in meta-analyses, sources of heterogeneity were not fully identified in this study. However, subgroup analysis and meta-regression did reveal significant effect modifiers. The largest effect was observed with interventions that included rapid HIV testing where the odds of receiving HIV test results were 22 times as high compared to ELISA testing. Subgroup analysis also revealed that these interventions were more effective in settings

where HIV testing is frequently conducted; STD clinics and HIV CT sites compared to emergency care and outreach settings. The interventions were also very effective in the ER/UCC setting. However, rapid testing was typically used in these settings, so the results are subject to confounding and should be interpreted with caution. There was almost no combined effect in the outreach setting that included needle exchanges and bath houses, in which case the OR was slightly greater than 1, but not significant. However, this analysis could have been confounded by the interventions used which included rapid testing, oral fluid testing and written pre-test counseling. For example, there was evidence that the rapid test was effective in these settings. The individual odds ratios in these settings for rapid testing were significant in the bath house (OR, 35.16; 95% CI, 4.81-270.6) and needle exchange (OR, 3.67; 95% CI, 1.63-8.25), which was not present in the same settings when oral fluid testing and written pre-test counseling was used.

There were also differences between the studies conducted in the same setting using the same HIV CT intervention. For example, all three of the studies conducted in the ER/UCC setting used the rapid test with the routine approach to testing, so the effects cannot be separated. However, differences in the execution of the studies may shed some light on the different effect sizes between these studies. A major difference is that one study (Kroc et al., 2002) used point-of-care testing in which clients were counseled, tested (including laboratory procedures) and had post-test counseling by the same study personnel at their point of care in the emergency room. Using this approach, 100% of clients received their HIV test results. Another difference was the laboratory used for HIV testing. In the study by Kelen et al. (1999), two different laboratories (located in the

hospital and the emergency room) were used, which resulted in different wait times and proportions of clients receiving their test results. When tests were conducted in the main hospital lab, 45% received their results with an average wait time of 107 minutes; in the emergency room satellite lab, 80% of clients received results with an average wait time of 48 minutes. Another difference is the wait time before the clients were offered testing. The study that was conducted in an urgent care center had excessively long (e.g., more than 6 hours) wait times before some clients were offered an HIV test; however the mean wait time was only 30-43 minutes longer than the other ER/UCC studies (del Rio et al., 2001). This may have contributed to the smaller effect size in this study compared to the other two emergency care sites. It could also indicate that urgent care centers should be considered organizationally different from emergency care centers.

While it is tempting to further investigate the sources of heterogeneity to produce more than an overall effect, there are dangers of over-interpreting data in meta-analysis. This is particularly a concern when data are clinically heterogeneous. Because these studies differ in client population, HIV risk group and baseline prevalence of HIV, there is extensive evidence of clinical heterogeneity. Since these variables were not reported in the same manner across studies, they cannot be investigated statistically. Accordingly, future meta-analyses should address the impact of these variables on the effectiveness of HIV CT interventions.

Summary

In summary, this meta-analysis demonstrates that alternatives to traditional two-visit, ELISA HIV CT can significantly improve receipt of HIV test results in variety of settings. Otherwise stated, conventional testing, the current standard of care, had the

least evidence for effectiveness. Rapid testing and routine rapid testing produced the strongest effect. Oral fluid testing and written pre-test counseling in outreach settings did not increase receipt of HIV test results. It appears that the interventions that eliminate the return visit for HIV test results are generally more effective at increasing return rates than those that facilitate pre-test counseling or are less invasive than serum testing. Given that some of these interventions have recently begun to diffuse into practice, this meta-analysis should be updated as new evidence and technologies emerge, for example the recently approved (by the Food and Drug Administration) finger stick rapid test that can provide test results in 20 minutes (CDC, 2002a).

This meta-analysis also provides direction for future research. A very small proportion of studies of HIV CT reported an outcome related to receipt of HIV test results; future studies should include this outcome as well as additional outcomes such as partner notification, entry into care and severity of disease for newly diagnosed clients. More details are needed on the content of pre and post-test counseling as well as adherence to CDC HIV CT guidelines. Finally, future studies should make an effort to be more thorough in reporting key variables related to HIV CT and how these variables were measured; for example, return rates / knowledge of serostatus, baseline prevalence rate, and eligibility and testing rates for HIV CT.

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ESSAY 2: THE COST-EFFECTIVENESS OF RAPID AND ROUTINE HIV COUNSELING AND TESTING STRATEGIES IN AN URBAN HOSPITAL EMERGENCY CARE SETTING

Emergency rooms (ERs) are becoming increasingly important in the identification of undiagnosed human immunodeficiency virus (HIV) (anonymous, 2002). Several studies have found that the prevalence of HIV is often higher in emergency care settings than other health care settings (Goggin, Davidson, Cantril, O'Keefe & Douglas, 2000; Kelen et al., 1989). In addition, emergency rooms and urgent care centers (ER/UCCs) often serve patients who lack a regular health care provider, so there is the potential to identify individuals that would otherwise not make contact with the health care system (Kelen, 1989; Rask, Williams, Parker & McNagny, 1994). New testing technologies and approaches to HIV counseling and testing (HIV CT), such as rapid testing and voluntary routine testing, may make HIV CT more attractive than the conventional risk-based approach (enzyme-linked immunosorbent assay [ELISA]) in the ER/UCC setting because screening for HIV risk factors and follow-up for test results in a busy ER are a major concern (Fincher-Mergi et al., 2002). HIV CT in the ER/UCC setting may therefore present an opportunity to identify HIV, provide linkages to treatment and provide counseling to prevent transmission of HIV.

Conventional HIV CT involves offering HIV CT based on risk factors and/or symptoms and testing using the ELISA test. Clients tested using ELISA must return to the testing center, typically in one to two weeks, for test results and post-test counseling. Reactive (positive) tests are followed by Western Blot, a high specificity confirmatory test. Rapid testing is an alternative testing technology for which test results are available in one to two hours, so in most cases, clients learn their HIV status in the first visit (CDC

1998). Clients who test positive on an initial rapid test are tested with Western Blot (in some cases this is preceded with ELISA); however, they are told their "preliminary positive results" and receive some post-test counseling. Similar to ELISA, clients must return to the testing center for confirmatory test results and additional post-test counseling. Routine HIV CT is an alternative in which clients (typically age 15-55) are routinely offered voluntary testing in populations with a high (greater than 1%) prevalence of HIV (Janssen et al., 1992; CDC, 1993). This approach is advantageous because clients may not divulge risk factors and/or clinicians may not recognize HIV risk factors or have time to offer testing (Wenrich, Carline, Curtis, Paauw & Ramsey, 1996).

While there is evidence that these alternatives to HIV CT are effective at identifying HIV-infected clients and informing clients of their serostatus in the ER setting, information is lacking for clinicians and policy makers to determine the economic value of implementing such programs (Hutchinson, 2003). Given the resource constraints for HIV prevention interventions, public health decision-makers must obtain information on how dollars invested compare to outcomes achieved and how to decide between several effective interventions for a given health problem. Cost-effectiveness analysis (CEA) addresses both of these issues by comparing the cost of an intervention to outcomes achieved. It typically compares the cost and outcomes of one intervention to an alternative that may be the standard or care or no intervention.

Previous studies have demonstrated that HIV CT using rapid testing or the voluntary routine approach is more cost-effective in clinical settings (Phillips & Fernyak, 2000; Owens, Nease & Harris et al., 1996; Farnham Gorsky, Holtgrave, Jones & Guinan, 1996). In the emergency room setting, costs have been characterized by Kelen, Shahan,

Quinn & the Project Educate Work Group (1999) in a study of voluntary routine rapid HIV testing; however, this study was primarily an effectiveness study and not a full cost-effectiveness analysis. With the exception of the latter, most HIV CT studies in hospital settings are model-based studies that were not conducted in conjunction with actual HIV CT interventions (Farnham, Pinkerton, Holtgrave & Johnson-Masotti, 2002). The purpose of this study is to examine the cost-effectiveness of three approaches to HIV CT in the ER setting: conventional testing, routine ELISA testing and routine rapid testing using cost and effectiveness data from interventions conducted in this study setting.

Method

I developed a decision-analytic model to evaluate the three HIV CT policy options in hospital ERs/UCCs. The CEA is an incremental analysis comparing conventional testing, the standard of care comparator, to ELISA testing using a routine approach and rapid testing using a routine approach. I include the following outcomes: cost per person who received HIV test results and cost per HIV-infected person who received HIV test results. I conducted the analysis from the provider perspective (e.g., public hospital) and the societal perspective in which I included all costs (e.g., productivity losses) and health effects. I adjusted all cost data to 2002 U.S. dollars for analysis and reporting using the Consumer Price Index (U.S. Department of Labor, 2003).

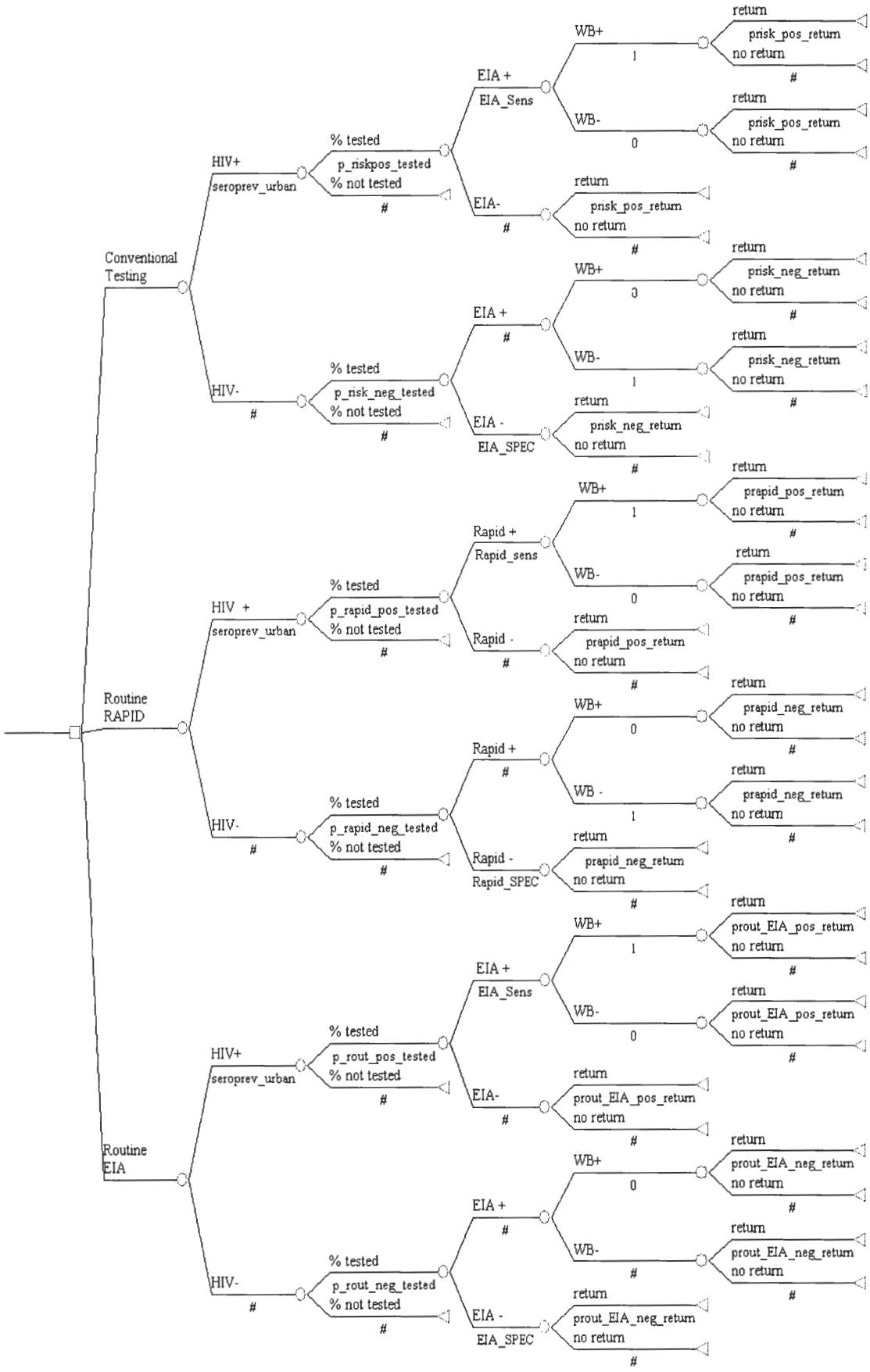
The CEA follows the reference case suggested by the U.S. Panel on Cost-Effectiveness in Health and Medicine or PCEHM (Gold, Siegel, Russell & Weinstein, 1996). The PCEHM reference case provides an explicit set of rules for conducting cost-effectiveness analyses. Rules associated with the PCEHM reference case include: 1)

discounting costs and health outcomes using a 3% discount rate, 2) including all relevant costs in the analysis, such as intervention and program costs, costs of averted illness and injury, 3) conducting sensitivity analysis to evaluate parameter uncertainty 4) using the societal perspective and 5) converting outcomes to quality adjusted life years (QALYs) where applicable and feasible. There are some aspects of the reference case that do not apply to this model: discounting is not applicable because future costs and outcomes (beyond one year) are not included and the use of final outcomes was not appropriate (see page 6).

Decision Analysis Model

To develop the decision model and conduct the analysis, I used DATA 4.0 software (Treeage, Inc.). The decision tree includes data on the probability of events occurring in the model (e.g., receiving HIV test results) as well data used to value the consequences (costs of HIV testing) (Figure 5). For effectiveness data, I used meta-analyses and single studies reported in the literature. I used published and unpublished data (e.g., final report of CDC funded study) of HIV CT studies in the ER/UCC setting for cost data. For cost data obtained from the literature, I only included studies conducted in the US study setting. The three decision branches represent three HIV CT strategies: conventional testing, routine testing using the ELISA test and routine testing using the rapid test. I did not include risk-based rapid testing as a screening strategy, because after systematically searching the literature, I did not identify published

Figure 5: Basic Decision Analytic Model


Conventional Testing
HIV+
seroprev_urban
% tested
p_riskpos_tested
% not tested
#
EIA +
EIA_Sens
WB+
1
return
prisk_pos_return
no return
#
WB-
0
return
prisk_pos_return
no return
#
EIA-
#
return
prisk_pos_return
no return
#
HIV-
#
% tested
p_risk_neg_tested
% not tested
#
EIA +
#
WB+
0
return
prisk_neg_return
no return
#
WB-
1
return
prisk_neg_return
no return
#
EIA -
EIA_SPEC
return
prisk_neg_return
no return
#
Routine RAPID
HIV +
seroprev_urban
% tested
p_rapid_pos_tested
% not tested
#
Rapid +
Rapid_sens
WB+
1
return
prapid_pos_return
no return
#
WB-
0
return
prapid_pos_return
no return
#
Rapid -
#
return
prapid_pos_return
no return
#
HIV-
#
% tested
p_rapid_neg_tested
% not tested
#
Rapid +
#
WB+
0
return
prapid_neg_return
no return
#
WB -
1
return
prapid_neg_return
no return
#
Rapid -
Rapid_SPEC
return
prapid_neg_return
no return
#
Routine EIA
HIV+
seroprev_urban
% tested
p_rout_pos_tested
% not tested
#
EIA +
EIA_Sens
WB+
1
return
prout_EIA_pos_return
no return
#
WB-
0
return
prout_EIA_pos_return
no return
#
EIA-
#
return
prout_EIA_pos_return
no return
#
HIV-
#
% tested
p_rout_neg_tested
% not tested
#
EIA +
#
WB+
0
return
prout_EIA_neg_return
no return
#
WB-
#
return
prout_EIA_neg_return
no return
#
EIA -
EIA_SPEC
return
prout_EIA_neg_return
no return
#

reports of that strategy being used in the ER/UCC setting. The economic summary measures included are the average cost-effectiveness ratio (ACER) and the incremental cost-effectiveness ratio (ICER). The average CE ratio is: net program cost / total health outcomes prevented. The incremental cost-effectiveness ratio is the ratio of the difference in costs between programs to the difference in health outcomes: (net cost program$_1$ – net cost program$_2$) / (health outcomes$_1$ – health outcomes$_2$). Incremental analyses are generally preferred in CEA; however, average analyses are appropriate when a no-program comparison is a feasible option (Gold et al., 1996). Since there is evidence that some ERs are not conducting HIV CT, an average analysis is appropriate (Fincher-Mergi et al., 2002).

Outcomes Measures. Similar to a previous cost-effectiveness analysis of HIV CT interventions, I considered the following intermediate health outcomes: receipt of correct HIV test result and receipt of correct HIV test result by an HIV-infected person (Farnham et al., 1996). The different outcomes have different implications relative to goals of HIV CT interventions, the identification of HIV cases and behavioral risk reduction. Including the cost per person identified as an outcome regardless of serostatus recognizes that screening brings value to uninfected clients by influencing risk-taking behavior (Higgins et al., 1991; Wegner, Linn, Epstein & Shapiro, 1991). Conversely, using the identification of HIV-infected clients as an outcome places value on linking HIV-infected clients to treatment and risk-reduction counseling to prevent the transmission of HIV. In a decision-analytic model, health outcomes or effects are assigned values (called pay-off values) between 0 and 1 (Table 4). For persons that received their correct HIV test

Table 4. Decision Model Probabilities and Pay-off Values

Probabilities	Base case Value (range for sensitivity)	Reference
HIV Seroprevalence	3.71	del Rio (2001), Kelen (1999), Kroc (2002), Groggin (2002)
ELISA Sensitivity	.988 (.984-.992)	Kowalski (2001)
ELISA Specificity	.989 (.989-.990)	Kowalski
Rapid Sensitivity	1.00 (.999-1.00)	Kelen, Kroc, Keenan (2001)
Rapid Specificity	.996 (.989-.998)	Kelen, Kroc, Keenan
WB Sensitivity	1.0	Farnham (1996)
WB Specificity	1.0	Farnham
Conventional Testing:		
Return HIV +	.60	del Rio,
Return HIV -	.25	del Rio, Kelen, Kroc
Routine ELISA:		
Return HIV +	.73	del Rio, Kelen, Kroc
Return HIV -	.25	del Rio, Kelen, Kroc (assumption)
Routine Rapid:		
Return HIV +	.85	del Rio, Kelen, Kroc
Return HIV + for WB	.81	Kelen, Kroc
Return HIV -	.67	del Rio, Kelen, Kroc
% Tested conventional testing	.07 (.035-.105)	del Rio
% Tested routine ELISA	.14 (.085-.225)	del Rio (assumption)
% Tested routine rapid	.27 (.135-.405)	Kroc
Pay-off Values		
Return for HIV test results: correct information	1.0	Farnham
Return for HIV test results: incorrect information	0	Farnham
Value of preliminary + rapid test	.99 (0-1.0)	Farnham

result, I assigned a value of "1". For persons that did not receive their test results or received an incorrect result, I assigned a value of "0". For the outcome of HIV-infected clients only, I assigned a "0" for an HIV negative person that receives their test result.

Following Farnham et al.(1996), I assigned a value of .99 for the individual who receives a "preliminary positive" HIV test result using rapid testing but did not return for confirmatory HIV test results and conducted sensitivity analysis on this parameter. The justification for valuing a preliminary positive rapid test result as almost equivalent to a confirmed positive is that post-test counseling is conducted for a preliminary positive client and the sensitivity and specificity of the rapid test is greater than 99%.

Following the PCEHM, I endeavored to include final health outcomes, life years saved and QALYs, in the model. Since my model is based on actual effectiveness data from HIV CT interventions, I searched for epidemiological evidence that the different HIV CT strategies in the ER/UCC setting lead to different final health outcomes, rather than make assumptions about effectiveness. The only data available that potentially link intermediate to final outcomes was CD4 t-cell count (a disease severity measure) reported by del Rio et al. (2001). In this study, a larger proportion of clients had a CD4 count >200 cells/μL, indicating that HIV infection had not progressed to acquired immunodeficiency syndrome (AIDS), using the routine approach compared to the risk-based approach. The difference, however, was not significant and the comparator was a historical control with different periods of measurement. Since I did not consider this evidence that the different strategies are causally linked to different health outcomes, I did not consider final outcomes appropriate for this model.

Model Probabilities. Model probabilities and data sources can be found in table 4. The first chance node is the probability a person tested is HIV infected which is modeled as HIV seroprevalence. I used a seroprevalence of 3.71%, averaging over four studies conducted in the ER/UCC setting in urban public hospitals and evaluated it with

sensitivity analysis (del Rio et al., 2001; Goggin et al., 2000, Kelen et al., 1999; Kroc et al., 2002).

The second chance node is the probability a client presenting to an ER/UCC who is eligible for testing is actually tested (number tested/number eligible). The two studies that reported eligibility had slightly different definitions: age 18-65 with unknown serostatus (del Rio et al., 2001) and age 18-60 (Kroc et al., 2002); however, the proportions of visits that were eligible were comparable (82% and 85% respectively). Most decision-analytic models use the proportion of clients tested who were offered testing for this chance node. However, an important difference in the routine versus risk-based approach is that more clients should be offered testing under the routine strategy. To capture the effect of routine testing, I used the proportion of eligible clients who were tested. I used data from Kroc et al. (2002) for the routine rapid testing arm and del Rio et al. (2001) for the risk-based and routine ELISA arms. The proportion of eligible clients tested was .27 for routine rapid testing and .07 for conventional testing (Kroc et al., 2002; del Rio et al., 2001). Del Rio et al. (2001) reported the proportion of eligibles tested (.17) for routine ELISA and routine rapid together, so I adjusted the routine ELISA arm downward by three tenths of a percentage point to account for a lower testing rate for the routine ELISA test (.14) and included it in sensitivity analysis. None of the studies reported the proportion of eligibles tested by HIV serostatus, so I made the assumption that participation rates did not differ by serostatus for base case analysis. Since participation rates may vary by serostatus and can have a significant impact on cost-effectiveness, I used sensitivity analysis to investigate the impact of differential participation rates (Paltiel & Kaplan, 1997). For each HIV CT strategy, I varied the

participation rate (proportion of eligibles tested) plus or minus fifty percent of its value.

The next two chance nodes represent the accuracy of the HIV test followed by the accuracy of the confirmatory Western Blot test. Since all of the studies used the ELISA test by Abbot, I used sensitivity and specificity estimates from a meta-analysis of the Abbot ELISA test for the initial ELISA test (Kowalski, Tu, Jia & Pagano, 2001). For the initial rapid test, I used average sensitivity and specificity data from the two ER/UCC studies (1.00 and .996, respectively) (Kelen et al., 1999; Kroc et al., 2002). For the next chance node, confirmatory testing with ELISA and the Western Blot, I used 1.0 for sensitivity and specificity. This is consistent with previous cost-effectiveness analyses that consider confirmatory testing sequences a perfect test in decision analysis (Farnham et al., 1996; Phillips & Fernyak, 2000).

The final chance node is the probability of a client returning for HIV test results and post-test counseling. Since return rates vary by type of HIV test and the client's serostatus, I used different return rate parameters based on serostatus and testing strategy. The probabilities I used were average return rates for the ER/UCC studies: for routine ELISA testing, the average return rates were 73% for HIV-infected clients and 25% HIV-uninfected and for routine rapid testing, the average return rates were 85% for HIV-infected clients and 67% for HIV-uninfected clients (del Rio et al., 2001; Kelen et al., 1999; Kroc et al. 2002). Only one study reported return rates for conventional testing and it was only for HIV-infected clients (60%) (del Rio et al., 2001); therefore, I used the return rate reported for routine ELISA testing for the HIV negative arm and evaluated return rates in sensitivity analysis.

Cost Data

I obtained cost data from published and unpublished reports of HIV CT interventions that used rapid and routine testing in the ER/UCC setting (Kallenborn, Price, Carrico & Davidson, 2001; Kelen et al., 1999 and Mugalla, 2002). Consistent with previous cost-effectiveness analyses of HIV CT interventions, I assume that hospitals already have the ability to conduct HIV CT; thus fixed costs were not included and cost estimates are the incremental costs of the different HIV CT strategies (Farnham et al., 1996; Phillips & Fernyak, 2000).

Table 5 shows costs incorporated into the model divided into price and quantity components. For laboratory costs and processing, I used data by Kallenborn et al. (2001) that includes labor costs, test supplies and disposables. To calculate client time to take the test, which can be considered a type of productivity loss, I used data on the median earnings of all workers and incorporated a fringe benefit rate of .224 (Haddix, Corso and Gorsky, 2003; Denavas-Walt & Cleveland, 2001; Grosse, 2003). With a salary plus fringe of $27,969.62, assuming a 250-day work year, I calculate an hourly productivity loss of $13.98. For pre-test counseling, I averaged the wage rate and time estimates reported when pre-test counseling was conducted by a physician and phlebotomist or a health educator (Mugalla, 2002; Kelen et al., 1999). For post-test counseling costs, I used the average estimates reported by Kelen, Mugalla and Phillips. Post-test counseling costs differed by test result: the average cost for post-test counseling an HIV-infected individual was $15.75, while an HIV negative individual was $3.75. I calculated productivity losses for pre-test counseling and post-test counseling and wait time for the rapid test results

Table 5: Resource Inventory

Description	# of units/ hours	Cost used /hourly wage rate	Cost per client ($)	Reference
Laboratory Costs				
Laboratory cost and processing: ELISA- (labor, test supplies and disposables)			12.98	Kallenborn, 2001
Laboratory cost and processing: ELISA+ (2 ELISAs and Western Blot)			78.47	Kallenborn
Laboratory cost and processing: Rapid – (labor, test supplies and disposables)			28.50	Kallenborn
Laboratory cost and processing: Rapid+ (rapid, ELISA and Western Blot)			93.98	Kallenborn
Western Blot			51.48	Mugalla,
Counseling Costs				
Pre-test counseling				
MD +	.02	50	1	Mugalla, 2002
Phlebotomy	.05	12.5	.63	Mugalla
or Counselor	.33	20	6.6 (4.94)	Kelen, 1999
Post-test counseling HIV +	.63 (.5-.75)	25	15.75	Kelen, Mugalla, Phillips
Post-test counseling HIV-	.15 (.13-.17)	25	3.75	Kelen, Mugalla, Phillips, 2000
Follow up on no returns HIV+	.25	25	6.25	Kelen
Follow up on no returns HIV-	.08	25	2	Kelen
Risk-based approach	1 minute 5 minutes	1.36 (min)	1.36 (1.36-6.8)	Phillips, DiFrancesco (2003)
Administrative services and materials			2.98	Mugalla
HIV-				
HIV +			3.35	Mugalla
Client Time (productivity losses)				
Pre-test counseling – all	.33	13.98	4.61	Kelen & Mugalla
Post-test counseling: rapid HIV-	.15 (.13-.17)	13.98	2.10	Kelen & Mugalla
Post-test counseling: rapid HIV+	.63 (.5-.75)	13.98	8.81	Kelen & Mugalla
Client wait time – rapid results	125.6	13.98	29.22	Kelen, del Rio, 2001, Kroc, 2002
Client wait time + travel time return visit	1.5-7 hrs	13.98	27.96 (27.96-97.86)	Farnham, 1996 Hutchinson, 2003
ELISA or Rapid (test positive clients)				

using counseling time data reported by Kelen and Mugalla. To calculate productivity losses due to return visit wait time and travel time, I used estimates used by Farnham et

al. (1996) as well as focus group data that included information on wait time in the UCC setting (Hutchinson, 2003). I also included costs for administrative services (e.g., clerical support – data recording and entry) which varied by sero-status (HIV-infected,$3.35 and HIV-uninfected, $2.98) (Mugalla, 2002) and counselor costs for follow-up on HIV-infected ($6.25) and HIV-uninfected clients($2.00) who did not return for their HIV test results (Kelen et al., 1999). Finally, I included the cost of a risk-based approach to testing based on 5 minutes of physician time ($6.80), but included it in sensitivity analysis for less than 1 minute based on anecdotal reports of the risk-based approach (Philips & Fernyak, 2000; di Francesco, 2003).

Table 6 shows net societal cost by type of HIV test for HIV-infected and uninfected individuals that received their HIV test results. For an HIV-uninfected individual under the conventional, risk-based ELISA strategy, net costs include the costs of an ELISA test, pre-test and post-test counseling, administrative services and materials, productivity losses for pre-test and post test counseling and client wait and travel time. For an HIV-infected individual, I added the cost of an additional ELISA and Western blot test, costs associated with longer post-test counseling for the health educator/counselor and associated productivity losses. For conventional testing, I added the cost of risk screening. The net societal cost of an HIV-uninfected client who received HIV test results with conventional testing was $65.62 and HIV-infected client was $149.69. The net societal cost under the routine ELISA (as was the practice in the included studies) strategy for an HIV negative and positive individual that received HIV test results was

Table 6. Net HIV CT Cost for a Client Receiving HIV Test Result Societal Perspective

Type of HIV Test	Routine Approach	Risk-Based Approach	Source
ELISA +			
laboratory costs and processing	$77.47	$77.47	Kallenborn, 2001
pre-test counseling	$4.94	$4.94	Kelen, 1999 & Mugalla (2002)
post-test counseling	$15.75	$15.75	Mugalla, 2002
administrative services & materials	$3.35	$3.35	Mugalla
client time pre-test counseling	$4.61	$4.61	Kelen & Mugalla
return visit wait/travel time	$27.96	$27.96	Farnham,1996& Hutchinson, 2003
client time post-test counseling	$8.81	$8.81	Kelen & Mugalla
risk-based approach	N/A	$6.80	Phillips (2002)
Net Cost:	$142.89	$149.69	
ELISA-			
laboratory costs and processing	$12.98	$12.98	Kallenborn
pre-test counseling	$4.94	$4.94	Kelen & Mugalla
post-test counseling	$3.75	$3.75	Mugalla
administrative services & materials	$2.98	$2.98	Mugalla
client time pre-test counseling	$4.61	$4.61	Kelen & Mugalla
return visit wait/travel time	$27.96	$27.96	Farnham, Hutchinson
client time post-test counseling	$2.10	$2.10	Kelen & Mugalla
risk-based approach	N/A	$6.80	Phillips
Net Cost:	$58.82	$65.62	
Rapid HIV+	Routine		
laboratory costs and processing	$92.96	----	Kallenborn
pre-test counseling	$4.94	----	Kelen & Mugalla
post-test counseling	$15.75	----	Mugalla
administrative services & materials	$3.35	----	Mugalla
Client wait time for rapid results	$29.22	----	Kelen, del Rio, Kroc 2002
client time pre-test counseling	$4.61	----	Kelen, Mugalla
return visit wait/travel time	$27.96	----	Farnham, Hutchinson
client time post-test counseling	$8.81	----	Kelen & Mugalla
Net Cost:	$187.60	----	
Rapid HIV-			
laboratory costs and processing	$27.40	----	Kallenborn
pre-test counseling	$4.94	----	Kelen & Mugalla
post-test counseling	$3.75	----	Mugalla
administrative services & materials	$2.98	----	Mugalla
client time pre-test counseling	$4.61	----	Kelen & Mugalla
client wait time for rapid results	$29.22	----	Kelen, del Rio, Kroc
client time post-test counseling	$2.10	----	Kelen & Mugalla
Net Cost:	$75	----	

$58.82 and $142.89, respectively.

To estimate societal costs for the rapid test (HIV-uninfected), I included the cost of the rapid test, pre and post-test counseling, administrative services and materials and productivity losses for pre and post-test counseling and wait time for rapid test results. For individuals who screened positive with the rapid test, I added the cost of an ELISA and Western blot, longer post test counseling costs (counselor labor costs and productivity losses) and return visit and travel time for rapid test results. The net societal cost of an HIV-uninfected individual who received their HIV test results with routine rapid testing was $75.00 and $187.60 for HIV-infected client.

The provider perspective only considers costs relevant to the provider, in this case, the hospital. Therefore, I excluded productivity losses. Net costs from the provider perspective are: an HIV negative person who received their HIV test results with conventional testing was $30.95 and HIV-infected client was $108.31. Net provider cost under the routine ELISA strategy for an HIV negative and positive individual that received HIV test results was $24.15 and $101.51, respectively. The cost for HIV negative clients who received their HIV test results with routine rapid testing was $39.07 and $117.00 for HIV-infected clients.

Results

Basecase Analysis

The results of the cost-effectiveness analysis from the societal and provider perspectives are presented in Tables 7 and 8 for outcome 1 in which all clients receive their HIV test results and outcome 2 in which HIV-infected clients receive their results.

Table 7. Results of Cost-Effectiveness Analysis: Societal Perspective

Strategy	Total Cost	Total Effect	ACER	Incr. Cost	Incr. Effect	ICER
Outcome 1: Cost per client receiving test results						
Conventional Testing	$ 3.30	.018	$177.04	----	----	----
Routine ELISA	$ 5.60	.037	$149.69	$2.3	.019	$123.29
Routine Rapid	$ 18.9	.184	$ 102.80	$13.30	.147	$90.84
Outcome 2: Cost per HIV-infected client receiving test results						
Conventional Testing	$ 3.30	.0015	$2,114.88	----	----	----
Routine ELISA	$ 5.60	.0037	$1,496.31	$2.3	.0022	$1,064.75
Routine Rapid	$ 18.9	.01	$1,893.13	$13.30	.0063	$1,858.24

Table 8. Results of Cost-Effectiveness Analysis: Provider Perspective

Strategy	Cost	Effects	ACER	Incr. Cost	Incr. Effect	ICER
Outcome I: Cost per all clients learning test results						
Conventional Testing	$2.30	.018	$126.66	----	----	----
Routine ELISA	$3.70	.037	$99.15	$1.40	.019	$72.60
Routine Rapid	$11.30	.0184	$61.56	$7.6	.147	$51.97
Outcome II: Cost per HIV-infected client learning test results						
Conventional Testing	$2.30	.0015	$1,513.03	----	----	----
Routine ELISA	$3.70	.0037	$991.15	$1.4	.0022	$627.05
Routine Rapid	$11.30	.01	$ 1,133.66	$7.6	.0066	$1,064.93

For each outcome, the expected costs are divided by the expected effect to obtain the cost-effectiveness ratios. I present both the average cost-effectiveness ratios (ACERs) which use a no-program comparator and incremental cost-effectiveness ratios (ICERs) that compare one intervention to the next least costly strategy.

Societal Perspective. The base case values of the model using the societal perspective are located in Table 7. For outcome I, in which all clients receive HIV test results, the routine rapid strategy is more cost-effective than routine ELISA testing and conventional testing. The cost per client who received HIV test results was $102.80 using the rapid test compared to $149.69 using the routine ELISA test, and $177.04 using conventional testing. When incrementally compared to conventional testing, the routine ELISA test costs an additional $123.29 per client who received HIV test results. When incrementally compared to routine ELISA testing, the routine rapid test cost an additional $90.84 per client who received HIV test results.

For outcome II, cost per HIV-infected client receiving results (Table 7), the expected costs are the same as for outcome I, but the expected effects are smaller since only HIV-infected clients are valued, the routine ELISA strategy is more cost-effective. The ACERs for HIV-infected clients receiving their HIV test results are as follows: routine ELISA, $1,496.31, routine rapid, $1,893.13 and conventional testing, $2,114.88. When incrementally compared to conventional testing the routine ELISA test costs $1064.75 per HIV-infected client and when incrementally compared to routine ELISA testing, the routine rapid test cost an additional $1,858.24 per HIV-infected client who received HIV test results.

Provider Perspective. The results from the provider perspective, in which productivity losses were not included in the model, are similar to the societal perspective results (Table 8). For all clients receiving correct HIV test results, the rapid test was the most cost-effective (ACER=$61.56, ICER=$51.97); but for HIV-infected clients, the routine ELISA was most cost-effective (ACER=$991.15, ICER=$627.05).

Sensitivity Analysis

For both outcomes, the results were robust under several scenarios. Using one-way sensitivity analysis (in which the value of one parameter is changed) on reference case values, varing the cost of the rapid and ELISA test by 25% did not change the the preferred strategy while holding all other parameters constant. Likewise, eliminating the cost of the risk-based approach to counseling and increasing the wait time to 6 hours for persons returning for HIV test results did not change the findings. Using two-way sensitivity analysis (in which two parameters are varied simultaneously), I varied the sensitivity and specificity of the rapid test across the values reported in the two studies conducted in the ER/UCC setting and the ELISA sensitivity and specificity, across the 95% confidence intervals reported in a meta-analysis on ELISA test performance. The results still favored routine rapid CT for all clients receiving their HIV test results and the routine ELISA CT for HIV-infected clients (Kelen et al., 1999; Kroc et al., 2002; Kowalski, et al., 2001).

For outcome I, cost per client receiving HIV test results, there was no impact of differential participation rates by serostatus or seroprevalence. When the proportion of eligible HIV-infected and HIV-uninfected clients that accepted testing was varied by 50%, there was no change in the results; the most cost-effective strategy was routine

rapid testing. Threshold analysis using return rates did, however, have an effect on the findings (Table 9). Holding all other parameters constant, if the return rate for HIV negative clients under the risk-based strategy increased from 23% to 55% or greater, conventional testing would be more cost-effective than rapid testing. Likewise, if the return rate for the routine rapid testing strategy for HIV-negative clients decreases from 67% to 38%, the optimal strategy would be routine ELISA testing. And finally, if the return rate increased from 25% to 44% for HIV negative clients under routine ELISA testing, then it would be more cost-effective than rapid testing.

Table 9. Threshold Values compared to Model Values: Return Rates for Post-test Counseling, Societal Perspective

HIV CT Strategy	Model Value	Outcome I* Threshold Value with new dominant strategy	Outcome II‡ Threshold Value with new dominant strategy
Dominant Strategy in base-case analysis		Routine rapid testing	Routine ELISA
Conventional HIV+	.60	----	----
Conventional HIV-	.25	≥.55 (conventional)	≤ .05 (conventional)
Routine ELISA HIV+	.73	----	----
Routine ELISA HIV-	.25	≥.44 (routine)	≥.57 (rapid)
Routine Rapid HIV +	.85	----	----
Routine Rapid HIV -	.67	≤.38 (routine)	≤.24 (rapid)

Outcome I* - Cost per client receiving HIV test results
Outcome II‡ - Cost per HIV-infected client receiving HIV test results

For outcome II, cost per HIV-infected client receiving results, changing the value of the preliminary positive rapid test did impact the result in the societal perspective. If a preliminary positive rapid test is valued at zero, conventional testing would be more cost-effective (ACER=$2,114.88) than routine rapid (ACER=$2,223.87), though the routine ELISA test is still the optimal solution (ACER=1,496.31).

Using threshold analysis, a type of sensitivity analysis in which parameters are varied to determine if there is a value that would change the results to favor a different strategy, I found that an increase in seroprevalence to 5.9% would make the rapid test more cost-effective than the routine ELISA test. There was no decrease in seroprevalence that would change the preferred strategy. I also found two scenarios in which return rates would change the cost-effectiveness of routine ELISA CT. Holding all other parameters constant, the conventional testing strategy would be the most cost-effective strategy if the return rate for HIV-uninfected clients were 5% or lower (Table 9). Additionally, the optimal CT strategy would be routine rapid testing if the return rate for the routine rapid strategy was between 0 and 24% for HIV-uninfected clients. Finally, routine rapid testing would be the most cost-effective strategy, holding all else constant, if the return rate for HIV-infected clients under routine ELISA testing is 57% or below, or if the return rate for HIV-uninfected clients is 57% or greater.

The parameter that had the largest effect in sensitivity analysis on outcome II, the cost-effectiveness of HIV-infected clients learning results, was the proportion of eligible clients tested. The base case data from the effectiveness studies assume that the proportion of eligible clients that accepted testing did not differ by serostatus and routine ELISA testing was the most cost-effective strategy. To address the possibility of an effect of participation rates differing by serostatus, I varied the parameters for each HIV CT strategy by up to 50% of the original value. As is evident in table 10, the break-even value would be surpassed about half of the time, most often favoring routine rapid testing. The cost-effectiveness ratio favored conventional testing with a 50% increase in HIV-infected clients or a 50% decrease uninfected clients tested with that strategy. As

observed by Paltiel and Kaplan (1997), the effect is largest for HIV-uninfected clients. In my model, I observed an effect with both a 50% and a 25% change in HIV-uninfected clients accepting routine ELISA and routine rapid HIV CT. In both of these cases, the routine rapid test becomes the most cost-effective strategy.

Table 10. Sensitivity Analysis on the Effect of Serostatus-dependent Testing Rate Societal Perspective, Outcome II

HIV CT Strategy and Original % percent of eligible participation	Serostatus	Sensitivity Analysis Value†	ACER	New Dominant Strategy*
Conventional (.07)	HIV+	.035	$1,496.31	----
		.105	$1,483.29	Conventional
	HIV-	.035	$1,167.49	Conventional
		.105	$1,496.31	----
Routine ELISA (.14)	HIV+	.085	$1,893.13	Routine rapid
		.225	$998.96	----
	HIV-	.085	$979.11	----
		.190‡	$1,893.13	Routine rapid
		.225	$1,893.13	Routine rapid
Routine Rapid HIV (.27)	HIV +	.135	$1,496.31	----
		.405	$1,318.32	Routine rapid
	HIV -	.135	$1030.92	Routine rapid
		.203 ‡	$1,462.02	Routine rapid
		.405	$1,496.31	----

Outcome II- HIV-infected clients receive their HIV test results
*represents a in dominate strategy from routine ELISA
†50% change in model value
‡25% change in model value

Discussion

This analysis shows that routine rapid testing is the most cost-effective HIV CT strategy for informing all clients of their serostatus from both the societal and provider perspectives. This is not surprising as the rapid test was much more effective; about 40%

more HIV-uninfected clients and 20% more HIV-infected clients received results with rapid than with ELISA strategies. Thus from an effectiveness standpoint, the rapid test offers the greatest advantage in increasing the number of HIV-negative clients receiving results. However, when the outcome is the cost per HIV-infected clients receiving results, the routine ELISA strategy is more cost-effective from both perspectives. The standard of care HIV CT method, conventional testing, was the least cost-effective HIV CT intervention in almost all of the scenarios explored by sensitivity analyses. The rapid test offered less of an effect for HIV-infected clients, only about 18% more HIV-infected clients received results than with the routine test and 25% more than with conventional testing. Additionally, the cost-per-client tested was lowest in the routine ELISA strategy.

These findings share important similarities with those of Farnham et al. (1996) in which the rapid test was generally more cost-effective than conventional testing at informing all clients and HIV-infected clients of their correct serostatus in publicly funded clinics. Both studies found that valuing the preliminary positive rapid test at zero makes conventional testing more cost-effective than rapid testing. However, the cost-effectiveness ratios favored routine ELISA testing in the present study, which was not evaluated by Farnham et al (1996). While the conclusions were similar, I found higher ACERs for all strategies than those reported by Farnham et al (1996). For example, for outcome II, the cost per HIV-infected clients receiving results, Farnham et al (1996). reported an ACER of $1047 for conventional testing and $678 for rapid testing (data adjusted to 2002 USD) compared to my $1,513 for conventional testing and $1,133 for rapid testing. An important difference is the study setting (publicly funded clinics versus ERs/UCCs) and differences in effectiveness data. Farnham et al. used higher return rates

for HIV-uninfected clients using ELISA (40%) and rapid testing (80%) and lower return rates for HIV-infected ELISA clients (60%). Additionally, Farnham et al. assumed that all clients were tested, while I used different proportions of clients tested based on testing strategy. A major distinction, however, is the inclusion of the routine approach to testing which generally had the most favorable cost-effectiveness ratios in the ER/UCC setting if the objective is to inform HIV-infected clients of their serostatus.

Sensitivity and threshold analysis show that return rates and seroprevalence can impact the findings. However, the threshold value for return rates for both outcomes seems highly unlikely with respect to what has been reported in the literature. The findings relevant to seroprevalence can be considered robust, except for the threshold value of outcome II (5.9% seroprevelance) that would favor routine rapid testing.

There is greater uncertainty around the possibility that serostatus-dependent testing rates are 25% or 50% higher or lower than the base case assumption, which changed the preferred strategy for outcome II to routine rapid testing in most cases. Because the model assumes no difference in participation by serostatus, there is likely to be some deviation from the model values when applied to real settings. From these analyses, it seems likely that "over-recruiting" HIV-uninfected clients would favor the HIV CT strategy in which the largest percentage of HIV-infected clients receive their result which in this case, is the routine rapid test. This study provides further evidence that differential participation in HIV CT by serostatus needs to be more fully evaluated in future CEAs of HIV CT methods.

This study has applicability to urban public hospital ERs and UCCs in the United States as the majority of the cost and effectiveness data came from high volume, level

one trauma centers (the highest trauma designation) in urban public hospitals. Though HIV prevalence in rural settings is much lower than urban settings, the sensitivity analysis did not show different findings at lower prevalence, though a prevalence greater than 5.9% would make the rapid test more cost-effective for both outcomes (Beltrami et al., 2001). It is important to note that seroprevalences greater than 5.9% have been observed in the ER setting, thus, a hospital's the decision to implement routine rapid versus routine ELISA HIV CT is less clear for hospitals with very high ER/UCC prevalence rates (Kelen et al., 1989).

An additional point that should be considered is the use of intermediate versus final outcomes. Ideally, a model would be able to predict long term and final health outcomes of these HIV CT strategies. To do this, one would have to link the HIV CT strategy to differences in disease severity. The small amount of data did not support differences in disease severity based on testing strategy. However, this is something that should be addressed in future cost-effectiveness analyses as the data become available.

Limitations

I have not been able to specifically address several issues pertaining to rapid testing in the ER setting that may affect the total cost of the rapid test. The first is the use of point-of-care testing, which was used in the study that had 100% return rate for the rapid test (Kroc et al., 2002). With point-of-care testing, an HIV client educator or counselor conducts pre-test counseling, phlebotomy, conducts the rapid test and post test counseling, which may have impacted the return rate in this study (Kroc et al., 2002). The additional costs of point of care testing were not included in this analysis, as they have not been assessed in the literature.

There are also situations in which the cost of the rapid test may be lower. Batch testing, conducting several rapid tests at one time to maximize the use of controls, has been used in the ER setting and typically reduces the cost of the rapid test (Mugalla, 2002). In addition, if a laboratory in the ER is used rather than the hospital's main lab, the wait time for the rapid test may be lower, which could affect return rates and productivity losses (Kelen et al., 1999). Though the cost implications of these specific practices were not assessed, sensitivity analysis on the cost of the rapid test and return rate did address changes in the total cost and effectiveness of the rapid test.

There are also organizational differences in UCCs vs. ERs that should be considered. Urgent care centers are walk-in clinics and in some public hospitals, they receive less severe clients triaged from the ER. Therefore, their set-up may be more similar to a regular medical clinic than an emergency room. This may make UCCs more attractive for HIV CT in that it would be less disruptive to provide counseling and testing. For example, if a client returns to an ER to get HIV test results, that client may have a long wait time due to acutely ill clients receiving priority through triage. However, in the reviewed studies, return rates for rapid test results were lowest and wait times highest in the UCC setting. Nevertheless, differences in these settings should be evaluated further for hospitals choosing between the UCC and ER setting.

This study provides decision-makers information on the cost and effectiveness of three HIV CT interventions on two outcomes: receipt of HIV test results by all clients tested and receipt of HIV test results among those who are HIV-infected. Therefore, these results must be compared with studies that measure the same intermediate outcomes, rather than those that measure final outcomes (e.g., QALYS and life years

saved) or different intermediate health outcomes (e.g., cases of Hepatitis B prevented through an ER vaccination program). In addition to limiting comparability between economic evaluations, use of intermediate outcome measures does not include the full impact of the intervention, such as events following diagnosis. The advantage of using an intermediate outcome, however, is that there is much less uncertainty in the model (Gold et al., 1996).

Conclusion

This cost-effectiveness analysis of three strategies for HIV CT screening in the ER setting highlights how program goals have important implications for cost-effectiveness of HIV CT interventions. If public health decision-makers are focused primarily on identifying HIV-infected clients, then the most cost-effective HIV CT strategy is routine ELISA. However, the findings for identifying HIV-infected clients should be interpreted with caution, as they were sensitive to differential participation rates by HIV status. Additionally, ERs and UCCs with a very high seroprevalence (greater than 5.9%) should note that the routine rapid test might be more cost-effective. If public health decision-makers place value on both positive and negative clients learning their serostatus, then rapid testing is the most cost-effective CT method. In almost all cases, conventional testing was less cost-effective than routine ELISA or rapid testing.

Additional research is needed to link the effectiveness of these HIV CT strategies to downstream outcomes such as the benefits of early treatment, partner notification, the effectiveness of counseling at preventing HIV infection as well as final health outcomes such as life year and quality-adjusted life year saved. Likewise serostatus-dependent

testing rates are needed so that they may be incorporated into models that assess the effectiveness and cost-effectiveness of HIV screening interventions.

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ESSAY 3: UNDERSTANDING THE CLIENT'S PERSPECTIVE ON NEW APPROACHES TO HIV TESTING: RESULTS FROM QUALITATIVE RESEARCH IN AN INNER-CITY URGENT CARE CENTER

Human immunodeficiency virus (HIV) counseling and testing (CT) is a critical first step toward prevention and early detection of HIV. However, failure to undergo HIV CT and failure to return for results following testing are significant barriers to prevention. An estimated 300,000 people in the United States are infected with HIV but do not know their serostatus (Centers for Disease Control, 2001a). In publicly funded HIV counseling and testing programs, 48% of clients who were tested did not return for test results and post-test counseling (CDC, 2001b). Return rates have been known to vary by population, testing technology and site (Keenan & Keenan, 2001; Molitor, Bell, Truax, Ruiz, & Sun, 1999). HIV-infected clients who do not know their serostatus miss the opportunity to institute early treatment such as antiretroviral therapy and undergo counseling to prevent transmission of HIV. The CDC has developed new HIV counseling and testing guidelines that promote early knowledge of HIV status and developed a new strategy for HIV prevention, the Serostatus Approach to Fighting the Epidemic (SAFE) that is focused on increasing knowledge of serostatus and linking clients to prevention and treatment services (CDC, 2001b) (Janssen et al., 2001).

To achieve goals related to HIV prevention, barriers to HIV CT must be addressed. Individuals at risk for HIV may not get tested for many reasons, including fear, stigma, and lack of recognition of risk factors. Health care provider-related barriers to offering HIV counseling and testing include discomfort obtaining a sex or drug use history, time constraints and patient denial of risk factors and some practitioners may not discuss HIV testing even in high-risk populations Boekeloo et al., 1991&

Rogstad, 1998). Thus clinicians employing the conventional, risk-based approach to testing may be missing opportunities to diagnose and treat HIV infection. In 1993, the CDC recommended routine voluntary HIV testing in high prevalence settings to identify undiagnosed HIV. Undiagnosed HIV is particularly a problem in inner-city hospitals (Walensky, Losina, Steger-Craven & Freedberg, 2002). There is evidence that newly diagnosed HIV patients in some inner-city hospitals may have had several encounters with the health care system before their diagnosis and thus missed opportunities to diagnosis HIV (Alexander, Sattah, Zeimer, and del Rio et al. 1998; Walensky et al., 2002). Accordingly, some inner-city hospitals have instituted HIV screening programs in emergency rooms and urgent care centers, which are often the sole source of health care for many high-risk patients (Kelen, Shahan, Quinn, & the Project Educate Work Group,1999; Kroc et al., 2002; delRio et al., 2001)

New approaches to HIV CT have been introduced that may address many of the barriers to testing and thus facilitate knowledge of serostatus and behavior change. With one approach, rapid testing (RT), patients receive their test results in the same day, typically within two hours, compared to the standard test which takes several days to weeks. Thus, rapid testing technology has the potential to reduce the barrier of wait time and failure to return for test results. Several studies conducted in the United States have concluded that the first FDA approved rapid test (the Single Use Diagnostic System {SUDS}) is feasible, practical and cost-effective for the diagnosis of HIV infection (Farnham, Gorsky, Holtgrave, Jones & Guinan, 1996; Kassler, Dillon, Haley, Jones & Goldman, 1997; Kelen et al., 1999). Similar results have been obtained with the recently approved OraQuick Rapid HIV-1 Antibody Test that can provide results in less than 20

minutes (CDC, 2002).

Routine voluntary testing is a population-based alternative to conventional, risk-based HIV CT. Using this strategy HIV testing is routinely recommended in entire clinical populations where HIV is highly prevalent compared to conventional testing in which testing is recommended to individuals with risk factors for HIV. This approach has the potential of reducing the barrier of patients not recognizing their own risk for HIV by promoting testing regardless of risk factors as well as the problem of provider bias in assessing who is at risk for HIV infection. Routine testing may also reduce the stigma associated with getting tested for HIV, since testing will not be recommended based on risk factors but as one more screening test.

Though rapid and routine HIV testing strategies have the potential to significantly increase the number of people who learn their serostatus, patient acceptability needs to be determined. Spielberg, Gorbach & Goldbaum (2001) have conducted focus groups and interviews in three at-risk populations (clients of STD clinics, gay men, and injection drug users) and found that clients prefer alternative testing strategies such as rapid testing and non-invasive testing. However, it is important to assess patient acceptability in the setting and population in which HIV CT is implemented. For example, for routine testing in a hospital setting, it is important to determine that informed consent is truly voluntary — that patients do not feel coerced if all patients are being offered testing and that the decision to test is not made under duress since patients may present for testing with an urgent medical problem. While there has been some exploration of patient acceptance of rapid testing in the emergency care setting, I am not aware of an in-depth qualitative assessment of HIV CT of rapid and routine testing in an urban urgent care center.

The objective of this study was to determine client perceptions of alternative HIV testing options in an inner-city urgent care clinic serving primarily an African American patient population. Specifically, this formative evaluation uses structured focus group methodology to gain insight into preferences for HIV testing and the social context from which HIV testing decisions are made. Since there does not appear to be empirical data on the acceptability of rapid and routing testing strategies in a similar population, an additional objective of this study is to generate hypotheses for future investigation. The focus groups were conducted during the formative evaluation phase of a larger clinical trial. This trial compared voluntary routine testing using the rapid test with same-day results (using SUDS®, Abbott Laboratories) to routine voluntary testing using enzyme immunoassay (EIA) with a 2-week return visit for test results at an urban public hospital (del Rio et al., 2001).

Method

I used focus group interviews to assess patient's attitudes toward and acceptance of rapid and routine testing, to generate hypotheses regarding the factors that influence HIV testing in this population and to inform the development of survey instruments to measure HIV counseling and testing behavior and preferences. I chose focus group methodology because of its ability to facilitate discovery of a target population's knowledge and attitudes regarding health issues. Additionally, focus groups are advantageous in gathering information on sensitive subjects and they allow for flexibility which is important in theory-building research (Witte, 1997). Finally, previous studies show that focus groups can be effectively employed in this predominantly African American population where there may be little trust in research process (Corbie-Smith,

Thomas, Williams and Moody-Ayers, 1999).

Description of Study Site

The study was conducted at the Urgent Care Center at an urban public hospital serving the indigent population of Atlanta, Georgia. The Urgent Care Center is a walk-in medical clinic that also serves non-emergent patients triaged from the emergency room. Accordingly, it is likely to be better suited to HIV screening than the hospital's level one emergency care center. HIV/AIDS is the second leading discharge diagnosis among adults at this institution, accounting for approximately 5% of all hospital discharges. This rate is well above the 1 per 1,000 that the CDC used as a cut off in 1993 to recommend routine HIV testing among hospitalized patients (CDC, 1993). Among patients with HIV/AIDS at this hospital, 89% were African American and 25% were women (del Rio, Zimmer, Patel, and Lennox, 1999). At the time of the study, the walk-in clinic was open seven days a week for a total of 80 hours per week and had an average of 4,200 patient visits per month. It is frequently the only source of health care for this under-served population (Rask, Williams, Parker & McNagny, 1994). In addition, this patient population frequently encounters a lack of transportation, a lack of insurance and other financial barriers to accessing health care.

Focus Group Recruitment and Methodology

Patients were recruited in the following manner. HIV testing was conducted during one-week periods employing the routine approach using rapid testing, the routine approach using ELISA testing and the risk-based approach using ELISA testing (the usual practice for the hospital). The focus groups were conducted during the weeks in which conventional testing was used. On routine testing weeks, all patients who entered

the clinic were offered an HIV educational brochure written at a 6th grade reading level that described the type of HIV test offered that week. Clinicians were instructed during those weeks to offer HIV testing to all patients aged 18 to 54 – employing a routine, voluntary approach. After completion of the clinic appointment, patients were screened for participation in the focus groups, regardless of whether they had given their consent to HIV testing. Ninety-two individuals were screened for participation, of which 47 reported to the focus group session and participated. Group assignment was based on the type of HIV test taken and the client's willingness to be tested. There were six different focus groups; for each gender there was a group who (1) accepted rapid testing, (2) accepted standard testing, and (3) refused testing. There was a $50.00 incentive for participants who completed the focus group session. The Emory University Human Investigations Committee, the CDC Institutional Review Board and the Grady Research Oversight Committee approved the study.

An African American professional moderator conducted the focus groups. The moderator's guide was divided by topic area and consisted of open-ended questions followed by a series of probes. Theories of behavioral decision-making were used to develop the focus group moderator's guide to provide a framework to evaluate how individuals perceive and evaluate alternative courses of action that included the study of risk perception, problem structuring and outcome valuation as well as stage models of behavior change (Holtgrave, Tinsley & Kay, 1995). The focus group interviews were conducted at the hospital at a location separate from the Urgent Care Center. At the beginning of each focus group, participants provided informed consent and received a written copy of the consent form. The interviews were audio taped and transcribed for

subsequent content analysis.

Analysis

Four independent coders analyzed the data using iterative content analysis. Two of the coders were physicians with expertise in minority health and HIV/AIDS and two were social scientists with expertise in community health and health services research, thus allowing for important insights to emerge from the different perspectives. For each iteration, each coder developed his/her own coding sheets using a combination of in-vivo (literal terms used by the research subjects) and open codes (those that have been interpreted by the investigator) (Berg, 1998). Consistent with the analysis of focus group data, the unit of analysis was the focus group. However, during this first iteration individual respondents were used as a second level of analysis to elucidate patterns of group dynamics. The primary coder used the individual analyses to develop a master record of the content analysis. In the next iteration, codes identifying the individual respondents were dropped leaving only the group as the unit of analysis. The coders met to discuss themes and resolve differences that generally revolved around interpretation and context of the codes. The objective of the final iteration was to further reduce the data by content areas and select quotations that represent themes, as well as outliers, within the content domains. Four major content domains were identified and twenty-eight sub-domains were identified. Any discrepancies between the coders were also resolved in this iteration. The primary coder then compared the results of the analysis with the transcripts to confirm validity of the content analysis.

Results

Characteristics of Study Participants

Forty-seven individuals participated in the six focus groups with an average group size of 8 (range = 5 to11). There were slightly more male participants (53%) than female. The characteristics of the focus group participants reflected the characteristics of the patient population. The participants were predominately African American (89%); other races represented were white (9%) and Asian/Pacific (2%). The average age of the participants was 41 (range = 25 to 55). The insurance status of the participants was as follows: 60% uninsured, 20% privately insured, 13% Medicaid, 4% Medicaid/Medicare, and 2% unknown. Finally, the participants had a relatively low educational status: 30% had less than a high school education, 40% had a high school education, 21% had some college education and 9% had a college degree or greater.

The major content domains include the following (Table 11):

Table 11. Content Domains

Major Content Domains	
1. HIV/AIDS Knowledge	3. Reasons for and Against Testing
2. Information Sources and Trust	4. Preference and Acceptability of Testing.
Sub domains	
1. What is HIV	10. Good things about testing
2. Transmission	11. Anonymity
3. Prevention	12. Reasons for not returning for test results
4. Treatment	13. Rapid testing
5. Ways to know HIV status	14. Regularity of testing
6. Meaning of HIV test	15. Routine testing
7. Incubation period	16. Permission to be tested
8. Reasons for not testing	17. Additional alternatives to testing
9. Bad things about testing	18. HIV information and Trust

HIV/AIDS Knowledge

Focus group participants had basic knowledge about HIV/AIDS. There was consensus that: 1) HIV is the virus that causes AIDS, 2) there is no cure for AIDS but there are treatments to improve survival and 3) HIV kills people by destruction of the immune system resulting in opportunistic infections. There was also awareness about prevention of HIV/AIDS. Interestingly, the only respondents to identify health education and awareness-raising efforts as a way to prevent HIV transmission were participants who refused to be tested. There were no differences by gender or testing group in terms of this basic HIV/AIDS knowledge.

Several misconceptions were identified that were equally distributed among the groups for example, that AIDS is a cancer, airborne or related to personal hygiene. Participants were as likely to name testing as a way to determine a person's HIV status as they were to say that observing signs and symptoms help you determine a person's status. There were no meaningful differences by gender or testing group in this area. There also appears to have been considerable confusion around the terms and concepts "incubation period" and "window period." For example, in a discussion of the incubation period for HIV, one participant said, "it might take five years to get to a point where the virus is detectable".

Most also agreed that re-testing is important since there may be false-positive or false-negative results and since a person's status can change over time. Suggested intervals for re-testing ranged from every other month to every year. Regarding HIV transmission, there was a greater focus on the low risk exchange of bodily fluids as a means of transmission (including exchanging blood through open cuts/sores,

saliva/kissing, and sweat) than types of high-risk sexual transmission (sexual intercourse, oral sex, and anal sex). Moreover, men were more likely than women to discuss the exchange of body fluids as a mode of transmission, as were participants who refused testing, implying that these groups do have an awareness of this high-risk behavior. However, comments from respondents in all groups suggest a poor understanding of the concept "exchange of body fluids." For example: "Anytime you go to any public place you come in contact with any kind of body fluids, I don't care whether it's saliva, blood or any kind of body fluid from another person that's infected, if it gets into an opening on you, then you have got it."

When asked about ways to determine a person's HIV status, participants were equally as likely to name HIV testing as they were to say that observing signs and symptoms can help you determine a person's status. The lack of differentiation between the two methods is cause for concern. Making decisions based upon physical signs and symptoms of HIV infection is unreliable and would likely result in testing when HIV has already progressed to AIDS. Additionally, this approach avoids direct questioning about HIV status and a discussion of HIV risk factors. It should be noted that this approach is not limited to patients, as health professionals may rely on visual assessment or stereotype assumptions to determine who is offered an HIV test.

HIV Information Sources and Trust

Respondents were asked about preferred sources of information about HIV/AIDS. Overwhelmingly, health care providers and health care points of service (hospitals and health departments) were named as good sources for information. Traditional media outlets such as television, radio and billboards were identified as preferred sources as

some mentioned they preferred not to read information about HIV/AIDS. The Internet and public libraries were also popular because of the relative privacy afforded by those sources. The CDC was mentioned as a source of "concrete information, not hearsay stuff" in two of the focus groups. In describing preferred sources, characteristics such as knowledge/expertise, trust, confidentiality, and convenience were mentioned. Several groups expressed the need for more information about HIV/AIDS: "You should see it everywhere, TV, bulletin boards, awareness groups." Some participants pointed out that not everybody would be receptive to information about HIV/AIDS: "Some people just don't want to face the harsh reality that they could get AIDS."

Focus group participants were asked whether or not they trusted information they receive about HIV/AIDS. The male groups were the least trusting of information; however, in two of the groups, they trusted the information because they felt they "had to." One respondent expressed distrust in disclosure of HIV test results: "The doctor may not have been honest, they don't have the heart to tell them (they are HIV positive)...Sometimes they put in on that piece of paper, but if you don't read that piece of paper, you don't know." Another common theme around distrust was the idea that the scientific community still doesn't know everything about the disease: "Like if it's carried in saliva or mosquitoes can transfer it... they have no clue what they are talking about."

Conspiracy Theories

Participants also discussed conspiracy theories, with members of male groups being more likely to raise them. Suggested conspirators include "white people, pharmaceutical companies, doctors and the government." One individual talked about the possibility of a "wacky doctor injecting people with the AIDS virus such as a KKK

(Ku Klux Klan) doctor." Another stated: "HIV comes from genocide and was probably invented during World War II." There are also myths about covert actions by the government, "there is a disease stronger than AIDS out there, man, and the government is taking everyone (with that disease) to an island and leaving them".

Both male and female groups expressed the idea that there is a cure for AIDS. The government and pharmaceutical companies were thought to already have a cure for AIDS and be withholding it because of financial profits of current AIDS treatments. Another common theme is that there is a cure/ treatment that only rich people can afford.

Reasons to Accept or Refuse Testing

Reasons to Accept Testing. Reasons to accept HIV testing fell into two general categories: those that were focused on risky behavior (practiced/practicing risky behavior; concerned about a partner's status; desire to prevent the spread of disease if infected), and those that were not (to determine status; to get treatment; to have peace of mind). Additionally, some females indicated that a reason to get tested was because "You don't trust your partner." It seems that participants view testing as beneficial even when personal behaviors that may put them at risk are not present. As one participant stated, "It's good to know where you stand." Finally, the fact that the test was free was the reason many participants were tested.

Reasons for Refusing Testing. For all of the focus group participants, fear was the greatest single reason given for not accepting an HIV test when offered. Many different types of fear were mentioned and some were gender specific. Men were more likely to report a fear of dying, as well as a fear of the emotional or psychological consequences of testing positive, such as anger, depression, guilt and bitterness. One male participant

stated, "If I got positive results, I am going to have thoughts about taking vengeance on the person I think gave it to me." Conversely, women were more likely to describe a fear of rejection from friends and family or being labeled as "gay or a drug user" as a reason to refuse testing. Across groups, concern about anonymity was also a reason for refusing testing. One respondent who refused testing stated that she was told, "Never ever get tested for HIV where they know your name and can get your medical records." Fear of employer discrimination was also expressed. Additional reasons included "irresponsibility" and "lack of loving one's self." Members of several of the focus groups said they would get tested if the test were more accurate, as these participants had known someone who had a false positive test. Cost was also mentioned as a barrier, particularly for those at high risk "A lot of high risk people have no money. They will buy a $10 rock (crack) rather than pay for a test."

The groups that refused testing were the only ones to identify convenience factors such as waiting for test results as reason for not getting tested. Many patients had waited several hours to be seen and, in the case of the rapid test, did not want to wait an additional two hours. Those who refused testing also had more concerns about anonymity than the groups that accepted testing. This was evident in both their reasons for not getting tested and ways to improve testing. Additionally, they were the only groups that cited "not at risk" as a reason for not being tested. Other reasons for not getting tested include not wanting to change one's behavior, and the stress of waiting for results. Finally, in the female group that refused testing, fear of becoming infected with HIV during testing was mentioned by several of the participants, who discussed the need to "see them (the phlebotomist) take out a new (sterilized) needle."

Reasons for Failure to Return for HIV Test Results

The reasons for not returning for test results were similar to the reasons for not getting tested for HIV. In nearly all of the focus groups, fear, loss of courage and inconvenience were common reasons for not returning for test results. As one respondent who did not return for HIV test results in the past suggested, "ignorance is bliss". Another common theme was the fear of telling their partner they were HIV positive. In one group, the counseling process contributed to fear of being HIV positive as evidenced by this quote: "When they tell you about HIV and why you might be at risk, you are too scared to know and come back." Additionally, as evident by one participant's comment, stigma associated with HIV testing was also a barrier to returning for results: "People do not return because they are shamefaced." Inconvenience was more frequently mentioned in the female focus groups. Also, in the case of anonymous testing, loss of a "secret number" was mentioned as a reason for not returning for test results. Finally, some patients misunderstood the testing process; they stated that they assumed if the HIV test were positive, the patients would be contacted: "if you tested positive – the health department would contact you anyway, right?" There was also the misperception that because patients may receive certified letters in the mail about testing positive for other diseases (e.g., hepatitis), they would receive certified letters if they were HIV positive.

Preference and Acceptability of HIV Testing

Attitudes towards Rapid HIV Testing. The rapid HIV test was overwhelmingly described as preferable to the standard HIV test based on the inconvenience of returning for HIV test results. A common theme about rapid testing is that people preferred the rapid test because the additional wait time of the standard test is more stressful and might

cause them to lose the courage to return for the test results. For example, one participant stated, "in a two hour period you could sit there or go to MacDonald's, but if you have a whole week, that's planting stuff in your head." However, many of the female participants felt that the length of wait time would not affect their decision to get tested. Typical responses for those who did not express preferences for rapid testing included "I'm looking for results. It doesn't matter if it takes a day or a week, I just want to know" and "A test is a test." The decision is if you decide to take it."

There was some concern about the accuracy of the rapid test among those who had received both types of tests. One person that refused testing stated "what I want to know is how reliable is this test?" Others felt that they would feel more confident if it took longer to get the results. Another negative attitude about rapid testing that was expressed by the female group that received the rapid test was that it "was like an assembly line, it is just so impersonal." One member of the group that received rapid testing stated that she didn't want to take the test but felt pressure because the doctor asked.

While the rapid test offers same-day results, it extended the patient's total visit to the clinic by at least two hours. As one patient described, "the rapid test was excellent, even though it wasn't rapid." In a several cases, participants who refused the rapid test stated they had waited up to seven hours before they were seen and "the additional two hours lead to 4,5,6 or 7 hours." Additionally, several participants who had refused the rapid test suggested that the hospital was slow at processing patients and should offer the rapid test when they arrive at the clinic before they are seen. Therefore, in some cases, institutional barriers thwarted the innovation of rapid testing by making it less, rather than

more convenient to patients.

Attitudes Towards Routine Testing. There was general support in all of the focus groups for routine testing; however, half of the groups specified that testing had to be voluntary. Of those who supported the idea of routine testing, most felt that it was worthwhile for the benefit of patients and that it would "save more people." Another common theme was that if patients had considered testing and the doctor also suggested it, they would be willing to consent to testing. Likewise, participants felt that some people who need to be tested would not be tested unless it was routine. There was discussion in one group that routine testing is beneficial for those who have other chronic diseases, since HIV/AIDS can aggravate these conditions. One group suggested that routine HIV testing should be mandatory at the state's expense and that perhaps people should be required to have a card with their HIV status and most recent test date. Some participants expressed concern that routine testing should not be done when you come in for common things like a cold, yet others felt that it should be done every time you go to the doctor "because most of the time people come to the doctor for an emergency." A few individuals stated that testing should be done only when HIV is suspected based on symptoms. Of those who did not support routine testing, the biggest concern was that it was too expensive and it might compromise confidentiality.

The focus group interviews also assessed whether or not patients thought routine testing was already being done, for example, if they thought that they had been tested for HIV without their consent. In general, participants held the view that legally they had to give their permission to be HIV tested; however, many were skeptical that this procedure was being followed. In all of the groups, participants believed that there are

circumstances when patients are tested without consent such as when there is a trauma (so that doctors can protect themselves) or when a patient is a minor. In many cases, participants described situations when they had been tested for HIV without their consent. Other individual respondents said, "Doctors do what they want…you don't know what is being checked on the lab sheet." One person also believed that you have to consent to being tested for HIV before receiving any medical care at the hospital.

Other Alternatives to Testing. In addition to decreasing waiting time, a number of characteristics were identified that participants felt might increase the likelihood of a person agreeing to be tested. A less invasive testing procedure was the most common comment. Alternatives to drawing blood that were mentioned included saliva testing, finger stick, urinalysis, hair analysis, skin, fingernail, stool, sweat and tear samples. Among participants who refused the HIV test, greater assurance of confidentiality such as use of a home test was the most frequently reported suggestion for increasing testing rates.

Summary of Focus Group Results

Results of the focus group interviews revealed that rapid testing would be preferred because it reduced the barriers of waiting and inconvenience as well as stress over test results; however, rapid testing was not preferred by those who waited several hours to be seen in the clinic. I also found that routine testing would be acceptable if it was voluntary though there were concerns about confidentiality. Fear, inconvenience and confusion over the process were major reasons for failure to return for test results. Fear, inconvenience and concerns about anonymity were the most common reasons for refusing testing. There were also gender differences related to fear: fear of emotional

reaction among men and fear of rejection from family/friends among women. Another important theme that was uncovered during the focus groups was that many individuals in this population did not trust information about HIV/AIDS and felt they could be and had been tested for HIV without their consent.

Limitations

I would like to acknowledge several limitations of our study. While the focus groups provide insight into the target population's preferences for methods of HIV testing and counseling, I point out that focus group methodology is not an appropriate methodology for elicitation of individual preferences.

Additionally, since the population was predominately low income, inner-city African Americans, I recommend using caution when generalizing these results to other populations. Also, as this study was conducted in an urban public hospital, some of the barriers and perceptions identified by this population may be specific to high volume public populations (e.g., wait time prior to being seen in the clinic).

Finally, one participant commented that he was learning a great deal from participating in the focus group. This is a concern since the participant may have accepted other participant's comments as factual information about HIV/AIDS. However, the moderator did provide all of the participants with HIV educational material before their departure from the focus group session. I mention this to raise awareness that despite best efforts in the consent process, focus group participants may misinterpret the purpose of the focus groups.

Discussion

Implications

While rapid testing was accepted in this population, our results highlight important factors that should be considered in implementing HIV prevention programs that involve rapid testing. Many participants did not feel confident about the accuracy and reliability of rapid tests for no other reason than the fast turn around of results. Therefore, issues of accuracy of the rapid test should be addressed during counseling and testing. Secondly, there is the issue of "how rapid is rapid". If processing the rapid test takes several hours for results to be delivered, then the benefit of reducing waiting time is greatly compromised. Likewise, if the rapid test is offered after the patient has already waited several hours to be seen, which occurred on a few occasions during the study, the utility of the rapid test is greatly compromised. Accordingly, total waiting time at the clinic as well as organizational/institutional issues should be considered in implementing the rapid test.

Routine, voluntary testing was accepted by most of the participants. In fact, many participants echoed the rationale for population-based testing regarding knowledge of serostatus with comments such as "it is important to know where you stand." For this study, HIV testing was offered free of charge; however, concerns about costs revealed in the focus group interviews could indicate that patients may not find routine testing acceptable if they bear the cost. There is some indication that because of its population-based nature, routine testing may reduce the barrier of stigma related to testing. One barrier that needs to be addressed for either of these testing modalities is concern about anonymity.

The focus group participants also felt that less-invasive testing methods such as saliva and finger stick testing would increase the likelihood of being tested. Accordingly, it is likely that this patient population would be accepting of the recently FDA approved OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) (CDC, 2002). OraQuick is a point of care rapid test that uses serum samples obtained from a finger stick.

One misconception that was particularly concerning was that the heath department would contact those who tested positive and failed to return for their test results. If this is a common misconception, then post-test counseling should specifically address the fact that even though HIV infection is reportable, the health department is not responsible for contacting individuals who test positive and do not return for their results.

These findings have theoretical implications about HIV CT in inner city, predominately African American patient populations. Fear of rejection of family and emotional reactions as well as trust in information and testing procedures around HIV/AIDS are important elements to be considered in refining HIV counseling interventions. Finally, the focus on low-risk modes of transmission over high-risk sexual modes of transmission may indicate there is still, after the second decade of HIV disease, a fair amount of misinformation and stigma. In addition, conspiracy theories about the origin of HIV infection remain salient. This finding shares similarities with previous research exploring conspiracy theories among African Americans regarding AIDS as well as general distrust regarding medical care (Klonoff & Landrine, 1999; Corbie-Smith, Thomas, St. George, 2002). These findings stress the importance of culturally sensitive AIDS prevention programs that address the issue of distrust, especially among African

American men.

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ESSAY 4: THE UTILITY OF A HEALTH TECHNOLOGY ASSESSMENT FRAMEWORKIN ASSESSING HIV COUNSELING AND TESTING METHODS

The conventional approach to HIV counseling and testing (HIV CT) consists of offering HIV CT to clients who are determined to be at-risk for HIV and testing clients with enzyme-linked immununoassay (ELISA). Because risk-based testing may miss HIV-infected individuals and clients who are tested often fail to return for test results, several alternative methods for HIV CT have been used to increase testing and receipt of HIV test results. These alternatives include routine testing, rapid testing, anonymous testing, oral fluid testing and variations in pre- and post-test counseling (e.g., use of telephone versus in-person visit).

Researchers have recently outlined policy questions that need to be answered about HIV CT interventions and CDC's Guidelines for HIV Counseling and Testing that are focused on HIV CT strategies that increase the number of people knowing their HIV status (Phillips, Bayer & Chen, 2003). The authors discuss the following five areas of inquiry to assess policy and practical implications of HIV CT: "1) Will the guidelines be adopted? 2) Will at-risk and infected individuals be identified for counseling and testing? 3) Will health care providers offer counseling and testing and patients accept counseling and testing, obtain their test results, seek treatment and change risky behaviors? 4) Will the guidelines be relatively cost-effective? 5) Will the guidelines be compatible with ethical standards?"

To answer such questions, one most go beyond the traditional medical model of assessing health interventions that is based in evaluating efficacy and consider additional evidence relevant to policy makers. Health technology assessment is a multi-method

approach to evaluating health interventions for the purpose of making policy decisions for improving the health of individuals and populations. In the context of HTA, the term "health technology" is meant to be interpreted broadly and refers to any intervention (e.g., drug, device, procedure, informatics, educational intervention) used to promote health or prevent disease (Banta, 1997). In addition to assessing evidence of efficacy, HTA evaluates effectiveness and safety, the economic impact and the consumer perspective which includes ethical and psychological outcomes (quality of life, health status). HTA also considers social effects such as equity issues related to access and availability of the technology, the organizational impact (both how the organization affects the technology and the impact of the organization on the technology) and practice patterns related to the technology and regulatory issues. Though there is no consensus on what constitutes a "standard HTA", evidence of effectiveness, impact on the consumer, particularly ethical issues and economic evidence are often considered core components of HTA (Liberati, Sheldon & Banta,1997).

This dissertation uses an HTA approach consisting of the core HTA methods to assess the evidence for efficacy and effectiveness, the consumer perspective and the economic impact of alternative HIV CT technologies. In this final chapter, I describe the utility of the HTA framework in informing policy decisions around HIV CT interventions. I present a general summary of the evidence from the three methods employed to evaluate HIV CT: meta-analysis (essay 1), cost-effectiveness analysis (essay 2) and qualitative assessment of the consumer perspective (essay 3) and highlight the evidence that specifically relates to rapid and routine testing in the emergency room/urgent care center (ER/UCC) setting. I discuss the utility of the HTA approach and

describe additional information that would be useful for making health policy decisions. Finally, I discuss the implications of HTA for the development of health policy and areas of future research.

HTA Findings of HIV CT Technologies in the ER/UCC Setting

Evidence on Efficacy, Effectiveness and Safety

The first question that needs to be answered about a health technology or program is whether or not it is effective and how it compares to the standard of care and other available alternatives. This process includes obtaining information on safety and potential harms of the technology. It is also important for public health decision-makers to have information about effectiveness of the program in a variety of settings and populations.

For HIV CT, a critical question is whether the patient actually receives the test results so that diagnosis, treatment and prevention counseling can occur. To evaluate evidence for effectiveness of alternative HIV CT methods at increasing receipt of HIV test results, I conducted meta-analysis of the HIV CT literature (Essay 1). I compared studies that used the following alternative testing methods: rapid testing, routine testing, oral fluid testing, anonymous registration, telephone post-test counseling, written pre-test counseling and combinations of methods (e.g., routine rapid testing) to studies that used conventional testing. Studies of HIV CT were included in the meta-analysis if they used an alternative HIV CT method and had a conventional testing control group (though some studies used ELISA testing with alternative counseling methods as the control as it was the standard of care in that setting) and reported return rates for HIV test results.

Alternative HIV CT methods were more effective in improving return rates than

conventional testing among all clients tested and HIV positive clients. Rapid testing, routine rapid testing and telephone post-test counseling were most effective at increasing return rates. There was also evidence for effectiveness for home-testing and anonymous testing. The evidence on oral fluid testing and written pre-test counseling, which were used in outreach settings, ranged from no effect to reducing receipt of HIV test results. Rapid testing was most frequently used and most effective. Compared to the other alternatives, the odds of receiving HIV test results were about 22 times higher with the rapid test. The alternative testing methods, particularly rapid testing, were most effective in HIV testing centers, STD clinics and the ER/UCC setting. The rapid test was the only technology that was effective in the outreach setting.

There are several limitations to this meta-analysis. There was heterogeneity (between study differences that account for the pooled effect size) in the pooled analysis and all of the subgroup analyses indicating that the effect modifiers were not fully identified. Reporting issues and confounded variables limited a more detailed assessment (e.g., meta-regression) of the sources of heterogeneity. However, residual heterogeneity is expected as these studies were conducted in different patient populations and study settings. With one exception, these studies were conducted in metropolitan areas with a high, greater than 1%, prevalence of HIV, thus caution should be use when generalizing to rural areas and populations that have a low prevalence of HIV.

Economic Impact

Once there is evidence for effectiveness, public health decision-makers must determine the economic value of the technology and how it compares to the standard of care and other available alternatives. Economic information also helps decision-makers

decide between several effective technologies.

I conducted a cost-effectiveness analysis using decision-analytic modeling to compare routine rapid testing, routine ELISA testing and conventional testing in the ER/UCC setting (Essay 2). I included cost and effectiveness data from the meta-analysis and from HIV CT interventions reported in the literature. I found that routine rapid testing was the most cost-effective HIV CT strategy for informing all clients of their serostatus from both the societal (includes all costs) and provider perspectives (e.g., includes costs incurred by the hospital). The routine ELISA strategy was more cost-effective at informing HIV-infected clients of their test results from both perspectives. Sensitivity analysis revealed uncertainty for this outcome with respect to seroprevalence (>5.9%) and testing rates by HIV serostatus (which assumed to be equal in the model) and generally made the routine rapid test the most cost-effective strategy. Though there was some uncertainty in the sensitivity analysis of return rates, the findings were robust compared to return rates observed in the literature. Conventional testing was the least cost-effective strategy at informing clients of their test results in almost all of the scenarios explored by sensitivity analyses.

Limitations of this CEA include organizational differences and differences in the HIV CT procedures that were not addressed in this analysis. The CEA is also limited by the use of intermediate outcomes (cost per client and cost per HIV-infected client receiving HIV test results). Accordingly, these findings are comparable only to other CEAs that evaluate the same outcomes and are not useful in making resource allocation decisions when deciding between other health problems. Finally, the CEA is most applicable to emergency rooms and urgent care centers in urban public hospitals.

The Consumer Perspective

Even if technologies and other interventions have demonstrated evidence for effectiveness and cost-effectiveness, it is essential to determine how consumers will be impacted and whether or not they will accept and/or use the technology. Therefore, it is necessary to obtain information on consumer preferences, psychological and social outcomes and ethical issues.

I evaluated the consumer perspective using qualitative analysis of focus group interviews conducted during a clinical trial comparing voluntary routine testing using rapid and ELISA testing at a UCC in an urban public hospital (Essay 3). Participants preferred the rapid test to conventional testing because it was more convenient, though there were concerns about accuracy. The participants accepted routine testing, but there were concerns about cost and privacy. However, many participants thought they had been tested for HIV without their consent. The participants also identified other alternatives that might make them more likely to undergo testing. Less invasive testing methods (e.g., finger stick, saliva testing and urine testing) and technologies that offer greater assurances of confidentiality and privacy, such as home testing, were generally preferred. Participants also cited the following reasons for not returning for HIV test results: feeling shame, inconvenience and confusion over the process.

The consumer perspective also revealed an ethical concern, that patients might feel coerced to undergo HIV CT with the routine approach. This is problematic because it suggests that informed consent using routine testing was not truly voluntary, which has been a concern about routine testing (Quinn, 1992). This finding is also relevant to the issue of safety as it indicates a potential "harm" with the routine procedure.

There was also a lack of trust in the available HIV information and some participants held conspiracy theories related to HIV/AIDS; for example, that HIV is a form of genocide and the government and pharmaceutical companies are withholding a cure. Important misconceptions about HIV CT were also revealed. For example, some believed if they tested positive and did not return for test results, the health department would find them or they would receive a certified letter like with other diseases (e.g., hepatitis).

Economic implications were also evident from the consumer perspective. The biggest concern among focus group participants about routine testing was expense and there was some indication that they would be less likely to undergo HIV CT if they had to pay for testing. This addresses the issue of "who pays" for the technology that, because of its focus on social cost, is not addressed in cost-effectiveness analysis.

The participants of the focus groups were low income, inner-city African Americans, so caution should be used when generalizing to other populations. Likewise the findings (e.g., barriers to returning for results) may be most relevant to high volume public hospitals. While insight into the target population's preferences for HIV CT technologies was obtained, a limitation of focus group methodology is that it is not appropriate methodology for eliciting individual preferences.

Implications for Counseling

This HTA has implications for pre- and post-test counseling. Using the routine approach to testing, it is important that clients understand that even though it is routinely offered, testing is voluntary and that they do not feel pressure to undergo HIV CT. For the rapid test, it will be necessary to give clients assurance about accuracy. Likewise,

clients tested with the routine approach should be given assurances about confidentiality and privacy. Misunderstanding regarding the need to return for test results is an important implication for pre-test counseling. The fact that clients may assume that practices regarding reporting HIV status are similar to other diseases (e.g., getting a certified letter if they test positive) needs to be addressed. For HIV CT in predominately African American populations of low socioeconomic status, the counseling process needs to be evaluated for cultural sensitivity, particularly with respect to addressing trust issues.

Evidence on the Organizational Impact

Though these methods did not specifically assess the organizational impact of the alternative HIV CT methods, organizational effects were evident in each of the HTA methods. The meta-analytic data provided some indication of the organizational characteristics that increased return rates for HIV CT in the ER/UCC setting; for example, using rapid testing, patients were more likely to get results using a point-of-care approach than if it was offered after a clinic visit that included long wait times. With point-of-care testing, an HIV client educator or counselor conducts pre-test counseling, phlebotomy, testing and post-test counseling. There were also shorter waiting times if testing was conducted in an ER/UCC laboratory instead of the main hospital laboratory. In the focus groups, clients suggested that HIV CT be offered when they checked into the clinic (UCC setting) so that they would not have to wait for the rapid test after the clinic visit was complete, thereby increasing their total clinic time. This result also has implications for testing in other clinical settings, that the overall wait time should be considered – not just the wait time for HIV CT. Additionally, there was anecdotal information that implementing a routine screening HIV CT program in an urgent care

Table 12. Results of Health Technology Assessment ER/UCC Setting

Aspect of HTA	**Routine Rapid**	**Routine ELISA**	**Conventional Testing (Risk-based ELISA)**
Effectiveness/ Safety	-Most effective	-Effective	-Least effective
Economic Impact	-Most cost-effective for all clients	-Most cost-effective for HIV-infected clients	-Least cost-effective
Consumer Acceptance	-Preferred, but concern about accuracy, confidentiality & cost	-Accepted, but concern about confidentiality & cost	-Least accepted
Consumer Attitudes/ Beliefs	-Distrust among some African Americans	-Distrust among some African Americans - Misunderstanding about need to return for results	- Distrust among some African Americans - Misunderstanding about need to return for results
Ethical Issues / Harms	-Pressure to consent to HIV CT	-Pressure to consent to HIV CT	
Organizational Issues	-Offer test when patient checks into clinic -Point of care testing most effective -ER lab most effective -Difficult to implement	-Difficult to implement	
Implications for Counseling	-Need to address accuracy -Need to address trust issue for some African American Populations	-Need to address confidentiality -Need to address trust issue for some African American Populations	-Need to address trust issue for some African American populations

center was disruptive to the normal operations of the clinic (di Francesco, 2003). Thus, additional efforts would be necessary for such a program to be integrated into practice.

Utility of HTA in Informing Policy Decision-Making about HIV CT

The value of the HTA approach is best demonstrated in the context of the policy

questions posed by Phillips et al. (2003). I therefore, provide general answers to the questions using the HTA findings specific to the HIV CT in the ER/UCC setting and outline the information gained from the HTA for each of the technologies (Table 12).

Question 1) "Will the guidelines be adopted?"

This question remains largely unanswered as many of the HIV CT technologies are early in their diffusion and an assessment of practice patterns was not conducted.

Question 2) "Will at-risk and infected individuals be identified for HIV CT?"

The meta-analytic data demonstrated that routine rapid testing is the most effective technology at identifying HIV-infected individuals and conventional testing is the least effective.

Question 3) "Will health care providers offer HIV CT and patients accept HIV CT, obtain their test results, seek treatment and change risky behaviors?"

The meta-analysis and focus group data found that acceptance, testing and receipt of results was highest with rapid testing and lowest with conventional testing. Outcomes related to seeking treatment and risky behaviors were not evaluated in the meta-analysis. The focus group data also provided insight into why clients might not accept testing and return for results; for example, trust issues, cost (e.g., who pays), confusion about the need to return for test results and the wait time prior to being offered testing.

Question 4) "Will the guidelines be relatively cost-effective?"

The cost-effectiveness analysis showed that compared to conventional and routine ELISA testing, routine rapid testing is more cost-effective for all clients learning their HIV test results. For HIV-infected clients, routine ELISA testing is most cost-effective.

Question 5) "Will the guidelines be compatible with ethical standards?"

The focus group data gave some indication that the routine approach may threaten voluntary participation.

Limitations

In addition to the limitations of the individual elements employed, there are a few limitations to this health technology assessment of HIV CT interventions in the ER/UCC setting. Many of the HIV CT technologies are in an early state of diffusion and new technologies have emerged since this HTA was conducted, thus it will need to be updated to account for changes in technology. For example, the recently approved Oraquick test, a finger stick rapid test with a 20-minute turn around time for test results, may impact the HTA findings since it is a less invasive test with a shorter waiting time, so it could potentially be more desirable to consumers and impact effectiveness and cost-effectiveness (CDC, 2002). Additionally, the HTA is most applicable to emergency rooms and urgent care centers in urban hospitals. The consumer perspective is also further limited to applicability to socio-economically disadvantaged African Americans.

This research did not evaluate all of the elements of HTA. For example, assessment of practice patterns and diffusion of the technologies was not conducted. Additionally, regulatory issues, such as approval by the Food and Drug Administration or reimbursement by Medicaid and other payors, were not assessed and can have a significant impact on the use of the technology. The effect of the HIV CT technology on the organization and providers was not formally assessed, though some information was obtained on how the organization impacts the technology (e.g., use of the ER lab vs. hospital lab).

Discussion

This HTA demonstrates the importance of examining public health decision-making from a variety of perspectives and provides decision-makers with comparative information on efficacy and effectiveness, the economic value of the HIV CT interventions, consumer acceptance, ethical and organizational considerations of HIV CT in the ER setting. The HTA framework adds information about different facets of health policy decision-making, thus providing a more coherent perspective for decision-making. For example, in considering only the evidence for effectiveness, a decision-maker would most likely choose rapid testing because receipt of HIV test results is greatest. However, the economic information demonstrated that routine ELISA testing is more cost-effective at informing HIV-infected patients of their test results, so making a decision based on effectiveness information alone would result in using a less efficient HIV CT strategy for that outcome. Likewise, if a decision was made based on effectiveness and cost-effectiveness, the routine rapid approach would be most desirable; however the consumer perspective revealed ethical issues related to voluntary participation that must also be considered. This HTA, therefore, highlights the complexity of public health decision-making and how the HTA approach provides a more coherent perspective.

It is also important to note how the elements of HTA are integrated. For example, adoption and diffusion of HIV CT technologies could be influenced by all of the aspects of HTA, evidence of effectiveness, consumer acceptability, cost-effectiveness, regulatory issues and organizational impact. Likewise, consumer acceptability of HIV CT impacts effectiveness of HIV CT by influencing willingness to be tested and return for HIV test results. Effectiveness is also a prerequisite of cost-effectiveness. The organizational impact of a technology also has implications on economic efficiency. If additional

resources are needed to make implementation of an HIV CT program acceptable to an organization, then cost-effectiveness is impacted. Additionally, regulatory and reimbursement issues (to both, the patient and provider) impact the decision to accept testing and/or implement an HIV CT program. Therefore, it is not only necessary that public health decision-makers consider the different elements of HTA, it also important to consider how the different elements impact each other.

This HTA also illustrates the value of using different research methods for policy decision-making. Two of the three methods used quantitative research and were designed to answer very specific questions about these technologies. The qualitative analysis, because of its grounded theory approach, informed not only consumer perceptions and preferences, but also organizational aspects, ethical issues and provided insight into issues around counseling. Therefore, it complemented the findings of the quantitative methods employed and added considerable value to the overall assessment of the technologies.

HTA and Implications for Policy

While information on effectiveness, cost-effectiveness, consumer perceptions and other elements of HTA is frequently assessed in the evaluation of health technologies, such information is not often considered together for policy decision-making. In the U.S. and abroad, there is primacy of evidence for effectiveness. Health policy decision-makers sometimes look at evidence for effectiveness and economic evidence; however, it is uncommon for decision-makers to simultaneously consider those data with evidence on the consumer perspective or the other elements of HTA. This is apparent in the many organizations that make "evidence-based" recommendations on health interventions. In

the U.S., the National Institutes of Health Consensus Development Process, the *U.S. Task Force on Preventive Services* and *The Guide to Community Preventive Services* generally only consider the evidence on efficacy and effectiveness when recommending health technologies for the U.S. population. One could therefore consider these "efficacy-based" or "effectiveness-based" recommendations. While it is appropriate that the first consideration be one of effectiveness, public health decision makers must consider other types of evidence for policy decision-making. The "evidence-based" decision-making process should therefore recognize the broader context in which decisions about the public's health are made.

Implications on Future Research in HIV CT

Future research should expand the HTA to other clinical settings and populations to increase applicability. Additionally, future cost-effectiveness analyses should include final outcomes (e.g., cost per life year saved, cost per quality adjusted life year saved) so that the economic findings can be comparable to other types interventions and the full economic value can be assessed.

Many effective and cost-effective technologies are not implemented for various reasons; therefore, future research should evaluate the current state of diffusion and practice patterns related to these technologies. It is important to assess factors related to use of the technologies such as client demand, clinician demand, health system factors and policy factors (e.g., regulatory or reimbursement issues). For example, there was some indication that client demand for these technologies may be impacted by who bears the cost. An additional method used in economic evaluation, contingent valuation (use of survey methodology to assess willingness to pay) could provide information on how

client demand would be affected by the cost of the alternative HIV CT methods. Adding the consumer perspective to the cost-effectiveness analysis would also provide useful information on how the consumer is impacted by the cost of HIV CT. Additionally, social and regulatory issues, such as who has access to the technologies and reimbursement by Medicaid and other payors, have a significant impact on the use of the technology and should be assessed. This information is valuable in identifying barriers to implementation as well as how to promote the rational diffusion of health technologies.

Evidence on the impact of the HIV CT technology on the organization and providers also needs to be addressed. For example, it would be necessary to identify the organizational and educational (e.g., provider education) requirements and changes necessary to implement a rapid testing program. Such requirements might be more difficult for teaching hospitals that rotate house staff (interns and residents) on a monthly basis. On the other hand, teaching hospitals, particularly those affiliated with universities are perceived as more receptive to using new technologies (Russell, 1979). It would also be important to determine how the program, particularly routine testing, affects the flow of a busy clinic or emergency room as well as other services delivered. This is particularly a concern in the ER setting in level-one trauma centers (the highest designation indicating the ability to care for the most critically ill patients) where taking care of acutely ill patients is the number one priority.

There were some ethical issues raised in this HTA that need to be more fully addressed, most notably the issue of voluntary participation with the routine approach to testing. One finding of the meta-analysis is that there was very little information on the content of counseling in the effectiveness studies. It will, therefore, be important to

determine if the alternative HIV CT strategies, which in many cases reduce the client's interaction with the counselor or clinician, provide adequate counseling services.

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Appendix A: Meta-Analysis Data Abstraction Form

Reference:	
Study Description:	
Study Design:	
Eligibility Criteria:	
Control/Comparison group 1:	
Control/Comparison group 2:	
Treatment group 1:	
Treatment group 2:	
Treatment group 3:	
Outcome Variables:	
# Approached:	
# Eligible and offered testing overall:	
# Eligible and offered testing control/comparison:	
# Eligible and offered testing experimental:	
# Tested overall:	
# Tested control/comparison:	
# Tested treatment:	
How receipt of results was defined:	
Receipt of results (%,OR) control/comparison:	
Receipt of results (%,OR) treatment:	
Receipt of results HIV +(%,OR) control/comparison:	
Receipt of results HIV +(%,OR) treatment:	

Other Reported Outcomes:	
control/comparison:_____	
treatment:_____	
control/comparison:_____	
treatment:_____	
Moderator/ Control Variables	
Study setting:	
City/State/ Country:	
Population Description of those tested:	
Gender:	
Race:	
Education:	
Age:	
Type of HIV Test:	
Counseling description:	
Incentives for testing:	
Incentives for returning for results:	
Wait time:	
Anonymous / Confidential?	
Sensitivity & Specificity:	
Baseline Prevalence:	
Intervention Prevalence:	
Intervention Duration:	
Publication Date:	

Appendix B. Focus Group Moderator's Guide

Knowledge of risk factors for HIV infection and reasons for testing

My first question is to talk with you about your knowledge of HIV infection. Someone tell me what is HIV?

- Any other thoughts on what is HIV?

What are some ways you can get HIV?

What are some of the ways you can't get HIV?

What is the best way to know if a person is infected with HIV or AIDS?

When I say the words HIV/AIDS test what come to your mind? How does it make you feel?

What can an HIV test tell you?

What does positive or negative mean?

What are ways to prevent you from getting infected?

If a person has been tested before why get re-tested?

How often?

Reasons for and Against Testing for HIV

Why would a person decide to take an HIV test?

- What are the good things about getting tested?

On the other hand, why would a person decide not to be tested?

- What is behind the fear? (If mentioned)
- What are the bad things about getting tested?

What kinds of things do you take into account when you are figuring out whether you need to be tested for HIV?

- Does the decision relate to your partner(s) behavior?
- Does knowing someone with HIV make you more or less likely to get tested?

Preferences and Acceptability of Testing

Do you think HIV testing *is* done every time a person goes to the doctor or hospital?

Do you think HIV tests *should* be done regularly like other blood tests?

Do you think people's permission is always asked before they are tested for HIV?

- Can an HIV test be done without the patient's permission?

Some people get tested for HIV/AIDS but never come back to find out they results, why do you think people do not come back for results?

If there was a test where you could get the results back the same day, how would that

affect your willingness to be tested?

- Would the waiting period affect your decision?

Would you have been more willing to be tested if a different kind of test was offered?

Would you be more likely to agree if you did't need to get a needle stick?

Is there anything about HIV testing you would change?

- What would make HIV testing more convenient for you?

HIV /AIDS Information Sources & Trust

If you wanted information about HIV, where would you go first?

- Tell me a little bit about why.
- How would you prefer to get information about HIV?

Do you trust information you get about HIV?

How much?

Those that do not trust the information you get about HIV, why don't you trust it?

Who do you trust?

Brochure Questions

You should have received a brochure before you got tested. What did you think of the design?

- So is the size good?
- How about the pictures?

What about the information on the inside - was it useful?

Is it a good way to counsel patients?

Did it affect your decision to be tested?

- How much?

Did you see the poster in the waiting room?

Did it effect your decision to get tested?

Any final comments?

BIOGRAPHICAL SKETCH

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Angela Blair Hutchinson was born in Savannah, Georgia on the 17th of June, 1968. Angela's previous education includes an A.B. degree in Psychology from the University of Georgia (1990) and a Masters of Public Health degree in Health Policy and Management (1993) from Emory University. As a doctoral student, Angela was awarded Doctoral Student of the Year for the Joint PhD Program by the School of Public Policy at the Georgia Institute of Technology. She was also selected to receive the Janice Holyfield Scholarship in Health Policy which she had to decline to accept a fellowship at the Centers for Disease Control and Prevention (CDC). Also as a doctoral student, Angela also taught Research Methods in the Andrew Young School of Policy Studies.

Currently employed as a behavioral scientist at the CDC's National Center for HIV, STD and TB Prevention, Division of HIV/AIDS Prevention, Angela conducts research on the effectiveness and cost-effectiveness of interventions to prevent HIV/AIDS. She is also a member of the Health Economics Research Group at CDC and a Working Group that is assessing the use of economic evaluation methods to value health. Her current research interests include HIV/AIDS prevention, economic evaluation, health technology assessment and health policy decision-making, meta-analysis, assessment of consumer preferences and health services for underserved populations.

Angela has authored a number of publications in peer-reviewed journals. Recent publications include "the Effect of Medicaid Managed Care on Children with Mental Health and Substance Abuse Disorders" published in *Mental Health Services Research* (2003). Angela also published a study, "Utilization of Technologies to Reduce Allogeneic Blood Exposure in the United States" in *Transfusion Medicine*, 2001 and "Purchasing Oncology Services: Summary Recommendations" that was published in the journal *Cancer*, 2000. In 1999, Angela published, "Development and Preliminary Validation of a Measure of Social Functioning for Adolescents with Physical Disabilities" in the *Journal of Rehabilitation Outcomes Measurement*. Angela also has a book chapter forthcoming, "Reviews of Economic Evaluations" in the *Guide to Community Preventive Services* and "A Systematic Review of Methods Used to Elicit Preferences in Women's Health Care", which is to be published in a Special Issue of the *Journal of the International Society of Technology Assessment in Health Care*.

Angela's previous research has centered in health technology assessment and health services research. She served as project director for the United States' role in the International Study of Peri-operative Transfusion (ISPOT). This study was a health technology assessment that evaluated the effectiveness, practice patterns and consumer and provider perceptions of technologies used to reduce transfusion transmitted infection in 10 countries. Angela has published work from this study in *Blood, Anesthesia & Analgesia, Transfusion Medicine and Archives of Internal Medicine* and in a book chapter, "The Results of an International Practice Variation Analysis" in *Alternative Approaches*

to Human Blood Resources in Clinical Practice (1998). Examples of other research conducted include developing a measurement package for the economic evaluation of drug abuse prevention programs, translation of economic evaluations for public health decision-makers, comparing consumer versus expert opinions about informing patient decision-making for genetic testing for heritable breast and ovarian cancer.

Angela has also served as a peer reviewer for several journals, *the Lancet*, *Morbidity Mortality Weekly Report*, *Journal of Health Care for the Poor and Underserved* and *Public Administration Review*. In addition, she served on the scientific review committee for the 2002 Annual meeting of the *Society for Medical Decision Making*.

Angela has also presented her work at a number of national and international conferences, *The International Society of Technology Assessment in Health care* annual meetings in Ottawa, Canada (1999), The Hauge, The Netherlands (2000), Berlin, Germany (2002); *Meeting of the International Study of Peri-operative Transfusion,* Edinburg, Scotland (1999); the *XIII International AIDS Conference,* Durban, South Africa (2000); the *Society for Medical Decision Making Annual Meeting*, Baltimore (2002) and the *Annual Meeting of the American Society of Clinical Oncology* (1998).

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