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AIDS and Behavior, Vol. 4, No. 1, 2000

The Voluntary HIV-1 Counseling and Testing Efficacy Study: Design and Methods

The Voluntary HIV-1 Counseling and Testing Efficacy Study Group: M. Claudes Kamenga,[1] Michael D. Sweat,[1] Isabelle De Zoysa,[1] Gina Dallabetta,[1] Thomas J. Coates,[2] Olga A. Grinstead[2,7] Steven E. Gregorich,[2] David C. Heilbron,[2] William P. Wolf,[2] Kyung-Hee Choi,[2] Julius Schachter,[2] Donald Balmer,[3] Francis Kihuho,[3] Stephen Moses,[3] Frank Plummer,[3] M. Gloria Sangiwa,[4] Margaret Hogan,[4] Japhet Kilewo,[4] Davis Mwakigile,[4] Colin Furlonge,[5] Kevin R. O'Reilly,[6] Samuel Kalibala,[6] Ben Nkowane,[6] and Eric van Praag[6]

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While HIV counseling and testing has been promoted as potentially effective for prevention, few controlled studies have been conducted. The Voluntary HIV Counseling and Testing Efficacy Study was a randomized clinical trial of the effectiveness of HIV counseling and testing in reducing sexual risk behavior in three developing countries: Tanzania, Kenya, and Trinidad. The trial will provide crucial information regarding the effectiveness, cost, and consequences of HIV counseling and testing for prevention. This paper describes the design and methods of the Voluntary HIV Counseling and Testing Efficacy Study. Following a discussion of the study objectives, the design and methods of the study are presented. Recruitment, consent, randomization, intervention, assessment, follow-up, training, and quality assurance procedures are described. Issues raised in the design and anticipated in the interpretation of the study outcomes are discussed, as well as potential policy and service delivery implications of the study findings.

KEY WORDS: HIV prevention; counseling; HIV testing; research design.

INTRODUCTION

The Voluntary Counseling and Testing Efficacy Study was a randomized clinical trial conducted in 1995–1998 to test the efficacy of voluntary HIV counseling and testing (HIV VCT) to reduce sexual risk behavior. The trial was conducted in three developing countries (Kenya, Tanzania, and Trinidad). It was designed to address ongoing questions about the efficacy of HIV VCT for prevention (Higgins *et al.*, 1991; Wolitski *et al.*, 1997), particularly the usefulness of VCT in the developing countries (Campbell *et al.*, 1997; DeZoysa *et al.*, 1995), and to respond to repeated calls for controlled studies of the efficacy of HIV VCT (Beardsell, 1994; Higgins *et al.*, 1991; Phillips and Coates, 1995). Earlier studies in developing countries support the effectiveness of HIV VCT for risk reduction, especially for couples (Allen *et al.*, 1992a, b; Kamenga *et al.*, 1991). A recent controlled study in the United States offered strong support for the effectiveness and feasibility of short counseling interventions with testing (Kamb *et al.*, 1998).

Even when HIV treatment is not readily available in developing countries, HIV VCT provides an opportunity for education and behavior change, and knowledge of serostatus allows individuals to plan,

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Characteristics of Individuals and Couples Seeking HIV-1 Prevention Services in Nairobi, Kenya: The Voluntary HIV-1 Counseling and Testing Efficacy Study

Donald Balmer,[1] Olga A. Grinstead,[2] Francis Kihuho,[1] Steven E. Gregorich,[2] Michael D. Sweat,[3] M. Claudes Kamenga,[4] Frank A. Plummer,[5] Kevin R. O'Reilly,[6] Samuel Kalibala,[7] Eric van Praag,[6] and Thomas J. Coates[2]

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This paper describes the recruitment and baseline characteristics of men, women, and couples who enrolled in the Voluntary Counseling and Testing Efficacy Study at the study site in Nairobi, Kenya. The purpose of this study was to test the effectiveness of Voluntary HIV Counseling and Testing (HIV VCT) to reduce sexual risk behavior. Between June 1995 and March 1996, 500 individual men, 500 individual women, and 515 couple members were recruited for a total sample of 1,515 participants. Participants were young (average age 29 years) and of low income. High levels of risk behavior and self-reported STD symptoms and a high rate of HIV seropositivity among those tested at baseline (15% of men and 27% of women) indicate that an at-risk sample was recruited. Women and participants reporting symptoms of a sexually transmitted infected were significantly more likely to be infected with HIV. Findings suggest that HIV VCT services combined with STD diagnosis and treatment and economic development services could motivate more at-risk individuals and couples to receive counseling and testing.

KEY WORDS: HIV; Africa; counseling and testing.

INTRODUCTION

Since 1985 when HIV transmission routes became known, health information campaigns have been very successful in educating Kenyans about HIV and AIDS (Garland *et al.*, 1993; Pattullo *et al.*, 1994). Unfortunately, these campaigns have not been successful in changing behavior, and new HIV infections continue to occur. In 1995 the national HIV prevalence rate was 7.5%, the urban prevalence was 13–14%, and the major transmission routes were heterosexual contact (75%), perinatal transmission (22%), and blood transfusion (3%) (USAID, 1996). Behavioral intervention offers a feasible strategy of preventing further infection and has assumed increasing importance as immediate hope for a cure or vaccine has dwindled (Choi and Coates, 1994). One possible method of reducing risk behavior is through voluntary HIV counseling and testing (VCT).

A number of studies have been conducted to evaluate the efficacy of HIV VCT for prevention (for reviews see Higgins *et al.*, 1991; Wolitski *et al.*, 1997). To date, however, data supporting the effectiveness of VCT for changing behavior and preventing new infections have been inconclusive. There is also some controversy regarding the appropriateness of in-

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Clients' Perspective of the Role of Voluntary Counseling and Testing in HIV/AIDS Prevention and Care in Dar Es Salaam, Tanzania: The Voluntary Counseling and Testing Efficacy Study

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There is a growing body of evidence that voluntary HIV counseling and testing (VCT) is effective for the primary prevention of HIV as well as for the care and support of individuals affected by HIV in developing countries. This qualitative study offers an additional perspective: the experiences and perceptions of men and women receiving VCT services. As a substudy of a large multisite clinical trial testing the effectiveness of VCT, 81 study participants at the Tanzania study site who were randomized to VCT at baseline were interviewed at the time of their 6-month follow-up. Findings are based on textual analysis of the following themes: HIV in the context of other life issues, motivations for receiving services, positive and negative consequences of VCT, and the role of VCT in risk reduction. Implications for service provision in developing countries are discussed.

KEY WORDS: HIV counseling and testing; qualitative interviews; developing countries.

INTRODUCTION

Voluntary HIV counseling and testing (VCT) has recently been recommended as an important HIV prevention tool in developing countries, as it reduces risk behaviors, is programmatically feasible, and is cost-effective (De Zoysa *et al.*, 1995; Higgins *et al.*, 1991; Sangiwa *et al.*, 1998; Sweat *et al.*, 1998; Wolitski *et al.*, 1997). In addition, HIV counseling with or without testing can play a beneficial role in the care and support of people living with AIDS and their families (Higgins *et al.*, 1991). On the basis of these findings, government agencies and individual donors working in Tanzania have been encouraged to support HIV counseling and testing activities.

Although some research indicates that the client-centered model of VCT as recommended by the U.S. Centers for Disease Control and Prevention is effective in modifying risk behaviors (CDC, 1998; Higgins *et al.*, 1991; Sangiwa *et al.*, 1998; Wolitski *et al.*, 1997), limited data are available on its appropriateness in a non-Western setting or on clients' own perspective of their experience with VCT. Providing culturally sensitive interventions is important both to ensure sustainability of services and to optimize behavior change (Scott and Mercer, 1994).

The literature available from East Africa indicates that VCT clients view professional counselors as an appropriate source of support and will seek their help (Dautzenberg *et al.*, 1992; Keogh *et al.*, 1994). However, seeking VCT services may be stigmatizing regardless of the test results. For example, a person who seeks HIV testing can be perceived as

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HIV-Related Risk Factors in a Population-Based Probability Sample of North and Central Trinidad: The Voluntary HIV-1 Counseling and Testing Efficacy Study

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A population-based probability sample of North and Central Trinidad collected information on 860 respondents' demographic characteristics, as well as the prevalence of sexual risk behaviors and precursors to sexual risk taking in the 2 months preceding interview. Precursors of sexual risk behavior included HIV transmission knowledge, condom possession, and alcohol and drug use prior to sexual intercourse. A 91% response rate was achieved. Overall, approximately 51% of respondents reported unprotected sexual intercourse with a primary sex partner (i.e., spouse or "steady" partner), and 4% reported unprotected sexual intercourse with a nonprimary partner (i.e., casual or commercial partner) during the 2 months prior to interview. Substantial variability on these risk behaviors was noted across demographic strata. Alcohol and drug use prior to intercourse was associated with reports of unprotected intercourse with primary and nonprimary partners. Those who kept condoms at home were less likely to report having unprotected sexual intercourse with both primary and nonprimary partners. The demographic indicators of marital status and respondent gender had indirect (i.e., *mediated*) effects, through one or more of the risk precursors, on sexual risk behaviors. Implications for the design and targeting of HIV-related interventions and services are discussed.

KEY WORDS: HIV; AIDS; risk behavior; population sample; probability sample.

INTRODUCTION

HIV prevention efforts require valid information on the HIV-related knowledge, attitudes, beliefs, and risk practices (KABP) of targeted populations. Updated data are necessary to identify research needs, evaluate trends, assess and target interventions, and advise public health policy (Bugingo *et al.*, 1993). In developing countries many interventions are national and generalized. In this situation it is important that such data are recent and representative of the general population (Cleland and Ferry, 1995). This article reports the findings from a recent survey of HIV-related KABPs in a population-based probability sample of North and Central Trinidad.

The estimated seroprevalence of HIV in Trinidad and Tobago is 1–2% (W. Charles, personal communication, April 1998; M. Lewis, personal communication, June 1998). Information regarding the prevalence of HIV-related KABPs among the general population of this country is limited. As in many

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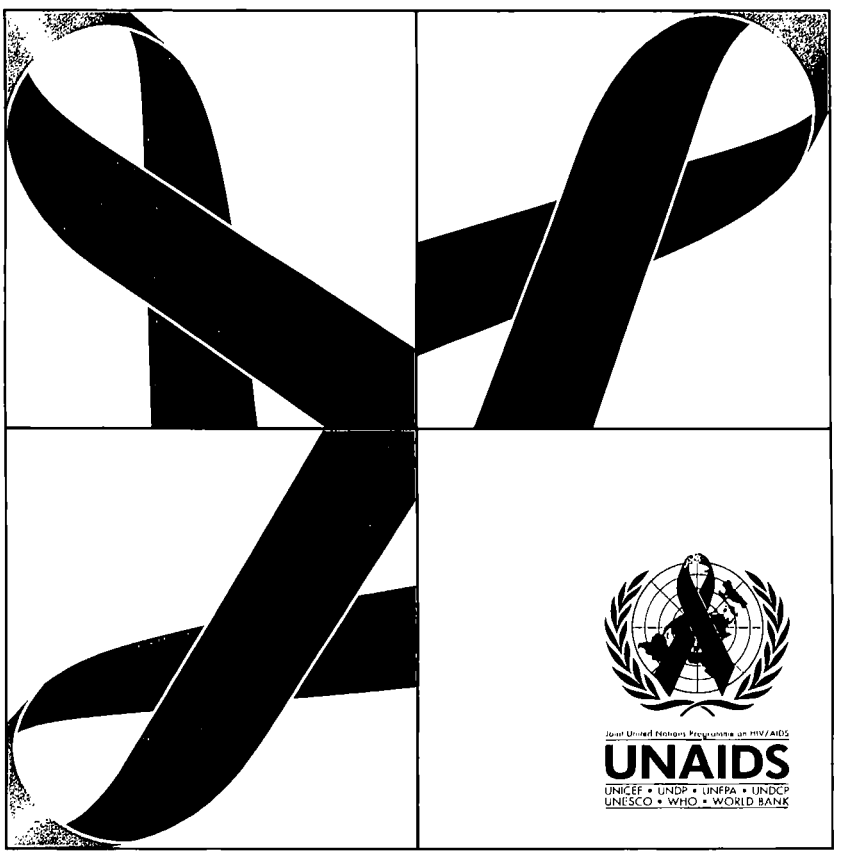

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