PARTICIPATING IN A CLINICAL TRIAL:
HIV-POSITIVE WOMEN’S EXPERIENCES AND DECISION MAKING PROCESSES

DISSERTATION

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By
Beth A. Canfield, M.P.H.

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The Ohio State University

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Dissertation Committee:
Professor Catherine Heaney, Adviser
Professor Nancy Reynolds
Professor Randi Love

Approved by

Adviser
Public Health Graduate Program
ABSTRACT

The use of drug therapies helps extend and improve the quantity and quality of life for HIV+ people. The rapid rate of viral resistance makes continued research into newer therapies vital. Under-recruitment of women into trials may limit health care practitioners' ability to provide optimal care for HIV+ women.

This research explored the process HIV+ women used to make decisions about enrolling and continuing participation in clinical trials. Grounded theory, which emphasizes systematic data collection and analysis, guided the qualitative methods. This qualitative study resulted in thick, rich descriptions of HIV+ women's experiences in clinical trials. Audio-taped face-to-face, semi-structured interviews lasted between 45 and 90 minutes. QSR NUD*IST software was used to facilitate data analysis. Open coding, axial coding, data immersion, and discussion with experts elucidated themes and discrepancies in the data.

Women older than 18 who were participating in a clinical antiretroviral trial were eligible. Twelve eligible women were interviewed. Six women were Caucasian; six were African-American. The ages of women ranged from 29 to 63. Five women were employed either full or part-time.
The decision to participate in a clinical trial was not troublesome for most of the women interviewed. Decisions to join a clinical trial are rooted in a socio-economic reality and may not require agonizing over pros and cons (especially as pros and cons assume a core base of knowledge of other options which was not found to exist here). The decision-making was based also on feelings of desperation (due to existing or potential health decline) and involve trust, altruism, and expectations of personal health benefits. These decisions may need to be re-framed from the rational framework(s) currently in vogue to one incorporating affective and socio-economic constructs. A strong, positive affective relationship with trial health care providers shaped and affected every area of the trial experience, including trial-related decision-making. Overall, these HIV+ women seemed very satisfied with their experiences in clinical trials.
I want to dedicate this work to the women who took time out of their lives to discuss their clinical trial participation to me. Our interviews were often emotional, and some of my questions inspired emotional and thoughtful answers. I remain honored and touched by their trust in me.
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VITA

December 1, 1974………………………….Born – Wooster, Ohio
1999…………………………………….M.P.H. Public Health, The Ohio State University
1999-2002………………………………Graduate Research Assistant,
The Ohio State University
2002 to present……………………….ASPH/CDC Fellow
National Center for Health Statistics

PUBLICATIONS

Research Publication


FIELDS OF STUDY

Major Field: Public Health
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Chapter 1

INTRODUCTION

Statement of the Problem

The Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS). HIV can be transmitted through bodily fluids such as semen, vaginal fluids, blood, and breast milk. Progression to AIDS is associated with opportunistic infections and death (Centers for Disease Control and Prevention [CDC], 2003). HIV/AIDS has become a pressing public health problem globally and in the United States.

HIV/AIDS affects more women every year. Almost 77,000 women in the United States have been diagnosed with AIDS (CDC, 2002). In 2002 minorities accounted for 80% of all AIDS cases among women in the United States although they represented fewer than 25% of all women in the United States (CDC, 2002). The Centers for Disease Control and Prevention estimate that between 120,000 and 160,000 women and female adolescents in the United States are living with HIV/AIDS (CDC, 2001). In 2001 over 11,000 women tested HIV+ and another 11,082 were diagnosed with AIDS (CDC, 2002).

Women made up 20% of all AIDS cases in the United States in 1999 (CDC, 2002). This proportion is expected to increase to 50% as the next generation of adolescent women begin HIV testing and/or become symptomatic (CDC, 2002). HIV incidence statistics are underestimates of infection in the population, both because
women may not be tested until they are symptomatic and have AIDS and because HIV testing and reporting requirements vary from state to state (CDC, 2002).

In any case, more and more women in all age groups are being infected with HIV (CDC, 2002). Sixty-seven percent of Ohio women with HIV/AIDS are 30-49 years old, and about 8 percent are 50 or older (Ohio Department of Health HIV/AIDS Surveillance program [ODHHAS], 2002).

In 2000, 997 women 15 to 44 years old were reported to be living with HIV in Ohio; also in 2000, 475 women were reported to be living with AIDS in Ohio (CDC, 2002). Ohio reported 180 new HIV diagnoses and 114 new AIDS cases among women in 2001 (CDC, 2002). African-American women living in Ohio are about 11 times more likely to have HIV than white women in Ohio (DeMartini, 2003).

The number of HIV/AIDS cases in Franklin County women has almost tripled over the past 10 years (DeMartini, 2003). The Columbus Health Department reported 275 women living with HIV/AIDS in Franklin County through the end of 2001 (O’Neil, 2001). Women made up 17 percent of the county’s HIV/AIDS cases (O’Neil, 2001). African-American women, who represented 19% of Franklin County’s population, made up 32% of the HIV/AIDS cases (O’Neil, 2001).

In Hamilton County at the end of 2001, there were 186 cases of women living with HIV/AIDS, which is about 17 percent of the total cases (Ohio Department of Health [ODH], 2002). Almost 52 percent of the female cases were among African-American women, who made up about 23 percent of the population (Ohio Department of Health [ODH], 2002).

The face of the HIV/AIDS epidemic has changed greatly in the past two decades. As the number of HIV-positive women increases, it is critical that research focusing on female biology, women’s roles in society, and psychosocial factors increase as well. Research findings from gay white men, the traditional HIV/AIDS research subjects, may not apply to HIV+ women.

HIV+ women have become more visible and vocal in the past decade. Their advocacy has drawn the attention of key policy-makers to gender-specific issues such as the biological differences in drug metabolism between men and women. While
traditionally it has been assumed that female biology was not significantly different from male biology, researchers have demonstrated the existence of female biological factors, like menstrual cycles, that may influence metabolism of pharmaceuticals and may influence aspects of infection like HIV blood levels (Gandhi et al., 2002). Furthermore, gender differences have been found in response to antiretroviral therapies (Currier, Spino, Grimes, Wofsy, Katzenstein, Hughes, Hammer, & Cotton, 2000).

No longer is a diagnosis of AIDS an immediate death sentence. AIDS prevalence has continued to increase, in part because deaths among people with AIDS declined for the first time in 1996 because of new combination treatment therapies (Paterson et al., 2000). HIV/AIDS treatment has changed drastically in the past two decades, and research focusing on the quality of life among those with HIV/AIDS is becoming as important as issues related to quantity of life. The use of drug therapies is considered to be the gold standard for treatment of HIV+ people. The rapid rate of viral mutation and resulting therapeutic resistance makes continued research into newer therapies vitally important (Casado et al., 2001; Coffin, 1995; Overbaugh & Bangham, 2001).

While the epidemiology and biology of HIV/AIDS for both sexes are relatively well-established, many psychosocial issues related to infection and treatment remain puzzling; one such issue is women’s personal decisions about participation in a clinical trial. There is debate whether enough women are choosing to join HIV/AIDS trials to result in informed, optimally effective care for HIV+ women.

**Purpose of the Study**

The purpose of this study is to explore HIV+ women’s experiences when participating in clinical trials, focusing on perceptions, iterative decision making, and impacts on their personal life stories. The research questions are:

- What are the major decision points in considering participation in a therapeutic clinical trial?
• What is the nature of the experience of participating in a therapeutic clinical trial for HIV+ women?

• How do women interpret this experience and incorporate it into their lives?

This research adds to existing knowledge by using qualitative methodology to explore how HIV+ women make decisions about enrolling in a clinical trial and continuing their participation. Implications for policy and practice guidelines are explored. This research is based on the specific perspectives and experiences of HIV+ women and is expected to be of interest to advocates, health care providers, and policy makers in the United States and in other developed countries.

**Structure of the Dissertation**

Chapter 2 reviews pertinent literature and contains background information on qualitative methodologies. Chapter 3 focuses on the specific qualitative techniques used in this study, data collection and analysis, recruitment issues, and describes the women interviewed. Chapter 4 contains interview data focusing on analytic themes and illustrative quotes. Chapter 5 discusses the interpretation of the data analysis, recommendations, and conclusions.
Chapter 2

REVIEW OF THE LITERATURE

Chapter 2 will review literature pertinent to this study. Sections include a definition of a clinical trial, information on HIV therapy treatment guidelines, information on women’s participation in HIV clinical trials, HIV stigma, previous unpublished research of the author, purpose and significance of the proposed study, the research questions, and a discussion of qualitative methodology and the theoretical paradigms used in this study.

Clinical Trial Definition

A clinical trial is a systematic research study that usually involves testing drugs for their safety and comparing them against a current treatment to determine their efficacy regarding a specific disease or symptom (Williams & Boykin, 1999). Randomized clinical trials are the gold standard for evaluating clinical outcomes and determining if experimental treatments perform better than current treatments (Sadler, Lantz, Fullerton, & Dault, 1999).

Clinical trials in HIV/AIDS research began in the 1980s and primarily consisted of gay white men, who formed advocacy groups and began demanding access to treatment early in drug development (El-Sadr & Capps, 1992; Marte & McGovern, 2000). Often clinical trials offer access to the newest therapies (Williams et al., 1997). As
women assume more of the country’s HIV/AIDS infection burden, clinical trials have been developed to meet their needs (Marte & McGovern, 2000).

HIV/AIDS trials are overseen by private pharmaceutical companies, the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Disease, and/or the Federal Drug Administration (FDA) (Marte & McGovern, 2000). Clinical trials may be stopped earlier than planned if results are very positive or very negative (Williams & Boykin, 1999). Early in the epidemic clinical trials primarily tested new, life-saving drugs; currently, very few trials use placebos (Williams & Boykin, 1999). HIV+ people in trials receive the current standard of care. Most HIV/AIDS trials use new combinations of drugs currently approved by the FDA (Williams & Boykin, 1999).

Drug companies have been wary of including women of childbearing potential in trials for decades. NIH allows the appropriate exclusion of women in trials (Eckenwiler, 1999). Both drug companies and the government wish to avoid liability for harm done to fetuses born to women who participated in a trial (Denenberg, 1990; Ethier et al., 1996; Kelly & Cordell, 1996; Williams et al., 1997). Women who have not been surgically sterilized may be discouraged or excluded from participation by being required to use multiple methods of birth control. This does nothing to facilitate a caring relationship or mutual trust with women who consider trial participation (Arno & Feiden, 1992; Denenberg, 1990; Hankins et al., 1998).

Women, as well as men, also may be deliberately excluded from protocols due to active or past drug use, a lack of competency in English, and an inability to care for themselves (Denenberg, 1990; Hankins et al., 1998). On the other hand, women may be included in clinical research to determine how best to prevent HIV transmission to offspring; regimens under study may not be those optimally suited for the woman herself (Shuster, 1996). Fetal health, as opposed to maternal-child health, drives some HIV/AIDS trials focusing on women (Eckenwiler, 1999).
HIV Therapies

The Panel on Clinical Practices for Treatment of HIV Infection (2001) issues recommendations on the use of antiretroviral therapies, also known as highly active antiretroviral therapy or HAART, for HIV+ adults and adolescents. HAART suppresses HIV disease activity, improves immunological function, and decreases morbidity and mortality in women and men (Gange, 2002). The panel’s guidelines recommend that all HIV+ individuals who have severe symptoms, such as wasting or AIDS, or are asymptomatic with a CD4+ T cell count below 200/mm³ begin treatment with antiretroviral drugs. Asymptomatic individuals with CD4+ T cell count between 200/mm³ and 350/mm³ generally should be offered therapy. When a person’s CD4+ T cell count is above 350/mm³ and the plasma HIV RNA is greater than 30,000 (bDNA) or greater than 55,000 (RT-PCR), the extension of an offer of therapy depends on the clinician’s judgement. Beginning therapy in HIV+ people whose CD4+ T cell count is above 350/mm³ and have plasma HIV RNA levels less than 30,000 (bDNA) or less than 55,000 (RT-PCR) is not generally recommended (Panel on Clinical Practices for Treatment of HIV Infection, 2001; Anderson, 2000). A study on women with HIV suggested HAART could safely be delayed until CD4+ T cell counts are below 200/mm³ (Anastos et al., 2002).

Patients and physicians may choose to delay therapy to avoid the inconvenience and side effects of a regime, delay drug resistance development, and preserve therapeutic options at the possible risk of immune system depletion, potential increased difficulty in suppressing HIV replication, and possible increased risk of transmitting HIV (Panel on Clinical Practices for Treatment of HIV Infection, 2001). Benefits of early therapy include easier control over HIV replication, delay of immune system compromise, reduced risk of resistance with complete HIV suppression, and a potentially decreased risk of HIV transmission. Risks of initiating early antiretroviral therapy include reduction in quality of life due to complex regimes, more cumulative side effects, earlier

A variety of therapeutic agents are used to treat HIV. The combination antiretroviral regimes are complex (Paterson et al., 2000). Generally, treatment regimes consist of two or three drugs chosen from three different antiretroviral classes: nucleoside reverse transcriptase inhibitor (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs). The choice of which combination of drugs to use to treat an individual's HIV infection depends on side effects, drug resistance, desirability of sparing a specific class of antiretroviral, and regime complexity (Panel on Clinical Practices for Treatment of HIV Infection, 2001). These clinical recommendations are drawn primarily from results of clinical trials (Panel on Clinical Practices for Treatment of HIV Infection, 2001).

**Women’s Participation in HIV Clinical Trials**

Clinical trials offer some definite advantages and drawbacks to participants. Advantages include access to new drugs for those who have exhausted all other treatment options and free extensive health care. However, the drug regime and office visits can be bothersome and tiresome. Women who take new drugs in trials may develop drug resistance to the drug or others like it while not getting any benefits due to incorrect dosing (Safreed Harmon, 1999). Drug development is driven by the rapid mutation of HIV (Casado et al., 2001; Coffin, 1995; Overbaugh & Bangham, 2001).

Women are under-represented among clinical trial participants. The proportion of women among participants recruited is generally much smaller than the proportion of HIV-positive women in the population. Though about 20% of AIDS cases in the United States are women, studies cite that women constitute between 5% to 40% of HIV/AIDS-related clinical trial participants, with most research studies reflecting the lower end of this range (Cotton, Finkelstein, He, and Feinberg, 1993; Farmer, Connors, and Simmons, 1996; Levine, 1990; Lynn, 1997; McGovern, Davis, M., Caschetta, 1994; Williams,
Singh, Dos Santos, Winfrey, and Mezger, 1997). A 1996 study found that among 156 privately sponsored U.S. trials, 24 enrolled no women and that the mean percentage of female enrollment was 11.6 percent (Struble, Toigo, Behrman, & Birnkran, 1996). Community programs for clinical research on AIDS (CPCRAs) usually involve more women; in New York City a CPCRA site has 41 percent women, while women represent 21 percent of AIDS cases there (Rodriguez-Trias & Marte, 1995). CPCRAs are more accessible to minorities as well (El-Sadr & Capps, 1992).

Even when women are recruited into trials in numbers that reflect the proportion of people affected by HIV/AIDS who are female, women report facing barriers to trial enrollment like scheduling difficulties and caregiving responsibilities (Merkatz, Summers, and Toigo, 1995). HIV+ women have been reported to be significantly less likely to have ever participated in a clinical trial (Stone, Mauch, Steger, Janas, and Craven, 1997) or to be currently enrolled in a clinical trial (Diaz et al., 1995).

One study found that women who did participate in trials were significantly more likely to be white and less likely to have ever used intravenous drugs than the national statistics for women reported to have AIDS (Cotton et al., 1993). Minorities are disproportionately under-represented in HIV/AIDS trials (El-Sadr & Capps, 1992). Under-recruitment of women into trials, especially minority and past or current substance-using women (who account for about half of women with AIDS), may limit health care practitioners’ abilities to provide optimally effective care for HIV+ women (Ethier, Ickovics, and Rodin, 1996; Hankins, Lapointe, and Walmsley, 1998). Thus, this is a social justice issue as well as a public health issue.

Social justice approaches aim to reduce social inequalities, which are often seen in the areas of gender, race, and socioeconomic status. Equal access to innovative drug therapies requires extra effort on the part of health care providers and trial recruitment staff. Study requirements that women be unable to become pregnant or to be sterilized in order to prevent infection of the fetus and subsequent liability may be discriminatory. Because research trials have a history of under-representing women, especially minority women, rectifying this inequality will take time, focused effort, and new strategies to educate these groups about clinical trial participation (Kelly & Cordell, 1996).
Important health benefits often are available to those who participate in research, which raises ethical concerns about access, as well as full participation of underrepresented groups (Williams et al., 1997). For example, McNaghten et al. found that in regular practices, men were more likely to be prescribed HAART (McNaghten et al., 2003). This may mean women are unduly pressured into clinical trial participation to receive therapies a general practitioner might not offer them. Women may not have access to a general practitioner. Women represent two-thirds of uninsured Americans (Rodriguez-Trias & Marte, 1995). HIV-positive women are less likely to have regular health care and more likely to lead chaotic lives in general (Sherer, Stieglitz, Narra, Jasek, Green, Moore, Shott, & Cohen, 2002). HIV-positive women may have less access to trials because clinical trial referrals often come from physicians (Rodriguez-Trias & Marte, 1995).

If women are not fully represented in trials and therapeutic efficacy and side effects are unknown, physicians will not be able to offer them the same quality of care as men. Full participation of women, including minorities and substance abusers, in HIV trials is desirable for a number of reasons beyond drug absorption differences between men and women. Participation would facilitate the generalization of research findings to the population of HIV+ women (Ethier et al., 1996; Hankins et al., 1998; Kelly & Cordell, 1996; Levine, 1990). Differences in genetics, social conditions, sex roles, and socio-economics, while complicating trial analysis by being possible confounders, are likely nonetheless to influence disease progression (Ethier et al., 1996; Williams et al., 1997).

Furthermore, gender differences have been found in response to antiretroviral therapies (Currier et al., 2000; Lucas, Chaisson, & Moore, 1999). Women have lower blood levels of HIV than men (Gandhi et al., 2002). Women often experience different side effects from ARVs, such as severe lactic acidosis and increased fat accumulation from NRTIs; women are less likely to experience increased triglycerides and other lipid abnormalities (Cotton, 2002). Outcomes of trial research generally form both policy and treatment guidelines; early in the epidemic women were not represented in research and
so policy and guidelines were unable to address women’s concerns regarding issues such as gynecological infections and cancers (Williams et al., 1997).

The full participation of women is essential for the results of a trial to be scientifically valid and contribute to medical knowledge (Williams et al., 1997). One study found that at least 15 percent of trial participants need to be female in order to detect clinically significant gender differences in therapy responses and toxicities (Currier, Spino, & Cotton, 1992). If small numbers of women are excluded from clinical trials, all HIV-positive women could be in jeopardy as doctors are forced to extrapolate trial results to women (Levine, 1990). Some trial outcomes or end points may be more appropriate for women than men; for example, gynecological outcomes or side effects of medication like cervical dysplasia or yeast infections are more pertinent or worrisome for women (Hankins et al., 1998). Atazanivir, a recently approved PI, was tested in trials that included enough women to determine the drug was experienced similarly in women and men (Squires, 2003). All clinical trials should be able to determine if gender effects are present.

Barriers to HIV clinical trial participation for women have been thoroughly studied in the current literature and include structural barriers, recruitment barriers, fertility issues, and fear of non-compliance. Structural or institutional barriers include the stratification based on wealth of America’s health care systems, as well as their fragmentation and specialization of services (Denenberg, 1990; Rodriguez-Trias & Marte, 1995). Women, who are more likely to live in poverty than men, may not have access to a primary health care provider, who could tell them about trials, and instead use emergency rooms for health care (Denenberg, 1990; Eckenwiler, 1999; Ethier et al., 1996; Rodriguez-Trias & Marte, 1995; Roth et al., 1998; Zorilla, 2000). Physicians often have the most influence over whether an individual will find out about and choose to enter a trial, so this is a significant barrier (Roth et al., 1998).

Often recruitment strategies for women, as discussed later, are more costly (Ethier et al., 1996; Williams et al., 1997). Paternalism, sexism and the male research paradigm discourage women’s participation in trials (Kelly & Cordell, 1996; Williams et al., 1997). Clinical trials often involve frequent visits, which may not be feasible for women with
caregiving responsibilities. As discussed below, women may be stereotyped as less cooperative research subjects because their lives are different from the idealized, completely adherent, non-childbearing male subjects’ lives.

Women, especially minority women, may not trust health care providers; this may be the result of the societal legacy of Tuskegee or personal experience (Williams et al., 1997). African-Americans frequently cite the government’s Tuskegee syphilis study as a reason they do not trust doctors (Corbie-Smith, Thomas, & St. George, 2002). Minorities have a historical distrust of clinical trials and may fear they will serve as guinea pigs (El-Sadr & Capps, 1992). Women who have been abused may experience intensely negative emotions during gynecological exams and may be uncomfortable discussing sensitive subjects with male health care providers.

Women are often stereotyped as non-compliant (Arno & Feiden, 1992; Denenberg, 1990; Williams et al., 1997), although a recent study showed women on HAART adhered to their regimen better (Squires, 2003). The issue of adherence to protocol is critical to trial administrators; breaches of protocol can drastically reduce a study’s validity and reliability. One study’s results indicated that adherence to protease inhibitor therapy needed to be at least 95 percent to optimize treatment outcomes (Paterson et al., 2000). Trials are conducted to find the optimal treatment outcome from the treatment under study and often expect perfect compliance with a complex regime. Compared to white men, women are seen as less likely to adhere to demanding study regimes (Williams et al., 1997). Furthermore, study protocols with multiple arms and site visits may be daunting and confusing to potential participants, male and female (Kelly & Cordell, 1996).

Often there is a discrepancy between the goals of trial staff and trial participants, which may make communication difficult. The goal of clinical trials is to find therapies that work for most people, not necessarily to improve the health of each trial participant (Kelly & Cordell, 1996; Williams et al., 1997; Williams & Boykin, 1999). However, participants usually want to improve their own personal health (Ross, Jeffords, & Gold, 1993). Altruism is another important motive for HIV/AIDS trial participation (Ross et al., 1993).
Personal barriers include uncertainty about how new therapies will affect a women’s reproductive system and interact with other medication and/or methadone (Denenberg, 1990; Hankins et al., 1998; Williams & Boykin, 1999). Side effects are often unknown and may be mild or severe (Williams & Boykin, 1999). Women tend to be immediate and extended family caregivers and may need child care or elder care services in order to make the time to participate in a trial geared toward their own needs (Denenberg, 1990; Kelly & Cordell, 1996; Roth et al., 1998; Williams et al., 1997; Williams & Boykin, 1999).

Women may also need transportation assistance and clinic appointments during the evening (Denenberg, 1990; Kelly & Cordell, 1996; Williams et al., 1997). Imprisonment, unemployment, periodic or constant homelessness, a history of sexual abuse, and lack of a telephone may make it impossible for women to enroll in a trial (Williams et al., 1997). Potential participants may perceive that participation will lower their quality of life (Roth et al., 1998). Lastly, the experience of being in a trial could be stressful, frightening, and uncomfortable for women or men (Williams et al., 1997; Williams & Boykin, 1999).

Various topics related to the current study appear in the literature. For example, research has focused on recruitment strategies for health care providers to increase the number of women in their trials. Much of the relevant literature deals with recruiting women with diseases other than HIV/AIDS (e.g. breast cancer) into clinical trials. Studies have examined reasons for participation in hypothetical trials (e.g. hormone replacement therapy; Wragg, Robinson, and Lilford, 2000) and demographics of female participants in HIV/AIDS trials in other countries like Canada with different health care systems (Hankins et al., 1998). Survival of HIV+ women on antiretroviral therapies through clinical trials has been another focus of HIV/AIDS research (Sha et al., 1995).

A majority of published research in this area reveals attention to trial recruitment and retention of HIV+ people, with a focus on strategies health care providers can use to increase recruitment and retention (Kelly & Cordell, 1996; Morse, Simon, Besch, and Walker, 1995; Ross, Jefferds, and Gold, 1993). Two of the inherent benefits of trial participation include access to new therapies and free health care from expert HIV care
providers (Kelly & Cordell, 1996; Williams et al., 1997). Often, even when a trial site cannot provide services, trial staff can refer women to local health clinics or other community resources (Williams et al., 1997). Staff members who have an understanding of the benefits of and barriers to trials will be better prepared to explain the trial protocol and help women make an informed decision about participation (Hankins et al., 1998).

Strategies used to recruit women include decentralization of trials or facilitating access to new therapies where health care is routinely obtained, shortening the distance women must travel to the study site, and provision of comprehensive information that allows the women’s full understanding and consent (Denenberg, 1990; Hankins et al., 1998; Rubin, 1996). Providing sites within the community that are not openly HIV specific may enable participation of women who are reluctant to disclose their serostatus (Williams et al., 1997). Making targeted recruitment and study information available at places women routinely go to access health care for themselves or their children can increase women’s access to clinical trials (Kelly & Cordell, 1996). Snowball recruiting, in which participants identify other potential participants, is another strategy that may be successful in recruiting women (Kelly & Cordell, 1996).

Women respond positively to an accepting, personalized, and friendly trial environment; comfortable waiting and private clinic spaces with freely available snacks and coffee make women feel welcome (Kelly & Cordell, 1996; Roth et al., 1998; Rubin, 1996). Informal conversation with staff and having staff members’ home phone numbers builds trust and relationships (Roth et al., 1998). Women value staff’s understanding and scheduling flexibility regarding missed appointments due to illness or hospitalization (Roth et al., 1998). Clinic staff members who are similar to study participants or culturally sensitive may enhance women’s comfort and trust during visits (Kelly & Cordell, 1996; Williams et al., 1997). Trial sites with a female primary investigator have been shown to enroll a larger percentage of women (Roth et al., 1998).

Home visits and scheduling flexibility (i.e., having clinic hours during the evening to accommodate work schedules) ease some of women’s barriers to participation. Tangible, meaningful incentives provided to women after a study visit or distributed periodically throughout the trial include a small monetary stipend, mugs, children’s
Tylenol, thermometers, T-shirts, baby items like diapers and clothes, meals, holiday outings or parties, birthday cards mailed to each participant, and tote bags (Kelly & Cordell, 1996; Roth et al., 1998; Williams et al., 1997). Supportive services on site like support groups, counseling with family member, and emergency drug treatment counselors will also enhance recruitment and adherence (Kelly & Cordell, 1996; Williams & Boykin, 1999). Essentially, any item or service that serves the needs of women in the context of her life experience will facilitate trial participation (Roth et al., 1998).

Women’s reasons to enroll in trials include obtaining health care services for themselves or their children, a general sense of well-being and the feeling of control over one’s health, gynecological care, and altruism (Kelly & Cordell, 1996; Roth et al., 1998; Williams et al., 1997). Often women enter a trial because staff nurses are able to take extra time to educate and counsel them about HIV (Kelly & Cordell, 1996; Roth et al., 1998).

Economic exchange models predict that researchers will gain study participants in exchange for free medical services and care, incentives, and information. Studies have shown the recruitment of women into HIV trials is more complicated than an economic exchange model would posit (Roth et al., 1998). This model does not account for altruism or the desire to give knowledge back to the HIV+ community (Roth et al., 1998).

While studies that involve diseases other than HIV/AIDS broaden our understanding of clinical trials, they often involve diseases that have a cure or lack the social stigma associated with HIV (Williams et al., 1997). Generally speaking, stigma is a powerful phenomena resulting from the pejorative treatment of a category of people, who are shunned by society at large and have less access to free and equal social participation (Alonzo & Reynolds, 1995).

The newer, more effective HIV therapies can lead to stigmatization. Protease inhibitor combination therapy and combinations of only nucleoside reverse transcriptase inhibitor regimes have been associated with certain noticable physical side effects, which may mark a women as HIV+. These side effects, referred to as lipodystrophy, include fat deposits on the breasts and breastcage (“buffalo hump”), fat deposits on the abdominal
area ("crix belly"), and fat wasting on peripheral areas of the body, including the cheeks, legs, arms, and buttocks (Carr et al., 1999; Ridolfo, Gervasoni, Bini, & Galli, 2000). After 21 months on protease inhibitor therapy, lipodystrophy affected 83 percent of study participants and was rated as severe by 11 percent of them (Carr et al., 1999).

Studies have shown that HIV+ people may forgo treatment and health care for as long as possible in order to avoid the widely acknowledged stigma of being HIV+, thus protecting their self-esteem, possibly at great risks to their health (Alonzo & Reynolds, 1995; Moneyham et al., 2000; Lentine et al., 2000). Women may be reluctant to participate in HIV specific research projects due to the ostracism and pity that may result from accidental disclosure (Roth et al., 1998; Williams et al., 1997). Due to the stigmatizing nature and complexity of HIV/AIDS, more focused studies are warranted.

The few quantitative studies investigating recruitment of HIV+ women into clinical trials have focused on benefits and barriers to participation and medical compliance (Stone, Mauch, & Steger, 1998; Roth et al., 1998); rarely do they examine trial participation in the context of a woman’s life. For example, it is unknown if women weigh trial costs and benefits differently than men, on whom most of the research about HIV/AIDS trial participation research has been conducted. Quantitative studies may force experiences into predetermined and possibly artificial categories that fail to adequately capture the richness and potential variability of women’s experiences and lives. Current research seems to focus on proscribing elements necessary to recruit more women into trials without a deeper understanding of why these elements are important to women and why they are missing in women’s pre-trial lives.

Missing from current literature published in peer-reviewed journals are the voices and experiences of HIV+ women themselves. These women’s experiences, while long shared with each other in support groups and web sites, have an untapped potential to inform scholars, policy-makers, educators, and health care professionals. A thorough literature review revealed no qualitative studies examining the recruitment of HIV+ women into clinical trials from the women’s points of view, nor how they integrated clinical trial participation into other aspects of their lives. A qualitative study like this one will be able to examine themes that emerge from conversations shaped by HIV+ women.
A few qualitative research studies included brief case sketches of both men and women (Williams & Boykin, 1999), included only pregnant or perinatal women (McGuire Bunting & Seaton, 1999), or incorporated trial participation into a program evaluation (Roth et al., 1998). Additional research, beyond staff-oriented recruitment and retention strategies, is needed to understand the nature of the experience of decision-making and then participating in a clinical trial for an HIV+ woman. If women are to be recruited into clinical trials in adequate numbers to detect gender-specific effects, it behooves the scientific community to learn from their recruitment and retention stories.

**Preliminary Research Conducted by the Author**

This preliminary research informed the present study and piqued the investigator’s interest in the topic. Throughout the fall of 1999 and the winter of 2000, representatives from 63 families (overall response rate: 78 percent) were interviewed as to their satisfaction with the services of the Immunodeficiency Clinic (IDC) at Children’s Hospital in Columbus, Ohio. This clinic serves families who are infected with or affected by HIV. If the families could not be interviewed in the clinic, then interviews were conducted over the phone. When the patient was a child, an adult representative for the family was interviewed and asked to report on the patient’s care. Thus, some respondents were patients and others were caregivers or family members. Sixty-seven percent of the patients interviewed at IDC were female.

Respondents were asked questions about their perceptions of clinic services. Both close-ended and open-ended questions were asked. Interviews were voluntary and confidential. Interviews were tape recorded, but once the responses were entered into the database, the tapes were erased. The interviews included questions about the nature of the services received, satisfaction with services, knowledge about HIV-related issues such as perinatal transmission and clinical trials, and recommendations for improvement of the program. Most interviews were conducted in a private room during the patients’ clinic visits.
One section of the questionnaire dealt with the issue of clinical trials. Patients were asked questions both about knowledge of clinical trials, their attitudes toward clinical trial participation, and about behaviors relating to trial participation.

Responses to Knowledge Questions

In this unpublished study patients were asked some basic questions about what they knew about clinical trials. Eleven respondents gave answers like “I don’t know” or “nothing” to a question asking them what clinical trials meant to them. Three gave one word answers like “study” or “medicine” that were vague and did not indicate substantive knowledge of clinical trials. Seven respondents answered with terms that were rather vague and seemed like they could be guessing; these types of responses include “Maybe that the clinic is trying something new out. It’d be helpful for us.” and “It sounds like an experiment or something.” The last four clients did not recognize the term “clinical trial,” but when the interviewers explained what a clinical trial was, clients responded by saying they were familiar with the concept but used different terminology for it. These clients were more familiar with the terms “protocol” or “research.”

Sixteen respondents gave an answer that seemed to indicate knowledge of clinical trials; these answers usually included something about medicine, studies, and an experiment. Typical answers included “It’s an experimental drug for trying to see if it can be used to treat illness” and “A drug’s being tested to see what outcome it has. It’s a study.” Four respondents used the words “guinea pig” or “lab rat” in their responses. All interviewees were given a basic explanation of what a clinical trial is after they had answered this question.

Questions about Attitudes

Participants were asked if they wished that there were more clinical trials available to them. Twenty-four (41%) wanted more clinical trials available to them, while thirty-four (59%) clients did not.
<table>
<thead>
<tr>
<th>Client Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all satisfied</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Quite satisfied</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Completely satisfied</td>
<td>32</td>
<td>51</td>
</tr>
</tbody>
</table>

Table 2.1: How satisfied are you with the information you receive about clinical trials?

The text in table 2.1 indicates that the majority of clients are either quite or completely satisfied with the information they receive about clinical trials. Clients indicated that they are receiving a level of information consistent with their wishes. They may want information and receive it from staff, or they may not want any information and receive none from staff.

Going through the interview data in which clients discussed what they perceived as good reasons to participate in a clinical trial, one of the most interesting things about this question was the number of reasons clients stated. Nineteen clients gave a single reason to participate. Three clients gave “don't know” answers. Two clients answered “none” or “nothing.” Nineteen clients gave two or more reasons to participate. One respondent's answer was garbled on the tape.

When the responses were sorted by content areas, of those who gave some reason(s) to participate, the majority of responses indicated that clients believe that trial participation will help themselves and/or others. Responses ranged from “To help find out more information; I figure enough people test drugs that they don’t need me” to “Everyone who’s HIV-positive should participate.” The majority of respondents (12) listed both altruistic and personal benefits related to clinical trial participation; typical
comments included “If it helps my son or someone else’s child. He’d help others even if the medications didn’t help him” and “If the medications are the best or to help other HIV-positive people.”

Ten respondents replied that improving one’s health was a good reason to participate in a clinical trial. Examples of their reasons are “If it helps make you better,” “For your health; you can get new medications not commonly available through trials,” and “To get more information and see what medications will work and which won’t.” Five clients gave answers indicating that furthering medical science was a good reason to participate in a trial. These respondents’ answers include “To aid in research and find effective drugs” and “You’ve got to improve treatment. There have got to be guinea pigs.”

Four clients listed altruism only as a good reason to participate. One client stated that “it may help others down the road.” Two patients would not consider participating in a trial unless “other medications weren’t working” and “if it was a last resort.” One client stated that participating in a clinical trial may be good “if you can handle taking your medications properly.”

Respondents were also asked to discuss good reasons not to participate in clinical trials. Three respondents replied they did not know of any. The same client’s answer that was lost to Question 5.5 was lost for this question as well. Twenty clients gave single reasons not to participate in a clinical trial.

When the responses were sorted by content analysis, the majority of clients (13) felt that the uncertainty surrounding clinical trials was a good reason not to participate. As one respondent said, “You don’t know what you’ll get or what side effects you’ll have or if it’ll work.” The largest sources of uncertainty mentioned were side effects and the efficacy of the study medication. Six respondents specifically mentioned fear of side effects and/or drug reactions; they commented “If you’re not sure about the medicine or if the trial is too overwhelming for the child” and “If there’s a considerable likelihood of a devastating side effect.” Eleven other respondents mentioned uncertainty about whether
the study medication would work. One parent said, “His life’s already in jeopardy; I don’t want to further jeopardize it.” Another patient commented, “If it won’t benefit you or those like you.”

Six clients mentioned trial regimes and inconvenience as a good reason not to participate in clinical trials. They said, “If you don’t like medications or aren’t good at compliance. I just take my medications when I remember; I’m not good with times” and “It may take too much time; it would depend on the study.” Four clients could not think of any good reasons not to participate in a trial; one man commented that “It’s selfish not to; somebody had to get you to the point you’re at.” Two clients responded that they would not participate in a trial because they do not want to take medicines now; one said “I might do trials when I feel I need to start medicines.”

Many clients had interesting comments about this question. One man said, “It’s too involved for me. I don’t want to hear and talk about HIV/AIDS all the time. I want to be happy.” Others gave denial, fear of being a guinea pig, not being able to swallow pills, not being qualified, or just not wanting to participate as good reasons not to join a trial.

During the interviews many clients talked about their positive therapeutic alliance with IDC staff and how that made participating in a trial less scary. One woman who was very leery about the decision to participate shared her agony over the pros and cons to clinical trial participation. When asked about good reasons not to participate, she said “Fear and not knowing if it’ll work or if you’ll have a reaction. IDC’s information and support helped me with my fear when I had to decide if I wanted him on a protocol the doctor suggested or not. I cornered one of the nurses and asked her what she would do if it were her child. She gave me advice, which I followed (by choice). I completely trust the staff.”
<table>
<thead>
<tr>
<th>Client Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>20</td>
<td>67</td>
</tr>
<tr>
<td>Somewhat easy</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>A little easy</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Not at all easy</td>
<td>3</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 2.2: How easy was it to decide to participate in the clinical trial?

The spread of responses in Table 2 is worthy of note. Obviously, only clients who indicated they had participated in a clinical trial answered this question. While it seemed during interviews that those who found this decision to be an easy one did not appear to think much about the decision, those who did not find it very easy tended to agonize over it, talking with family members, health professionals, and clergy before coming to a final decision.

Questions about how well clients understood the risks involved in the trial, how worried they were about side effects, and how worried they were about the study medication making their condition worse were asked to further understanding about the decision to participate in a clinical trial.

The vast majority of clients felt they completely understood the risks involved in the trial. This is rather contradictory to what the research indicates and may be due to a number of factors. Patients may have such an established relationship with trusted staff that patients feel that they do not need to understand the risks so thoroughly because they trust their health care provider. The staff members may be very good at explaining trial risks in a language these clients understand. Plus, several of the respondents interviewed were knowledgeable about health care and very savvy about doing their own research on trials and medicines.
### Table 2.3: How worried were you about possible side effects from the medication that you take/took during the clinical trial?

<table>
<thead>
<tr>
<th>Client Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all worried</td>
<td>11</td>
<td>39</td>
</tr>
<tr>
<td>A little worried</td>
<td>9</td>
<td>32</td>
</tr>
<tr>
<td>Somewhat worried</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Very worried</td>
<td>5</td>
<td>18</td>
</tr>
</tbody>
</table>

The contrast between the responses to how worrisome clients felt side effects of medications versus how worrisome clients felt the medications might be to their condition was intriguing. Twenty-one clients (75%) were not at all worried medications from a clinical trial might make their condition worse. Five patients (18%) felt a little worried that the medication might make their condition worse, while two clients (7%) were very worried that the study medication might make their condition worse. Concerns about side effects tended to be more spread throughout the range of responses, indicating clients may want more information about side effects. A few clients who may consider trial participation might benefit from discussions about their current prognosis versus a hypothetical prognosis on study medications.

### Questions about Behaviors

Thirty-three (52%) respondents responded that they had participated in a clinical trial. It should be pointed out that the occasional respondent may have believed he or she participated in a clinical trial when other questions revealed the participation had been in a research study. Thirty (48%) respondents replied they had never participated in a clinical trial. These 30 patients were then asked if clinic staff had ever told them about
clinical trials for which the patients might be eligible. Twenty (69%) clients remembered clinic staff telling them about applicable clinical trials, while nine (31%) did not.

Once they had decided to participate, continuation in the trial becomes an issue. Clients who had participated in a clinical trial were also asked if they could quit the clinical trial whenever they wished. Only one person out of the thirty-one who answered this question believed that he/she could not quit the trial whenever he/she wanted. Most clients were most emphatic about the fact that they did have the ability to quit the trial whenever they wanted to. A few respondents had quit trials in the past. Health care provider “retribution” or being labeled as “non-compliant” was not a large concern for this group of clients. Trial and clinic staff members are doing a good job of letting this group of patients know they may quit participating in a trial whenever they wish.

This preliminary research experience, along with information found in the literature, guided this current research project. Once the content areas of a research project were explored, choices about appropriate methodology were explored. This study’s goal was to understand the experience of participating in a clinical trial beyond what can be conveyed quantitatively. Qualitative methodologies elucidated these points of interest.

Qualitative Methodology

Qualitative methodologies are often used in exploratory studies and are appropriate to use when little is known about the study questions (Strauss & Corbin, 1990). They attempt to improve the understanding of experiences through rich, detailed description. Qualitative research does not test hypotheses nor theories. Data emerges from informant interactions, where the investigator is the primary data collection and analysis instrument; other instruments may be used, and a variety of techniques are available to assist the researcher in making sense of findings.

Qualitative research generally involves trying to interpret, or make sense of, phenomena in their natural setting using one or a mix of methodologies (Denzin & Lincoln, 2000). Qualitative methodologies are an appropriate choice for this research that
explores the topic of HIV+ women’s participation in clinical trials. Much can be gained from discovering the participants’ perspectives through thick description when investigating experiences and decision-making processes; qualitative research allows the uncovering of participant’s feelings and experiences with minimal direction from researchers (Crabtree & Miller, 1992; Denzin & Lincoln, 2000).

Descriptive statistics based on quantitative studies of participants’ benefits and barriers are already adequately described in the current literature. Qualitative research involves a limited number of informants and attempts to uncover “lived experience” (Crabtree & Miller, 1992). The goal of qualitative research is not to generalize findings to an entire population but to gain greater understanding of a given social issue. Interviews were chosen as the conduit of data collection; observations would have unduly invaded women’s privacy without elucidating cognitively orientated decisions. No archival data related to the issues under exploration exist.

Often quantitative studies are undertaken after exploratory qualitative research has taken place, so that areas of interest and potential problems have already been identified. However, in this case, the published research shows no record of qualitative research conducted in this area. Qualitative methodologies allow themes beyond what can be captured on a survey form to emerge. Results of this qualitative study may inform future qualitative or quantitative work in this area.

Another strength of qualitative research is that it takes place in a naturally occurring setting (in this case, a unit where women receive clinical trial related information and care or her home where she takes her trial medicines) during ordinary events. This grounds the data in everyday life and takes the context of the setting and event into account (Miles & Huberman, 1994; Denzin & Lincoln, 2000). Most women were interviewed immediately before or after their clinic appointments, and this may have helped make the clinical trial unit, trial procedures, and interview protocol more immediate and relevant to the interviewee.

Qualitative designs allow enough flexibility to let the data emerge, while at the same time being tight enough to provide clarity and focus (Miles & Huberman, 1994). Emergence of data is especially important when undertaking an exploratory study. This
qualitative study was based on emergent design, a technique wherein data collection and analysis occur simultaneously (Strauss & Corbin, 1998; Patton, 1990). Immediately after an interview was conducted, the researcher ideally transcribed the data, wrote up field notes, and reflected on the experience of data collection. However, due to circumstances discussed in the limitations section of chapter 5, a few weeks or months often passed between the interview and its transcription. Reflections were always written up within a few hours to a day or two after the interview was conducted.

Within the qualitative research frameworks are a variety of study designs. The main study designs are the phenomenological study, the case study, and the grounded theory study. While all these designs have the same goal, to describe and understand experiences and processes through rich, holistic data, they each make separate assumptions and make different methodological choices.

Phenomenology research, which is often philosophical in nature, investigates a concept or phenomenon (Creswell, 1998). Because this was an exploratory study, it was unknown which phenomena were pertinent to the issues under study and so the choice of what phenomenon to study would have been difficult. The end goal of a phenomenological study is to relate the essential structure of the experience, that is, the one underlying meaning of the experience (Creswell, 1998). The primary investigator had no training or background in phenomenology.

Case study research investigates phenomena in the context of real life (Yin, 1989). Case studies highlight the features of social life, such as behavioral patterns and social interactions (Hamal, Dufour, & Fortin, 1993). Once case studies had a specific role in sociological research. Over time, case studies became analogous to an exploratory investigation that preceded statistical research able to verify or repudiate a general theory (Hamal et al., 1993).

While the definition of a case study is controversial, there is some general concensus on components of a case study (Lincoln & Guba, 1985). Case studies often draw from multiple evidence sources such as transcripts, archival records, and observations; they can draw on purely qualitative methods, purely quantitative methods, or mixed methodologies (Yin, 1989). The case study builds on the reader’s knowledge
and enhances it to provide a vicarious experience. One commonly recognized structure of a case study includes the problem, the context, the issues under investigation, and what can be learned (Lincoln & Guba, 1985).

Selection of a case would have been difficult in this particular research study; a case could have been defined as a woman, a trial site, or a specific clinical trial protocol. Selection of an ideal case is also controversial and procedures vary (Hamal et al., 1993). Cases need to be bounded by a time and a place (Creswell, 1998). Given the small population under study, further bounds would have resulted in too few women to identify common themes, which was a major goal of the research.

Strauss and Corbin developed a methodology called grounded theory to refer to procedures leading to theories derived from systematically collected and analyzed data (Strauss and Corbin, 1998). Grounded theory studies are often used for exploratory research. The main goal of a grounded theory study is to develop substantive theory by allowing it to emerge from the data; theories derived thusly are more realistic and often offer more useful intervention actions (Strauss and Corbin, 1998). Grounded theory studies usually depend on interview data (Creswell, 1998). Unlike phenomenology and case studies, grounded theory studies often do not include a literature review, which might bias the investigator, or initial research questions (Creswell, 1998).

Experiences investigated by grounded theory research do not need to be bounded by specific time frames and locations, nor do they need to be grounded in philosophy. Another goal of this research effort was to develop relationships of emergent categories identified as important by the women interviewed; grounded theory gives guidelines on how to do this while being methodologically rigorous (Strauss & Corbin, 1998).

This study was based on grounded theory, and frameworks were informed by the data (Strauss & Corbin, 1990; Strauss & Corbin, 1998). Qualitative methods that are guided by grounded theory use systematic data collection and analysis to derive theoretical frameworks inductively; these methods were chosen because of the scarcity of information on the research topic and the study's focus on decision-making processes. Grounded theory is an appropriate methodological choice for research questions concerning experiences and processes (Morse, 1994).
While this study used a grounded theory-based approach to data collection and analysis, it was not strictly a grounded theory study per se. A literature review was conducted prior to the beginning of the study, so the investigator did enter the research grounded in issues likely to emerge from the interviews. Specific research questions were developed to guide the investigator and interview protocol. Other deviations from pure grounded theory methodology were discussed in the next chapter and in Chapter 5.

**Theoretical Paradigms**

While different qualitative research methods exist, there are theoretical perspectives that inform and cut across methods. Inevitably narrative, qualitative data necessitates questions about meaning-making and questions of epistemology and ontology (Josselson and Lieblich, 1995).

This research was based on a feminist-based, interpretive paradigm. Feminist qualitative research attempts to have as its purpose the practice of research for women instead of being about women (Olesen, 2000). A variety of qualitative research styles and methods are used in feminist research, but generally these researchers assume that interpreting women’s reports of experiences should be the focus of research (Olesen, 1998). Women’s subjective truths are validated as sources of knowledge (Harding, 1987).

In feminist research, the positivistic boundaries between investigator and subject are repudiated (Chase, 1996). Investigators reveal their own background, beliefs, biases, and assumptions about reality as readily as they reveal those of their participants; feminist epistemology posits that objectivity is increased and interpretive distortion is decreased by introducing subjectivity into the research process (Harding, 1987). Researchers often identify their race, gender, class, and culture in the spirit of decrying the “objectivist” stance of historically androcentric research and acknowledging the relationship dynamic between researcher and researched (Harding, 1987). The interviewer of this research project is a white female raised in an Anglo-Saxon, middle-upper class environment; possible effects of her background on the research will be investigated in Chapter 5.
Feminist research centers on women’s experiences and situations and suggests changes in the institutions that shape those experiences and situations to improve social justice for women (Harding, 1987; Olesen, 2000). Problematic issues that drive scientific research are seen from female experiences; these experiences make up the “reality” against which hypotheses ought to be tested (Harding, 1987).

Often women in men’s narrative accounts are non-heroic, typecast, and objectified (Gergen and Gergen, 1993). Women’s narrative accounts or stories tend to contain multiple, intermingled story lines, as opposed to the linearity of men’s stories; women’s stories tend to contain a larger, more diverse cast of characters and a greater ranges of emotions (Gergen and Gergen, 1993). Thus, women deserve their own focus in research and a chance to their own stories, regardless of complexity and interpretive difficulty.

Grounded theory-based data analysis is mainly interpretive (Strauss and Corbin, 1998). Interpretation of human experiences is the ultimate goal of narrative qualitative research (Josselson and Lieblich, 1995). Interpretivism is the underlying epistemological paradigm guiding this qualitative research and posits that human action is inherently meaningful (Kaplan & Maxwell, 1994; Schwandt, 2000). Interpretivism focuses on the complexity of humans trying to make sense of their situation as it evolves (Kaplan & Maxwell, 1994). Situational context is critical to interpretive analysis (Josselson and Lieblich, 1995). People try to make sense of phenomena by assigning meanings to them; interpretivism posits that knowledge of social reality is gained through social constructions like meanings (Orlikowski & Baroudi, 1991). The critical reflection inherent in interpretive research aims to be both politically and self-transformative (i.e. affect both the actor and the relevant political institutions); either way, there is an unraveling of multiple meanings of the action of interest (Schwandt, 2000).

Interpretive understanding is a process used by a researcher to gain information about the meaning of an action by inquiring into the actors’ definitions of the situation and their motivations for an action (Schwandt, 2000). What a participant says as well as what is left unsaid may be interpreted on multiple levels, by the participant who knows and understands the context and also by the researcher who may be able to connect with
themes from other stories as well as social situations or constructs of which the participant may be unaware. A semi-structure or open interview protocol allows both the researcher and the researched to weave a coherent narrative out of authentic language from which to construct meanings from reported actions and events.

This feministic, interpretivist framework is meant to honor and acknowledge the life complexity of women who have HIV/AIDS and to discover how they have made their way in an inequitable social world. As both the researcher and the participants were female, looking at the data through a feminist lens seemed appropriate. The researcher’s aim was to treat each woman as an authority on her own life and experience; the role of naïve student was easy to play, appropriate, and seemed to allow the participants to correct her and divert the interview at times to areas of inquiry of interest to themselves.

**Research Questions**

A gap exists in the literature documenting what HIV+ women’s decision-making processes are regarding clinical trial participation and what their experiences entail. Qualitative methodologies are an appropriate choice for investigating the research questions. The purpose of this research is to explore HIV+ women’s experiences when participating in clinical trials, focusing on perceptions, iterative decision-making, and impacts on their personal life stories.

This research adds to existing knowledge by using qualitative methodology to explore the process by which HIV+ women make decisions about enrolling and continuing participation in a clinical trial. Implications for policy and practice guidelines are explored. This research is based on the specific perspectives and experiences of HIV+ women in clinical trials and is expected to be of interest to advocates, health care providers, and policy makers in the U.S. and in other developed countries.
Research Questions

- What are the major decision points in considering participation in a therapeutic clinical trial?

- What is the nature of the experience of participating in a therapeutic clinical trial for HIV+ women?

- How do women interpret this experience and incorporate it into their lives?
Chapter 3

METHODOLOGY

This chapter reviews the study design, recruitment, the study population, data collection procedures, data analysis techniques, and Kappa scores for the codebook.

Study Design

Semi-structured, in-depth interviews were conducted with 12 HIV+ women who were participating in a clinical trial in Columbus, Ohio or Cincinnati, Ohio. A semi-structured protocol was chosen to allow women to guide and shape the interview to assist in individual and sharing meaning-making. The complexity of the resulting narratives did made the data analysis process more difficult but also resulted in the rich, thick data that qualitative methods were developed to gather. If the researcher had some pre-conceived notions about these women’s realities and been more oriented toward a positivistic epistemology, a more structured data collection method would have been more suitable; while a guiding framework was in place to give some structure to the research process, this study was ultimately exploratory and meant to discover how women’s realities intersected with the clinical trial process.
Recruitment

Women were recruited through the AIDS Clinical Trials Unit (ACTU) at The Ohio State University Hospital and the Infectious Disease Center of the University of Cincinnati Medical at various stages in trial participation.

Research participants had to be enrolled currently in a clinical drug trial or have had completed a drug trial in the past three months to be eligible for the interview. Nurses were told that all women who were female, HIV+, and were or had recently been enrolled in a drug trial at OSU or UC were invited to participate in this study.

Recruitment for this research study was a time-intensive effort. The majority of the same barriers discussed earlier that HIV+ women face when participating in trials, like lack of transportation and poor health, were relevant for this study as well. Additionally, nurses may have chosen to broach interview participation only when seeing clients face to face; some trial participants have appointments every two or three months. Clients were recruited for approximately eight months, beginning in December 2001 after Internal Review Board (IRB) approval was obtained from OSU; the protocol number was 01B0150. IRB approval from UC was obtained in January 2002. Interviews were completed in May 2002 at both sites.

Study nurses at both sites were “gatekeepers” and recruited women who were eligible. The interviewer met with staff who would be recruiting at least once at each site to explain the study and answer questions. Flyers, which can be found in Appendix G, were given to staff to give to potential participants and were posted around the clinic area. The interviewer also wrote up recruitment scripts, which can be found in Appendix F, for staff when they let their clients know about the study.

Research nurses sought the women’s permission to allow the researcher to contact them, describe the study, and seek informed consent. In Columbus one nurse informed all the other ACTU research nurses about the study, and each nurse told his or her eligible clients about the study. In Cincinnati there was one nurse primarily responsible for recruiting women eligible for the study. Interested women from the OSU trial site were given the interviewer’s phone numbers and contacted her about participating. Interested
women from UC gave their nurse permission to share her name and phone number with the interviewer, who then called them. Beth Canfield interviewed each woman.

The Eligible Population

The entire population of HIV+ women who were eligible to participate in the study at both data collection sites numbered about 24 women. Columbus clients are primarily Caucasian; although the Cincinnati location’s clientele was more diverse and composed more of a mix of Caucasian and African-American women. Purposive sampling (Patton, 1990) restriction of the inclusion criteria, or stratification was not practical due to the small population.

Practically speaking, it was realistic to expect that about 12 women would be recruited into the study. Traditionally, HIV+ women have been difficult to recruit, so a 50 percent goal was very reasonable. Studies of most exploratory research focusing on women with HIV usually have fairly small sample sizes (Heard, Tassie, Kazatchkine, & Orth, 2002). Other qualitative or mixed-methods studies of people with HIV/AIDS occasionally result in sample sizes as small as eight, although most exploratory studies focused on HIV+ women have recruited from 12 to 24 women (Crossley, 1998; Green & Sobo, 2000; Leenerts & Magilvy, 2000; Sherman, 2001). Recruitment difficulties stem from illness, caregiving responsibilities, lack of transportation, and stigma.

Small numbers of interviews do not generally hinder qualitative data analysis, as long as data saturation is reached (Patton, 1990). Data saturation, also called theoretical saturation or redundancy sampling, is the point in data collection where significantly less new information is collected from each new interview (Crabtree & Miller, 1999; Lincoln & Guba, 1985; Patton, 1990). Generally, qualitative research studies aim to collect data until the point of data saturation, which results in a more convincing case for the findings (Crabtree & Miller, 1999). There is no specific number of interviews required to reach data saturation; it varies from study to study. Theoretical saturation was achieved by the final interview, as the last few interviews provided less and less new information and insights, with the final interview containing almost none.
Study Population

At the end of the data collection period, 14 women had completed interviews. Table 1 describes the demographic information for these 14 women.
### Table 3.1: Participant Information

<table>
<thead>
<tr>
<th>Demographic Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AIDS vs. HIV Diagnoses</strong></td>
<td></td>
</tr>
<tr>
<td>Participants with an AIDS diagnosis</td>
<td>5</td>
</tr>
<tr>
<td>Participants without an AIDS diagnosis</td>
<td>7 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>6 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>6</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>29-39 years</td>
<td>2</td>
</tr>
<tr>
<td>40-49 years</td>
<td>8 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td>50-59 years</td>
<td>0</td>
</tr>
<tr>
<td>60 or older</td>
<td>2</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>5</td>
</tr>
<tr>
<td>Unemployed</td>
<td>7 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td><strong>Relationship Status</strong></td>
<td></td>
</tr>
<tr>
<td>In a romantic relationship</td>
<td>4 (as well as 1 of the non-eligible women)</td>
</tr>
<tr>
<td>Not in a romantic relationship</td>
<td>8 (as well as 1 of the non-eligible women)</td>
</tr>
<tr>
<td><strong>Caregiving Status</strong></td>
<td></td>
</tr>
<tr>
<td>Caregiver</td>
<td>6</td>
</tr>
<tr>
<td>Non-caregiver</td>
<td>6 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Below high school</td>
<td>4 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td>High school or GED</td>
<td>4</td>
</tr>
<tr>
<td>Above high school</td>
<td>4</td>
</tr>
<tr>
<td><strong>Location of care</strong></td>
<td></td>
</tr>
<tr>
<td>OSU</td>
<td>6</td>
</tr>
<tr>
<td>UC</td>
<td>6 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td><strong>Interview site</strong></td>
<td></td>
</tr>
<tr>
<td>Clinic</td>
<td>6 (as well as the 2 non-eligible women)</td>
</tr>
<tr>
<td>Interviewee’s home</td>
<td>5</td>
</tr>
<tr>
<td>Interviewee’s car</td>
<td>1</td>
</tr>
</tbody>
</table>
All of the eligible women were enrolled in an antiretroviral clinical trial at the time of the interview. Half of the eligible respondents received their care at the ACTU Outpatient Clinic in Columbus, Ohio, and the other half of the women received care at the ACTU in Holmes Hospital in Cincinnati, Ohio. Half of the participants were African-American, and half were Caucasian. Interviewees ranged in age from 29 to 63 with most women being in their 40s. All but three women had children, who were usually adults or older adolescents; a few women were caregivers for their grandchildren.

Five women interviewed were employed either full or part time. Four women had completed a year or more of college; five women had graduated from high school or received their GED; five women had less than a high school education. Seven women were either single or divorced, with another going through divorce proceedings at the time of her interview. Two women were widows, and four were either married or living with their male partner. Four eligible women admitted in the interview that they had used drugs and/or alcohol in the past; they all emphasized they were clean now. Two women reported being treated for depression. Five of the eligible women had been diagnosed with AIDS.

Women who were recruited may differ from those who were not. The only research nurse who gave feedback about eligible women’s refusal reasons cited lack of time for one client and privacy issues for another. The only demographic information available from OSU to date was information on women seen in their clinic, as opposed to women seen in the research/clinical trial unit. However, this information is still useful. At OSU there are 298 HIV-positive female clients, who make up 15% of the clinic patients. Women’s average age is 39.6 years old. One hundred and twenty-one of these women, or 41%, have been diagnosed with AIDS. About half the female clients are Caucasian; the other half, 132, are mainly Black, with other women being of another racial/ethnic group or of unknown racial/ethnic background (S. Ventresca, personal electronic communication, July 16, 2003).

Women interviewed at OSU seem to be similar to other OSU clinic patients, except in race/ethnicity. Five out of the six OSU women interviewed were Caucasian,
while only half the clinic population is Caucasian. However, it is possible that OSU’s female trial participants are different from the clients receiving traditional care. UC’s trial site demographics are unavailable.

Data Collection

The first phone call with an interested HIV-positive woman in a clinical trial covered the information on the script (see Appendix F), and a meeting time and place was scheduled for the interview. Scheduling was based on what days and times were convenient for each woman; when they had appointments at the trial site within a week or 2, the interview was often scheduled there either before or after her appointment. Women were also asked if they would like a reminder phone call the day before the interview; if they requested one, then the interviewer called to confirm the interview day and time.

Interviews primarily took place in unoccupied rooms at the clinic site, preferably before or after trial visits, for the women’s convenience; however, if a woman had just had a clinic visit or preferred not to have the interview there, she was interviewed at her home. After arriving at the interview site, an appropriate place to conduct the interview was found; ensuring the comfort and privacy of the respondent was of foremost concern. Usually the participant and interviewer exchanged small talk about the weather or traffic while this took place. Interviews occurred in several types of locations including living rooms, clerical offices, clinical rooms, and a car. Once a location was found, the interviewer set up the tape recorder, gathered forms, and read the background information script (see Appendix F) to the interviewee. No interviewees had questions after the script. They were then given the consent form to sign and a copy to keep (see Appendices J and K). If the woman was an OSU client, she received a sheet with mental health resources (see Appendix I) as stipulated by OSU’s IRB. The interviews generally lasted between 60 and 90 minutes, although some were as short as 45 minutes.

Incentives of 35 dollars per interview were provided to the women to thank them for their time. Thirty-five dollars was chosen as the incentive amount because it was
sizable enough to be attractive to women, compared favorably with incentives offered to these women from other studies, and compensated them for their time and effort, while not being such a high amount as to be coercive.

Each participant was given an envelope with 35 dollars in cash after completing the written consent form and before beginning the interview, as per IRB requirements. Cash was used because not all women had a bank or bank account. Women who traveled to the trial site on the day of their interview were given parking or cab vouchers by the ACTU staff.

The researcher and the interview protocol consisted of the data collection instruments. The interview protocol was based on the theoretical framework derived from the study’s research questions. The literature and the previously discussed preliminary, unpublished work undertaken two years ago informed a working conceptual model, which elucidated some of the findings. This conceptual model incorporated many of the concepts and measures explored by Ickovics and Meisler (1997) in their study of factors related to adherence in AIDS clinical trials. The four major areas in the framework are patient characteristics, patient’s social network, the patient’s perceptions of the clinic, trial, and treatment regime characteristics, and the patient-provider relationship. One other area of interest represented in the model is other psychosocial factors, which included quality of life, religious and spiritual beliefs, self-efficacy, and reproductive decision-making.

Patient characteristics of interest included alcohol and recreational drug use, age, education, racial/ethnic identity, employment status, symptomatology, and immunologic status. The patient's social network included dimensions of quality, demands, supports, and undermining characteristics like stigma, as well as the components like family, friends, and clergy who comprise the network itself. The patient's perceptions of the clinic, trial, and treatment regime characteristics was composed of regime duration and complexity, side effects, perceived efficacy of treatment, knowledge of trial regime, intent to adhere to the regime, perceived costs and benefits of the regime, incentives, transportation details, child-care arrangements, characteristics of the clinic environment, scheduling, and confidentiality. The patient’s relationship with both the primary care
provider and the trial staff included the patient's perception of their competence, the affective nature of the relationship, communication between both health care environments, overall satisfaction with each provider, and the clinical trial referral process.

Some demographic information also was collected on each interviewee during the interview and through specific questions in the protocol. Information that includes age, family composition, care-giving responsibilities, and time since HIV diagnosis may contribute differently to each woman’s experience and life story. Research nurses or other clinic staff members served as resources for clarification of clinical trial procedures or basic demographic information about interviewees when the researcher had questions stemming from an interview.

Ethnographic interviewing techniques were used in this study (Spradley, 1979). The interview guide or protocol, which may be found in Appendix B, is a list of general questions that was explored during each semi-structured interview. Semi-structured interviews are focused, guided, and open-ended conversations created by both interview parties (Crabtree & Miller, 1992). This less structured, flexible format ensured that major content areas were covered and allowed both the interviewer and the respondent to guide and shape the interview. The researcher was free to probe comments within the predetermined content areas in the interview guide. Semi-structured interviews promote the understanding of the interviewee’s experiences and interpretations of those experiences, thus addressing the study’s research questions (Crabtree & Miller, 1992).

Iterative protocol development was used, though not extensively. This method determines if the guideline’s content or wording needs revision to be understood by the target audiences. It also may elicit native language terms unknown to the researcher (Spradley, 1979). As the interviews unfolded, it became apparent that women understood the questions as written in the protocol. Due to the small sample size and differences in geography, education, articulateness, and prior interview experience between women, it was felt that no sweeping protocol changes could be made. Focus was on keeping the data as comparable as possible.
During the course of two interviews, interviews 10 and 11, it became apparent that these women were not involved in a clinical trial; in that respect, the protocol also functioned as a screening tool. Most of the questions worked well for women whether they were in trials or not. Women who were not eligible required more explanation for some of the trial-specific questions, and the protocol had to be changed slightly for their special circumstances.

After confirming with trial staff that the women who participated in interviews 10 and 11 were not enrolled in a clinical anti-retroviral trial, those interviews were not included in data analysis. These two interviews were not transcribed verbatim. The transcripts were analyzed after the remainder of the data has been coded axially to identify any confirmatory or disconfirmatory information about ideas about the research questions generated from the eligible interviews. Data collection resulted in a set of over 200 pages of transcribed interview and reflection text.

**Data Analysis**

Each interview was audio-taped, although the quality of the recording varied. Women consented to the audio-taping of their interview when they signed the consent form. No one objected to the taping; in fact, many women forgot about the tape recorder and microphone, which was only used in later interviews, to improve the sound quality of the tape.

The researcher or a professional transcriptionist transcribed each interview verbatim. The primary investigator verified and edited all transcribed interviews by comparing the transcribed text with the audio-taped interview. Then the text file was readied to be imported into NUD*IST. A few of the first few interview transcripts were submitted to the dissertation committee to solicit feedback. Two later interviews were also shared with the committee.

Informal researcher reflections on the circumstances surrounding the interview, feelings about the interview, and other issues of interest were either written or audio-taped. Reflective remarks are an essential part of the process of data collection (Crabtree
& Miller, 1994; Patton, 1990). Reflexivity is a process of self-criticism and self-reflection. Reflections often speculate on how the interviewer affected or was affected by data collection procedures, and they generally include comments, points of confusion or dismay, insights, and connections between interviews (Crabtree & Miller, 1994). Periodically, researcher reflections, accompanied by their transcripts, were submitted to dissertation committee members to elicit other responses and possible interpretations of the data.

Reflections on the research experience helped the researcher make her biases as explicit as possible; biases, while expected and normal, need to be clarified and examined in order to lessen their impact on data collection and analysis. In qualitative research the researcher is the primary data collection instrument, so her biases may affect data analysis and interpretation (Patton, 1990). Constant reflexivity allowed the researcher to interact with the data in a deeper way required by interpretivist paradigms (Crabtree & Miller, 1994).

Analysis began after each interview was complete. Informal ‘mulling over’ of the interview and verbal or written reflections helped the primary investigator focus on points that were similar or that differed from previous interviews; probes for following interviews were based on each previous interview. Grounded theory stresses the need for interplay between data collection and analysis (Strauss and Corbin, 1998). This allowed the protocol to accommodate new topics, as well as lessen the focus on some other topics.

The researcher also kept an audit trail, a paper or computerized record of the recruitment and data analysis processes as they evolved. This ensures an accurate record of the methods and procedures of the study as it emerged, which enhances its confirmability, credibility, and dependability; the audit trail allows individuals other than the researcher to examine the process and final product of the study (Lincoln & Guba, 1985; Miles & Huberman, 1994). Audit trail documents included e-mail messages, notes scribbled in notebooks, or memos typed into NUD*IST. This process can elicit other researchers’ perceptions of the reality of the interviewee.

Strauss and Corbin (1998, page 3) define coding as “the analytic processes through which data are fractured, conceptualized, and integrated to form theory.” Coding
was the major part of the data analysis process (Crabtree & Miller, 1992; Miles & Huberman, 1994; Strauss and Corbin, 1998). As is standard in grounded theory studies, codes were generated by the researcher and informed by the data, although some a priori categories were used to inform the data reduction process (Strauss & Corbin, 1998). A priori codes were drawn from the conceptual frameworks and the literature. The working structure of a priori codes may be found in Appendix C. Again, other experts’ opinions and thoughts were solicited in order to incorporate multiple viewpoints. Appendices D and E contain the revised open coding scheme and the revised axial coding codebook.

A codebook and definition sheet were compiled and revised repeatedly after completion of the last interview. Codes were initially based on the a priori codes identified before the study began; these codes were reduced to a list of 26 codes with which to begin open coding (Strauss and Corbin, 1998). Codes used in open coding were not mutually exclusive. These 26 codes were tested when the primary researcher and another member of the dissertation committee used them to code the same interview; after coding they met to compare notes on the codes, which were felt to have adequately captured most of the information in the interview related to the research questions.

Very general, open coding was done first for the 12 interviews. Documents were coded on paper, and then that coding was transferred to the NUD*IST file. Open coding, where all the interview data will be grouped into categories, was used initially (Strauss & Corbin, 1990). This iterative and dynamic process created descriptive categories that composed a preliminary analytic framework. Hierarchical categories of coding were used to identify and categorize themes and patterns found to emerge from the data during open coding (Strauss & Corbin, 1998). Lines were chosen as the text units for coding to facilitate the finer coding necessary for more focused coding.

The data were coded and re-coded repeatedly throughout data collection and analysis; each stage of coding built on previous codes as codes became progressively more focused, a process called axial coding common in grounded theory studies (Strauss & Corbin, 1998). At the study’s conclusion the end product anticipated was an
interpretation of how HIV+ women make the decision to participate in a therapeutic clinical trial and the ramifications of that decision into the context of other areas of their lives.

QSR NUD*IST computer software was used for data analysis (Qualitative Solutions and Research, 1997). NUD*IST easily accommodates a hierarchical coding style. All text were initially coded in the index system of NUD*IST. While paper codes were put into the computer software, the researcher also reviewed data to add codes or delete codes to ensure accuracy and completeness of open coding. Then content was re-coded within the same NUD*IST project.

The immersion/crystallization technique of data analysis was used to keep the researcher as close to the data as possible (Miles & Huberman, 1994; Borkan, 1999). This technique allows the data to speak to the researcher, as the data is reviewed repeatedly and allowed to ‘settle’ in the researcher’s mind. By being close to the data, the researcher was more easily able to identify themes, patterns, and discrepancies throughout the data. NUD*IST facilitated the progressively focused coding was used in conjunction with the immersion/crystallization technique (Borkan, 1999, Strauss & Corbin, 1998).

After open coding was complete, axial coding began. Data previously coded using open coding were pulled out, examined, and then coded in a more focused manner using new codes when necessary (Strauss and Corbin, 1998). The order of focused coding was as follows: decision codes, patient’s perceptions of the clinic, trial, and treatment regime characteristics, patient’s social network, other psychological factors, patient-provider relationship, patient characteristics, and other; combinations of these open codes then were examined. Decision content was axially coded first because it was the main crux of the research questions. During coding, both confirmatory and disconfirmatory cases were identified (Lincoln & Guba, 1985; Crabtree & Miller, 1999). After the axial coding for each major code group was complete, findings and discussion were submitted to a member of the dissertation committee for feedback.

NUD*IST also has a function that allows the researcher to write memos that can be linked to specific interviews or a specific section within an interview. Memos were
used to remind the researcher of ideas, musings, and other possible directions for analyses whenever they came to mind during the coding and analysis process. Memos were also written in a text file and jotted down on Post-it Notes.

**Kappa Information**

Kappa values are calculated to determine confidence in the codes’ clarity and to document the trustworthiness of the data. Only coding done by the primary investigator was used for analysis. Intracoder reliability was assessed using coding performed in March and June of 2003 by the primary investigator, using the procedures as discussed in Carey, Morgan, and Oxtoby (1996).

Kappa values were calculated for the six major sets of codes. Interview coding was examined line by line and used the major codes. The Kappa values were calculated by scoring an agreement when at either time a response was coded in the same major code (i.e., if at one time a chunk had been coded as disease status and at the other the other time had been coded as an interviewee characteristic, it was scored as an agreement). The total number of coding chunks for the calculations was 352 text units or speaker chunks.

<table>
<thead>
<tr>
<th>Perceptions of Trial</th>
<th>March 2003 Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2003 Coding</td>
<td>Present</td>
</tr>
<tr>
<td>Present</td>
<td>189</td>
</tr>
<tr>
<td>Absent</td>
<td>18</td>
</tr>
</tbody>
</table>

**Kappa Value = .8431**

Table 3.2: Coding comparison and Kappa value for the perceptions of trial code
<table>
<thead>
<tr>
<th>Interviewee Characteristics</th>
<th>March 2003 Coding</th>
</tr>
</thead>
<tbody>
<tr>
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**Kappa Value = .6195**

Table 3.3: Coding comparison and Kappa value for the interviewee characteristics code

A Kappa value of .9 or higher is thought to indicate a good code (Carey et al., 1996; Miles and Huberman, 1994). Obviously, neither of these codes have terribly high intracoder reliability, although perceptions of the trial approaches the .9 benchmark. However, both codes have decent Kappa values; Kappa values used in fieldwork tend to be acceptable at levels slightly below benchmark levels. The bulk of the interview data was coded under perceptions of the trial, so its Kappa values indicate a good working usage of that particular coding category. From the interviewee characteristics’ Kappa value, it may be concluded that procedures on how to use this code may be vague or that its definition in the codebook may be vague. This codebook should be revised further and not be published as is nor given to anyone else to build off of without advising caution.

Carey et al. (1996) suggests the reliability statistic is not appropriate when any cell value is 0. Assigned coding was so similar for the other four coding categories that Kappa values could not be calculated due to zero values in one of the dissimilar coding rows in the 2 by 2 table. The lack of a Kappa value for the remaining categories does indicate the primary investigator’s consistent coding.
<table>
<thead>
<tr>
<th>Other</th>
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Table 3.4: Coding comparison for the other code

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Table 3.5: Coding comparison for the other psychological factors code

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Table 3.6: Coding comparison for the interviewee’s social network code
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Table 3.7: Coding comparison for the decision code
Chapter 4

RESULTS

This chapter focuses on the results of the interview data, beginning with the interviewee’s infection and diagnosis information and then moving to each of the research questions. Two parenthesis marks () note a place in the interview where the interviewee’s exact remarks cannot be transcribed. While data from the two non-eligible women are not presented, it should be noted that their interviews yielded no additional major themes or information.

Infection and Diagnosis Stories

The initial interview question (“How did you find out you had HIV?”) elicited entwined narratives of symptoms (for women who had them), diagnosis, infection attribution, and care-seeking behavior. Each woman had a unique story. Women had different experiences, fears, and beliefs, but some story themes were consistent. Their stories provide an important context for subsequent decision-making and experiences.

Relevant contextual information included infection and diagnosis stories, HIV symptoms experienced, AIDS diagnosis, and relevant life events around the time of diagnosis and/or trial entry. This information is critical to the following research questions for two reasons. First, it provides some contextual background describing
women’s frames of mind and experiences leading up to being referred into a trial. Second, this information tended to be woven in with how a woman began the medical process that ultimately led her to her clinical trial.

Five (1, 3, 6, 7, 9) women reported visiting several doctors for a combination of symptoms, which eventually resulted in a diagnosis of HIV. A typical comment was:

So I was going to all these doctors, you know, internists and this test and EKGs and, I mean, emergency rooms and people were treating me for like viruses, you know, some of the doctors. I was taking antibiotics and then one doctor would be upset, but anyhow this doctor did diagnose it (HIV).

BC: Why don’t we start by talking a bit about your HIV. How did you first find out that you had HIV?
IW9: Through a test. I was taken ill; this was in 1992, and I had been seen in the emergency room at the University Hospital several times on a two week span, and the symptoms I was having was: diarrhea, fatigue, just feeling like blah, and while I was seen at the University once they treated me for dehydration, they treated me for low potassium. They treated me for an ulcer. I didn’t have a physician at the time so it was suggested that…I get a physician. So I had chose to go to a community clinic that was in the area where I lived, and I went in as a new patient. So as a new patient you have all this blood work done, and…the doctor told me that the first blood work I had done that there was some enzymes secreting from my liver, and he initially thought maybe I might have hepatitis virus.

Another interviewee spent no time in the interview talking about how she got HIV. Her partner at that time was also HIV+; they broke up a little while after being diagnosed. Another interviewee was interviewed with her husband; all she would say about her transmission risk was that she had no idea how she was infected. Her husband is HIV-negative. Interviewee 6, whose partner is also negative, did not talk about her risk at all except to say she had partners who might not have been monogamous with her. Interviewee 7 seemed to think she got HIV from her husband, although she never directly said so during the interview.
Three women found out they were HIV+ directly from or indirectly through their partners.

IW2: I found out when my husband had…sick; he had pneumonia…So when we found out for sure that he did have it, it wasn’t just that he had HIV, he actually had AIDS at that point. So I went to the doctor’s office (for an HIV test), and I figured there was no way I could not be positive.

Another woman said, “They told me when he was dying in the hospital, one of the nurses told me she thought it was best that I go get checked.” She later said, “Actually if he hadn’t of died I probably would have killed him.”

For these women it was quite clear how they had contracted HIV. The woman just quoted knew her ex-partner to be promiscuous, but Interviewee 2 was very worried about whether her husband had cheated on her or whether he had been infected at work. This uncertainty was very troubling for her.

IW2: And that’s one thing I’ll never know. From talking to the people at OSU, it (HIV) is not really that easy to get. I asked my husband when he was in the hospital, “How could you have gotten this?” He said, “Well, I got cut a few times while working on the squad.” They always say it’s possible, but not probable…of course, I wasn’t going to be drilling my husband when he was lying there in a ventilator, you know? I couldn’t really talk to him anyway, because all he could do was write. (Pause) So. But I really don’t think my husband cheated on me. He was always home. He always did things with the kids, coached their soccer team and stuff like that.

Interviewee 12 called home on Thanksgiving and found out her ex-husband had died from AIDS. She recalls, “I got a letter in the mail saying come to the clinic, and they took my blood. They said I had HIV.” It was unclear what clinic she visited and if her ex-husband had identified her as a previous partner. She had some cognitive difficulties and some of her interview contained inconsistencies.

Sometimes these women’s diagnoses were completely random and happened before they experienced any symptoms of HIV/AIDS. One woman was tested after her
daughter was born with high blood pressure and asthma. Her baby was HIV-negative, but she was diagnosed with HIV then. She was a previous drug user who had “been tricking.” Also, she had been with a bisexual man.

Interviewee 5 found out she had HIV after she donated plasma.

BC: Okay. Uh, why don’t we begin by talking a bit about your HIV. How did you first find out you had HIV?
IW5: Uh, I was donating plasma a year ago...It was a shock…I got a phone call saying I need to come in and speak to the lady from Seratec and she said that I had positive HIV testing…So that was a bombshell. After my second positive test, I was determined to make sure I had a second one for what I went through...so far everything’s okay. It was a little bit of a shock, but, you know, you just work through it. There’s not much you can do.

In a similar story, interviewee 10 was diagnosed with HIV after giving blood at a blood drive at work. Interviewee 10 said, “I had a bad feeling something was wrong, but I never dreamed it was HIV. I thought it was hepatitis to be honest with you.” Both interviewees 5 and 10 got calls requesting them to come to the agency, where they talked about their diagnosis to a doctor for a period of time. Neither woman speculated at all about her infection during the interview.

Interviewee 11 got her HIV test because of an incident at work:

IW11: I work for a mental retardation/developmental center, where I’m dealing with MRDD residents, and one of them bit me. I had to go to occupational health, and one of the things they wanted was an HIV test as a result of the fight. I thought, ‘well, no problem.’ Well, they called me and wanted me to come back, and I thought ‘well, you know.’ Then it dawned on me; it could be that I’m positive.

She either was exposed to HIV through sexual partners or through blood transfusions she received before screening for HIV in the blood supply became routine.

Only interviewee 9 was routinely getting HIV tests, as a result of her previous drug use and promiscuity.

Diagnosis was a shock, a bombshell for all these women. Interviewee 12 said, “When I first found out, I couldn’t believe it.” It was evident that these women had
pieced together a coherent narrative about their infection, symptoms (whether they were aware of them at the time or retrospectively after their diagnosis), and diagnosis. Each woman’s story has a twist, so trying to find common themes was difficult.

Two women reported contemplating suicide after their diagnosis. They felt hopeless. All they knew about HIV was that it turned into AIDS, which killed people. Interviewee 12 remembers “They said I had HIV. So I just, I was too damn through, then I just would have killed myself, but my husband stopped me.”

IW11: I went in, and sure enough, when the doctor told me (her HIV test had come back positive) I was horrified. He gave me no direction, only that I had it. BC: He didn’t tell you anything else?
IW11: No! Nothing. I mean, I contemplated suicide; I probably wouldn’t have done it, OK? But I contemplated.

Some women mentioned that being diagnosed with HIV was an eye opener. They said they know what life is worth now; that life is too short and is to be treasured.

IW5: Life’s already too short so you know, like, I got to enjoy it, too. I never realized how much until…when you actually get something like this thrown at you then you actually realize what it is worth.

**HIV/AIDS Symptoms and AIDS Diagnosis**

In terms of their current health, women usually had an “illness story” that was entwined with their “diagnosis story”, which was often entwined with their “infection” and “treatment” stories as well. As previously discussed, women reported sometimes having HIV symptoms, having other health conditions, and being diagnosed with AIDS.

Eleven women had symptoms of some sort before they were diagnosed; sometimes they sought help for these symptoms, and sometimes they identified symptoms after they had been diagnosed. Women often had to see a series of doctors before they were diagnosed. When asked about their health, they usually gave a before and after (HIV medicine) answer. Symptoms women reported suffering before diagnosis included: memory loss, leg pain due to nerve damage, illegible handwriting, dehydration,
shingles, bladder infections, weight loss, vaginal discharge, large pore on her face, low potassium, infections, tendonitis, diarrhea, fatigue, sinus infections, depression, worse than normal allergies, pneumonia (for one woman, repeated cases of pneumonia), thrush, fevers, Guillen Barre’s syndrome, dizziness, influenza (often followed by bronchitis), sore throat, ulcer, and seeing spots. These are symptoms and not side effects of their HIV regimens.

Three women reported thinking their symptoms from HIV were due to menopause or aging. These women tended to discount their symptoms and did not seek medical attention for them.

IW2: I try to think back, but it’s hard, because when my husband got sick, they said he probably had it for seven years. I did notice that, I don’t want to be gross, but for the past couple of years before he’d gotten sick, it seemed like I had a vaginal discharge. I never went to the doctor about it; that’s kind of embarrassing. I thought maybe it was because I was starting to go through menopause.

BC: Have you had any symptoms of HIV?
IW10: No. The only thing I can think of, I mean I’ve tried, you know, they asked me when I first came that day. I mean, you know, occasionally I’d find myself a little bit more fatigued than normal but I chalked it up I was getting old, you know so.

Women also had other health conditions in addition to HIV. Interviewees reported also having high blood pressure, allergies, arthritis, moles, cervical dysplasia (it was uncertain when she began having this, so it may be related to the HIV), bursitis, and angina.

In addition to their initial diagnosis with HIV, six women have been diagnosed with AIDS. Sometimes this caused additional stress, and some women questioned what AIDS meant; interviewee 11 asked the interviewer during the interview at what point someone could be diagnosed with AIDS. This lack of basic knowledge was common. Another woman asked during her interview what the difference was between HIV and AIDS.

Some women, upon learning they had been diagnosed with AIDS, seemed almost to repeat the process of disbelief, grief, and coping that they experienced when they
found out they were HIV+. For these women, AIDS represents a real marker in terms of their health and well-being; they did not see it as an almost arbitrary diagnosis but as a diagnosis associated with decline and death. Once someone is diagnosed with AIDS, they will always be considered to have AIDS, regardless of how healthy they feel. These women seemed to feel it was almost unfair for them to be stuck with a diagnosis made at one point in time later on when they were feeling healthier.

BC: OK. Have you been diagnosed with AIDS?
IW2: Yeah. Well, see I always thought that I just had HIV. Because when I had to go to the doctor’s office they drew blood and the nurse just called me, well not the nurse, but the doctor who called me and she said I was positive. I always just thought it was HIV. Of course I never knew that much about it. And he (her husband) always told me it was people who had two or more life threatening diseases would be considered someone who had AIDS. If they had HIV and two or more life-threatening diseases. I thought I wasn’t in that category, and I was looking on the internet and it said that if your T4 or T cell count-if it was under 200 then you were considered to have AIDS. Bummer, you know? Because I just thought I was HIV-positive. I called my nurse and she said, ‘Oh, don’t worry about it; it’s just you know’…before, it (her CD4 count) was always really low. It was under 200, so I guess I’m considered as having AIDS.

BC: Have you been diagnosed with AIDS?
IW3: Yes. Yes, I was diagnosed with AIDS the first time I went to the- I mean, I guess it was the second time I went to the clinic. Yeah, that second appointment. So, and, you know, once you have that diagnosis, it never goes away.

As voiced by interviewee 3, most women reported feeling healthy at the time of the interview but were uncertain how their health would be in the future: “I’m not sick to where tomorrow I’m afraid I’m going to die. You know, don’t feel sorry for me, because I’m probably as healthy right now as I ever will be.”

Life Events

In addition to their individual health issues during the diagnosis process, some women found that other aspects of their lives were changing and/or at risk of being
changed by their HIV/AIDS status. The interviewees, except for one who was quite debilitated by side effects of her regimen, lead very active and busy lives.

Employment issues were not relevant for most of these women. Two worked a lot (40-60 hours per week) and reported that keeping busy helped them mentally and meant they did not have time to worry about their HIV. One woman who also held a full-time job and who was relatively new to the trial told me about how flexible her new employer was about giving her days off so that she could “go to the doctor” (she had not disclosed to her new employer). About 75% of the women interviewed were not employed, and most did not report actively seeking employment. A few said they were going to look for a part-time job in the future or would like to work more if their health permitted it. Interviewee 9 reported doing HIV-related volunteer work.

This particular group of women had varied family composition and responsibilities. Six women had adult children. Five women were raising children. One woman was raising her grandchild as well. Two of the women interviewed were very actively involved in their grandchildren’s lives. Two women were married, with another woman in the process of getting a divorce. Relationships with friends and family will be discussed in more depth later in this chapter.

Four women (3, 5, 10, and 12) moved shortly after they were diagnosed. This added to their general life instability and personal chaos. Chaos seemed to be caused by life events high in stress, such as moving into another house, moving in with parents, being homeless (or having to face that as a possibility), or moving to a different town. Interviewee 10’s experiences are an extreme example of how quickly life can change.

IW10: …I found out I had HIV. The next day was my first year (wedding) anniversary. The day after that I lost my job; the next day was my 42 anniversary (she meant birthday); the next day my husband tells me he’s having an affair.

Each woman interviewed had a unique background; her infection, diagnosis, and particular life events provided the background for her decision to join a clinical trial and her experiences once enrolled in the trial.
Question #1

What are the major decision points in considering participation in a therapeutic clinical trial?

Women tended in the interviews to skip over or possibly reduce the actual decision-making into one small step of a much larger story of their infection, diagnosis, and treatment. Women often took into account their medical insurance or lack thereof, current health status, worries about their future health status, whether they had others to help them with the decision, expectations of personal benefit, and altruism. Many women did not remember details either of the information session held before they formally could enter the trial or of the informed consent paperwork they signed after deciding to join a trial.

Referral Process into a Clinical Trial

Before a woman can make a decision about whether participating in a trial would be beneficial, she needs to know that a trial is available. Women’s memories about the decision to participate in a trial usually involved how they found out about the trial. Women came into trials from many different paths, some straightforward, some so winding it was difficult to keep track of whom they had spoken with and where they had gotten care. Only interviewee 11 reported deliberately seeking out the trial; she learned about OSU’s clinical trials from a HIV/AIDS call center volunteer; all the other women were referred to a clinical trial site. Other women at OSU were either referred by staff at the IDC in Children’s Hospital, from another agency or case manager in Columbus, or from staff who provided regular, non-trial care. Women in Cincinnati were generally referred to the trial by staff who provided regular, non-trial care.

Staff at Children’s Hospital of Columbus referred two of the six OSU interviewees to the clinical trials area at OSU. Interviewees 2 and 10 chose to do the clinical trials at OSU instead of receiving care at Children’s for the free care and medicines; one talks about her referral process:
IW2: He (her doctor at Children’s) told me about the clinical trial, because he’s at OSU and at Children’s every once in a while or whatever. Because I was going to go to Children’s Hospital for my treatment; I thought they were pretty nice and everything…But I do like it a lot better at OSU than I did at Children’s anyway. So I’m glad I go there for my treatment.

One physician or nurse at the OSU trial site did refer Interviewee 8 to a trial.

BC: Can you tell me about the visit when you came in and they told you about the trial?
IW8: I don’t even think I remember. Ann just said that she thinks I needed to try it and she thought it would be good for me. And I trust her and that was it. I got into it and that’s when I met doctor, because I knew Ann first and then I got to know Susie and it was like instant friendship thing.

The other women who joined trials at OSU were referred by a case manager from the Columbus Health Department, a family physician, and an AIDS hotline volunteer. However, employees of their local health department referred all the women receiving care in Cincinnati to the trial unit for regular health care. Once they began receiving regular (i.e., non-trial) care, trial staff told them about the trials. The distinction from recruitment in Columbus is that women in Cincinnati were all getting regular care from the IDC, which is in the same location as the ACTU, before they joined a clinical trial.

IW6: When they, when I first found out, uh, Paula came to see me, which is like, I guess, she’s like one of the head ones over there, and she just asked me was I interested.

IW7: Of course getting into these studies has been a godsend because I wouldn’t, don’t know how I could even afford the medicines that they give you, I mean it’s extremely, extremely expensive.
BC: Did Dr. Harris recommend that you join a study here?
IW7: Uh-huh. She heads the study, or not study- Wilson has the study- but she has this, uh, for me anyhow. She’s my internist…And then, uh, she got me into a study here, just I, I just made it, you know, because of my whatever it is- the blood cells and all (refers to her viral load and T cell study cutoff).
A few women report being strongly encouraged to join a trial by the trial staff.

IW6: And about, then that’s when the lady was talking to me like ‘just do it’ and ‘it’s free’ and ‘not long’ because people been on that for research longer than me, I think I was like one of the last ones...

IW7: Well I really don’t know too much about all that because I just, whatever they want me to do I’m doing it. (I laugh) It’s helping me, it’s going fine.

Women were put into the trial they were eligible for; in other words, they did not get to pick from different trials. Women reported not having to make that particular decision. Interviewee 2 was the only woman who volunteered her trial’s ACTG number.

BC: Did you get to choose what trial you wanted to be on or was this trial the only one that they had?
IW2: No, they didn’t give me any choice at all. I know I’m on study 384, but I tell that to some of my doctors and that’s meaningless for them. But because I’d never been on any drugs before, I guess that had something to do with it.

Medical Insurance

Most women discussed medical insurance when they related issues surrounding their decision to join a clinical trial. Ten out of the 12 women discussed medical insurance; there were not any questions in the protocol pertaining to insurance, so this topic was unprompted. As stated before, medical insurance was the most important issue surrounding a woman’s decision to participate in a clinical trial. Five women reported having health insurance, although one was fighting with her company about whether her HIV was pre-existing or not. Six women reported not having health insurance, and one woman was applying for Social Security, which usually includes Medicare/Medicaid. One woman without insurance discussed her effort to get health insurance:

IW8: She said there’s always something so because I don’t think I could afford it, because when I got sick I applied for Social Security. I wanted something to compensate the hours that I wasn’t working. And when they denied me I just said, ‘Well, maybe it’s a blessing in disguise because I can’t live off of my check once
a month’. And so when they denied me I, I was kind of hurt because I wanted the medical card because I have high blood pressure too. And so, you know, I couldn’t afford to keep going back and forth to the doctor’s just to have a checkup and get my medication for my high blood pressure pills. So I talked to Susie, and Dr. Smith gives me a physical so she just writes me out prescriptions because they have to have a list of all the medications that I was on. So she just gives me my prescriptions and so.

BC: So you don’t even need to go see another doctor?

IW8: No. Well, I can’t afford it because I don’t have any medical insurance and medical insurance, and I don’t work forty hours at work so I would have to get private insurance. They sent me a list of them (insurers) and for just me alone it’s like $800 a month.

Two women just suffered from bad luck and timing. One lost her job (and health insurance) a few days after she was diagnosed. Interviewee 1 is fighting her insurance company to try and prove that her HIV was not a pre-existing condition.

IW10: …they said maybe I should come over here, because, at the time I got laid off with my job, two days after I found out about it (HIV). So I had no insurance; they couldn’t; my husband tried to put me on his insurance, but because it’s a pre-existing condition they wouldn’t accept me.

Health insurance is a definite source of stress and worry for women without it; it was a source of stress even for women with insurance benefits, as they often struggled to figure out if their policy covered the medications. For interviewee 2 this was coupled with the stress of losing her husband; “I was really afraid because my health insurance was through my husband, and I did not know if I was going to have any insurance or anything.”

Interviewee 3 relates her fear about not having medical insurance, “If the medicines are still working for me…I’ll be getting my medicines free from ADAP. But then, there goes all my doctors. I won’t have a doctor to take care of me.” ADAP is the AIDS Drug Assistance Program run by the state of Ohio. Interviewee 3 was under the impression she could only receive care from the ACTU staff if she was in a trial. Another woman, who does have health insurance through her job, dreams of starting her own business and wondered in the interview if someone at the clinic will be able to help her with her medicines and care.
Entwined with women’s talk about medical insurance is their amazement over the cost of HIV medications. Typical comments include: “I don’t know how you would afford them…we couldn’t spring for these (medications); I don’t know what the heck we’d do without the trial.” “And, you know, the medicine is, like, extremely expensive and I thought how can I even afford to even think about going to the doctor, let alone pay for the medication”. Even with an insurance co-pay, one woman would spend about $50 per month for the medications she is on now. As she is living on a fixed income, that amount may still be problematic for her budget. Another woman said she would spend $75 a month. One woman said that her medication was $1,700 per month; this figure seemed consistent with the literature and other women’s statements. Concerns about money seemed to be the biggest factor in women deciding to join a trial.

IW10: …they thought this (joining a clinical trial) would be the best for me because of the medical bills and the expense that this would be the best thing for me because and to me the process of going through divorce, no job, no insurance. I have to have it, so they just figured this would be best if I come over here and done the clinical trials. And I agreed, okay, and I really didn’t know what else to do, you know. You know, they’re telling me you have to have this (HIV medication). Well, how can I have this if I don’t have $1,500 or $1,600 a month they hang you for medication? That’s what it would cost me.

There seems to be a feeling amongst the women of a lack of options, though many knew they could also get their medications through ADAP/Ryan White type programs. As noted before, the cost of the regimes is daunting and so is the paperwork needed for Ohio’s Aids Drug Assistance Program. When a woman tended to gush about how wonderful the trial is, most of the time she did that in the context of how expensive the medications are and how she could never afford them and how much she needs them. Free medications were the biggest reason women chose trial participation over ‘regular’ care at a clinic.

BC: Why did you decide to join the trial?
IW8: Because I didn’t have health insurance to go any place else. And like I said, I have been coming up here for a long time on and off to have my blood tested to see if it was time to get on medication. And everybody up here treated me just
like I was a normal person so when I got sick, and I didn’t have health insurance with my job because I started working part time when I got sick, and then I wasn’t working at all because I was sick. They told me about the clinical trials. They said, hey, you don’t have to pay for no medication or doctor’s visits or nothing; I was like cool.

This woman also mentioned that she knew she was eligible for reimbursement or payment for one of her medications that she paid $30 a month for; however, she decided doing the paperwork was “too much to get into” and that she would continue to pay it out of her pocket.

**Current and Future Health Status**

Women reported that their current health status played a large role in their decisions; they also worried about their future health and well-being while considering their decision.

IW2: …Of course I wanted to get on the drugs right away, since my husband had died. I wanted to stay as healthy as I could. I wanted to get on the drugs, so I was anxious to get on the drugs.

Death or fear of death was something most women had thought about. Women with more symptoms tended to see the choice between life and death as the choice between the trial and not being in the trial. Several women were diagnosed when close to death and/or reported they felt like they were dying when they began the trial. A few women reported being ill enough (or in a few cases, fearful about becoming very ill) that they literally saw being in the trial as their chance at life.

BC: OK. What made you think of going to the AIDS clinical trial unit? IW3: I felt like I was dying. My doctor, he wasn’t really familiar with what was going on, but I think he knew enough to know that I was pretty sick the way I was. I didn’t realize I was as sick as I was. I was pretty much unable to work by then. I wasn’t sure about what my income was going to be. And then I did lose my job. That was it. That was the only way I hoped that I was going to survive, I guess. Because I felt pretty ill.
Even women who were fairly healthy when diagnosed report starting the trial/starting the meds because they were afraid of dying. Interviewee 11 related, “Then, the next thing (after being diagnosed with HIV) was, well, hell I’m going to die anyhow. I did not know there was any hope for me whatsoever.” For her the decision to join the trial “was really easy. I mean, if it’s something that’s going to help me to get this thing down so that I can survive, I love it. I will go on other trials for them also.”

Uncertainty and fear were other factors for most women; they experienced uncertainty about how to handle the new role of HIV+ patient and fear of death and/or declining health. Whether the woman was concerned about her current health, her future health, or both, at some point she must have either decided by herself or with a health care provider that medications would be beneficial.

To Consult Others or Not

Almost all the women said they made the decision by themselves (or with their health care providers). Interviewee 1 made her decision alone, although she did have people she could talk to about the decision; she said, “If I’m dying, I’ll go (to the trial). I decided. I mean, I told him (her husband) about it, but I’m going with it (says emphatically).” Only two women remembered talking to people outside the clinic about the trial. Perhaps not incidentally, those women were relatively healthy at the time.

IW2: My sister-in-law is a nurse at Mt. Carmel West, and I asked her opinion about this clinical trial they said I should get on. I go ‘do you think it would be a good idea?’ She said, ‘Oh, yeah. People want to get on those all the time, Because she’s an oncology nurse, and she said people with cancer want to get on those all the time. She said she thought it would be really good, and then when she said yeah; she definitely gave me the thumbs-up on it. So I pretty much decided then to do it…Well, I had seen the one doctor at Children’s who also treats people at OSU. He said if I wanted to get on that study, the clinical study, that I would have to go to OSU to do it. I can’t remember; I think I talked to my sister-in-law and then I decided I wanted to do it. And then I probably had to go back to Children’s and see him one more time and I told him I wanted to get on it. He set up an appointment for me; my first appointment when I talked to that counselor, I guess
you’d call her, who just talked about my situation with me. I was like, yeah, get me started. I want to start taking drugs so I can get better. Even though at that time, I felt fine.

Interviewee 5 was prepared for her referral to a clinical trial by her case worker.

BC: Did you ask anybody’s advice about being in the study?
IW5: My worker through the Health Department, him and I talked about it, and he had mentioned it too when he first started helping me. And he’s been with me from the first time they notified the Health Department, so he’s been there from the start, day one. I asked him a lot of questions and asked him what he thinks, but he did tell me that they made mention of research, and he kind of prepared me before they even told me over here about it…He was saying that depending on what your blood level is and how far advanced you are as to whether you’re a candidate or not. So I guess mine got caught early enough so...

BC: Okay. What made you decide to be in a trial?
IW12: I didn’t. They just put me in one. They said I need it. They, they just want me in a clinical trial. Paula did. That’s when I met Paula. Told me I was going to be in a study program and I said okay, sounds good.
BC: Okay. So they told you about it and you just kind of said okay whatever?
IW12: Mm-hmm. I got to get some help, get my medication.

Expectations of Personal Benefit and Altruism

Most women had a sense of wanting to see immediate personal benefit coupled with a longer term increase in scientific understanding of the disease to help end HIV/AIDS. Data regarding how women expected their health to improve as a result of trial participation was provided earlier in this section. It should be noted that eventually, should a cure be found from research, women did expect to benefit from it.

IW7: Well, the girls (trial nurses) told me about it (the trial) and what it was, you know, but, no. I was very open to it. I wanted to, you know, at least my gosh if they could help me or someone else with the study, yes, it’s really a wonderful thing. Hopefully, it ends up being I’m the winner, you know, but…

Women also cited altruism as a primary or secondary reason to participate in the trial. Four women mentioned they hoped their participation in research would help lead to
a cure for HIV or keep them healthy until researchers found a cure. After discussing her insurance status and desire to take medications, interviewee 2 said, “I told her (her trial nurse) I thought it (the clinical trial) was good, especially if you think you can help other people. That’s a big incentive.” Interviewee 5’s primary reason for joining was helping scientific research.

IW5: I was kind of in between (trying to decide whether or not to join the trial). I wasn’t sure, but I was at the point that if it’s going to work then I guess that’s what we’ll do. Whatever, you know, whatever’s going to work and help do the job. I don’t know. I was hesitant, though, there for a while. I was really hesitant. I guess I just had to think, and I thought about it…I had to take time and make a decision anyway and decided a month after I found out all this and then I was like well…I do; do I want to go through this? So I figured the research would be something. If there’s a way to find a cure, then maybe we can do it. I hope.

Participating in research that found a cure for HIV was another way women hoped to both help others and themselves. Interviewee 7 mentioned the cure twice in her interview:

IW7: And, you know, you don’t know what, what is going to happen or…hopefully…they’ll have a cure before long…

A few women spoke of the trial giving them a reason for living (to give back) and a sense of purpose.

IW2: One of the reasons I kind of wanted to be on it…I was feeling really mentally bad at that time. I thought, if there’s something I can do to help somebody else, I would gladly do it. I would not want anyone else to have to go through what I went through. That’s another reason I wanted to be on it. I thought if I could help them figure out something better to help other people.

BC: How does being in the clinical trial fit into your life? IW9: Basically what I, I already explained; it’s just my way of being able to give back to help somebody else. I’m, my life for me is a service. It took me a long time to accept that I’m a servant, and that’s what I do. That’s my purpose and I just…I want to do what I was intended to do, so that maybe one day I could hear the Lord say, ‘a job well done.’
Information Session

Trial staff members at OSU have a policy of arranging an information session once a woman expresses interest in joining a trial. Interviewee 2 mentioned she went and “talked to someone about her situation.” One woman mentioned this as rather a nuisance session because she could not get her medications at this visit; she had to make a separate appointment to come back and get her medications. When women did not bring up an information session on her own, the interviewer asked her specifically about it. Most women reported not remembering a specific information session, as memories of their first few visits seemed jumbled.

IW11: That was when I was bitten. I think it was like the beginning of November. I think I came here the end of November, and then they wanted me to come back and see the doctor. I came and saw Denise. Denise Smith, a social worker. And it didn’t seem like they were in a major hurry to get me started on the program. They might have also been figuring out how I would handle it, if I wanted to do it or not. But, no, I think I started my medication in um, January.

One UC trial participant who participated in several trials discussed her information sessions:

BC: What happens when you start a new trial, like do they sit down and explain everything to you or?
IW9: Yeah.
BC: What’s that like?
IW9: Helpful, I mean because, you know, it’s the more information I have about, you know, the trials, of what will be required in the trials, you know, helps to make a, helps your decision on whether I want to be involved with it or not.

BC: Okay. Uh, can you tell me about your, the visit when you came in and they told you about the trial?
IW8: I don’t even think I remember. Ann just said that she thinks I needed to try it, and she thought it would be good for me, and I trust her, and that was it.
These information sessions may have assisted decision-making for women who were not sure at this point whether or not to join a trial. Only a few women reported an initial meeting or an information session, so not many details were learned about them, such as how long they lasted or if there was an incentive other than potential participation offered for attending an initial setting. Women may have forgotten about this session, or they decided it was not important enough to share because they just had a conversation and read some forms (i.e., did not do anything to actually impact their health). It does seem likely that most women had already made up their minds to enter the trial, if they were eligible, by this point.

Informed Consent

Very few women report remembering what paperwork they signed when they decided to join their trial. No questions in the protocol directly assessed the issue of informed consent, as it was assumed that the women would remember some of the seemingly more important details of their trial, like how long the trial would last. However, much of the interview protocol dealt with information women should have received at the time they signed consent paperwork, such as whether their trial had a placebo element or how long their trial was scheduled to last.

Two women mentioned consent forms specifically during the interview. Interviewee 3 remembers, “So, um, yes, I mean I signed all kinds of consent, Well, let me think. It wasn’t that first day, but I did sign consent forms that week because of the medications. They started me on my meds that week.” Interviewee 11 mentions consent forms rather blithely. “I mean they had to go through a lot of paperwork and had to sign a lot of consent forms and dah, dah, dah, dah, dah, you know, so it was, it was a long day.”

That women appear to view the consent forms as a trivial detail that just adds to the length of their appointment and as something to deal with as soon as possible has some ethical implications discussed in the next chapter.
Question #2

What is the nature of the experience of participating in a therapeutic clinical trial for HIV+ women?

This data will cover what the trial is like when women begin, what happens during their appointments, trial logistics, what their regimens are like, how they feel about their regimens, what body changes and side effects they experienced, how they adjust to their regimen, how the trial changes over time for them, what trial care entails, whether or not women feel like guinea pigs, and how they feel about confidentiality.

Starting the Trial

Several women reported that their trial experience often fell into two categories: the initial visits and trial ‘maintenance.’ The initial phase of the trial was characterized by fear, uncertainty, frequent visits, and was when they began their regimen. A few women who were fairly new to their trials were able to recall what the first appointment at the trial site was like.

BC: What was your first appointment like here?
IW10: My stomach was in knots because I didn’t know what to expect, you know, the unknown to me, well to anyone, is scary. Once I met Jim (her trial nurse) within minutes I was so comfortable with him, I felt so at ease...But, like I said, once I was here for a few minutes, and I got all the story off my chest, I felt really comfortable with Jim...But, no, like I said I was real nervous, I didn’t hardly sleep the night before that (her first trial appointment) because I didn’t know what to expect. I didn’t know the kind of questions they was going to ask. I just didn’t know. I was terrified. You know, it was all new to me okay...how long am I going to be here? The day was long. I mean they had to go through a lot of paperwork and had to sign a lot of consent forms...so it was, it was a long day, but, like I said, after I was here a few minutes then one-on-one with Jim, I felt real at ease, so each time I come now, each time gets better and better. You know, the first day was just terrifying, nerve wracking. I thought I was going to throw up; I was so nervous, but I made it, thank God.

BC: OK. What was your first appointment like?
IW3: Well, they took a lot of blood. (We laughed.) Um, I think they really put me through the mill. I mean, I think that it’s kind of like having a baby; you forget how sick you was. Yeah, they took a lot of blood, and of course they just; you saw a doctor, and of course they took all your weight and vitals and, you know, and what symptoms you’d been having.

BC: Did they explain to you what the trial was going to involve?

IW3: Yes, but I think you know at the time you’re feeling that bad that, um. I mean they’re pouring a lot of things into your brain, you know, trying to tell you about the programs that are available and financials, you know, finances. Uh, peer support, and the groups and all that. But I don’t really think that; I mean I don’t know if I cared to hear about it or not. Probably not. But I heard about it anyway. I mean you heard pretty much a whole lot of stuff that week. So, um, yes, I mean, I signed all kinds of consent. Well let me think. It wasn’t that first day, but I did sign consent forms that week because of the medications. They started me on my meds that week. Yes, and I don’t remember if it was the second visit or the third visit. But they started me up right away, and then of course, the study that I was picked and chosen to be in...random thing by a computer or whatever. I had a nurse that called me once a week, and, um, so any questions or any adverse reactions or anything that, you know, I needed to discuss, I guess I discussed with her. Because I don’t; I mean I can’t remember, how quickly I went back, but I mean I went back fairly quickly, but in the meantime I still talked to her.

Trial Appointments

Although it was not included in the question protocol, the interviewer asked the first few interviewees what happened during their trial appointments; the interviewer wanted to get a sense of what happened to the women while they were at the trial site. After about 4 or 5 interviews, the components of the clinic visit seemed very similar between women and across sites, so it was removed as a regular question from the protocol.

There were many common elements of all the appointments. Women generally got a clinic room, had their vital signs taken, talked with trial staff about their health, had blood drawn, had any special sub-study or other research project activities, chatted with their trial nurse, set up their next appointment, and got refills of their regimens. Women were on different trials, so the protocols did differ slightly.
It sounded like interviewee 2 was in a special sub-study, along with a few of the other women interviewed.

IW2: Like I said, sometimes they’ll do the measurements and the Dexascan, I might have to go do those. I was having to do that glucose tolerance, where you drink that. I’d have to fast before I went in. I could take my one pill on an empty stomach, but I couldn’t take my other pills before I’d go in. They’d take the blood, and then I’d have to drink that bottle of whatever it is; it tastes like orange soda or something. Then they’d take my blood again. I don’t know exactly what they were checking for. I think they stopped that now for this last year, the extended year. They’re not going to do that anymore. So the last time I went for my long appointment, I didn’t have to drink that, but they still did the measurements and Dexascan and draw my blood.

BC: How often do you come in usually?
IW7: Uh, whatever the study says. Sometimes it likes, uh, they want to see me in six weeks; sometimes they want to see you in four weeks. It just depends. One week, now this week they measured, the study measures your arms, your neck, uh, stomach, hips, weight, blood pressure and then, uh, what else, and then I give several tubes of blood, I don’t know how many they take. And then I’ll come in another time and they will only take maybe one tube of blood and not do all those measurements. So there’s certain times that they’re doing the part of the study that asks for that.

Four women from time to time shifted from first person to second person during the interview. This seemed to be when they were talking about what happened during their clinic appointments that may have de-humanized and/or embarrassed them. Interviewee 3 had been speaking in first person until she began describing the embarrassing parts of her appointment.

IW3: So I can tell you, well, clear up until this last time the big thing was where you walk; you get your weight and everything; they drew your blood. And then after they drew your blood, you went back to your room and that was your visit where the doctor had to see you. You had to drink that orange stuff in 5 minutes, and you had to fill out your papers and everything because from the time you finished drinking your orange stuff until they had to take your blood a half hour later. So they drew two different times. Let’s see, after you saw the doctor, oh, then you had to do your little thing in the cup. (We laugh.) And then after you did that, they measured you. So you stripped down, all except your bra and your panties, and they measure everything three times. In millimeters, not inches. And,
that visit there is the time you have the two nurses. Because one measures, and the other records, so they have a regular schedule, how they do that.

(Later in the interview)

BC: So there aren’t any bad things that you can think of?
IW3: I don’t think so. I mean, other than just you know, getting used to being, and you get used to it, what they’re going to do to you. The days that you fast, they want you to pee in a bottle. When you’ve had nothing to drink that morning, how are you supposed to pee? (We laugh.) So you just get used to knowing they’re going to take whatever-14 vials of blood, 20 vials of blood. It just used to amaze me so much, but you get used to it. And you’re so surprised when for some reason they don’t take that many.

BC: Have you been in any other studies…
IW1: No.
BC: Other than this? Not at all?
IW1: No…They (refers to ‘psych tests’ as she calls them) are so horrible. You have to like, the one that I hate, there’s just the numbers scattered all across the paper, you start from one, then you gotta find two, and she’s like timing you. Then you gotta find three; then you go back to four. I hate that one. Three years of college, you’d think I’d be able to connect the dots!

As mentioned before, some women’s trials incorporated other studies. Sometimes these studies required extra data collection and longer visits. Two women report disliking the surveys given through the trial. IW1 mentions this again later in her interview.

BC: Okay. Uh, what are some bad things about being in the trial?
IW9: All of the questions. That’s about it…I don’t know, it seems, I know this information that you’re looking for it is only certain ways to, uh, ask for that information but, uh, if we could just, if they could just, uh, decrease the questionnaires to about like four open questions or something and it would just be better. That’s it.
BC: Okay. And are you talking about your trial diary or questionnaires like the ones you were doing to help?
IW9: I’m talking about the other questionnaires. Not the diaries, but the questionnaires.

One woman, however, specifically mentioned that she did not mind the surveys done through her trial.

IW6: …that’s one of the advantages. It’s somebody checking up on you, you know, asking if there’s any problems; do we need to change something? I
mean...like you interviewing me now or whatever... and you go in there (ACTU), they have a survey too you have to do every so often. So, you know, you can tell like if you don’t like it (the regimen). They ask you some kind of the same questions like: Does it constantly remind you every time you take it? Is it too many?

Trial Logistics

Women enjoyed the less-frequent appointments after being enrolled in a trial for a longer period of time. Transportation and scheduling proved daunting, but not insurmountable, challenges.

In terms of scheduling, women generally experienced many appointments during a short span of time in the beginning of the trial. Eventually, more and more time would pass between trial appointments. Women reported enjoying the scheduling flexibility the staff members offered.

BC: And it sounds like you like going once every two months a lot.
IW2: Yeah, better than once a week, that’s for sure! (We laugh)

BC: Okay. And how often do you go over there?
IW6: Like at first it was, uh, like seemed like every other week and that’s what they told you to when you do the research. It’s, it is like you there all the time, so a lot of people don’t like it. Let’s see with Liz, she will work with you. I have to be at work at 9:00. She will say run up here around 8:00 and she will come to work earlier than she has to, you know what I’m saying. So at first it was like every other week, then it spreads out like it goes to like four weeks, then they’ll go to eight, you know, so it just spreads out.

BC: Right. So were you seeing Jim (her trial nurse) every two weeks?
IW10: Every two weeks, yeah.
BC: Okay. Is that like indefinitely?
IW10: No, I think he said I had to go every two weeks for two months and then I’m only going to come for once a month unless I have problems. And then the reason they want to keep a close eye on me is because of the new meds, I don’t know, because everybody does different with things to see how I was coping with the meds, keep a close eye on my labs. Then I’ll only come once a month.
Interviewee 8 schedules her work site visits around her trial appointments.

BC: Okay. How convenient is that for you?
IW8: That’s great. I mean even when I had to come like every four weeks and then every six week and then every eight weeks it didn’t bother me because I always scheduled it around getting off of work. And when I got sick last, last year I cut back my hours of work. So I usually try to be off of work no later than 12:00 pm.

Interviewee 10 schedules her day off around her next trial appointment.

BC: Okay. Uh, do you have problems getting time off to come here?
IW10: No, that’s the best thing about this job that I started. He said if I would let him know a week in advance before they make a schedule. There’s no problem, and so far, like when I go back to work tomorrow the first thing I will tell him is May 14 I have to be back. You know, I need May 14 off and when they do the schedule, when the receptionist does the schedule, she just automatically on my name just puts a cross there and says ‘needs the day off’, and they’ve not had a bit of problem with it, so that was one good thing. Because, you know, starting a new job you just can’t say, well, I need this day, this day and this day off. They’re going to go, ‘Okay sure she’s really going to be dependable isn’t she?’ But I mean I told him at the interview that morning that, uh, you know, I’m in the process of moving; I have a doctor I have to go see at least once every two weeks, and I’m going to have to have that day off. Is that a problem? And he was ‘nope.’

However, Interviewee 3 found that scheduling her appointments ahead of time was difficult.

IW3: Two months in advance! But they’re so, they roll with the punches over there. You know, you fight the traffic and you’re late and there’s wrecks and you know. I’ve been over there, I either keep my appointments or totally miss them, because I have to be out of the house for so many hours before my appointment over there, so I know way ahead of time whether I’m going to make it or not. I don’t think there’s very many, two or three times in all these years, that I couldn’t make my appointment. Because I scheduled my appointment, sometimes knowing that because of the time my appointment is, you know, you don’t take your medicine until noon if you’re there at 8 o’clock in the morning and you’ve got to leave the house here by 6:30, so you’ve got to be up a few hours before that so you can be done going to the bathroom. So, see it’s like…It’s not like easy. It’s
not easy, but they are so good over there. There’s a lot of people that don’t have, like I can drive over there, they have to take buses and the buses run late. Or they overslept.

Interviewee 9 was the only woman who mentioned a long wait to see her trial doctor. She was also the woman who mentioned she would like a reminder call about her appointment a day or two before.

BC: Is coming here once every three months convenient for you?
IW9: Mm-hmm, yes. Yes it is. Even though I love Dr. Doe I wouldn’t want to have to sit and wait on her every now and then. (We laugh.) So about once every three months I’m, I’m, I’m, I’m geared up to, you know, to be patient and stuff.

One interviewee mentioned that the frequent appointments in the beginning, soon after she was diagnosed, served as an unpleasant reminder of her HIV. Interviewee 6 said, “at the beginning, just found out, it (repeated trial appointments) is like constant reminder, you have it, you know what I’m saying, take care of, it was just constant on my mind. But now I’m, I don’t really think about it.”

Both trial site staff gave trial participants parking vouchers. Interviewees 2 and 7 specifically mentioned parking for free was something they liked about the trial; women appreciated that courtesy, although interviewee 1 related that it was difficult to remember to get it validated.

Other women wished the trial location was more convenient.

BC: Okay. Uh, if I could give you a magic wand that would change one thing about your experience here at OSU what would you change?
IW10: Wow. Mm, that I never had it to begin with! But that don’t have nothing to do with OSU. Uh, if it was two blocks down the street instead of two hours and a half away. I don’t know. (We laugh.)

BC: OK. And do you have problems fitting that in with your work schedule?
IW11: Sometimes! (She laughs.) I manage. You know, I live so far away is the major problem.
BC: And you drive about an hour to get here?
IW11: About 45 minutes to an hour.
Interviewee 11 also volunteered that her gasoline expenses for the drive were compensated. Also, both she and interviewee 3 mentioned they did not mind the drive very much; both women were happy to be able to get care outside their local area. However, interviewee 12 mentioned she was looking into finding another clinic closer to her home; waiting for her bus or cab to take her to the clinic made her leg sore.

Regimen Components

Women found it difficult to remembering what drugs they were on. Most of them have generic names as well, and they are all difficult to pronounce. The interviewer carried around a chart with names, pictures, and dosage instructions for the more common medications to help women remember what they were taking. Usually, they would identify them not by name, but by picture. Some women said they had the names written down for when they went to the doctor.

IW7: I’m not real good on knowing, naming medicines. I really have no interest in knowing, you know how people can rattle off prescriptions and name medical stuff. I do not excel in it, nor do I even care about it. It frightens me because I’m not, I don’t like to take medicines. I just take this because I have to.

On the other hand, interviewee 3 knew her drug names off the top of her head, as did interviewee 9.

Daily Regimen Schedules

Women also described their regimen schedule, which can be complicated, inconvenient, and require high motivation.

BC: What about timing your meals? Are you able to time your meals so you can eat with your kids? Or do you just eat a couple extra snacks during the day?
IW2: When I first got on the study I talked to the pharmacist there at OSU and she told me how to take my drugs and everything. How like that one drug I have to take it on an empty stomach. So I take that first thing in the morning. I had
thought that she had said that I had to wait exactly one hour after I took this first one, the Videx or DDL, whatever they call it, that I had to eat 300 calories at least to take my morning pills. She said it works best if you wait 12 hours to take them again. Then I have a pill that I’m supposed to take at bedtime. But I don’t really eat at 7 a.m., because I don’t usually get up that early. (We laugh.) When I talked to my nurse at OSU, she was concerned about my weight and she called that pharmacist. She said you don’t have to, as long as I take the first pill of the day on an empty stomach I don’t have to eat right away. Sometimes I might go back to bed if I’m really tired, after I get the kids off to school. And then I’ll eat, and that might be two and a half hours later or something, and then I’ll take my pills. I try to take them 12 hours from then. It’s not that big a deal if it’s not exact. But like my Susie told me, she had some people who were taking all their pills at one time. (We laugh.) I was trying to be really precise with them. Each day would be different. I would take my pills early on Friday, but then the next day is Saturday and I slept in late. If I took them at 10 that night, and the next morning I wouldn’t get up until 10 am, so for each day I try to make it first pill then (the other pills) one hour and then 12 hours later, but she said I could lighten up on that a little and try to get more back into my routine that I used to have so that it would be easier to gain weight. So whenever I’m the least bit hungry, I always make sure I try and eat something. If I’m hungry at all, I eat. I would think, well, I don’t want to eat now, because in two hours I’m going to have to eat again and I won’t be hungry, but it’s be too early to eat my pill. Because I have to eat before I take some of them. So now if I’m hungry, I just go ahead and eat. And then I’ll maybe just eat a bowl of ice cream, which isn’t hard to get down. And if you get the full-strength stuff, not the frozen yogurt, you can get the 300 calories easy.

BC: What is your, like your schedule? Like, in terms of eating and drugs?
IW3: Right now? OK. (She laughs.) Right now, it seems like, um, and it really is a schedule. I mean, it’s a schedule. Like I said, I take my Sustiva; I take it, um, approximately 10 o’clock at night, because I don’t have to take it with food. And then the Combivir and Nelfinivir I take about 11-11:30. I mean, it’s supposed to be taken every 12 hours. You’re not supposed to go off that schedule. So, um, but you have to have 300 calories and fat, at least some fat and that 300 calories so, um. And it highly depends on the food schedule too. But I try and get at least some calories down with it. And then in the morning, you know, 12 hours from when I took it the night before. I take it with my coffee, my coffee. Because I mean, I drink a lot of milk and use some sugar in it, in my coffee. So that’s, you know, I try and I don’t know if I have 300 calories or not.
Some women reported their regimes were a bit simpler.

IW5: I take the Combivir, the Combivir and the Trizivir I take twice a day. And, uh, Sustiva I take at night and it’s three tablets. I take them at night, three capsules.

IW9: I really have a decent regimen at this time. I take medication twice a day and I don’t take but, uh, two HIV medications in the morning, and I take four at night, four pills at night and two in the morning and that’s my regimen.
BC: Do you have to take them with food?
IW9: No. Actually the one, uh, Videx I take on an empty stomach. That’s why I take it in the morning. But no, no other special conditions or anything. Well the Zerit I’m supposed to take like twelve hours.

Interviewee 2 mentioned she was in ACTG 384, as is interviewee 12; her study nurse shared this information with the interviewer. Most of the women interviewed probably were on the same trial, but there is enough flexibility in the protocols that they are not all on the same drugs. If participants have side effects or allergies, providers can switch them to other drugs.

Experiences With and Feelings About the Regimen

Most women did not like taking the trial medications. They expressed dismay about all kinds of things: the number of pills, actual side effects, perceived side effects (the list of possible side effects, which leads to ‘false’ side effects that can be as distressing and threatening as the real ones), medications as a reminder they have got HIV/AIDS, trying to hide medications, the spacing, the swallowing, having to take pills when feeling fine, having to keep more food in the house to take with medications, and having to take pills with food when not hungry.

Interviewee 3 went into detail about what her procedure for taking her medications involves.

IW3: Oh, well, um. I take the Nelfinivir … I take 12 hours apart. I take 5 of them.
BC: At one time?
IW3: Uhhuh. 5 in the morning and 5 at night. Because they’re study meds, they’re not coated. Shame on them! See, my friend that just went in the hospital, they sent him his real medicine here, because he was staying here when he was so very ill. They came coated.

BC: Oh! So that’s how you know.

IW3: Uhhuh.

BC: So do they go down funny?

IW3: Oh, they just get your tongue and sometimes they just stick! The longer I’ve taken them, I guess you just learn how to take them and not let that happen. But every now and then you just get lacksidaisical about taking them, because you just take them. You just throw them down and you’re thinking about something else or whatever, and about the time where you think, ‘boy, I haven’t had trouble getting these down for such a long, long time.’ About the time you think that, something’s going to happen.

BC: What do you do to avoid that?

IW3: I’ve just learned how to take them. I’ve just learned how to take them. If you don’t, I mean if you differentiate just the least little bit, it’s not pleasant.

BC: Do you drink them like with pop or coffee?

IW3: Uh, throw them down with water. Throw them with water. Yeah. And then, I always, I guess am either drinking coffee in the mornings, so I either drink coffee afterward or something. (She laughs) Yeah, they’re definitely not coated!

BC: Is it just the Nelfinivir?

IW3: Yeah, the Sustiva is capsules and then the Combivir, you know it’s says right on the thing that it’s legit and it’s a coated...You know it’s coated because it makes the other ones seem very uncoated. (She laughs.)

BC: Yeah, you can really tell the difference then?

IW3: Mmhmm. Yeah. But I just throw them down. I try not to think about it. My friend said, ‘how do you do that?’ I said, ‘I don’t know. I don’t know how I do it.’ But then sometimes they go down and sometimes they don’t. I don’t take them one at a time. I would never, ever get them down. Never.

BC: So you just pour them in your hand and (mimic tossing pills down my throat)?

IW3: I pour them in my hand (we laugh).

BC: Sounds like a science!

IW3: It really is! See, I have to think about it when I’m not doing it. I pour them in my hand. I guess when I throw them in my mouth, I probably take a little bit of a breath, and when I’m drinking them, I throw my head back. So I’m not trying to breathe; I’ve already got oxygen in my lungs. Essentially, I think you can’t breathe when you’re throwing them down, because sometimes they go down your windpipe instead of where they’re supposed to go.

IW12: Uh-huh, yeah, it’s, uh, one’s, the one in the morning is not up here but it’s just a white pill, something like that. I can’t swallow so I got to open it and just pour it in.

BC: Okay.
IW12: And, uh, they know I can’t swallow so I take one of these in the morning, one of these in the afternoon.

IW4: Medicine’s amazing; it is. I hate medicine. I take nine a day, dang! It should only be two or three.

Interviewee 9 said taking her trial medications reminds her of her HIV. This could be a genuine reflection of the symbolic nature of the regimen, but she also mentioned elsewhere in her interview that one of the trial questionnaires she filled out asked if taking the drugs was a reminder of her HIV.

BC: Okay. What was it like at first, when you first started (your regimen)?
IW6: A reminder. It’s kind of like that. You know what I’m saying like constant, but that’s for me, it’s just a reminder. And then I don’t like medicine so just taking it, you know, knowing you have to, to help you out so and then after, uh, knowing that it’s going to help you, then I just kind of figured that out. I do what I have to do.

Side Effects

Weight problems (gains and losses) were problematic for these women. As seen in much other research, HIV and its treatments do cause changes to the body, along with all the other side effects they cause. Two women seemed particularly concerned about their weight.

IW2: Yeah, before I always wanted to lose weight and now it’s like I can’t gain it. I’ve noticed my legs have gotten a lot thinner. It’s nice in the wintertime because people aren’t saying ‘oh, your legs are so skinny.’ [She does the high-pitched, nagging voice again] The core of my body doesn’t look that bad. My arms and my legs are really thin. My veins kinda stick out and stuff. [She rolls up her pants leg to show me how thin her legs are and traces a few veins for me.] So it’s kinda nice to be able to cover them up. In the summertime, I want to wear shorts and be cool! One time my nurse was concerned about me and how much weight I had lost, and I guess she wanted me to try and gain more weight. I was weighing like 120, which is really the perfect weight for my height. Right now I only weigh like 108, so I guess I’m a little bit underweight. But I don’t think I look that bad! [I shake my head no.] She’ll tell me to eat ice cream and not to drink diet soda. That’s one thing; I always used to drink Diet Coke. She said not to drink diet pop
anymore. So now I drink the full-strength stuff. So I don’t eat anything that’s diet. I eat potato chips and chocolate. I love chocolate! (We laugh.) Of course, I did that anyway, you know? But I always felt guilty about it. (We laugh.)

Later in the interview she remarks:

IW2: Yeah, because my stomach (is) still kind of pudgy. Like I said, the core of my body looks pretty much the same, but my arms and legs seem like they’ve lost a lot. Even though I have lost weight through all of it.

IW3: Uh, well, physically, everything has changed. I used to be, I used to walk miles and miles everyday. I mean, I still keep, I still take good care of myself as far as my health and my physical being. And they have me eating so much that I was getting, got heavy. That didn’t make me feel good. But then when I started losing weight again, it was like, it was almost a flashback (she laughs).

BC: From when you were sick?
IW3: When I was sick. But physically I’m built different now.

This woman experienced life-altering side effects with her regimen. However, her experience was unique. Most women interviewed reported mild side effects or side effects that improved over time.

IW3: So that if I am taking placebos I don’t have to take them anymore, but I’ve never felt that I was taking placebos, I guess. Because I had, I mean I have, reactions to the medication.

BC: Okay, so it’s not just a sugar pill?
IW3: I don’t think so. No, I really don’t think so.

BC: What kind of reaction did you have?

IW3: Well, the one I would take in the evenings, that I never took any other time of the day, would make you, I don’t know, dizzy? I don’t know if I’d want to say dizzy or it almost affected you in the morning, when you tried to get up. It made it hard to get up in the morning. Almost like you were dizzy or drunk. (We laugh.) They said that that’s one you take in the evenings, and it almost seemed like way back then, the earlier I took it in the evening, the easier it was for me to get up in the morning, even though it was really, really hard to get up. You almost couldn’t get up. You almost couldn’t get up. You’d get up to take medicine, and you’d be back on the couch asleep. It’s just um, side effects. Side effects, definitely. Side effects. And then, of course, the diarrhea never, it changed. I mean, it never went away, but eventually has gotten to where, and I think it’s a side effect, at least right now. I really don’t think that if I went off my medicines, it would be. It wouldn’t go away, but it would be changed back to like what it was. It’s different.
It’s different. Um, side effects, oh, other than just the nausea and having to take medicine when you didn’t want to take it, and take it with food when you didn’t feel like eating. I mean, relatively healthy I am right now, other than, and the schedule I keep with my medicines depends on the schedule that I hit the bathroom. I can’t; I don’t dare leave the apartment before 11 or 12 o’clock every day. Yeah. So, if I’m up at 7 or 8, I mean, that’s, that’s my morning. That’s my morning.

BC: Taking your pills and in the bathroom?
IW3: Yeah. And then I take my pills at about five hours, I mean, and it depends on my monthly schedule too, my monthly and my cycle and all that. But I’ve got about, if I’m lucky, five good hours in the afternoon before I start hitting the bathroom again. But, then, it wasn’t like that yesterday or the day before. (She laughs) So I only had like, three good hours yesterday and the day before. So, from like, it seems almost like if I took my medicine at 11 o’clock in the morning so I would, maybe it was all out of my system, you know, that 12-hour schedule, so from like 11 to 2 I’m in pretty good shape. Those last couple days, it’s been bad in the afternoons and so it just pretty much sets my schedule. I set my schedule around it. But then there’s days where I, I’m fine. But, uh, I have more leeway in just the three hours. Sometimes it’s more like five hours. So it’s, it hasn’t been easy; I just understand that’s how it probably will have to be.

Adjusting to the Regimen

The regimen or combination of drugs, the reason most women chose to join the trial, required some adjustment in the women’s lifestyle so they could take certain drugs at certain times on a full or empty stomach. They experienced side effects as mentioned above, as well as challenges adhering to their new regimes. The strategies women use to make taking their medications bearable are interesting. They take them with full-fat ice cream, which is palatable even if they are not hungry. They keep medications and water by their beds. Partners remind them to take their meds. They seem very aware of how important adherence is and devise all kinds of strategies to try and adhere to their regimen. When these women discuss adherence, it usually seems to be in the context of stories about what they do to optimize adherence.

About half the women discussed how well they took their medications. One took her morning meds with coffee, which apparently is not recommended. One reported routinely forgetting her afternoon dose. Other women prided themselves on never missing a dose. Most women report trying to do the best they can; they know that
adherence will extend the time the drugs work but are aware at the same time those particular drugs could stop working at any time. Adherence tended to be easier as women got used to the regimen routine. One woman described herself as ‘religious’ about taking her meds. One other reported it was like her ‘job;' it seemed like she reported being desperate to get better. Interviewee 2 discusses how her children motivate her to treat her HIV:

IW2: Of course, I want to live; also so I want to take my pills. Especially since my husband’s gone, I want to think about my children, take care of them. I know they want me to live; they want ME instead of somebody else (taking care of them). Sometimes it is hard; sometimes I feel like giving up, but I can’t. I’ve got to do this (take her HIV medications).

Physically taking the pills was an individual experience ranging in comfort from an awful ordeal to a mindless painless routine. However, women seem to interpret the basic experience of taking their meds as the ‘price’ for choosing or having health and life.

IW3: They say my chances are, the more I stick to my regime and the more I stick to my schedule and take my medicines like I’m supposed to, that’s the better. But that’s no guarantee either, because someday they’re just going to quit working.

IW5: But it’s an easy schedule. I just pretty much stick with it and keep them on the same time, try to keep them on the same timetable. It helps. I might have missed a dose or two here and there, but that’s when I first started and it was hard getting used to getting up and taking medicines and then having them there everyday. All day, and twice a day, two or three times a day. That was hard. BC: How did you like get yourself into the habit of taking your medicine? IW5: I just, I say I just make my time limit a routine thing. The first one was when I got out of bed in the morning…The first thing I would do is grab my first a.m. dosage and have it right there…That was pretty much how I kept up with it, so the morning dosage is the main one, and I get it before I even get my coffee and that’s pretty unusual for me because I’m the coffee person. (We laugh.) BC: Okay. Do you keep your pills in the kitchen or by your bed or…? IW5: In the cabinet, well in the medicine cabinet, but they’re in a, like a Monday, Tuesday, Wednesday thing so (probably means a pill organizer). BC: Okay.
IW5: And an a.m. and p.m. case so I got them all where I know which one, they’re all there. It’s easier that way too.
IW8: But maybe about in the whole year that I’ve been on it maybe three times, maybe four at the most I’ll go past five hours. Have I ran over to the point that I didn’t get it at 7:00, then I took it between 8:00 and 9:00 but I did take it...
BC: Okay.
IW8: Uh, that one next day. Even with a headache and sick and everything I’ve always taken that medication, so I’ve never missed a dose.
BC: It sounds like you’re very proud of that.
IW8: Well, uh, the disease in itself is terrible but they have medication that can help me. So I mean if they’re willing to help me extend my life I should be willing to help myself to help them...

Women reported trying to follow their providers’ instructions precisely, often losing some of the flexibility needed to successfully integrate medication regimens into their lives. Providers may expect non-adherence and over-dictate to some very motivated women like those who chose to join trials. Two women, interviewees 6 and 7, described how they take their doses during the workday, as they had not disclosed to anyone at work. This may make trial participation more difficult for those who work. However, they did have strategies in place.

Women usually reported problems about taking the medications exactly 12 hours apart to the health care providers, who would then tell the women she could introduce some flexibility into the regimen to help her stick to it for the long term. For example, Interviewee 6 was having difficulty taking her medications exactly 12 hours apart, in part due to her work schedule.

IW6: But now, I mean, as long as you do it within a 14-hour period it’s not that serious no more, like it used to be. You know, so that, that helped. They said they want you to take it because I was doing it, you know, trying to eat breakfast, take it by 8:00, get dressed, go to work…I told her I was like it’s just too much. She said you supposed to do it within, what do I want to say? I’m looking for the word, and get what matches with your lifestyle I guess. So like if I eat lunch, I eat lunch with my kids at 11:00; take care of them, and I wait maybe two hours-about 1:00 I take it. So that was like relaxing for me. I’m not rushing. I want to eat something at 11:00. You know what I’m saying. I don’t have to get up early to eat no breakfast if I don’t want to. You know, I normally, and even in the weekends by then I’m up because sometimes I try to sleep in. I try to so by then I mean, you know, it was lunchtime. By 11:00 I’m eating breakfast so then I got to take it. You know, so it still kind of work because I know I’m not going to get up at 8:00 on a Saturday. You know what I’m saying. So that’s what I was worried about, so
I mean that’s what she said, no, just when you take it at 11:00 that will count 14 hours and take it, you know, well if it starts at 10:00 you can take it at 10 hours if you want to…Because you’ve got till 14…To actually you have to take it again. To get it in your system, so then that made me feel better. So then I was like okay for the first time. I was like I can’t do this 8:00, you know. I think that then I have to take it by 6:00.

BC: And at night?

IW6: Because it wasn’t my period and sometimes I out. I’m like, well, I don’t have it. You know what I’m saying so it was just, I, I mean it was just getting on my nerves. So then I’m oh, I don’t know if I want to do this, and that’s when she (her trial nurse) told me just switch your time and try that. So then I like that better.

BC: Well, I want to ask you about something you said earlier. With your noon doses of medicine. How do you remind yourself to take those if you’re running about as you do?

IW7: It’s not easy. Kristen gave me a timer. Well this is a riot it goes off. Somebody says you got something going off in your purse. Oh, oh, oh it’s that timer I said I must have hit that when I put it in. (We laugh.) You know, I’m not going to stop and say, oh well, I have to take my medicines here and then you go on. And oh my God, that’s right, I got to take that. I try. See I’m not a set time person. In other words my lunch could go anywhere. If there’s going to be a lunch, anywhere from when I’m hungry, which could be at 11:00, 11:30 until 2:00 in the afternoon. Because sometimes you know how you get that hunger, and then, all of sudden it’s gone. And then if you’re with somebody, and you’re having lunch you’re not going to pull those things out. So you got to try to do it in your car. It’s not easy. That’s the hardest one of all. So I even have the timer going off. She gave me that. She said maybe this will help you. And she said most people do have that hard time. And that’s so dumb because it really is time that you’ve got your purse right next to you. You’ve got your four, you know, grab a four and I thought, sometimes I thought why couldn’t I put two more in the morning and two more at night. I didn’t do it, but I saw that and I’m wondering if that’s what they’re doing there. If that’s not the answer.

BC: Yeah and you could ask her about that.

IW7: Because I told her I still have troubles doing that, unfortunately. I said, and she said it’s, I think she said that’s the placebo. I don’t know. So far I’ve been really good on my tests and everything you know.

The idea of taking a placebo can be problematic for women on trials with a placebo arm. One woman said she wondered if all her drugs were placebos, then said she didn’t think so, but she did wonder. The only woman to quit a previous trial quit because she was either getting the real drug or a placebo and decided the discomfort and
inconvenience didn’t merit continuing with the research study. A few women wanted to
know what the placebo pills were so they could stop taking them.

BC: OK. And have you been on the same combination of drugs?
IW2: Mnhmm. Yeah, and I still don’t know if some of my drugs are placebos.
You know how they do that. Some of them… I could show them to you, show
you my bottles and stuff that I take. Big ones (bottles). I go to the doctor and they
ask what I take and I say ‘Oh… I don’t know’. (We laugh.) I can’t pronounce
those words. Nelfinivir, that’s one of them that says it could be a placebo. When I
was going to go on the clinical trial, one of the nurses or ladies from over there at
Children’s Hospital. They do treat adults over there, and I was going to go over
there. She said just to make sure they had her on two drugs. I asked them (at
OSU) that, and they said, ‘Yes, at least two of your drugs will be the real thing
and not a placebo.

Later on, she mentions she would be willing to go on another trial “if all those are
really (active) drugs. I don’t know if they’re placebos. I have a feeling they all are
(placebos), but I don’t know.”

BC: Is it possible that any of the medication you’re on could be a placebo?
IW8: I have no idea.
BC: Or, no, non-active? Okay.
IW8: I have no idea. If, if it is, uh, Susie has never said anything to me.
BC: Okay.
IW8: What is placebo?
BC: Uh, it’s generally just like a sugar pill.
IW8: No.
BC: You know, looks like the same, okay. Some trials do have and some trials
don’t.
IW8: I don’t think so because I showed you the list of the ones that I was on and I
don’t think so. No, nobody, I don’t, if they did tell me I, I don’t remember.

Interviewee 9, who had been on trials previously, reported that she quit a study
because she was not sure if she was receiving active medication or a placebo.

IW9: Well if I’m not mistaken it’s ritonavir, Norvir, which now I see is the
medication that they use (from the medicine chart on the wall). But it was a, it
was a trial which involved, uh, sticks. Uh, it involved injections and blood work.
And I didn’t like the fact that, uh, not knowing whether I was getting a placebo or
the medication and having to get this shot every month. It just, I did it for a while but the shot caused some soreness in my arm. And I felt like if my arm was going to be sore I wanted to know whether I was getting medication or not, you know so. Yeah, I quit that one.

**Trial Maintenance**

As women adjusted to their regimen, they reported that their trial experience was not generally as big a part of their lives, though it does remain so for some women. They may need to iron out some remaining adherence issues, but they had grown used to the clinic appointments and were grateful not to make visits as frequently. After starting the trial and getting into their regimen, women go through a re-adjustment phase. In this phase they begin to realize that they will be doing whatever their regimen demands for life.

BC: All right. Uh, is being in a clinical trial a big part of your life?
IW6: In the beginning because of going all the time. Is that what you mean?
BC: Yeah. So the appointments at first?
IW6: Yeah, it was like, yeah, too many things. It was too much to me. But then now it’s like, like I said, just a checkup, to have my checkup, you know.

BC: Yeah, um, would you say that you schedule the trial stuff into your life or that you schedule your life into the trial stuff?
IW3: Schedule my life into the trials. (Pause.) Schedule my life into the trial, and I have always scheduled my life around the illness and the symptoms and the other stuff that’s going on. It’s just kind of something; I guess you have to do it. I can’t imagine how you would, it would be the other way around and be successful.

BC: Is being in the study a big part of your life?
IW7: Uh, not a big just, but it’s, it’s one of my things I look forward to, you know, coming in that monthly or semi monthly. I mean I don’t, you know, I move things around to, uh, be here because I know it’s important that I get the tests, I get my meds. And, uh, but it’s not like I, you know, go to bed with it on my mind or anything like that.

BC: Okay. Uh, is being in the trial a big part of your life?
IW8: You mean do I focus on that? No. If I don’t got to come I don’t think about it. It’s just, I have other things to get into whether than to worry about my clinical
trials. Now when it’s time for my appointments that I center on being here on time and doing what I have to do, uh, have my testing and stuff done. But other than that, no, I don’t focus on them.

In this later phase of trial participation, women found strategies for dealing with whatever is not convenient, often with the help of trial staff. Also, as Interviewee 6 noted, the appointment scheduling moves from weekly appointments to appointments every two or three months.

**Trial Care**

The care provided by the trial was very important to the women interviewed. Ten women out of the 12 reported receiving all their care through the study. Women valued the specialized care, comfortable communication, and education they received from their trial staff. A very strong affective bond to their trial nurse was felt by most of the women. As mentioned before, trial providers often go beyond the scope of the trial in providing care to these women. Perhaps for all these reasons, women reported enormous, almost blind, trust in their trial health care providers. Care received through the trial was seen as much better than care received from a regular physician.

Providers that women talked about included doctors, nurses (who comprised most of the data in this area), pharmacists, social workers/case managers, and nutritionists. Generally, women distinguished between the providers, but sometimes the lines blurred. Their personal study/research nurse was their primary care provider, and their contact with her/him extended beyond the physical boundary of the clinic. Some women only saw their doctors every few months; others saw them every visit.

Almost all women replaced their primary health care providers with the trial staff and reported receiving their care at the trial unit.

BC: Okay. Uh, do you still see a physician at the Community Health Center?
IW9: No.
BC: No. Do you get all your care here?
IW9: I get all my care here. Yeah, I get all my care from Dr. Doe and she just been, she has been my primary care physician now for about, uh, seven years.
BC: That’s good. That’s wonderful. Do you see the same (trial) doctor at OSU?
IW2: I always try to, because I like him a lot. It’s nice to see the same ones. You get used to them.

BC: Do you get all your medical care there, or do you have other physicians that you go see?
IW2: The one doctor that was always my husband and my doctor, our family doctor, I only think I’ve been to him once since I’ve been on the trial. It was because I couldn’t get a flu shot one year; they didn’t have it. So I went there, and he was able to give it to me. He told me if he could ever do anything for me that he’d do it. I also had gone to a dermatologist a couple of times; I have a lot of moles on my body, and I’ve had those removed. If I have a health concern and I know I’m going to OSU, I figure I can always ask that doctor while I’m there anyway. (We laugh.) But I really haven’t gotten sick.

IW5: Unless there’s, like I said, if I feel real down or I feel like there’s, you know, there’s something else besides the virus going on. Then I’ll call, either call my regular doctor of if I can’t get to her I’ll call Susie, and Susie will have me come in and Dr. Baker will come and see me. He’ll come over to the research clinic over there and give me my exam and see what he thinks so.

BC: Okay. Uh, where do you usually go for health care when you’re not feeling well?
IW7: Here. I just call.

The two women who received care elsewhere noted that the trial staff did or had offered to keep their other providers informed about the trial.

BC: Uh, where do you usually go for health care if you’re sick or?
IW10: Well I have a doctor here, uh, in Columbus because see I just recently moved here from another state about seven years ago. So I have a doctor here. Uh, and I think the last time I was here Jim asked me if I, if he could, if he could go ahead and send lab results (to her doctor in Columbus) because he knows nothing, because I only have to go to him like maybe once a year for a pap smear or something like that.

IW3: I mean, and they know at the clinic what I take and, um, they send him (her non-trial physician) copies of my test and stuff. And I didn’t know that. They really keep him posted, because it had been a couple of years since I’d, well not a couple years, but a year, I guess. Because he gave me my flu shot this year, but he didn’t give me one last year; I had it at the clinic so I didn’t go to see him last year.
They relied on their doctor’s technical knowledge and communication skills. Women also frequently reported a positive affective relationship with the trial staff, especially their trial nurses. Also, some of these women seem to speak of doctors and other health care providers with a certain reverence.

All women spoke positively about the technical skills of their care providers, be they nurses, nutritionists, or physicians.

IW1: There’s two (nurses) in there I just absolutely adore. Rebecca, she can take blood off me. Nobody else can without… I mean, my hands are fine, but nobody ever can get them.

Interviewee 1 also reported the only negative event with trial staff.

IW1: Except for that one guy. He’s new. I think he was like in vet classes. (He) Busted out one vein. Scraped my bone in the other, by the other one. Hurt a lot. It was a big day too. I just looked at Susie. She was like, “maybe that’s all we need.”

Interviewee 9 relates that she came to Infectious Disease Unit just for the specialized knowledge and technical skill of the providers there.

IW9: He (her previous physician) referred me here. He took care of me for a couple of years and, uh, he just really wasn’t, well, he thought as though, uh, he wasn’t as educated as it would be here… For whatever reason and, uh, you know, I was comfortable with him for a couple of years. And, of course, at that time we wasn’t even talking about medication or anything so. When it kind of got to the area of where we were talking about early intervention with the medication, then he wanted me to see more of a specialist. So he referred me here.

BC: No. That’s good. You’re not. (She laughs.) Um, how do you feel coming to a clinic that’s for people with HIV?
IW11: I think it’s the only thing to do. I have a doctor that is like a half mile down the road from me in the country. She’s wonderful, and I would trust her. She has a nurse who works there. I don’t know how many HIV patients she’s had. I wasn’t going to take the risk. That’s why I came here.
BC: For the special care? Specialized?
IW11: And to get away from my area.
Women reported feeling comfortable with the amount and type of communication between the trial staff and themselves.

BC: OK. Do they ever call you at home to check up on you? (Pause) Or do you basically just talk to her when you go?
IW1: A little bit. She, I’ve called her before. Just like, you know, to see if she got my test results back. She’s telephoned to see how I’m feeling, things like that.

Education provided by trial staff members is another important and valuable communication component.

IW9: They really make you feel comfortable. I never leave here feeling like I didn’t understand anything that was going on. Everything’s explained in detail (We laugh.) and sometimes pictures they even drawn.

IW10: Because like, ‘Can you explain this to me; what is all these numbers (her viral load and T cell counts)?’ So he (her trial nurse) broke it down and really, uh, made me understand it a little better this morning because I, I saw these numbers and I’m like, oh my God, what do these numbers mean? So I was like, ‘Hey, explain this to me,’ so he broke it down and it really helped to explain this number’s supposed to do this and this number’s supposed to do that.

But, as interviewee 3 pointed out, communication could be hampered by a woman’s health; also, at some points in the trial, communication flows one way and a woman may be required to hear information in which she is not interested.

BC: Um, did they explain to you what the trial was going to involve?
IW3: Um, yes, but I think you know at the time you’re feeling that bad that um. I mean they’re pouring a lot of things into your brain, you know, trying to tell you about the programs that are available and financials, you know, finances. Uh, peer support, and the groups and all that. I think at that time, I wasn’t really, well, I guess I’ve never been much of a group support thing. You know, I never really enjoyed that. But I don’t really think that, I mean I don’t know if I cared to hear about it or not. Probably not. But I heard about it anyway. I mean, you heard pretty much a whole lot of stuff that week.

These women have a personal relationship with their trial staff. Women reported loving their health care providers through the trial. They appreciated the trust,
communication, and accessibility of the health care providers and tried to facilitate the trial staff having trust in them. For example, some women reported having their nurse or doctors’ home phone numbers, or they said they could call the trial staff whenever about whatever was bothering them. While communication was seen as supportive and friendly, it also usually involved a health or medical issue.

Trial staff was very flexible with these women and gave those who live farther away extra pills in case they missed a visit. Staff members seem to meet women where they are at and go from there. This relationship with providers seemed to be critical for some women and much less so for others. Continuity with the same providers was important to women. Each woman has a special trial nurse who takes her vital signs, answers questions, etc. for her. This relationship is especially strong and a great source of support for women interviewed.

IW7: Oh, the people here are, are the greatest. I mean, I can talk to Kristen about vacation, you know, you just talk natural. Outside of medical we talk about kids, grandkids, her kids, my kids, you know, vacations, my jobs that I do, crazy jobs that I do just things like that. They’re just very warm and don’t circle just around medicine, medical stuff, huh-uh, not at all. I can call her up and, you know, in a minute and ask her a question. I’ve done that before…it’s such lovely people; I spend too much time blabbing, you know. And it’s not that I don’t have anybody else to talk to. It’s just that you feel so relaxed, and Kristen never looks at her clock or her watch. I’m going, gosh, we’ve been blabbing for 40 minutes now. They’re never pushing you out the door or, you know, there’s so much different than when you go to a regular doctor, you’re in and out.

BC: Are there any other good things about participating? I know you said the free drugs and the free care…are there any other benefits to you? IW2: I think just the moral support, especially my doctor that I see there and the nurses and all the people I see there. They’re all kind to me, and it seems like they’re so understanding. When I found out (she was HIV+) it was really scary. You don’t want to tell anybody, because you’re afraid they’re going to look down on you. And think the worst. But they’re all so sympathetic. Lots of times I go in there and I’ll talk to my nurse, and we’ll sit and just talk. I just love her to death. She’s so sweet. It’s helped a lot.
Interviewee 8 enjoys seeing her trial health care providers.

IW8: It’s just all friendly and when I see my nutritionist I give him a hug and, uh, hug Susie and ask about Ann and I haven’t had any downside because the first time I met Dr. Smith, my doctor, it was like she came in and I was really sick and I was feeling really, really bad because I had waiting so long to get on the medication but I didn’t really need it and I think the medication works better if you don’t need it and then you get on it when, at a point where you should be on it. And it’s like the first thing she said when she came in she goes ‘you have to forgive me because my hands are really cold’. When she touched me and I just broke down crying and she goes ‘okay, what’s wrong?’ and I’m like the fact that you touched me with your bare hands, that makes me feel good about myself. So before the whole thing was over with; we were just having this nice conversation, and she was like I mean why wouldn’t I touch you with my hands, you know, you don’t have anything, you don’t have anything, no open wounds, we’re not sharing anything so it, it, I haven’t had any downside. And Dr. Smith has never led me down a path where I should undermine myself or anything that’s being done I’m, you know, so everything is pretty positive, past positive. (Later in the interview, in response to my question about why she joined the trial). It wasn’t for the money or nothing. It was because they treated me like I was a person and that, uh, when you have any kind of disease that’s when, that’s when you need to feel like you’re a person, like you’re not some kind of leper or something like that…They don’t see me as a HIV positive woman because that’s what it has regressed to now. Because I’m on the medication, because I have an immune system now…I mean nobody looks down at me like ‘there goes another one,’ but everybody’s just so friendly. When they see me they see me as IW8, not IW8 the lady with HIV.

Interviewee 10 relates her feelings toward her research nurse. “And Jim (her research nurse) is great. I just love Jim to death. He is sweet. He is a comfort, yes he is.” Interviewee 12 says, “They’re wonderful. Paula’s my doctor and there’s Kelly, Miss Patty. They’re all wonderful. I love all of them.”

IW6: But when Liz, she’ll be like, “Just come on in and I just want to talk to you, see how you’re doing.” She kind of keep up on me. Call for anything, just see how you’re doing; I kind of like that because she said some people think it’s nerve-wracking. But I like it because then I know I’m okay... So I feel more secure. I would say just that, uh, dealing with like it is like you’ve got your own private nurse. One time I couldn’t get over there or something to get my medicine, and she brought it to me. You know, you never have nobody do that, you know what I’m saying. I even got her something for Christmas.
Interviewee 9 mentioned her doctor when asked to whom she felt close.

IW9: I’m close to my doctor.
BC: Okay. So you count her as family sort of?
IW9: Yeah, yeah. You know, she’s my family. If she don’t keep me well I won’t have a family, you know. But she’s cool. I like her anyway. We have a very good rapport.

As mentioned before, many women said their trial doctor gave them physicals and prescriptions for conditions other than their HIV/AIDS, like depression or high blood pressure. Their trial health care providers were treating at least two women interviewed for depression. Women seemed to integrate receiving care into their trial experience; many women said they were not sure where they would go for care after their trial ended. Care was seen as a benefit of trial participation, even though several women received HIV/AIDS care at the clinics to which both trial units are attached before beginning their trial. Providers are seen as integral to the trial, for the initial referral and thereafter for specific support and trial information.

In contrast to how some women reported feeling about their previous care providers, women generally reported very positive experiences with their care providers at the trial units. The specialized HIV/AIDS knowledge was one reason women were willing to travel an hour or more to go to the trial unit, as women saw local doctors as not having the knowledge to guide them to the best medications.

Interviewee 8 appreciated the time her research nurse, Susie, spent reassuring her about perceived side effects.

IW8: I worry about everything, and it’s like okay they say that if you have this disease you’re get a blotch with this medication. So if I see a pimple I’m like, oh, my God, that’s a side effect. Am I going to have to call off this medication? So I’ll call Susie and she goes no, IW8, I don’t think so, but if it makes you feel better come on in. And I did for a while there and after a while, you know, they, they, it, it wasn’t like ‘okay you’re just being ridiculous.’ No, they, they took it to heart.
Once trust was established (sometimes before), women tended to give complete control over their health to these providers; many women said they did whatever their health care providers told them to, even if they did not know or understand the reason behind this advice. While such trust is clearly a positive thing, there are enormous ethical issues here, which will be discussed further in the next chapter.

IW9: Uh, I’ve been, uh, on different trials. So I guess I’m kind of like a guinea pig around here. But it’s okay. They had to know if something comes up hey, call IW9; she’ll probably do it. But they’re good nurses here, and I trust them so.

BC: So it’s just whatever they have for you that day?
IW3: Yeah, I never ask. I never ask no questions. (We laugh) I just let them take as much blood as they want. I do what they (trial staff) ask.
BC: Do they tell you what they take the blood for?
IW3: No, and at one time, I’m sure I signed forms or something for it. I guess I’ve kind of taken that opinion or that attitude, kind of the whole time I was in the study over there. Whatever I had to do to get, not well again, but healthy enough to where I can at least have a, be alive. That was my job; I mean, I had lost my job at the time, so that was my job, to throw those pills down my throat when they told me.

IW8: She (her trial nurse) used to help me in a lot of this and so together, boy, they got me situated. They got me, uh, involved in a lot of, uh, I’ve been to just about every clinical trial. Uh, every little survey that they have I’ve, I’ve been in every one of them, and I don’t question them because I’m, I trust them with my life and I know that they’re not going to tell me anything that’s going to harm me. So if she said “Hey, talk to this person,” or “Hey, get on this medication,” or hey, do this, do that,” I know that they’re only telling me because they’re trying to help me. So I don’t question them, and I do (what they ask/tell me to), and so far they’ve never steered me wrong.

IW9: So you know when you go in to see her (her trial nurse) that you’re going to be okay when you leave her. She’s just, she’s just like that; you know; she doesn’t just come in, see how you’re doing, tap on you, take your blood pressure, and then leave. She wants to know really how you’re doing, you know. So we talk. We talk about family and kids, and she’s really, just really great; so everybody I know that has her as a, as a doctor, we all feel the same way about her.

Very often women compared and contrasted trial care with care at a regular, non-trial physician’s practice. Trial care was usually seen to be superior.
IW1’s husband: I don’t think at a regular doctor…she wouldn’t get the same treatment.
IW1: No.
IW1’s husband: Just wouldn’t be the same.
BC: Was it like more specialized?
IW1’s husband: Yes.
BC: Or were they more friendly?
IW1’s husband: Yes. It’s like you’re a person. It’s much better than going to the doctor’s office, I think. You go in, and they don’t even usually look at you. You know, that’s their attitude. I pay you a bunch of money, and there (at a regular physician’s office) it’s like nobody cares.

IW7: … They (trial staff) are never pushing you out the door or, you know, there’s so much difference than when you go to a regular doctor, you’re in and out. Here they, they talk to you about anything and if they don’t know an answer they’ll try to find one for you. She’s helped me in a lot of things, different things…But I find, that’s what, that’s what I like about sometimes, uh, clinics and studies, University Hospital, Women’s Health Initiative. They really take time to help that person, you know, because mine was financially mostly but…they’re going to help you out as much as they can, where if you go to your doctor’s office or somebody, you know. They’re not going to recommend that you go to a (specialist); they’re just going to say well, no, you just sat down with him, and it’s now 50 dollars.

One woman noted that adherence to the regimen may influence the level of care received.

IW3: She’s my study nurse. I think she’s probably made things easy all these years. I think if you have somebody over there that doesn’t, I don’t know, I want to say bend over backwards. I think this is probably not a very nice thing to say, but I think the more you stick to your regime, the more they’re willing to go out of their way and do for you.

Guinea Pigs

Seven women mentioned the phrase ‘guinea pig’ during their interview. They acknowledged that they might be guinea pigs testing out new regimens, but as individuals they do not seem to feel like they personally are guinea pigs. While only one woman mentioned it specifically, these women may see themselves in a sisterhood of sorts with other women on their same regimen. I.e., “I may be a guinea pig, but I know I’m not
alone in this, so I do not really mind it so much.” The data suggests the “guinea pig” factor, while part of some women’s consciousness, is not really problematic for this group of women.

BC: If a friend asked you about being in a trial, what would you tell her?
IW2: I’d say, if you’ve got the time, do it. I think they’re great. That’s one thing too, when I talked to Dr. Jones, who asked me if I wanted to be on the trial. He said, ‘It’s not like we’re going to be using you as a guinea pig, trying out weird drugs on you or something like that.’ So he told me that and of course I believed him, because I believe doctors. I didn’t feel like…
BC: They were going to experiment on you?
IW2: Right. The way he explained it was that they didn’t know what combinations of drugs worked best. Do A and C work better? Or do A and B work better? So if they don’t know; I’m sure they know a lot more than if I just went to a regular general practitioner here close to my house - what drugs to prescribe.

IW6: Yeah. So it wasn’t like I was like the first one and only one, then I became the guinea pig or whatever. They had already had they people (i.e., some people had already been enrolled in the protocol and had begun the regime for the trial she joined). So that’s why she was, like, go ahead just do it, it’s free.

IW10: At first I was afraid I’d feel like a guinea pig, you know, but that’s just, you know, your mind playing tricks on you, you know. But I really don’t have anything bad to say about it. So far it’s been wonderful. And everybody here has been, you know, has really tried to explain. Any question I ask I believe with all my heart if I need to sit here and talk to Jim for three hours he would sit there and talk to me for three hours. The same with the case manager or whoever, you know, so I really don’t have any bad, bad experience so far with it.
BC: Is that what helps you from not feel like a guinea pig?
IW10: Mm-hmm, Mm-hmm, Mm-hmm.
BC: They talk to you.

Confidentiality

Trial unit staff and data collection were seen as confidential. As voiced by Interviewee 6, the general feeling seemed to be that “They know how to keep this confidential.”
BC: Okay. What do you think about your personal information being kept here? Does it bother you?
IW5: No. I know it’s confidential and it’s not to go out of this area, so it don’t bother me.

Interviewee 7 was not quite certain how her information was protected, but she seemed to feel confident it was.

IW7: But, uh, I don’t know, I don’t know what the, I don’t know what the rules are. Maybe if there is any because I know that’s one of the most kept, uh, you know. You can go by a number and when they do my blood test and that so that the name, my name isn’t floating down the blood bank somewhere…Uh-huh, the girls, the people that work here are, you know, seem like they’re very discreet. They’ll see you maybe on the street or something, “Hi, IW7, how are you?”

BC: Do you ever worry about your personal information being kept here?
IW8: No, not really. I don’t think that they would potentially set you up to be embarrassed…they all…know that I’m very private, so everybody respects that. So Susie automatically knew that when she called, she wouldn’t tell them (IW8’s kids), you know, what it about. The, uh, Columbus AIDS Task Force went out and called this social worker here; she wouldn’t say who she was, and when she sends me out the literature, it doesn’t say that on it or anything like that. So they all, they’ve been pretty good about making, make me feel comfortable about, uh, having the disease and being in the studies and getting the information and everything.

Interviewee 10 experienced concerns about confidentiality at Children’s but felt comfortable at OSU.

IW10: But the only thing that bothered me about Children’s is when I went in to get my lab results we went in this room and there was a man and a woman sitting here, I think another woman sitting here, another man and woman sitting here. The nurse was telling me what tests they were taking and freely talking about this disease, and I know they had to hear it. I mean it’d be like if somebody was sitting right over there by that windowsill they’re going to hear what we’re saying. And I felt really uncomfortable that everybody was hearing what she was saying to me.

BC: Right. (Pause as I flip through the interview guide) Okay. What do you think about your personal information being kept here?
IW10: As far as like my, all my personal stuff staying here?
BC: Yeah, like your name and…
IW10: I don’t have a problem with that, no. I think they keep everything real confidential. I mean, I mean, you know, like the receptionist, you know, she knows why I’m here I mean, you know, because that’s her job too. But no, I feel real comfortable with my personal stuff being here. I don’t have a problem with that at all.

However, interviewee 9 had an unpleasant experience with a former member of the trial staff and a concern about confidentiality in the waiting room.

BC: What do you think about your personal information being kept at the clinic?
IW9: I don’t have a problem with it, but everybody’s not where I am. You know, that’s just where I’m at. But you got to understand there’s laws around confidentiality. Like I said, because it’s, it’s just a desire in me that, you know, if my information will help somebody I don’t, I don’t, I don’t practice a whole lot of that for me, confidentiality, it doesn’t, you know. People have broken my confidentiality and, and it’s bothered me, you know. I really don’t, I don’t like to meet - the reason why it bothered me is because I don’t like to meet people that already know me. Anybody that knows me knows that I’m real honest and straightforward, and I’m not ashamed of me. It happened once here at the clinic and actually it was, uh, it was, it was a mess. But it was, uh, it was another patient who saw me here and disclosed some information. It didn’t really bother me. It got back to my boss, and my boss called me in the office and told me what had happened. The nurse here called my supervisor and my boss, because her client had some concerns about confidentiality. My boss told me, she said, she broke your confidence, you know, by calling (me). She said because she don’t know whether I knew or not. It doesn’t really matter because my boss did know, but she was letting me know did I have a problem with the nurse, because she would have got her in trouble. And I said no, just let it go, you know, because it did not bother me like that so. But other than that, no. I’m having no problems with it.

However, interviewee 9 did have other concerns about other clients’ privacy.

IW9: Anonymity at the reception area is not like it used to be.
BC: Okay. Do they call you by name, or do you have to sign in your name?
IW9: You have to sign in your name. You used to only would use your first name, you know, they’d call you by your first name. There was conversations that are being held like right there in the reception area, behind the desk. I just overheard conversations about other patients’ stuff, and I just thought that that was, for somebody who come in here who…may just have found out they’re HIV positive and was just coming into the clinic, scared to death, don’t want anybody to know. You know, that it might infringe on their level of comfort ability. And if I can stand here at the desk and listen on conversations and the other patients’ charts,
sometimes you hear names. I guess there should be more separation between the
waiting area or the entrance area and what goes on behind the desk.

Question #3
How do women interpret this experience and incorporate it into their lives?

Data related to answering this research question include stress, religious and
spiritual beliefs, stigma, social networks, disclosing of HIV status, interactions with other
clients, disclosure to non-trial health care providers, affect on future family size,
monitoring counts, meaning of the trial, overall satisfaction and improvements, and
uncertainty about life after the trial ends.

Stress

Common causes of stress either discussed already or to be discussed in the next
section include understanding that regimens will not work forever, dealing with health
insurance, disclosure, and family. Interviewee 3 explicitly stated how stressful just having
HIV/AIDS is. “There’s a lot of stress. A lot of stress that goes right along with it (HIV).”
Interviewees 3, 6, and 10 explained that stress makes their disease worse, so they try not
to worry about anything too much. Interview 6 explained, “stress, it brings out your
illnesses, so it’s like I try not to worry about stuff.”

IW3: My T-cell count is great, as long as I stay out of stressful situations. (We
laugh) I actually hit a level where a doctor at the clinic had told me I’d never see
it. Clear way back when, I was told I’d never see 300. Before this friend of mine
got sick and I got involved with that situation, my T-cell count went up to 455. It
only took about two months to fall 150 points again. I was real surprised; I mean,
I knew that stress was bad, but I never realized it was that bad. I’ve been
undetectable (her viral load is undetectable) for a little over two years now as far
as the virus, the viral load.
Interviewee 10 relates how stressful worrying about the cost of medication is.

IW10: If I pay for my meds, how am I going to have gas money, food money, I mean, you know, clothing, the necessity things, you know, that you have to have to live, you know, so. Yeah, I think that is, that’s a big, that’s a big thing not knowing not knowing that, that I have to pay for it, you know. Stress, because they just keep telling me stress is the, stress is one of the things that they want to keep me from…if you make $95,000 a year, you’re still stressed. But stress has a lot to do with the meds, the lab, because stress can make you have a nervous breakdown. It can do a lot of things to your body. I always try not to be stressed, but when they say you need $1,500 or I can’t give you this med this month…

Interviewee 3 is one of the women being treated for depression.

BC: Do you have any other medications that you’re on?  
IW3: I take, I’m trying to think, Zoloft for my depression, anxiety, whatever, stress (she laughs) All rolled into one!

Interviewee 1 sums up how stressful her life has been.

BC: Has there ever been a time where you wanted to drop out of the trial?  
IW1: There have been times I wanted to drop off the planet. But, no I haven’t.

Many women discussed how they have or are trying to reduce their stress in general. A few women have distanced themselves from stressful people and situations since being diagnosed. Interviewee 3 talked about having to distance herself from her friend with AIDS.

IW3: It was very, very scary. Almost to the point where I couldn’t be around him no more. I haven’t seen him for a couple weeks. I feel bad, because I felt like I left him. But I couldn’t handle it.  
BC: That’s so stressful.  
IW3: Yeah. Just couldn’t do it anymore. And I wish I could’ve. My whole being wants to help, but I can’t.

Three interviewees mentioned that they kept busy to avoid worrying about their HIV.
BC: (We were discussing other options that would give her medications for free after her trial ends). So, talk with Susie because she would probably have better information than I do. But there are several programs that exist to help people with the medications. Again, don’t, try not to stress about that because…
IW11: I won’t.
BC: That’s what people always tell me, don’t worry - we cover people. One way or another.
IW11: I don’t stress myself. I’m so busy all the time, that I don’t have time to stress. I don’t let it take up rent space in my head. (We laugh)

IW7: So anyhow, there’s, you know, there’s a lot of different things so you think I’m busy?
BC: Yeah I have a sense of that.
IW7: So I don’t have time to worry about myself or all that. I just keep on…doing what I’m supposed do and then coming in here checking in with the girls.

Almost all the women have a hopeful, positive outlook despite the stress and uncertainty in their lives. They find a positive twist on just about anything. Despite being treated for depression, Interviewee 5 said, “I’ve got another thirty years to aggravate you (referring to her mother), so don’t worry about it (her HIV).”

Religious and Spiritual Beliefs

A few women reported a belief in God helped them get through their diagnosis and the first part of their trial experience. Only interviewee 9 said that her beliefs influence their decision to participate in a trial.

BC: Okay. Uh, how does being in the clinical trial fit into your life?
IW9: (Pause) How does it fit? Basically what I, I already explained. It’s just my way of being able to give back to help somebody else. I’m, my life for me is a service. It took me a long time to accept that I’m a servant, and that’s what I do. That’s my purpose and I just, I want to do what I was intended to do so that maybe one day I could hear the Lord say, “a job well done.”
No woman said that God would not want them taking medicine; in contrast, women who chose to discuss this topic with me had an attitude of ‘if He helps you by giving you medications, you would do well to take them.’ God served as a primary source of support for three or four women (again, who chose to discuss their religious beliefs) out of the 12 interviewed. Interviewee 4 says she “just prays day by day.”

BC: Okay. Have your religious or spiritual beliefs played any part in your decision to be in a trial?
IW6: Not really to, uh, not really to be in the trial, because my religious belief is to feel that I don’t have it, and it’s gone. I don’t worry about it, you know, and because of that I don’t feel, besides having to take it I don’t feel like, I feel safe, you know what I’m saying. So I mean I could look at it that way but to decide to do it, you know. I don’t want to contradict myself - because I feel if I really went that, you know, that spiritually, then I wouldn’t have took it. You know what I’m saying? So I just feel, I just look at it like this is His way of saying, this is my way of helping you to get rid. So then I take the medicine.

Being diagnosed with HIV did cause a crisis in faith for 2 of the women interviewed; they seemed to want to believe and pray but weren’t sure God would listen.

BC: OK. Have any of your religious or spiritual beliefs been affected or affected your decision to participate in a clinical trial?
IW2: No, not really. Not at all. I try to be just as religious and believe in God as much as I always did… They always say if you pray to God and then believe it’s really going to happen; I did that when my husband was sick, and it didn’t happen. I was sure he was going to get better and he didn’t. So it seems like whenever I pray to Him for anything that was really important, I never got it. [Her eyes fill with tears now, and her eyes were red and her voice cracks a bit on tape.]

BC: Yeah. Have any of your religious or spiritual beliefs played any part?
IW11: No. I used to thank God every night for giving me another day after the cancer surgery. I thank Him occasionally. I’m a little bit angry. I mean, like I said, it doesn’t seem fair. And I’m a nice person. I really am. No, I’m sorry to say it has not pulled me closer to my religion. I’m a Methodist, but I don’t practice. I do believe in God. Um, I think He’s probably helped pull me through the cancer. Life is what we make it, you know? The cancer, I thought was going to pull me down so I couldn’t mentally get back. I said, ‘No way, this thing is not going to get me.’ Just like I feel with the HIV. I want to do everything I can to come out of this. I want to go back into praying and pray for a cure.
However, three other women prayed heavily when they found out they were HIV+ and drew strength from God. Interviewee 7 mentions that she “prayed her guts out” after she found out she was diagnosed.

BC: How could any of your religious or spiritual beliefs play a part in having HIV and treating HIV for you?

IW8: Well as if with any disease, uh, you always have to have belief in God that, you know, if you’re mentally strong you can somewhat help yourself physically. So I mean it’s basically about the same…I feel like if I catch a cold and I haven’t prayed in a couple of weeks, I ask God and say, okay you’re slipping, you know. I try to stay on top of it. I, I don’t preach to nobody…I maintain my own beliefs, and I don’t try to push them off on anybody. But even if I wasn’t sick I always feel like God has a positive, uh, force on your life, period. The fact that you get up every morning and make it through a day, that that’s God’s doing. So whether you’re 150 percent health with nothing or stricken with cancer or AIDS, as long as you have a belief in God, there is some help with the medication.

IW10: God, He’s brought me through this. Without Him I would, I probably would have had a nervous breakdown or had to be in a rubber room somewhere because you just, you don’t, it don’t happen everyday - everything that I went through within two weeks of my life there, you know… I believe with all my heart, if I hadn’t had God I don’t know what I would have done. I believe I would have, really, really had a nervous breakdown because there’s been days, there’s been nights that I needed to talk to someone. And had Him. I didn’t want to call somebody at 3:00 in the morning and they’d hear me crying and the same story over and over again. So, oh yeah, without Him I probably wouldn’t sitting here smiling with you today. I’d probably be in a rubber room somewhere tied up in a straightjacket. I mean, that’s my honest opinion. Without Him I don’t think I could have done this.

BC: It’s been a big source of support for you?

IW10: Oh, oh, 110 (percent). Oh yeah, oh yes, most definitely.

Religious women also mentioned that they felt God had a purpose for them, as a result of or in spite of having HIV.

IW7: Hopefully, they really do find something here. Because my life could be pretty short, and I don’t like that at all, you know - that’s the only thing. Sometimes I think about that and more so as everyday goes by, and you get a little bit older and then you think, God, He’s given me a long time. I think there’s something else I got to do yet.
During the interviews, women seemed very aware of the stigma of having HIV/AIDS. Women seem to be uncomfortable saying HIV or saying it in their regular speaking voice at first, as though they felt the stigma of just discussing HIV. Some women tended to use euphemisms for HIV like ‘ill’ or ‘sick’ instead of saying HIV or AIDS. IW7, for example, dropped her voice the first time she said HIV during our interview; she whispered, “who put me through a lot of these tests and then finally he did a blood test and then he’s the one that diagnosed and told me I had HIV.” This was not an easy thing to count, but the initial discomfort of saying HIV or AIDS aloud happened during interviews 2, 3, and 8.

IW8: If I call Susie (her study nurse) and express some kind of concerns or something she’ll go, “Well, I don’t think it’s the disease.” What, what she does is say ‘the disease’ (HIV). She says, “I don’t think it’s your illness so maybe I think you just have a cold.”

Women seemed to enjoy talking about their friends and family during the interview. Discussion of their social networks was entwined with those to whom they had chosen to disclose their HIV status, as well as the stigma they thought they would or actually did experience as a result of disclosure. Overall, women seemed to get the contact, help, and support they needed through their existing networks.

In terms of network content, women usually listed partners (if they had them), siblings, parents, children, extended family, trial staff, best friends, other friends, and co-workers as part(s) of their social network. Interviewees 9 and 10 mentioned other HIV+ people as on the fringe of their social network. Only Interviewee 10 mentioned God.

BC: So, I know we talked about this a little bit, but can you tell me a little bit about your family and friends, people that you’re close to?
IW1: Well, I’ve got that (referring to husband).
BC: OK, your husband.
IW1’s husband: Yes!
IW1: My sisters. My youngest daughter. My oldest daughter. Girlfriends. And, uh, ()
IW1’s husband: Dad, Mary.
IW1: () Right.
BC: OK. And they all know that you have HIV?
IW1: (nods)
IW1’s husband: Yeah, then my sister and her husband. ()
BC: And do they all know that you’re in a trial?
IW1: My dad does. My sister knows. I think you do (refers to husband).
IW1’s husband: They almost all know.

Privacy and disclosure, themes that generally include family or friends, are important themes appearing frequently in the data. Women may choose to be private, or privacy may be part of their basic nature or personality. Interviewee 11 says, “I’ve been very secretive, very quiet; there’s only 2 of my closest friends that know that know this. One in Philadelphia, Pennsylvania, and one here in Ohio.”

IW7: So it was a terrible, terrible, you know. I mean what else can you think of? All I thought of was everything you read, which everybody dies eventually within, you know. You don’t even know and, and, uh, you’re an outcast, and I got five kids and a husband, so I held that all inside myself. I did. I just thought, I’m not going to tell anybody. I’m very, very, very private. Not with a lot of things, but I was brought up to be private.

BC: Does it seem like a lot of your friends look down on the disease?
IW8: To tell you the God’s honest truth, even before the disease I never had a lot of friends. I like staying to myself because I have a temper, because I don’t like being bothered with. I like my privacy so, therefore, I’ve more or less kind of stayed to myself a lot.

Often women chose not to disclose not because they personally had experienced stigma, but simply from the great fear that they or people close to them would be stigmatized. Sometimes, women chose to disclose or not on the advice of providers trying to realistically prepare the women for potential disclosure consequences.

IW2: Of course when my husband died, all my family came to the funeral and everything. My youngest sister and her husband were here, and I had to go over to Children’s Hospital that day for an appointment, because that’s when I was going about once a week or every couple days it seemed. So I told them (sister and her husband) and they were really sympathetic and everything. I asked them though not to tell anybody else. Being from a small town, I didn’t feel that they would
understand. When I first went over there to Children’s Hospital, I talked to this one doctor. I don’t remember what his name was, because he was one that worked at Children’s there. He talked to me for a long time and told me that lots of people, sometimes your family, will disown you or don’t want to be around you. I was so afraid that would happen to me. My husband’s family really hasn’t done that, except for his brother in a way. I just didn’t want to tell the rest of my family - what good would it do? It’s not going to help me. Living so far away, it’s like a four hour drive. So I’m not that close, whereas if it was an hour or something…[Pause] I guess that’s it. I guess I was afraid to tell people, because I didn’t want them to turn against me, you know?

Women devoted a fair amount of the interview talking about the stigma they felt or worried about because they were HIV-positive. It is worth noting that even men who knew they were infected did not tell these women interviewed; infected men may well chose to keep their HIV a secret from their sexual partners and spouses.

IW11: I feel if some people knew, they’d be on a witch hunt, you know. I don’t want to have to deal with it. My family really wouldn’t understand. My father’s still living; he’ll be 88 in a month. I have a sister and brother alive. I have two nephews and a niece. That’s my immediate family. I have no children of my own. I really don’t want any of them knowing. I really don’t. I get the feeling that they’d be like this every time I was around.

Women who were relatively open about their status discussed how and to whom they chose to disclose.

IW3: My relationships, all of my relationships are different. I’ve lost good friends. I’ve gained friends. But you always kind of keep that distance, I think. I don’t know. I guess I’m just too private a person. I’m not hiding. My family knows I’m ill. My son now knows I’m ill. A lot of my friends know I’m ill. So, I mean, eventually I’ve opened up to people and told them that I am ill. But, then, a lot of people still don’t know I’m sick. And people, you know, you get in the rumor mill and these small, in these small little communities.

IW4: They can all just deal with it. My oldest kids know but I ain’t never told my man. My two oldest kids know. (The other two kids don’t know she has HIV.) When I told him, my son cried like a baby. Oh God, I got asthma ( ). I said, “ain’t gonna die.” I trust; I felt so sorry for him; I mean he seriously cried. I said,
oh man, so I said ( ) cried like a baby. My older daughter, I, I think it’s kind of bother her, but she’s going, you know what I’m saying? ( ) my mom but she has never cried but my friends really it’s bad ( ).

IW10: I feel it (her HIV status) is really not anyone’s business but my friends, my family, my doctor and the people in the medical field that needs to know. Everybody don’t need to know how I feel about it, you know. I don’t think everybody needs to know, because I don’t want people treating me any different. That was my biggest thing. I didn’t want, first I wasn’t going to tell nobody, and I’m so glad; I can’t keep this inside me; I would burst. But I just want people to treat me any different because I have the virus, you know, and so far people have hugged me and invited me to their homes. I’ve used their showers. I mean the whole thing in my mind was telling me people’s going to say well you can come and visit but don’t drink out of my stuff and don’t use my bathroom because it was a mind thing, you know. But, uh, just, uh, all my family knows and like I said a few friends. That’s, that’s about it.

Reasons for being open about their status vary. Women said having HIV was too big a burden to carry alone. A woman’s diagnosis may come at a time of other health and social problems, like losing a partner; those losses may affect how she makes disclosure decisions.

Benefits of being open varied as well. One woman had a sister-in-law in nursing who served as an informational source of support about trial participation. Women often were relieved after disclosing to friends and family and could be more open with them.

Often a woman, even one who ends up disclosing widely along her network, needed time after diagnosis to process what has happened to her and her life. Only then did some women say they could consider telling others. Disclosure, for some women, happened all at once. Others, like Interviewee 3, waited and watched for good times, like when she was healthy, to tell people she was ill.

BC: So it (being in a trial) was just kind of an accepted thing that you did? IW3: Yeah. Just the few people who knew. There wasn’t even a whole lot of people that knew. It’s just been going on for such a long time that eventually I told my mom and dad. Of course, I think I told people; I told more people since I’ve gotten healthier than when I was sick.
BC: OK. Do you think that’s because you just had more energy?
IW3: Um, yeah. Maybe I could deal with it at the time. It was like I could
approach it a little differently. You know, I’m not sick to where tomorrow I’m afraid I’m going to die. You know, don’t feel sorry for me, because I’m probably as healthy right now as I ever will be.

Interviewee 2 waited to tell her children she had HIV until they had time to cope with losing their father to AIDS.

IW2: I didn’t tell my kids either for a long time (that she was HIV+). I finally told them this past summer. It was a great relief to me to be able to tell them, because I felt bad about lying to them. You know how one lie leads to another. I told them if they ever wanted to go with me they could. But, you know, they don’t wanna. So I don’t really talk that much about it with them. I just say I’ve gotta go to OSU, and they know what it’s for.

It bears noting, however, that even women who are more open about their HIV status may encounter people or situations where they choose not to disclose. This is also an example of selective disclosure, or in this case, non-disclosure. Interviewee 2, for example, told one of her friends about her HIV/AIDS but asked her friend not to tell her husband, as he might not want her kids to play with the couple’s kids any more. This is a good example of how non-disclosure may protect not only the woman herself but also others in the woman’s network.

IW2: My close friend here does, because I told her right away. I knew she would be really sympathetic, which she was. She was great. I made her promise not to tell her husband, because he’s the type of person. If he had found out about it, he would say ‘oh your kids can’t…See that’s another thing that worried me. I was afraid if people would find out they’d say ‘well your kids can’t go to their house anymore’ or something like that. That’s definitely a reason (not to tell people). I wouldn’t want them hurt by that. They love to bring their friends home and stuff.

Also, once a woman opens up and discloses to one person, she may begin a chain reaction of disclosure to people she did not want to know. For example, interviewee 12’s boyfriend actually disclosed to several of her friends and neighbors against her wishes.

IW12: He (her friend and ex-boyfriend/ex-husband) talks real loud about my business. I don’t want anybody to know my business. No sir, I keep to myself,
know what I’m saying? If I want somebody to know my business I’ll tell you myself. We broke up and had a fight, so he went and tell everybody on the street that I’m HIV, and I said, ‘you bastard.’ I said, ‘oh, no you didn’t’. Because like I was drinking anyway and then that made me drink anymore. And then I lived with this guy. This guy was a while back ago thank goodness; he took me in, and IW12’s ex-boyfriend just came out and told him I was HIV. I said, ‘you bastard.’ I said, ‘I’m not going to go to bed with the goddamn man.’ (Her) ex-boyfriend talks a lot that’s why, you know, we really don’t get along. That’s why I stay to myself, because I realize.

BC: Yeah, sounds like he’s really into sharing that you’re HIV.
IW12: You know, for real. It just pisses me off, you know what I’m saying. Then when I went, you know, got locked up, they found out that I had HIV because of (her ex-boyfriend) because (her ex-boyfriend) told one person. One person told the other person. Well, the girls in jail, they were supportive, great about that; they was supportive.

On the other hand, interviewee 2 discusses how she unknowingly went against her husband’s disclosure wishes.

IW2: When my husband was sick, my husband didn’t want me to tell anybody. I felt really bad, because I was in complete shock when the doctor called me up and told me on the phone when he was in the hospital and told me that he had AIDS. I forget what he said, but I said, ‘do you mean he’s HIV+?’ He said, ‘no he has AIDS.’ I was completely freaked out. When I had taken my husband to the hospital at Mount Carmel East, we had put his mother down as the contact. Well, they must have called her as soon as they had found out. She called me up and she said, ‘oh, IW2, what’s wrong with your husband?’ I told her, because I just couldn’t keep it all to myself. I needed someone to talk to, so I did tell his brother, his 2 sisters, and his mom. Then when I went to see my husband in the hospital, after they had found out what he had, they put him on a ventilator, so I really couldn’t talk to him. He had to write. He asked me if I wanted to tell anybody, and I said, ‘well do you?’ He said no; he didn’t want me to tell anybody. He was always like that, really private. So I felt really bad. I thought oh no, he’s going to kill me now, because I already told his brother and sisters. I thought oh well, when he gets better, I’ll go ahead and tell him I told them. I went and called all the people I had told, like his brother and his mom and his 2 sisters, and I said, ‘do not tell anybody else because my husband doesn’t want anyone to know.’ Well, they end up telling some of the cousins and stuff like that; I really felt betrayed. And I know that I did that, because I felt so bad myself for already going ahead and telling people. But it was just too much for me to handle. I just couldn’t keep it all to myself.
As another example of selective disclosure, women may selectively disclose to people they perceive can handle that information; Interviewee 11, for example, told a friend she was a little close to who was a psychologist, because Interviewee 11 knew her friend could deal with it.

IW11: Just like my friend in Pennsylvania, I hadn’t talked to her for 7 years, and I called and told her. She has her Ph.D. in psychology, and I knew she’d be able to deal with it. I have not told anyone else (beside another friend she mentioned earlier).

Women who did not disclose at all or to very many people cited many reasons for being secretive about their statues include protecting others, not wanting different or special treatment, and protecting herself from stigma and/or gossip.

IW8: …it was like we were just good, real good friends, but I don’t think she would look down on the disease, because she and I have never talked about it. But I would never tell her because she does gossip. I don’t have a lot of friends, and mainly it’s for safety purposes, because I’m not a trouble maker but somebody else is. All it takes is for somebody to say well you know such and such next door did this, and all it takes for you to be like yeah that was wrong, and the next thing you know it’s all blown out of proportion; and you’re the one who was doing all the gossiping and stuff. And I don’t like getting into that because I don’t like trouble so...

Other women had experiences that warned them disclosure was not safe.

IW5: A lot of people that I know of heard a lot of people talk, say that their family threwed them out. They lost best friends. And that’s what I was afraid of, and I was scared to tell anybody. That’s why it took me two to three months or so to start really letting people know, but once I gradually worked my way there, I thought well, okay, I guess everybody’s not like everybody else. (We laugh) Just goes to show some people are different, I guess.

IW7: I have heard that; you cannot believe. I work, you’re not from Cincinnati, but in this little southern belt, they have a discrimination problem here, as you’ve probably have read. The reason is because you’ve got the south coming up here. I’ve been in real estate while all of this was going on. So we were in a car one day and were going to see a house, and there was a trip going to be given away if someone sold one of these new homes to a cruise. I’m in there too, and we were
talking about well, if you get that cruise, you’re going to have to share a room with someone, and this one little southern girl said, ‘well, I don’t care who I sleep with as long as they’re not Black, and they don’t have AIDS.’ But that was her, how much she hated one or the other. I thought I’m never ever going to forget that.

Interviewee 8 has only disclosed to four people. She wants to tell another good friend about her HIV, but he “frowns down on” HIV/AIDS, and she does not want to lose his friendship. This was also a common theme for other women. Like Interviewee 7, Interviewee 8 has decided not to disclose to certain people because she knows they have negative attitudes toward HIV/AIDS.

IW8: It’s just; it’s my business. They (her friends) don’t tell (me) lots of the things that they get into, so I feel like things are…I’m not putting any of them in any kind of danger, so I don’t find it’s any of their business. And of course I already know some of my friends’ opinions about it. It’s just like sometimes we’ll come up on a conversation, and then I’ll say, ‘well, you know, how would you feel if’ (someone/you/I had HIV – their response would be) “oh, no!”

Interviewee 7 never told her husband she was HIV+; this woman hid her shingles and was planning to postpone a medical procedure that might have alerted her children that she had HIV. She did disclose to a close girlfriend, who has since passed away. Now, she says only God and the trial staff know she has HIV. She is also in the Women’s Health Initiative, which she uses to explain her presence at Holmes.

IW7: So she’s (a girlfriend who knew IW7 had HIV) gone, so no one else but Kristen and people here know anything. My husband passed away, uh, three years ago, so he never knew it. My kids don’t have no idea, and I’m just like that. I wouldn’t (tell them) because I’ve read good things and bad things, and the worst thing that could happen to me is that your family would withdraw, and that’s what happens with a lot of people that tell somebody…I just tell them (her children) I go to the women’s health initiative up there, and they give you, well at one time they were giving me the estrogen or whatever. I was in that…I mean it’s not like an unusual circumstance where you’re in a neighborhood where you don’t belong, or you’re in a building that you don’t belong, because thank goodness they’re (WHI and ACTU) all right here.
Later on she talks about bringing her young grandson to her trial appointments.

IW7: And they’d give him. They have like a fund, I guess, where they give little kids things, or they had some maybe Christmas or something. So they gave him this dinosaur, and it was a green satin dinosaur, and my daughter said ‘well where did he get that?’ Oh, we had, we went and visited; I said something. I forget what it was but I didn’t even think about that one, you know. They still have it. I look at that, and I think if she knew that I brought him up here. They would not know it; they did not know that. But I had to take care of him so he’s going where I’m going. But see, had I maybe told them, they may not have even let me take care of him. I don’t know if they’d be that kind, but who knows how people are going to react? Then, too, when this woman sat in the back of that car and said that, I’m thinking my God, people really do think like that.

A woman’s support network can only do certain things for her if they know she has HIV/AIDS; some women weighed the pros and cons and seemed to decide they would not receive enough support to balance out possible rejection via disclosure.

Women receiving care in urban centers did not seem to worry very much about accidental disclosure; a few women told people they had other diseases or were in another study to explain why they were going to the clinic.

IW8: I asked Susie one time, ‘is it just people who have AIDS that come here?’ She goes, ‘oh, no’. So I tell everybody that I have sickle cell, so if they see me out there, then they’ll know that I’m coming up here for my sickle cell, because this is not only for people who are HIV and have AIDS. She said it’s for all infectious diseases.

BC: Well, you had talked a little bit earlier about the stigma, and how people may look down on people with HIV. Do you ever worry about people seeing you going to and from the clinic or that a lot of your personal information’s being kept at the clinic?
IW2: No, not really. This is a pretty big town. If this was my hometown, maybe (she’d worry). I’m not from Columbus; I’m from a small town in a nearby state. I never feel that there. Anyone that’s there that I usually talk to…and I’ve never run into to somebody (she knows) there. You know, someone that I know from [the Columbus suburb where she lives]. I’ve never ran into anybody, so I’ve never had that problem. But I did kind of think about moving back home, because that’s where all my family is. My husband’s family is here. I thought, well maybe I could move back home with my family. But I’m on this trial, and I like that. And of course I wouldn’t want to the doctor there; I’d want to go to a bigger city so
it’d be more anonymous. If people I went to high school with were working in that office, I’d feel funny about it. But I’ve never had that happen. Of course the people I see that I always talk to are very nice. I never feel like they (say or think) ‘eww! Get away’ or something. [We laugh] Like they’re afraid to touch me or something. [said jokingly.] Because that’s hard, you know?

Some women did report negative experiences due to disclosure.

BC: OK. What kind of good things or benefits are there for you about driving to Columbus and getting your care at a clinic just for people with HIV?
IW3: (Sighs) Just getting away from my hometown. Getting away from people that would talk about you and gossip about you. It’s funny. I didn’t, I didn’t even apply for like, programs and things in my hometown. I guess, by rights, I probably should have. (Pause) For that reason. Gossip is a very hurtful thing. I’ve lost a lot of friends for that reason. And I’ve gained friends. But, um, the hurt on losing friends far outweighs everything else.

IW2: Even my husband’s brother, I think he alienated himself from me a little bit, which has hurt me a little bit. I don’t know if he thinks it (the HIV) was my fault or something. He used to come see us once a week. Definitely when he moved here to Columbus, he would come see us all the time. Every Friday night, he’d come over and we’d get pizza and stuff. Well, he doesn’t ever come around anymore. I think it’s kinda hurt the kids, because they feel like no one ever comes to see us from his side of the family.

Another theme in this data was women not disclosing their HIV/AIDS status to protect others. Women do not want ‘to bring others down’ and have people worrying about them. One woman said her family just does not share much, and she seems to believe she is respecting family norms by not telling many family members. A prevailing attitude among non-disclosers was that there is nothing the network can do, so why burden them?

IW7: …sometimes people just get so hung up on, on the low part, and you think ‘oh, gosh, they don’t need to know that,’ and I think my family would, they would just crumble.

BC: Okay. Do you have plans to tell your other children (about your HIV)?
IW8: No. (said very quickly) Because they have their own lives and the last thing they need. My oldest girl, the only time she worries about it is if I get sick, then she gets really concerned for me.
Of course, women who do not choose to disclose their HIV status to their network do not talk to them about the trial.

BC: Did you talk to anybody about participating in the study?
IW7: With what?
BC: Here, just about being in the study or?
IW7: Anybody other than the people here? No. No, huh-uh, I didn’t tell them I was in the AIDS study or, you know, anything like that.

One woman chose to disclose her HIV status but not her participation in the trial.

BC: Yeah. (Pause) Who knows that you’re on a trial besides the people here at the clinic?
IW9: Nobody.
BC: Okay. If you have to tell your boyfriend where you’re going, do you just sort of go?
IW9: I just tell him I’m going to the appointment.
BC: Okay. (Pause) Does he ever see your medication?
IW9: Yes. He doesn’t ask me questions. He just asks me did I take my medication. He’s just concerned about my health, that’s all.
BC: Okay, so he doesn’t know the details just as long as you’re feeling okay?
IW9: Yeah. He just makes sure I take my medication. Which, even if I didn’t take it and tell him I took it, it wouldn’t matter just as long as, but he’s supportive so.

Women who did tell their families often reported their families became very protective of them as a result. Women noted how disclosure often stressed out their parents, and they discussed how their parents were dealing with them having HIV. Interviewee 10 mentioned that she felt “smothered” by her family’s concern for her after she disclosed. Family and friends either have accompanied or had offered to accompany several women to the clinic.

IW5: At first it kind of bothered me. Even being HIV positive, it bothered me. How do you tell the people? How do you tell your family? How do you? I hid it for two months from my whole family before I actually told them up front. That was, but it’s no different. They don’t treat me any different for it. I think they baby me more now though.
BC: Your family?
IW5: Yeah. We’ve always been close, but it seems like they baby me more. Well, they’ll say, ‘Just how do you feel today? Are you doing okay?’ and just everyday being like that, so that’s why I keep telling them I’m going to be here for another thirty years, just accept that and leave me alone. (We laugh) I’m not through yet. They’re backing off more now because I’ve been telling them. Said I know that you worry, and I know you’re that worried, but everyday is fine now. If I think there’s something you should know, I’ll tell you. They’re scared I won’t. You know, you hid it for two months. And I’ve been more open about everything; there’s a lot more friends that knows. It hasn’t changed nothing; that’s the thing. That was always my biggest thing. I thought it was going to be pushed away, or you know, people would think God, you have a disease; go away; I don’t want to talk to you, because you’re going to give me something; I don’t want it. It’s not been like that. That’s the good thing. No, it’s not been like that. At least the family and friends that I have.

BC: Okay. Who knows that you are participating in a trial?
IW10: My sister. She usually comes, but she can’t get off work this one in time. X (the friend who came with her) and my mom and dad, probably my immediate family, my sisters and brothers, just, probably not like aunts, uncles and cousins but just my brothers, sisters, mom, and dad. That’s about it.
BC: Okay. What do they think about you being in a trial?
IW10: Well, they just keep saying ‘is it helping?’ and ‘how do you, do you feel comfortable?’ As long as I say, ‘okay’ then they’re supportive more or less, you know. If I said, ‘oh my God I can’t go back there,’ then they’d be like then don’t go. They’re just supporting me no matter what my decision is; then they’re backing me 100%, you know. Do you need anything? Do you need gas money? Do you want me to take you today? Don’t go by yourself, and support. If I hadn’t had this one here sitting here beside me, I don’t know what I would have done (We laugh). So, yeah, they’ve been very supportive about me, and I think that’s how it should be…(her mom) came down here, and I wanted my dad to come too, because they’re really having a harder time than me now. And when my mom came down last time, I think it, last time it was like a reality check. This was really happening, sitting out there seeing all the signs and the little things she was; she was overwhelmed, you know. So I was wanting Dad to come today, but I knew I had to meet with you, which I wouldn’t have cared if my dad was sitting here, but I really needed that time by myself driving down yesterday. It really done me a big...done me good, because everybody needs some space.

The woman’s network worries about her, and some members use her counts to help themselves track her health and progress. In one case a woman’s research nurse helped explain HIV and her medications to her mother, which comforted her. Eventually,
though, the woman’s HIV seems to become routine after a period of time, which may mean that she has integrated her disease into her life and that her loved ones have come to terms with her disease.

BC: OK. Have they been supportive of you being a guinea pig (she used this term earlier in the interview)?
IW1: Yes. I guess. My dad worries. (We laugh) You know, I’ll phone them and give them T scores. They go, ‘What’s your result? What’s your result?’ I haven’t gotten them back yet. That’s unbelievable (strong emphasis), how long that takes!

Among the women interviewed, trial participation did not seem to impact the network much at all. No effects like inconvenience to the network were mentioned during the interviews. Often, trial staff did provide education for family and friends who accompanied women to trial appointments.

BC: Do any of the people in your life know you’re in a clinical trial?
IW3: Yes. I don’t think really too many people think too much about it. I mean, it was so immediately almost right away that the medicine started helping that nobody ever, ever questioned anything almost.
BC: Like, ‘why are you on it?’ because it was obvious that was what you needed?
IW3: Oh, yeah! Just because, well, and at the time, there was just a very few, I’m trying to think; well I didn’t have many people that knew right away, but almost, everybody knew even that I was doctoring for 6 months before that anyway. So I guess nobody really even questioned (her being in a trial) when I told anybody; I told my girlfriends. I have a good friend here in town and I told her. I have 2 good girlfriends that live out of town, so I told them. At the time, of course, my boyfriend, we were still seeing each other. So, and that’s no longer. So I lost my life’s partner there. And he knew so I mean, and you know, I was still seeing him, so you know I had support. I guess nobody ever said anything about me belonging to the study.

BC: Do they know, uh, that you’re in a study?
IW5: Yeah.
BC: What do they think about it?
IW5: Well they think it’s pretty good too. I guess the way they look at it is being on a study means it’s not advanced, and it’s not like they’re not going to see me get real sick right away. So that’s where they’re calm; they’re confident about it on that part. They said they feel as long as I’m a candidate for the study, I’m not real sick so. I think that helps me too. I just think about it that way. Okay, I’ll think about it that way, which I guess is a positive too.
BC: What do your friend and your daughter and your sister think about you being in the trial? Do they know or?
IW8: Uh-huh. They think it’s great, because I’m getting the help that I need, and they ain’t got to worry about my medications or anything like that so.

Women’s networks tended not to care much about them being in the trial one way or another, as far as the woman herself knew. Her network wanted her to be healthy, and often the trial participation relieved the network of worry, worry about her health in general and financial worries related to the cost of medicines. A woman’s network, especially those having dependents, was cited as a motivation to adhere to the regimen.

BC: (Pause) Do you think your participating in a trial has changed your relationship with your (family members)?
IW1: Um, not really.

BC: What do your friends and family think about you being in a clinical trial?
IW2: They think it’s great. It’s fine, you know?

Some women did bring family and friends with them to their clinic appointments.

BC: Do you ever feel uncomfortable going to the clinic or?
IW1: Only when my dad goes.

BC: Who do you talk to about the trial? Like if you have an appointment…
IW2: You like the trial questions don’t you? That’s your thing, isn’t it? [said dryly] Mostly I just talk to my nurse about it. She’s great. I love her. I already said that, didn’t I? [We laugh] I have a friend, my boyfriend I guess you’d call him, that I talk to. He sees me almost every weekend, but I’ve told him a lot about it. One time he even went with me to one of my appointments that I had at the clinic, because he just wanted to see what it was like. I talk to him about it. Of course, I talk to my nurse, which is my trial nurse. The doctor, if I have any concerns about something. Then, my one friend I have here in Columbus. I talk to her about it sometimes.

Interactions with Other Clients

Women do not seem to interact much with other clients in the waiting rooms, although sometimes they will exchange chit-chat. Women appreciated the non-
judgmental atmosphere in the clinic, where they do not worry too much about stigma because everyone who is there is sick in some way. (It seems to be a ‘you don’t judge me and I’ll not judge you atmosphere’). It is ironic a bit; women do not want to wait in a crowded waiting room, yet they do like to see other people when they go.

BC: Are there any bad things about going to a clinic that’s just for people with HIV?
IW2: Not really. We’re all in the same boat. Hopefully they’re not looking down on me, because I’m sure not looking down on them!

IW3: Yes. I guess going over there; it wasn’t so taboo either. Like I say, I haven’t got with any support groups over there, but being sick. Everybody’s sick over there. And it’s not even from, it’s not even from HIV. It made me feel better about myself.

BC: What are some good things about participating in a trial?
IW12: Well, I get to talk to other people that in my condition, you know, how they feel. Some feel worse; some feels the same as me, and that helps me a lot; I’m not alone. You feel alone, because I’m dying by myself. I’m not alone because other people got the same thing. Other people got it worse than me. They got AIDS; some of them may be dying, you know; so it helps, you know, to meet with people there too.

While women can chose freely to disclose to almost everyone they know, trial staff know these women have HIV, as did the interviewer for this study. All women were aware of and usually sensitive to the stigma of having HIV/AIDS. The trial staff members and the clinic were seen as offering an open, accepting atmosphere perceived as lacking in the ‘real world’ women inhabited. Other people’s ignorance about their disease, and the resulting stigma, hurt women.

BC: So you would encourage her to go? To participate?
IW1: Definitely. You feel better about yourself.
BC: Yeah. Does it make you feel better about yourself?
IW1: Nods
BC: Why?
IW1: (Pause) Because I don’t have to hide it.
BC: You can go there and be open about who you are?
IW1: Nods.
BC: Are there any other good things about participating? I know you said the free drugs and the free care...are there any other benefits to you?
IW2: I think just the moral support, especially my doctor that I see there and the nurses and all the people I see there. They’re all kind to me, and it seems like they’re so understanding. When I found out (she was HIV+) it was really scary. You don’t want to tell anybody, because you’re afraid they’re going to look down on you and think the worst. But they’re all so sympathetic. Lots of times I go in there, and I’ll talk to my nurse, and we’ll sit and just talk. I just love her to death. She’s so sweet. It’s helped a lot. But besides that, I guess that’s the main things.

These women saw trial staff and the interviewer of this study, to some extent, as people who would not think less of them for having HIV. They were ‘safe’ somehow to talk about unpleasant things. Women did not have to worry about ‘taking care’ of staff or the interviewer as they would if they told their families or friends the worries they shared with staff and the interviewer.

IW7: I don’t like to tell people things that brings them down; what I mean, like, I can tell you about my girlfriend, and you’re sorry for that. But, uh, you know, you would just kind of keep on going, and sometimes people just get so hung up on, on the low part. And you think ‘oh, gosh, they don’t need to know that’.

IW12: You know what I mean? I talk to strangers better than I talk to my parents, my people. You know what I’m saying? I feel better. I get a lot of stuff out, and I feel comfortable talking to strangers. I talk to you, I feel good; go to my doctors, my counselor, I feel much better...I didn’t like talking to a lot of people, so on a one-on-one I get things out like I want to.

Disclosure to Non-trial Health Care Providers

Women expressed discomfort about disclosing their HIV to non-trial health care providers. A few just do not tell their health care providers. Sometimes the trial staff members serve as information resources for women with questions about disclosure to other providers.

IW2: I had to change health insurance through my late husband’s workplace, because the rates were going up too high. So I have to change dentists, and I’m not really looking forward to having to fill out another form and telling them about you know (her HIV). They’re strangers. Of course when my husband died, I
had to do that because I switched insurance (plans); I couldn’t go to the same dentist. Those dentists have always been really nice to me. I think health care professionals...maybe everyone would be like that...but they...

BC: They are at least more knowledgeable.

IW2: Yeah. When we go to the dentist again, this new dentist, I’m sure I’m going to have to fill all that stuff out. I was really scared about that. I asked my nurse if I had to write that (HIV) on there; she asked the other nurse. She said I should always tell them; that way if they see something, they can cure it. [Pause] But telling strangers is not really what I want to do. [She laughs.]

IW7: So I asked Dr. Harris; I asked her if you have to disclose. But...

BC: Do your other health care providers know that you have HIV, or is it just the people at Holmes?

IW7: Only, only here. Yeah. Not even the Dr. Miller that was up there, the OB GYN doctor that did the decolonization and the tests. I never told him. You know, they should be wearing a mask and gloves anyhow. (We laugh).

BC: Where do you usually go for healthcare if you’re sick or?

IW10: Well I have a doctor here in Columbus, because I just recently moved here from another state about seven years ago. I think the last time I was here, Jim asked me if he could go ahead and send lab results, because he knows nothing because I only have to go to him like maybe once a year for a pap smear or something like that. So it’s not like I see him every six months, and I haven’t even told him. I just didn’t really feel like I need to tell my family doctor ‘oh guess what, you know,’ because they take precautions when they draw blood; they use their gloves and that so, but I think Jim, the last time I was here, he was going to send over some lab results to him.

Yet, later in the interview interviewee 10 acknowledges that it is important for health care providers to know about her HIV.

IW10: I haven’t even told them what it is because I feel it’s really not anyone’s business but my friends, my family, my doctor, and the people in the medical field that needs to know. Everybody don’t need to know how I feel about it.

BC: OK, and that’s the only other thing that you’re doing health care wise?

IW11: I’m not even there now, because I’m waiting until September once the dental is part of my program at work. I can’t get into him. I’ll probably call in August, because they probably won’t give me an appointment until October anyway with him. Prosthodontists are few and far between. And I haven’t told him. I haven’t been back since I found this out. I don’t know if I should. I mean, they wear gloves and masks and they treat everyone like you are anyhow, which is smart.
Interviewees 2, 5, and 8 had disclosed their status to their non-trial health care providers.

Desire for Children

Being on study regimes (or on any kind of HIV medicine) may affect one’s decisions about family size. This theme was not an issue for most women, perhaps because the sample was older than expected. One woman, Interviewee 6, was young (29) and had no children at all. She talked about how much she wanted children and how worried she was that she would risk passing HIV to them; also, some HIV medications are contraindicated during pregnancy. Another woman wanted children, too; however, she planned to adopt.

IW6: Then another thing that was bothering me. People say you can’t have kids and stuff like that... and then they was telling like they had medicine that you could take and still have children, and then that made me feel better too. Because I’m like, ‘oh it’s over,’ because I don’t have children. So that’s like, you know, it didn’t like I was wild or something like that, just the person that I was with, so that bothered me a whole lot. I think that bothered me the most. It was just like I can’t have kids.

Interviewee 12 also mentioned a longing for children.

IW12: I can’t have any more kids. That’s another thing. I want a baby so bad, because all these people they don’t care about those kids. You know how you see them on TV? And I can’t have kids, and I want to adopt. I want a baby so bad. I seen a baby on TV. I want a baby so bad. I told IW12’s ex-boyfriend that, and he said, ‘you’d be a good mother’. I raised my son, raised my sister’s baby; yeah, I want a baby so bad. As a matter of fact me and IW12’s ex-boyfriend were talking about that last night. How I love kids. I love babies. Right now I got to get myself together first and be stronger. And then I’ll adopt. I’ll get a child.
The Importance of Counts

Most women and their families monitored their CD4 counts and viral load counts very carefully. Women did discuss the perceived efficacy of the meds during most of the interviews. They are very vigilant about keeping track of their counts (with a few exceptions). Their viral load and T cell counts are how they determine if the medications are working and, by extension, if taking the medications are worth it. Improvements may ‘validate’ their decision to join the trial. They were especially thrilled when they reached levels health care providers told them they’d never reach.

Women didn’t focus very much on how they were feeling (i.e. using indicators like less fatigue) to determine if the meds were working. Interviewee 9 said, “The only thing I can see, only thing that I hope the medication is doing is to decrease my viral load and increase my T-cells. But health wise, feeling wise, they don’t do nothing for me.”

IW1: I’m glad I did now, but my viral load (was in the millions - fieldnotes) So. And I think that my CD count was 6 (about 6-fieldnotes) so…
BC: (Long pause) And have your numbers improved?
IW1: Yes. Remarkably. I’m down to 65 (says in a questioning tone, directed at husband) on my viral (load), and 169 (says hesitantly) on my CD. Yeah.
BC: Congratulations!
IW1: Yeah, yeah, I know. I was playing with her; I said, ‘what?’ When she tells me, I say, ‘how much, what?’ (I laugh) That first time I started crying; I was like ‘oh my God, it’s working actually.’ Because I hear horror stories about how it affects women differently, and…

Interviewee 11 reported her viral load decreased from 82,000 in her blood count to minus 17. A few women were not sure what counts were supposed to go in what direction, though. Interviewee 5 said, “It’s helping. It’s bringing my viral load and my T cells down very good so, so that’s all that matters.” However, T-cells going down is a negative clinical outcome.
IW10: Like Jim said this morning, as far as I know, other than a little sick to my stomach and fatigue, which that’s just one of the side effects, that this medicine evidently because one number’s dropping; the other number’s going up, which is what it’s supposed to do. So far it’s working for me. I just found that out this morning.

BC: Did he tell you what your CD4 and your viral load are?

IW10: Uh-huh. (She finds a sheet with a list of her counts at this and previous visits).

IW10: Uh, let’s see the CD4 right now is 19 and the viral load is, uh, 787; it was started out at 46. (46,000 maybe?) I need to look at those numbers. That’s what it started out at, which that is why they went with the medicine, and now it’s dropped down to 787 he said, which is wonderful. See these numbers were supposed to drop; these numbers were supposed to go up. But right now they’re not, but he’s going to wait a couple more weeks on, maybe on this med and see. As long as these numbers go down, and these go up, then the medicine’s working for me.

BC: Right. So your viral load has decreased a lot, but your CD4 counts haven’t really?

IW10: No, they’re staying 21, 19. But he told me, give it a couple more weeks and see what this result that they took blood today; see what it does; maybe when I come back in two weeks, maybe it is starting to rise again. You know it’s kind of one of those, okay let’s do this, and see if this works.

The women who did not monitor closely usually knew these measurements had improved, even if they were not aware of their exact values.

BC: Have you been diagnosed with AIDS?

IW4: Yeah I ( ) AIDS now, yeah.

BC: Yeah? Do you know what your T cell count is?

IW4: No, I gotta look; let me look. I don’t got the time to mess around with April 19. I don’t got the time to mess around with April 19. I don’t know none of it. I know my, uh, C count but what is the C test? No this, what is it? I know that was up. Mm-hmm. I don’t know. I just pray day by day.

BC: Do you know what your counts are?

IW7: No, I don’t. She said they were really good.

BC: They’re good?

IW7: Real good. That’s all. I don’t even know if that’s supposed to be up or down.
Describing the Trial

In terms of thinking about the trial itself, most women were unsure how to define or describe a trial. Most offered the reference of a regular doctor’s visit with more blood draws. Women do not seem to differentiate much between being in a trial and getting regular treatment, except in the trial medications are free; most women receive their primary care through the trial and may see them as the same thing. The question asking how a woman would describe her trial was not asked of all interviewees.

BC: How would you define a clinical trial? If you were explaining it to somebody, what would you say?
IW2: Geez, that’s a toughy! [We laugh] I guess I would explain to them what I do, about how I go every couple months and what they do to me. My clinical trial might be different than someone else’s for something else. I would tell them it’s a good thing.

Interviewees 5 and 6 view the trial as a checkup.

BC: In your opinion what is a clinical trial? Like if you were having to describe it to somebody what would you say?
IW5: I don’t know about that one. Uh, shoot. I don’t know. I guess just it’s hard to describe it.
BC: Yeah, it is.
IW5: It’s, I don’t know. It’s so basic, like your basic doctor care to me. I mean just to monitor and make sure everything goes the way it should be going, and it’s not like you’re getting poked with fifty million needles every time you come in the door, so it’s nothing like that, just your basic blood work and maybe an extra tube or so.

Almost all of them understood the trial was a study or research of some kind. There is confusion (which partly led to the 2 ineligible interviews) between a drug trial and other non-antiretroviral trials or non-therapeutic studies (women interviewed seem to be in a fair number of those, too – be it monitoring side effects or psychosocial-type questionnaires).
BC: Did they explain to you what a clinical trial was?
IW10: I talked to so many people it seemed like they did. Basically what it was, I mean I want to get this right, basically they’re studying my blood. Something about, something about a study; correct me if I’m wrong too, because I talked to so many different people, and it’s so overwhelming sometimes. I’m thinking, well is this what they said, or did they say this? Something about a study like a research trying to figure out if this med’s really working, or do they need to do; something about just a study like a research. That’s what I, basically what I thought it was. Am I right?
BC: Yeah.
IW10: Okay, like am I right; I guess that’s right. I don’t know.

In some cases it seemed as though women included everything that went on at the trial site as part of the trial. For example, interviewee 1 said the trial helped pay their rent, when a social worker associated with the clinical trial unit probably had applied on the her behalf to a housing assistance program.

Overall Satisfaction and Improvements

All women reported that they were very satisfied with their trial experience. No one reported wanting to quit their trial.

BC: Now, have you ever thought about dropping out of the trial?
IW3: No. No. Just because it’s always worked.

BC: Have you ever wanted to drop out of the trial?
IW10: I hadn’t even thought about it. No.
BC: Can you imagine a time or something that would happen that would make you want to drop out of the trial?
IW10: No.

BC: Oh, no. Have you ever wanted to drop out of the trial?
IW11: Never. No way!
BC: I kind of thought so, but I should ask.
IW11: I’d be too frightened.
BC: About what would happen if you weren’t on the medicine?
IW11: Yes, I would be too frightened. Trials are very important to me right now.
Only one woman reported any practical improvements she would like to see the trial units incorporate. She offered suggestions for the clinic at UC: bring back appointment reminder phone calls and make sure staff at the reception desk do not talk about clients by name; she was the only one to offer any suggestions for improvement. All other interviewees either responded they could not think of any improvements, they would change getting HIV in the first place, or they would like the unit to be closer to their homes.

BC: If you could change one thing about your whole research study experience, what would you change? 
IW5: Just not to have the virus to be in the research program to begin with would be about the only thing. (We laugh.)

There were few complaints about anything that could realistically be changed or fixed. As previously discussed, two women complained about how long it took to get their counts back; this is especially problematic since some women (and their friends and family) use the counts to track health/disease status.

Interviewee 6 decided she would keep the trial medication as long as it worked for her and forgo a new trial regimen once her trial ended, but she said she would join another trial if that medication stopped working for her.

BC: Would you be in another research study if this one ended? 
IW6: I thought about that. I was wondering. I think if they came out with one with lesse pills and, like I said, it’s been people on it for a few months, a few months before me…I might consider it. Other than that, if these are working I’m just going to stick with what I got. I’ll probably keep what I have. You know what I’m saying. Just as long as I can.

The other eleven women would do another trial once their clinical trial ended.

BC: Would you participate in another trial after this one ended? 
IW10: Oh yeah. Because I know it’s been very helpful.
BC: Okay. Would you participate in another study; like, if this one ran out, would you do another one?
IW5: Oh sure. Yeah, as long as they’re available.

Uncertainty About the Future

Uncertainty about the future came up often when women discussed their decisions to be in a trial. They did not know what would happen to them after the trial ended. A few women had a general idea, but even they seemed a bit perturbed about exactly how they would get their care and meds. These seemed to be pretty scary thoughts.

This notion of what would happen to them after their current trial ended emerged after they were asked if they would decide to be in another trial. This question was asked to reveal more about their overall satisfaction with the trial. Very few women knew how long their trial would last. When asked, they seemed to become a bit stressed. Many women did not know what would happen after their current trial ended, and a few asked the interviewer about what other options existed. Most mentioned they would have to ask their trial nurse about other options at their next visit. This uncertainty, which a few women voiced unprompted by the question, was very distressing for these women. For those who see the trial as their link to life, it was especially distressing. Women who had been in multiple trials already were not quite as concerned.

Seven women seemed to be very concerned about what would happen to them after their trial ended. There may be some connection between how long women have been in care or been in other studies and their attitudes about the future (be it laissez faire or deeply worried). Women who had been in other studies and/or received “regular” care at the unit seemed less concerned about what would happen to them, while women whose first care experience was in a trial seemed much more concerned.

BC: OK. After this one expires or is over, whenever it happens…
IW3: After the study goes away?
BC: Yes, thank you. Would you consider being in another one?
IW3: Yeah, see I can’t say no. Because there’s never any knowing how long these medicines are going to work for me. Like she said, there’s no guarantee. A year
from now, there may not be a study for me. May not be a study for me. If the
medicines are still working for me, I have an income limitation, which I’m no
where near an income limitation, but I’ll be getting my medicines free from
ADAP. But then, there goes all my doctors. I won’t have a doctor to take care of
me.

Interviewee10 was concerned enough that she initiated a conversation with the
interviewer after the interview ended; she wanted more information about the trials and
other programs that could help her get care and medications.

IW10: The only question I really have I guess, the concern is, does the clinical
trails just last a certain period or do they last as long as I need them or?
BC: I would ask Jim (her study nurse). Generally they are for like a year or two
years or a year and a half. Sometimes they extend them so, you know, you’ll be
on the trial for a yea, and they’ll say, well, you know, we want to continue to
extend this period. So they’ll extend it. There’s often like follow-up trials where
they sometimes keep you on the medicine and just kind of check in with you
every so often to see how you’re doing.
IW10: What if, say five years from now, I still can’t get on any insurance because
of the condition, and I don’t have the money, then, then what? You see where I’m
going. Well, then, what do I do if they say you have to have this medicine. Well, I
don’t have this money.
BC: There will either be new trials that you could possibly participate in if you’re
eligible for it. Ohio has the Ryan White Care Act.
IW10: Yeah, I think that’s the one Children’s Hospital, the Ryan, yeah, the money
help, something about.
BC: Yeah, and then I think if you make under a certain amount of money;
honestly, I’m not sure what that amount is; you can qualify for the program and
get your drugs for free.
IW10: Right. I know from day one at Children’s Hospital here, they kept telling
me you’re going to get your medicine no matter what; they cannot deny you of
this so, because that was my biggest thing, because I even asked Jim that day. I
said when the day I was getting to take it, I said, ‘do I have to take these?’ And he
was like yeah, you know, I’d love to tell you no, IW10, you don’t have to ,but
yes, you have to take them. So my biggest concern was okay, I’m on this trial, say
for two years. And then they’ll say well, okay, you’re not eligible. Then what, you
know? I’m sure, I mean I hope, in two years that if I’m making enough money
yeah, I’ll pay for it but who’s to say?

BC: OK. Hmm…(she laughs) Do you know how long this trial will last?
IW11: No. I am concerned about that. I do have medical insurance where I’m at
with United Health, which is Riverside. I also know that that medication in that
bag I just picked up is $1700 a month. And they keep telling me not to worry
about it; they’ll have new trials. They’ll have something else to come out. I’ve always been a good guinea pig, and that’s fine with me. (We laugh) Don’t you love my attitude?

Interviewee 5 never mentioned she was concerned about the length of her clinical trial, but she had four more years left on her trial. The length of her trial may have made her more comfortable because she would have time to look into other options. The other women who did not seem as concerned about their clinical trial often said something about how there would always be some program or maybe another trial that they could join. Perhaps they felt like they had enough options that they did not have to worry as much about their future care and medications.

BC: How long have you been taking them?
IW7: Oh well, when the study started, which she just said something about they’re going to do it 48 more weeks. I think she said that I’ve been doing it over 200, 200 weeks.
BC: 200 weeks, okay. About three or four years?
IW7: Oh gee, it don’t seem like that, but maybe so. Time goes by so fast, you know. And you just do. Yes, she said that because they had said the study would be this long now, and they think they’re going to do it about another 48 more weeks.
BC: Okay. And are you going, do you plan to join another study?
IW7: And then there’s, she said there’s a possibility that one might overlap the end of this one or they might just continue this; there’s always something.

**Summary**

This is a summary of the data from Chapter 4.

Infections and Diagnosis Stories/Background

Almost half the women were symptomatic when they were diagnosed. Three women found out they were at risk from partners; two were diagnosed after donating
blood products. One woman was diagnosed as part of a work-up for her sickly child, and one was diagnosed after a routine HIV test. Six women had been diagnosed with AIDS, the meaning of which disturbed and confused some of them.

Women generally had coherent narratives they offered during the first part of the interview. In terms of their lives and health, uncertainty, fear, and change were common after diagnosis and were followed by acceptance and a search for treatment.

Trial Enrollment

Women in Columbus were referred from different sources. All Cincinnati women were referred by trial staff affiliated with the clinic from which they received their regular, pre-trial care.

The main reason women chose to enroll in the trial was worries about insurance (co-pays or lack of) and the high cost of HIV therapies. Women were often encouraged to enroll by trial staff (some of whom could be confused with regular care staff by women receiving care at the unit before enrollment in the trial). Most women were unsure of many of the details of their trial.

Question #1 – Decision-making Processes

Based on the data, decision-making did not involve talking to others beyond the trial staff. Women cited a number of concerns and desires related to this decision. They wanted to stay healthy; there was a great fear of disability and/or death, regardless of current health status. Trial participation may be a way for women to deal with uncertainty and fear after HIV diagnosis; “one decision to rule them all” or the idea that by making one decision to participate in a trial women need not make further decisions about their care and treatment; the set trial care regimen and schedule may relieve the woman of many further decisions and re-cast her in the familiar role of “patient” with others (trial staff) advocating and finding resources for her.
Trial participation negated the need for health insurance and/or disclosure to one’s health insurance provider. Trial staff members do the paperwork necessary for the woman to get her free medications. Other programs like ADAP or Ryan White, which provide free medications, were considered less beneficial because they do not provide free, specialized care and/or are more hassle because the woman would need to be proactive and deal with paperwork.

Women fully expected to receive personal health benefits through trial participation; although altruism was commonly cited as a reason for participation, it was not generally a woman’s first concern. A personal, trusting relationship with trial staff affected many women’s decisions to participate. Information sessions, which many women did not remember, probably affected their decisions. Most women also did not remember, report, or understand the informed consent paperwork and process. Sub-studies associated with the trial may be mixed up in a woman’s mind with her main clinical trial.

Question #2 – Nature of the Experience

In terms of the timeline of the trial and the time it required from the woman, there seemed to be two distinct stages of the trial. The initial period, the first few weeks, were characterized by frequent visits to ensure safety and efficacy of the regimen and fear and uncertainty on the woman’s part. This period is followed by a maintenance period, where the appointments are routine and more comfortable for the woman, as she now has a relationship with her providers and knows what to expect from the appointment.

Appointments were reported to be too frequent at the beginning of the trial. The women who had been in their trial longer enjoyed going once every two to three months. Scheduling appointments in advance was beneficial for women who worked, although one woman mentioned scheduling so far in advance meant she often forget when her appointment was while another had a hard time predicting how her side effects would be so far in advance. Women reported that they did not wait very long before or during their appointments, except for one woman who waited to see her doctor.
Women identified some common elements that make up their routine trial appointments. They are taken to a room. Their vital signs are taken, and they update their study nurse on how they are doing. Blood is drawn; medications are given to the women. Then they converse with their nurses and schedule their next appointment. Occasionally, they see the trial doctor. There are parts of the visits that are embarrassing, like stripping for the body measurements. Surveys and blood draws seem to cause some inconvenience and discomfort, but typically women seemed okay with the trial appointment experience.

Transportation to and from the clinic and appointment scheduling were issues discussed in every interview. Parking vouchers were appreciated. Women’s desires about how far the clinic should ideally be from home varied. Some women wanted the clinic to be close and convenient, while others wanted some distance between the clinic and their community.

In terms of the regimen, women discussed their schedule and adherence as well as how they felt about the regimen and their personal experiences with it. Women had difficulty remembering the names of their medications; most of them identified them to the interviewer by picture or by looking at the label. However, they knew their dosing schedule. Some women were on a placebo, which was acceptable for most, though some wanted to know for sure what medications they were taking. Some women speculated as to which medication was placebo.

Women reported a desire to be adherent and compliant. They reported how important it was to take the regimen on schedule; a few women initially over-complied. Other women let things slide a bit more by not taking their medication with 300 calories or forgetting their afternoon dosage. Women reported working out a livable, reasonable solution with the help of the trial staff.

No one reported liking the process of taking medications. They spoke in terms of ‘having’ to take them. Women did not care for the regimen’s side effects either. Most of the time, this was couched as women made it through the initial adjustment period of uncomfortable side effects and then reported that the side effects were preferable to HIV/AIDS symptoms.
The adjustment period for taking the regimen, the reason women joined the study to begin with, was more difficult than for the clinic visits. Women adapted many strategies to make the regimen schedule easier to remember, and it got easier for them as time passed. Women seemed to think this was the “price” they paid for choosing to live. This adjustment varied for women. For women who had just begun their regimen, adjusting to the daily routine was problematic. Other women who had been on their medications longer had to mentally adjust to the realization that they would be on these or similar drug schedules their entire lives.

The care provided by the trial was generally the only source of health care for these women and was very important to them. Women discussed the trial care as superior to ‘regular’ doctor’s office care. Women relied on the trial staff’s expertise and recommendations; they gave these health care providers control and decision-making power.

For the women interviewed, relationships with the trial staff were extremely important. Staff members provided trust, comfort, and affection in that there is no stigma attached to the women’s HIV, and there is an acknowledgment of their humanity and dignity. This was often juxtaposed in the interview with the fear, uncertainty, and anxiety a woman experienced not just from society because of her HIV, but due to her own lack of knowledge about HIV and its treatments.

Women reported that they did not feel like guinea pigs. They did not seem to focus much on the experimental nature of the trial, so it was not problematic for them. If a woman did worry about it at first, she seemed to make peace with it eventually, with the help of the trial staff.

Confidentiality was not a concern for women interviewed, except for one woman at UC who was concerned more for others than herself. Women trusted the staff to keep their information private.
The main themes in this section include stress, religious and spiritual beliefs, stigma, social networks and disclosure, health status tracking, meaning of the trial, overall satisfaction, and uncertainty about the future.

Stress was a common theme in the interviews. Women reported a number of stressors. Despite this stress, women seemed to be upbeat during most interviews. Some of the most common stressors included acknowledging her regimen could fail at any time, the high cost of HIV medications, her health and future, and how stress itself could negatively impact health. Women coped a variety of ways; some were on anti-depressants, while others kept busy, kept away from stressful people and/or situations, and turned to their religious or spiritual beliefs for comfort.

Religious and spiritual beliefs helped some women deal with their positive diagnosis. Their relationship with God was supportive for three or four women, while diagnosis precipitated a crisis of faith for two other women. These beliefs gave some women a sense or feeling of purpose in life; these women, along with a few others who did not express firm religious beliefs, seemed to see their trial participation as a way to serve God or other people and “give back” while improving their own personal health so they could continue to serve in other ways.

The stigma felt by interviewees from HIV was variable, but almost all women reported some feelings of stigmatism. It was difficult for some women, in the beginning of the interview, to even say “HIV” out loud. While few women reported actually experiencing stigma, the perceived stigma of HIV infection was felt by almost all women.

Women interviewed described two layers of disclosure: they disclosed their infection and/or they disclosed their clinical trial participation. Disclosure was influenced by perceived stigma, how private the woman was, stories heard from or about other HIV-positive people, and provider advice.
Three types of disclosure styles were described. All women needed time to deal with their health status themselves before they began disclosing to others; women also struggled with the timing of disclosure. African-American women seemed more hesitant to disclose their status.

Women described themselves as open about their HIV, private, and/or selective. Women who chose to be open about their HIV believed it was too much to carry alone and said they could not keep their status to themselves. These women may not disclose in certain circumstances to protect others. Women who chose to be private about their HIV may tell another person or two, but generally just the trial staff know they have HIV; these women consider themselves to just be private people and did not think their status is anyone’s business. Private women thought up excuses for their presence at the trial site. Selective disclosure seemed to be an individual balance of maximizing the benefits of disclosure and decreasing the stigma; these women usually disclosed to the people to whom they were closest who would be able to deal with the information.

Impact on network seemed to encompass the same two issues: diagnosis and trial disclosure. Diagnosis affected partners, parents, and children the most. Women often described their parents becoming more protective after finding out her HIV-positive status. A few women moved in with their parents during this time, either to ease the parent’s mind or to deal with other life events.

People in the woman’s network, if there are any, who know about her HIV infection know about her trial participation. Network members, as reported by the women interviewed, think of the trial participation as just regular treatment and care. A woman’s network will often accompany her to one or more trial appointments, to support her and learn more themselves. Trial participation did not seem to impact any networks. Friends and family who knew about the trial seemed relieved that women were getting care and free medications, which relieved them of worrying about the women.

Women also discussed how they felt about seeing other HIV-positive people at the trial site. For the most part women did not seem to mind going to a clinic for HIV-positive people. Many expressed an attitude of “we’re all in the same boat.” It helped some women feel less alone.
Trial staff members know the woman’s HIV status. Women reported that they liked not hiding their HIV status at the clinic. Staff provided them with moral support; in addition they did not feel any stigma at the site. A few women reported feeling comfortable talking about HIV and anything else in their lives to trial staff without worrying if staff could deal with it, because it was their job.

Disclosure to non-trial providers was discomforting for most women. Women were not knowledgeable about what they were required to disclose, and they reported not wanting to disclose, especially when seeing a new provider. Universal precautions made women feel like they did not need to disclose, because there was a very low risk of infecting the provider.

Counts were very important to most women. Many women knew their exact counts, but almost all women knew the direction of their counts and if they were improving. Women also had some questions about counts that they discussed with staff. They were not always certain what direction meant improvement or the difference between the two measures.

The definition and/or meaning of her trial proved difficult for women to articulate. The question about how a woman would define a clinical trial was dropped after a few interviews, when it became clear women had a general idea, at best, what a trial was and could not always articulate what it meant to her. Most women described the clinical trial as being similar to a regular doctor’s appointment or check-up with more blood draws. Only a few women mentioned the experimental nature of the trial.

All women reporting being satisfied with their trial experience and only one woman suggested any viable trial improvements. Women did not want to quit the trial, although one woman reported she wanted to while trying to adjust to her medication regimen. All women but one reported wanting to be in another trial after their current trial ended. Some women were fearful about what would happen to them after their trials ended. Many did not know how long their current trials lasted; this uncertainty was stressful.

Improvements suggested included making reminder phone calls for appointments and improving patient confidentiality in the reception area of one of the interview sites.
While not mentioned as something that could be improved, a few women did complain about how long it took to get their T-cell and viral load results back.
Chapter 5

DISCUSSION AND CONCLUSIONS

This chapter focuses on interpreting the data presented in the previous chapter and deriving conclusions. The following sections are included: discussion, conclusions, recommendations and implications, reflections and limitations, and suggestions for future work.

Discussion

This section contains conclusions regarding the results presented in Chapter 4 on decision-making and the nature of the experience of being in a clinical trial.

Decision-Making

The women in this study were not as interested in the topic of how they decided to join the clinical trial as they were in other topics. Less data was collected on this research question than anticipated, roughly ten pages of quotes related to decision-making. The interviewer made a point, after the sparse data from the first few interviews, to focus conversation on the trial and probe as much as possible about how the woman decided to join the trial. Also, the interviewer brought up trial decision-making again after the woman had a chance to tell more of her story to see if discussing the trial or trial site had
led to any new information. Often, women remembered other bits of information that they had left out initially. Toward the beginning of the interview, women were often concurrently explaining their trial, relating their personal diagnosis/treatment story, and trying to remember how they were referred to the trial. These three strands of conversation were more interesting for the women, a conclusion based on quantity of speech and time allotted to topics. Women tended in the interviews to skip over or possibly reduce the actual decision-making into one small step of a much larger story or dialogue about their diagnosis, infection, and treatment.

During the interviews, the women’s focus shifted from their trial experience to their lives. The focus women had on telling their stories could well be the result of the first question of the interview protocol “Tell me about how you first found out you had HIV/AIDS.” That question sounds a lot like “Tell me a story,” which was what usually happened in the interviews. That initial question may have set the tone for the rest of the interview and put the focus on a woman’s story rather than her clinical trial experience. It may also be another indication of how important context is and that women felt like they needed to talk more about their lives in general to explain their decision-making and experience. Although this could be due to the protocol, the fact that women felt the clinical trial was not an important part of their story seems to be important conceptually.

Frameworks

Two different frameworks for understanding decision-making arise from the data. The data indicate women entered a trial either after having received care or very shortly after diagnosis with the trial being their first HIV health care experience. Both frameworks contain similar elements that were important to women in both groups, but timing influenced which elements were most important to an HIV+ woman as she decided to join a clinical trial. Time confounds these frameworks, as the data do not allow discrimination between factor differences due to time and those due to the trial process. Figure 5.1 on the next page shows the decision-making framework for women who received pre-trial care. Along the continuum from diagnosis to the decision to join a
trial, factors vary in strength; for example, emotions such as fear and shock are most
distressing at diagnosis and ebb over time (Raveis, Siegal, & Gorey, 1998). Decision-
making framework components will be discussed in the next section.
Figure 5.1: Decision-making framework for women receiving pre-trial care
In Figure 5.1 the important points in time leading up to the decision to join a trial are the emergence of symptoms for some women, diagnosis, entry into care, referral to a trial, a trial information session, and the actual decision. Women discussed both factors internal to themselves like emotions and social support as well as external factors like stigma and a lack of options for care.

Women who were experiencing symptoms before diagnosis often were able to draw upon a high level of social support as their health declined and they searched for a doctor who could diagnose them. Some women relied on their strong religious and spiritual beliefs to help them through the crisis of poor health. These beliefs often helped carry them through the rest of the timeline’s events.

When women were diagnosed, they reported not having any or many choices for care and feeling stigmatized. The stigma led them to feel uncertain about how their friends and family would react to them having HIV. As the high cost of HIV medicines is fairly well known to the general public, they also worried about how they would pay for medications to help them either improve their health or maintain their health. Women felt a number of distressing emotions upon diagnosis; these emotions included shock, grief, fear, anxiety, anger, betrayal, disbelief, and desperation.

In this version of the framework, women were referred upon or after diagnosis to a clinic for care. Once a symptomatic woman entered care, her health stabilized as she was treated for opportunistic infections. Providers monitored both healthy women and symptomatic women. Patient-provider trust began to build; women had an opportunity to ask questions about their HIV/AIDS in a non-stigmatizing atmosphere where, regardless of how open they were in other areas of their lives, they could incorporate HIV into their identity without risking social rejection. Women felt safe in care, as they believed that their providers and the medications, whether they were taking medications or not, would safeguard their health. Providers may have told women about the efficacy of HIV medications before women’s immune systems progressed enough to need them.

Regular care providers referred women into clinical trials; if a woman was interested, an information session was held where the trial staff members would have given her information about the trial and determined if she was eligible. At the point of
referral was when women seemed to be informed that the trial would provide them with free regimens. This negated their earlier worries about being able to afford the medications. For women in this framework, free medications through the trial and a very high level of patient-provider trust were the most important factors in deciding to join a clinical trial.

Figure 5.2 shows more specific details of a single woman who entered care before deciding to join a trial. She did not disclose her status to many people. She was so conscious of the stigma of having HIV she told people she had sickle cell in case she ran into anyone she knew at the hospital. The non-stigmatizing atmosphere of the clinic and trial unit, along with worries about how she would pay for her HIV regimen and a very strong trust in her health care providers, was a very important factor in her decision to join a trial. After deciding to join her trial, the few people she did tell about her HIV did not have to worry about how she would afford her HIV medications either.

Women reported their first clinical trial visits were all sort of a blur. Anxiety, a feeling of being overwhelmed, and fear seem to be the predominant feelings women remembered from their first visits. They also recalled lots of paperwork but not any specific information from that paperwork.

Figure 5.3 shows the decision-making framework for women who did not receive HIV-related care before they decided to join a clinical trial. The experiences of having symptoms and being diagnosed are identical to those discussed above. However, women in this framework were not referred to a site for HIV-related health care. Referrals came from sources like a place where a woman was planning on getting care until she learned she would receive free medications from a trial, an HIV/AIDS hotline, and social workers.

Generally, women went from diagnosis to trial entry quite quickly; thus, their distressing emotions, like desperation and fear, had not begun to ebb nor had their health improved by the time of the referral and information session. Decisions to join a clinical trial under these circumstances were driven by discomforting emotions, worries about the high cost of HIV medications, and the expectation that joining a trial would improve a woman’s personal health.
The decision to join a clinical trial came, for many OSU women, very closely after their diagnosis with HIV and/or AIDS; it seems many women came to their diagnosis and/or clinical trial during times of intense stress (loss of spouse and/or job and/or health). Often, they were very ill and/or “nervous wrecks” when they began the trial. Consequently, many of them do not remember much about their first several visits, what consent forms they signed, etc; during this tumultuous period, many details seem to escape women (i.e., details about their preliminary information visit, exactly what consent forms they signed, who told them about the trial, etc.)

Figure 5.4 shows an example of a woman who joined a trial without receiving health care. Her decision to join was driven solely by anxiety and fear about the cost of regimens. She reported signing her consent forms on the same day she had her information session.
Figure 5.2: Decision-making timeline example of a woman who received pre-trial care
Figure 5.3: Decision-making framework for women without pre-trial care
Figure 5.4: Decision-making timeline example of a woman without pre-trial care
Generally, women in this study were economically disadvantaged. Lack of medical insurance and inability to pay for expensive HIV medications were the most important and most cited reason women chose to join a trial. Other research has shown potential HIV/AIDS trial participants were more willing to consider trial participation if they had lower incomes (Sengupta, Straus, DeVellis, Crouse Quinn, & Devillis, 2000). Participation in research could be particularly compelling for economically disadvantaged and/or unemployed women without access to health care. This undermines the voluntary participation ideal (Eckenwiler, 1999).

Access to free, specialized care was another very important incentive for these women. This has also been found in other studies (Schrooten, Borchert, Dreezen, Baratta, Smets, Kosmidis, Goebel, Wilkins, and Colebunde, 2001; Sengupta et al., 2000). HIV+ women tend to have less access to specialized HIV care than men (Valenti, 2002). Receiving care from specialized HIV/AIDS providers has been associated with improved quality of care and a longer life (Valenti, 2002).

Poor women tend not to have access to primary care services (Denenberg, 1990); indeed, during interviews, many women mentioned being diagnosed or receiving care for symptoms in the emergency room. Denenberg (1990) states, “Drug trials cannot become a substitute for health care services” (p. 74). Ethically speaking, it is undesirable to have a clinician focusing on a study protocol also attempt to be a patient’s primary care provider. Typically, a primary care provider is not restrained by study protocols and is able to provide optimal care for each individual. Yet women in this study report that they do use the trial care resources available to them as primary care.

The women also joined trials to improve their own personal health. Generally in consent forms for biomedical research, it is made clear that there are risks involved and that treatments may or may not help any given individual. Another related theme that emerged throughout the study was how a woman felt the trial helped her take care of herself. Taking care of herself implies a sense of agency, where the woman deliberately attempts to actively improve her health, not seen when women talk about the actual
decision-making process, where women seem to be somewhat passive agents following recommendations.

Preliminary research and other published studies have shown participants do join trials to improve their personal health (Coletti et al., 2003; Ives, Troop, Waters, Davies, Higgs, and Easterbrook, 2001; Levine, 1990; Sengupta et al., 2000). Coletti et al. (2003) found results supporting what they term the “therapeutic misconception”, where participants suppress information conveyed in the informed consent process in favor of a belief that the trial has been designed to meet their individual needs. Women in this study share this “therapeutic misconception.” Levine (1990) stated that this was a common misperception. Women here seemed to expect treatment, which has the patient’s improvement as its primary goal; however, they were engaged in research, which has knowledge acquisition as its primary goal (Levine, 1990).

Ives et al. (2001) evaluated an information booklet, Clinical trials in HIV and AIDS: Information for people who are thinking about joining a trial; the group randomized to receive this booklet were more likely to have joined clinical trials for personal health benefits, so information given during an information session may affect reasons to join a trial. Perhaps women in this current study were given some written or verbal information during the information session indicating an improvement in their health was a likely result of trial participation.

Willingness of incarcerated women to take experimental HIV medications was correlated with perceived susceptibility to declining health (Mostashari, Riley, Selwyn, & Altice, 1998). In addition to benefits related to the trial, women in the current study reported receiving regular health care for conditions like depression and high blood pressure through their trial health care providers. In a gender-based viral load comparison article, most of the 13 longitudinal cohort studies reviewed provided some level of routine health care (Gandhi et al., 2002).

Another common reason HIV+ people join trials is to access new therapies (Ives et al., 2001). Interestingly, none of the women interviewed identified this as a reason she chose to join her trial. However, because most women had joined a trial shortly after
being diagnosed or after becoming symptomatic, they may not have become resistant to all the available regimens, which usually necessitates seeking out novel treatments.

Women may be making the decision to join the trial with a clear mind, or they may not. They may understand what is going on, but it seems in the first informational visits, too much information is being given to them; they do not remember it and may not ask questions then about things they question later (e.g. how long the trial will last). A few women reported signing whatever staff put in front of them. That is a good example of how desperate they are to join the trial and get the free medications. Only one woman volunteered the ACTG number of her study during the interview; most women did not know their ACTG trial number. Most women either never knew or had forgotten and apparently deemed irrelevant information about their trial.

While only one woman reported being told to join the trial, other women discussed how trial staff encouraged them to join a trial. Women interviewed tended to report that their health care providers or referral sources thought or decided that clinical trial participation was the best choice for them. Many women seemed to interpret their health care provider’s remarks as recommendations (which they very well may have been) to join the trials or as ‘official endorsement’ of the trials. Sometimes, even when the woman indicated the decision was hers, it seems to have been made in the context of ‘this person knows my circumstances (health, finances, etc.) and thinks the trial is best for me.’ This encouragement by staff to join needs to be tempered with more information about the trial to assist those women who want to make more independent decisions about participation.

In contrast 92 percent of a sample of European HIV+ trial participants felt they were “very informed” or “very well informed” about their trial prior to enrollment (Schrooten et al., 2001). This finding is at odds with the majority of the literature, which finds HIV+ trial participants generally have poor knowledge of their specific trial protocols (Ives et al., 2001). Participants in the Schrooten et al. (2001) study may have perceived themselves to be well informed. With the exception of some knowledge about their regimen dosing schedule, women in this study also seem to have poor knowledge about their clinical trial.
Almost one-quarter of HIV clinical trial participants in Europe surveyed felt they had been pushed into participating in their trial (Schrooten et al., 2001). Four percent, an amount the authors deemed “unacceptable,” reported that they had not signed a consent form for the trial (Schrooten et al., 2001). While women interviewed did not generally indicate words as strong as “pushed into,” they did report being encouraged. It seems like a very fine line between the two. Joining trials on the advice of a doctor is not uncommon (Ives et al., 2001).

Women generally did not report having received counseling about the experimental nature of the therapeutic trials, although based on the data it is impossible to speculate on what actually occurred. Most of these women, under better circumstances, are probably perfectly capable of advocating for their health. However, fear, uncertainty, and worry added to their stress levels. Providers may have counseled them based on a general provider perception their clients are rational and capable of discerning the provider’s role, which is to enroll people in trials. A woman might not have been in a frame of mind to be capable of this discernment and interpreted provider remarks based on her frame of reference, her private doctor, who does have a patient’s best interests at heart without balancing them with the need for scientific advancement.

In addition, in Cincinnati, staff may play dual roles, or be perceived as having dual roles. Women receiving regular care there may be approached by trial-specific staff introduced as another nurse at the site. It is easy to see how clients may think that the trial-specific nurse is making the recommendation to join a trial based solely on their situations. They may easily be persuaded that the trial is the best thing for them if they equate the trial nurse with a regular-care nurse. A trusting relationship has already developed between the client and the care facility staff members, and this trust seems to be a critical piece in women deciding to join a trial.

The trial and trial staff seemed to provide a safe haven from the judgment women felt they would have in the outside world. Women reported it was a place where they did not have to hide who they were and could be known as HIV+ women without worrying about being shunned or rejected. For the very private women, this was the only place they could be open about having HIV.
Women acknowledged they had support and/or resources to discuss trial participation with, but often they chose to make the decision alone; granted, family concerns about their health are taken into consideration, but it is seen as a personal choice. (The previous statement may not apply to women who do not disclose; they may not have anyone to discuss participation with except their health care providers, who may have their own biases).

In contrast, in a study for HIV vaccine participants, 74 percent of people who went through the first informed consent session discussed the information presented with someone else; potential subjects most commonly discussed it with friends, spouses or partners, co-workers, and immediate family members (Coletti et al., 2003). In a study of women with HIV, participants described talking to their peer groups and mothers about whether they should begin monotherapy (Misener & Sowell, 1998).

It seems unlikely that the women that interviewed really were knowledgeable about their other treatment options. A few asked the interviewer about other options for care and treatment once the interview had begun, and they started thinking about what would happen when their trial ended. The interviewer usually named Ryan White and ADAP programs but referred them to their trial nurses to learn more.

This decision-making does not seem problematic for most women interviewed; they discuss deciding to join a clinical trial as a pragmatic, almost obvious solution to improving their personal health. Their trials give these HIV+ women access to care and medications they otherwise might not be able to find or afford, with the caveat of programs funded by federal and state funds. The regimented clinical trial atmosphere may be reassuring for a newly diagnosed person; they are told what to take and how to take it and who their care providers will be and how often they will see them. It seems like that eliminates a lot of other decisions, which has advantages and disadvantages. This seems likely in light of a study of cancer patients that found respondents who demanded greater participation in decision making were less likely to join a clinical trial (Llewellyn-Thomas, McGreal, Theil, Fine, and Erlichman, 1991).

Implications of the decision, one of which seems be the expectation of personal benefit, are seen as important, but often women seem to reduce the expected, complicated
cognitive process to “hurry up and get better or hurry up and stay well.” These women tended not to sit around and ponder their diagnoses and life situations; most of them sought care and access to medications shortly after diagnosis. The interviews convey a sense of desperation, with women wanting to do something, almost anything, to increase their life span and quality. An article in a magazine by and for HIV-positive people notes that treatment decisions are life-and-death decisions (Lucey & Zangeneh, 1999).

Other similar studies in the literature identify common barriers or cons to trial participation; barriers include concerns about side effects, effectiveness, and restriction of long-term regimen options (Ives et al., 2001). No woman interviewed, in recounting her decision to participate in a trial, mentioned any specific barriers to participation. It could be women did not know enough to expect barriers, accepted the barriers, or had forgotten that she initially feared certain barriers.

Other studies have shown that distrust of research or the government affect or may affect potential African-American participants’ decisions to participate in HIV/AIDS clinical trials (El-Sadr & Capps, 1992; Sengupta et al., 2000). However, women interviewed for this study did not mention distrusting either the researchers or governmental agencies involved in clinical trials. It seems likely that HIV+ women who do have these feelings of distrust may not choose to enroll in a trial and thus would not have been included in the study. However, the two women interviewed who were not eligible for the study (because they were not enrolled in a clinical trial) did not express feelings of distrust. It could be that women interviewed did have these feelings but chose not to share them with a Caucasian interviewer. Another possible explanation is that trial staff rapport may bridge or heal distrustful feelings.

Theorizing

Previous research in this area, as discussed in Chapter 2, has focused on reducing barriers and increasing benefits to trial participation to improve clinical trial accrual. Many models and frameworks (i.e., the Health Belief Model (Rosenstock, 1974); the Transtheoretical Model (Prochaska & Velicer, 1997); and Ickovichs and Meisler’s (1997)
model of recruitment, adherence, and retention in AIDS clinical trials) approach trial recruitment from a cognitive perspective. While it appears eminently reasonable to assume potential participants engage cognitively in their decision-making, the results of this study suggest otherwise.

Women interviewed conveyed a clear and urgent sense of desperation upon discovering they were HIV+. Diagnosis frequently causes one of two possible effects: a woman enters denial and/or repression, which leads to inaction, or she may spring into action to find care to avoid undesirable outcomes (Raveis et al., 1998). Women in this study chose the latter course. They were desperate to find a way to avoid death, the most undesirable outcome of all, yet they were all working with limited resources. Some were in states of personal chaos during and after diagnosis. Clinical trials seemed to them a lifeline, a savior. None of these women, even those who took time to decide whether to participate and discussed participation with others, reported engaging in any cognitive processes, such as thinking about pros and cons of participation.

However, most of the literature based on clinical trial decision-making is based on cognitive models; they assume rational thinking and are often based on pros and cons (Llewellyn-Thomas et al., 1991). It must be emphasized that this study shows no evidence that women lack the capacity for rational thought and decision-making. It points instead to the inclusion of other criteria, such as affect, in addition to or instead of rational decision-making elements.

One study assuming rational decision-making hypothesized that patients who defer decision-making to their health care providers might be more susceptible to the primary investigator’s enthusiasm for the trial; decision-making is suggested to be a more labile state that depends highly on context (Llewellyn-Thomas et al., 1991). Thus, there is some further support for affect and context influencing decision-making.

A striking example of the lack of cognitive processing found in this study is the genuine lack of awareness of risks at the beginning of the trial. Common risks of trial participation include a decrease in health due to ineffective medications, side effects, and
resistance to a regimen due to inadequate dosage, which could lead to earlier therapy burn-out (Safreed Harmon, 1999). However, women did not discuss any of these risks when talking about how they decided to join a trial.

What did come across in the interviews clearly were the emotions they were feeling at the time. Fear, ignorance, depression, grief, stress, and confusion all were commonly reported emotions. These emotions may have been so overwhelming that women grabbed the first option available, trial participation, and held on to it very tightly. This may explain the lack of reported cognitive processing in the decision-making process. Cognitive models like the ones mentioned above do not appear to reflect the decision-making data well.

Women also reported feeling great amounts of stress. Stress occurs when the external demands of a person’s life outweigh the internal resources the person possesses and the person perceives the external demand to be important or threatening (Lerman & Glantz, 1997). Stress has been found to decrease individuals’ abilities to process information quickly (Kolich & Wong-Reiger, 1999).

The women’s biggest fear was death, and they coped with it by joining a clinical trial. Fear is a negative emotion felt in response to a threat that is relevant and significant and is often accompanied by high levels of arousal (Easterling and Leventhal, 1989; Witte, 1992). High levels of arousal have been found to decrease cognitive performance (Jepson & Chaiken, 1990). Fear may encompass other negative emotions and feelings such as anxiety, nausea, and fright. Rogers (1983) found that self-reported fear corresponded well to levels of physiological arousal. Thus, the fear that women self-reported is an adequate measure.

All health communications have the potential to arouse fear (Leventhal, Safer, & Panagis, 1983). Even the memory of a pertinent past fear may affect long-term actions (Leventhal, Safer, & Panagis, 1983). Patients should be seen as problem solvers who do the best they can to evaluate their situation and develop coping methods (Leventhal, Safer, & Panagis, 1983).

Fear appears to limit cognitive processing, especially at high levels (Jepson & Chaiken, 1990; Wood, 2000). Subjects who reported high fear of cancer found fewer
errors in a message about cancer checkups and were more persuaded by the message than those reporting lower fear (Jepson & Chaiken, 1990). High levels of fear and high issue involvement may lead to less thorough cognitive processing (Jepson & Chaiken, 1990). Jepson & Chaiken (1990) raise another interesting point by adding monitoring and blunting coping styles to the mix of what may influence decision-making. Assessing how a person attends to information periodically may help clinicians understand a client’s information needs; this also may be useful to know in an initial information session also.

Maddux and Rogers (1983) identified a somewhat illogical hyperdefensive strategy used when people had high expectations of being exposed to danger; people were then more easily convinced by information that offered the chance to avoid danger. As a response to their desperate circumstances, people gave a “final push” to act both to reduce their anxiety as well as reduce danger before sinking into helplessness and resignation (Maddux & Rogers, 1983). This strategy seems to be similar to what women reported in this study: “why not join a trial; what do I have to lose?”

Studies suggest one may rely more on one’s mood as a source of information in decision-making when the decision is complex and hard to make based on a piecemeal processing strategy, when little other information is known, when the judgment is affective, and when attention to the decision is limited (Schwartz & Clore, 1994). It is also suggested that as one becomes more aware of one’s feelings, other sources of information relevant to the decision may be ignored (Schwartz & Clore, 1994). Using feelings or mood to make a decision is also possible when too much information is presented, time to make the decision is limited, or attention is limited to an extent that does not allow systematic use of available information (Schwartz & Clore, 1994). While emotions may affect judgments directly, Schwartz and Clore (1994) conclude it is more likely emotions affect motivation than behavior.

A study of AIDS public service announcements determined that people high in affective orientation used their feelings to guide behavior and decision-making more (Dillard, Plotnick, Godbold, Freimuth, & Edgar, 1996). Dillard et al. (1996) also found affect led directly to attitudes about the message in people with low involvement in the subject matter. Low involvement may indicate a lack of agency as well as a lack of
interest or relevance (Dillard et al., 1996). While cognitive activity was present, it had no reliable association with the decision whether to accept the message (Dillard et al., 1996).

Women in this study appeared to lack a cognitive experience when deciding to participate in their trials. However, cognition is very much involved in the process of informed consent. Informed consent assumes potential participants are interested in and able to process important information. Results of this study indicate otherwise. Implications for practice will be discussed in a later section.

Summary

There is not evidence of a complex decision-making process. Clinical trial participation is a relatively easy and convenient way of filling a gap in care and medication between what a woman has access to and what she feels she needs access to. There are many factors and issues that seem to play a part in her decision. The EPPM (Witte, 1992) is a model that may be useful in elucidating why people may decide to join a clinical trial; further research needed to assess the generalizability of the results of this small, inductive study.

Hypotheses Generated

The following hypotheses about decision-making are generated by the data:

- After diagnosis with HIV, women face uncertainty, fear, life changes, acceptance, and then action.

- Information sessions are not ideal teaching moments, due to the women’s high affective arousal. It is unlikely most information given at this time is processed or retained.
• Women who do not disclose their HIV or trial participation to others in their social networks may be more dependent upon the opinions and recommendations of trial staff.

• The major reasons HIV+ women choose to participate in clinical trials include inability to pay for HIV therapies, expectation of personal health benefits, and a referral to or recommendation of the trial by a trusted health care provider.

• Women who enter trials after receiving HIV-related care rely heavily on a trusted provider’s referral to join a trial in their decision-making.

• Women who enter trials without receiving HIV-related care rely heavily on discomforting emotions like desperation after diagnosis as well as in their decision-making.

The Experience of Being in a Clinical Trial

The following topics, with which the women were most engaged, will be discussed: adherence, relationships with trial staff members, stigma and disclosure, and interpretation and meaning of the clinical trial.

Adherence

A post-analysis literature review found that, for the most part, the findings from this study are quite similar to those existing in the literature. The current study was informed by constructs in Ickovics and Meisler’s (1997) adherence framework. Their framework also deals with adherence not only to regimen adherence but also to aspects of trial adherence, such as keeping scheduled appointments. Characteristics of trial adherence, conceptualized here as overall satisfaction with the trial, will be discussed in a
later section. The major concepts they posit will relate to adherence to a clinical trial and a regimen include patient characteristics, regimen effects, patient-provider relationship, clinic setting, and disease status (Ickovics and Meisler, 1997).

In this study, patient-provider relationships and regimen effects had the greatest impact on regimen adherence. Women wanted to comply with their providers’ instruction because of the trusting, friendly relationship; they also had a strong belief in the efficacy of their regimen to improve or maintain their health. These beliefs were supported by the improvements in their T-cell and viral load counts.

Ickovics and Meisler (1997) identified perceptions of the health care provider’s technical skill, affective tone of relationship, communication, and overall satisfaction to be important components of the patient-provider relationship. Women who receive medical information about regimens and have psychological and social support, which women in this study reported receiving from trial providers, adhere to regimens better (Squires, 2003). In another example of the ways physicians can influence adherence, physician’s beliefs regarding the efficacy of the regimen have been shown to directly correlate with HIV-positive women’s regimen adherence (Squires, 2003).

In the current study all of these issues were important content domains of the patient-provider relationship. Here, the patient-provider relationship seemed to impact regular adherence the most by enabling open dialogue between the woman and her provider about the regimen and how it was working. Trial nurses were often able to suggest changes to the woman’s schedule or lifestyle to increase adherence; also, they were able to advise strict compliers who were having difficulty to relax their dosing schedules somewhat.

Ickovics and Meisler’s (1997) regimen complexity seemed to be the largest barrier to adherence in the current study. Women with simpler regimens (i.e., fewer pills and/or dietary requirements) seemed to talk less about their regimens in the interviews and seemed to have an easier time adhering. This has been reported frequently in the literature (Johnston Roberts & Mann, 2000; Reynolds, Neidig, & Brashers, 1999; Stone, Hogan, Schuman, Rompalo, Howard, Korkontzelou, & Smith, 2001).
There is more than a sense of irony in the fact that women joined their clinical trials to access medications, only to deplore taking the medications once they were in the trial! Women acknowledged the enormous potential the medications have to improve their health, as well as the difficulty involved with adhering to the dosing schedule for each medication. Ickovics and Meisler (1997) also hypothesize side effects affected adherence, which was supported here also. However, trial phase, assignment to placebos and/or random assignment of regimen, and regimen duration were not identified in this study as important adherence issues, as they were in Ickovics and Meisler (1997). This could be due to the fact that many women did not possess or volunteer this information.

Patient characteristics include sociodemographics, substance use, and psychosocial factors, such as perceived regimen efficacy, knowledge of trial regimen, intent to adhere and past adherence, perceived cost and benefits of regimen, and social support (Ickovics and Meisler, 1997). There was no indication in the current study that sociodemographics or substance use played a role in adherence, except that employment tended to make dosing more difficult. All the listed psychosocial features were found to impact adherence.

While a few women did speculate if the medications were helping their health, overall women had high perceived regimen efficacies; improvements in their counts bolstered their efficacy beliefs. The women interviewed reported that they and members of their network, when they disclosed, usually measure their health status using T-cell and viral load counts. This was interesting because women did not think of improvement in terms of actually feeling better or having fewer opportunistic infections. Even when women were not exactly sure what their counts were, they almost all cited them as 'proof' the trial regimen was helping them!

Women seemed to have an adequate understanding of their regimens; while most could not name their medications, they knew their dosing schedules and food requirements. While adherence intentions were not in the protocol, some women did spontaneously voice high adherence intentions and pride in their ability to adhere. Costs and benefits of the regimen balanced each other out for most women.
Reynolds, Neidig, and Brasher (1999) found HIV+ people on antiretroviral medications constantly assessed their medications’ costs and benefits; when benefits outweighed costs, their lifestyles were altered to accommodate the regimen; when costs outweighed benefits, the medications were discontinued (Reynolds et al., 1999). One woman in the current study reported a similar process of weighing the cost and benefits of her trial regimen; with the help of her trial nurse, she was able to continue with her regimen. Other women were aware of the costs, but there was little evidence of a cost-benefit assessment.

Women reported various levels of social support related to adherence. Those women with partners frequently remarked affectionately that their partners “nagged” them about taking their medications. While women seemed to think it increased their adherence, “nagging” is not necessarily consistent with the idea of social support, nor is it necessarily resulting in increased adherence. Murphy, Greenwell, & Hoffman (2002) found that being an HIV+ woman with a partner was associated with lower adherence, which somewhat is odds with how these women describe their partner’s effects on adherence.

Johnson-Roberts & Mann (2000) point out that disclosure and adherence are related. Working women who had not disclosed to employers and co-workers had to devise strategies to take medications at work; this resulted in both temporary and permanent adherence problems. This is interesting in light of another study that found being employed was a predictor of good compliance (Cox, 2002). Women in the current study who were employed either had disclosed to their employer and reported good adherence, had not disclosed but had no afternoon dose, or had not disclosed to their employer and did have trouble taking the afternoon dose at work.

The clinic’s atmosphere and their HIV/AIDS disease status seemed to have little effect on women in this study in terms of adherence to regimen. Women did enjoy the non-judgmental environment of the clinical trial, but this did not appear to influence adherence. All women seemed to have similar levels of adherence and adherence
intentions, regardless of disease status. Women who felt near death were highly motivated to adhere for health improvements, while women who began a regimen fairly healthy seemed very motivated to stay healthy.

Cox (2002) found that economically disadvantaged clinical trial patients had better adherence; she speculates that could be due to how grateful they are to receive free medications through an HIV/AIDS research study or how well they have learned to navigate dependence on health care systems. The current study found that women were as likely to be overly compliant, to try to follow provider’s instructions rigidly, as they were to be non-compliant. That may stem from Cox’s (2002) speculations, women’s initial desperation, willingness to put their lives in the hands of the trial regime and staff, and/or the education about the importance of adherence that staff must provide. Reynolds et al. (1999) found similar results, with HIV+ people on an antiretroviral regimen using many strategies to be adherent.

Although no woman explicitly stated it, participants on a trial, looking to prolong their lives, may be so fearful of repercussions (i.e., being expelled from the trial) they go above and beyond to comply with instructions. Whether women were over-compliant or non-compliant, adjusting their regimens to their lives was possible through the help of trial staff.

It is disconcerting to realize that so many of the women interviewed were unable to verbalize what medications they were taking. Neither the generic drug names nor the brand names of HIV medications are particularly easy to remember. Women’s medications were often labeled with the generic name, which was more scientific and probably meaningless to them. Names often contain nine to twelve letters. In addition, drugs often have an abbreviated name, such as ZVD; this can confuse women as well.

With the recent focus on medical errors (i.e., Gurwitz, Field, Harrold, Rothschild, Debellis, Seger, Cadoret, Fish, Garber, Kelleher, & Bates, 2003; Lassetter & Warnick, 2003), it would seem these women may be at a higher risk for interaction errors with other new medications they may need if they are unable to tell other providers and pharmacists what drugs they take. A study of HIV+ trial participants in United Kingdom
found 87 percent of participants could name the components of their regimen at two to six months after enrollment (Ives et al., 2001). Very few women interviewed could name their regimens without looking at the bottles.

Relationships with Trial Staff Members

Distrust of the medical establishment is a commonly accepted notion (see e.g., Misener & Sowell, 1998) among certain patient groups, like minorities or the economically disadvantaged. One of the most striking findings of this study was the trust and rapport that existed, to degrees ranging from accepting acquaintance to warm friendship, between women and their trial-related health care providers.

The notion of clinical equipoise refers to the genuine uncertainty among health care providers about whether a new treatment or the standard treatment works best; equipoise is a fundamental assumption of clinical trial research (Baum, 1990; Botros, 1990; Freedman, 1987). Randomized clinical trials are the gold standard used to compare existing treatments with newer, promising treatments. Individual health care providers have an ethical duty to give patients what they believe to be the best treatment (Botros, 1990). Ignorance about the best treatment is a prerequisite for a provider referring a patient to a randomized clinical trial (Baum, 1990).

It is argued that providers often do have information and/or preferences for treatments in trials, which leads to a dilemma over values of scientific advancement versus an individual patient’s outcome (Botros, 1990). Clinical trial ethics are based upon three core principles: justice, respect, and beneficence (Wermeling & Selwitz, 1993). Justice refers to the equal recruitment, treatment, and sharing of risks and benefits across all people to whom the research is pertinent. Respect for persons involves treating individuals as autonomous agents who have the right to self-determination; it also mandates protection for those who are unable to make autonomous decisions, like children. Beneficence refers to improving social welfare, as well as both doing no harm to participants and minimizing possible risks while maximizing possible benefits (Levine, 1990; Wermeling & Selwitz, 1993).
Informed consent, based on the respect for persons principle, would appear to assuage this dilemma of scientific advancement versus an individual’s health status. However, it is argued that patients often have a poor understanding of their condition and a great amount of fear (as seen in this study), which would indicate some difficulties in patients’ understanding what providers are saying and comprehending the need for randomization (Baum, 1990). Informed consent also assumes a patient knows the regimen she will take is aimed primarily at benefiting future patients rather than herself (Botros, 1990). It is striking that women may “know” information about their clinical trial but seem to think the scientific equipoise idea is outside their own personal trial experience. This data mirror the notion of therapeutic misconception (Coletti et al., 2003).

Also, the women interviewed have hard, numerical data, their counts, that reinforce this notion of the trial helping them personally. This is not always true of other types of clinical trials. Perhaps these objective indicators of disease status may improve even if women are not receiving an optimal regimen. Trial enrollment in and of itself may have an effect on counts, because women are experiencing psychosocial improvements like less stress and feelings of control and reassurance (Gray & Cason, 2002).

The comfort, reassurance, and security that the providers gave within the trial itself were invaluable to these women, who tended to be very aware of their physical vulnerability and vulnerability to the stigma of having HIV/AIDS. Women were very appreciative of the care they received, and those women who made comparisons rated the trial care superior to regular doctor care. The trial also gave the security of not having to pay for the drugs. Women in this study did not seem to realize they may not be receiving optimal therapeutic regimens for their personal health. They did not report trial clinicians explaining that to them nor reminding them of that fact.

Ironically enough, the trust, comfort, and affection may create situations where a woman does whatever staff members recommend without hearing what is involved and what other options are. Individual women may not mind giving up information to gain such a positive relationship. However, the implications, given the most basic assumptions
of clinical trials and informed consent, are troubling. Staff are to be commended for creating such a strong rapport, but perhaps rapport building ought to commence after recruitment into the trial.

Originally, in the a priori coding scheme, there were two main categories of codes relating to the trial: one focused on the trial itself (regimen, adherence, clinical environment, etc.) and one focused on the staff (communication, perception of skill, etc.). What emerged from the interviews was how entwined the original two categories were for the women. They perceived the trial staff as an integral part of the trial; in fact, women often talked about the staff as much or more than any other part of the trial experience. The staff information was unable to be separated from the rest of the trial data. After combining the two categories into a single major code, coding progressed more smoothly and became more reflective of the data.

Stigma and Disclosure

Privacy and disclosure, themes that generally include family or friends, are important themes appearing frequently in the data, whereas undermining did not seem as prevalent an idea. The ideas of privacy and disclosure do seem to differ from what women consider undermining, but their overall reactions and emotions to all three things seem similar. Undermining was not a word they used, but privacy was. Thus, the original coding category’s name was changed to better reflect the data.

Generally, themes related to stigma and disclosure echo those found in the literature. Women seemed to have more fear of than experience with stigma and rejection; these attitudes influenced their disclosure decisions. Stigma and disclosure did not seem to impact the trial experience or vice versa, with the exception of the open, relatively stigma-free trial site atmosphere.

HIV-related stigma was felt, though not necessarily experienced, by all women in this study. While the general population of the United States expressed less overt expressions of HIV/AIDS stigmatizations during the 1990s, nearly 20 percent of the population feared someone with HIV/AIDS (Herek, Capitanio, and Widaman, 2002).
Almost 33 percent felt discomfort and had negative feelings towards people with HIV/AIDS (Herek, Capitanio, and Widaman, 2002). Another study found stigmatizing attitudes were more likely among men, whites, people with a high school education, people older than 55, and those in poorer health; those who gave stigmatizing responses were twice as likely to be misinformed about HIV/AIDS (Lentine, Hersey, Iannacchione, Laird, McClamroch, and Thalji, 2000).

HIV+ women are more likely than HIV+ men to feel highly stigmatized and ashamed of their HIV status (Green & Sobo, 2000). Women’s home-based role in society increases their vulnerability to neighborhood stigma (Green & Sobo, 2000).

Despite the evidence that stigma exists in society and social relationships are commonly disrupted by HIV diagnosis (Green & Sobo, 2000,) women in this study reported few incidents of actual personal stigma experiences. Of course, when a stigmatizing experience occurred, it had a great impact on them and influenced them by decreasing disclosures. Women may be feeling and fearing more stigma than they actually experience from stories they have heard about other people with HIV/AIDS via observations, stories told by health care providers, or friends (Moneyham et al., 1996).

Moneyham et al. (1996) found four different stigma-related perceptions: distancing, overgeneralizing stereotypes, social discomfort, and pity. Distancing refers to the HIV+ women’s belief that others want to keep a social distance from people with HIV. HIV+ women also believed that society saw all HIV+ people stereotypically, as drug users or women who are promiscuous; Green and Sobo (2000) found this as well. Social discomfort was felt when people who knew about the woman’s HIV status changed their behaviors subtly yet pretended overtly to be okay with her status. Pity refers to how people they disclosed to felt sorry for them (Moneyham et al., 1996). All four themes were also found in this study. They have also been found in more general HIV/AIDS stigma research (Alonzo and Reynolds, 1995).

Alonzo and Reynolds (1995) developed a four stage HIV/AIDS stigma trajectory: (1.) At risk, before people have been tested but suspect they may have HIV; (2.) Diagnosis, where people’s identity must incorporate being HIV+; (3.) Latent, where people are still fairly healthy; and (4.) Manifest, where a person develops AIDS. Women
in the current study had all been diagnosed, and most seem to hover somewhere around
the diagnosis and latent stages. Diagnosis with HIV means incorporating it into their
identity and struggling with whom to tell (Alonzo and Reynolds, 1995). In the latent
stage the woman has come to terms, more or less, with her new identity and now must
continue to make disclosure and/or concealment decisions (Alonzo and Reynolds, 1995).

Women in this study did struggle with the disclosure issues identified for the
latter two stages of the stigma trajectory. However, Alonzo and Reynolds’ (1995)
trajectory incorporates a health continuum along with a disclosure process. Many women
seem to have reached the health-related aspects of the manifest stage before or during
diagnosis. Most concealed their status during times of severe illness and eventually
returned to the disclosure processes identified in the diagnosis stage once their health had
stabilized.

Women seemed to have three styles of disclosure: open, limited, and private,
although almost every woman had her own rationale and timing for disclosure or non-
disclosure of her HIV/AIDS. Disclosure decisions varied with a woman’s personality,
health, fear, community type, and the openness and accepting natures of other people in
her social network. African-American women seem to fall more into the private category,
as do Caucasian women from smaller communities.

Disclosure, while it carries the risk of losing important relationships, also has the
potential to strengthen relationships (Green & Sobo, 2000). While women were fairly
straightforward about their losses, whether losing the relationship or having it negatively
altered, they did not directly indicate whether any of their relationships had improved.
They reported relationships with parents and children may have become more intense, as
others needed to become care-givers or at least try on that role. While concern and
understanding from important people were appreciated, this concern sometimes felt
smothering.

Disclosure about her status did change a few women’s relationships with family
and friends. A few women noted they lost friends, and others had a few family members
who kept a distance after HIV disclosure. After a bad experience, a woman may isolate
herself to minimize the chance she will get hurt again. Losses are painful. Women’s
experiences varied; some had all positive disclosure experiences; others had mainly negative ones. There is enormous fear here; women are afraid that their children will not let them see their grandchildren, that they will be fired, or that others will look down on them. Other women do not disclose to protect loved ones; studies have found that people may discriminate against others in an HIV+ person’s social network (Green & Sobo, 2000; Reynolds & Alonzo, 1998).

No woman interviewed appeared to be socially isolated due to her HIV/AIDS status. Green and Sobo (2000) found that, contrary to popular assumptions, HIV+ people’s social networks do not necessarily shrink after disclosure. While rejection does happen, it does not appear to be the norm; a clear gap exists between beliefs about rejection and reality (Green & Sobo, 2000).

Most studies on stigma, disclosure, and social relationships have been done with male subjects. Green and Sobo (2000) found HIV+ women tended to have larger and closer social networks than HIV+ men; however, like the women in the current study, their female participants reported higher levels of stress due to care-giving, friendship, and romantic relationships.

In a study of HIV+ women’s decisions to disclose, the majority of women had disclosed to close family and friends, some sex partners, and health care professionals (Sowell, Seals, Jimlips, and Julious, 2003). Disclosure was found to be very difficult for some women. Three categories about how women made disclosure decisions were found (Sowell et al., 2003). Full disclosure meant telling everyone in the social network, even new acquaintances, about her HIV status; this was not found in the current study. Criteria for disclosure was a more common method of disclosure; women chose to disclose to people to whom they were closest or who needed to know, if they felt an accepting relationship with the person, and if they thought the person could keep the information confidential (Sowell et al., 2003). Most of the women in the current study used these criteria and this strategy as well. Emotional disclosure was the second most-common disclosure strategy and was based also on how close they felt to someone as well as feeling or trusting through prayer that this person could be told (Sowell et al., 2003). Women in the current study used this strategy less frequently than the criteria.
Most women disclosed during the first week after diagnosis (Sowell et al., 2003). The current study indicates most women waited a few weeks or months before disclosure occurred. Almost all women in the Sowell et al. study (2003) had disclosed to their health care providers. Women in the current study expressed serious reservations about disclosing to non-trial health care providers. Also, the Sowell et al. (2003) study included very few non-disclosers, which the current study did include.

Women seemed to think their trial participation had a minimal impact on their social network. In the literature, women cite family concerns and responsibilities as reasons not to participate in trials (Denenberg, 1990). Here, women just worked appointments into their schedule. Of course, most women interviewed had grown children, but some did still have care-giving responsibilities that they worked around. Women with care-giving responsibilities were very concerned about infecting their children and/or grandchildren. One woman remarked being with her grandson provided her with stress relief and gave her time to clear her mind. This is also unexpected, given the literature, which tends to focus on children solely in terms of competition with a trial for the woman’s time and energy. One reason for the discrepancy may be the older age of participants and the fact that only a few had child-rearing responsibilities.

Interpretation and Meanings

Women’s interpretations of the trial were tangled up with their interpretations of being HIV+. In the interview, women did not seem to agonize over the decision to participate in a trial, perhaps because the decision was so easy. Many women see trial participation as a lifeline, which goes against the reductionist approach of the trial as a solely scientific experiment. The lifeline metaphor seems very apt and relevant, given the data. The lifeline metaphor is detailed in Figure 5.5.
Context of Most Decision-Making

Figure 5.5: Trial Lifeline
In terms of meanings, some women come back to altruism; that is, trial participation is meaningful in that they are contributing something to the existing HIV/AIDS research. A few women tied that in with their spiritual beliefs; they feel their lives are to serve and see trial participation as service. It is worth noting that even though women express a desire to help, many of them frame that in terms of finding a cure; it was implied usually that that cure would eventually benefit them, too.

Many studies have shown that altruism is a common reason for clinical trial participation (Piroth, Callerot, Grappin, Duong, Buisson, Poertier, and Chavenet, 2001; Schrooten, Borchert, Dreezen, Baratta, Smets, Kosmidis, Goebel, Wilkins, and Colebunde, 2001; Sengupta et al., 2000). However, it was a secondary reason for women interviewed in this study. A study of African-Americans found over 80 percent felt that altruism was either a “very” or “extremely” important part of their decision to participate in a clinical trial; altruism was more important to those participants than personal benefit (Sengupta et al., 2000).

The search for meaning out of the trauma of being diagnosed with HIV may lead to trial participation, where individuals can contribute to society and create a positive social aspect of their HIV positivity (Piroth et al., 2001). A few women interviewed spoke of wanting to give something back and needing to know they could contribute something useful out of their diagnosis; however, none fully articulated the social link. As stated before, in contrast with other research, neither altruism nor a search for meaning was their main motivation for participation.

Defining or explaining a clinical trial was a difficult cognitive task for these women. Most of them compared it to standard doctor’s care, which is disconcerting because, again, they seem to miss the experimental nature of the trial. Sometimes women said it was a “study” or “research,” but there was no follow up to see what those words meant to them. At the time it was assumed the interviewees thought the same thing as the interviewer did, undoubtedly a mistake. Nothing in their explanations of the trial fit with an understanding of how scientists view “research.” This question was asked of all of the first interviewees, then as time permitted, as it seemed to tax and quiz women more than it resulted in useful information. Informed consent requirements indicate that a
participant ought to be able to explain her trial and its implications (Schrooten et al., 2001). Perhaps the stress of diagnosis and/or the complicated nature of the trial regimen make this impossible or unlikely for many participants.

Women were also somewhat divided on whether the trial was a big part of their lives. For one woman whose meds gave her awful side effects, the trial meds were an enormous part of her life, because her diarrhea set her schedule. Other women said the only time they thought the trial was part of their lives was on days they had clinic appointments. Often women thought it was a bigger part of their lives earlier in the trial and became less so over time.

These two different ways of thinking about the role the trial plays in a woman’s lives could be due to the question (‘Is being in the trial a big part of your life?’), which should be reworded if used in future research, based on what was learned during the interviews, that for some women, the trial was a shot at life. Some women seemed to believe it was their only shot at life. Interviewee 3 mentioned specifically that she joined the trial to stay alive. It seems very sad that experimental research is some women’s lifelines, as clinical trials often are lifelines only for people who have burnt out on all the available therapies. Most women in the study had never been on antiretroviral regimens and could have received optimal, personalized care through a physician or clinic.

Another important point is that while no cognitive processing was found in the initial decision-making process, women were able to identify benefits and barriers to continued trial participation as summarized in Appendix H. This suggests more of a danger control model, as the threat of death is perceived to be lessened once participation is under way. This may also be the result of a secondary appraisal (Witte, 1998). Also, women were aware they had the option of quitting their trials, but only one of them had really given it some thought.

Although they were able to articulate these benefits and barriers, most were thrown into a state of confusion and uncertainty when asked about a new threat, life after their trial ended. It appeared most hoped that another trial for which they would be eligible would come along and “rescue” them. Women do not appear to have a mindset or motivation to seek out other options, even after discomforting emotions ebb. If a
cognitive component is lacking in the initial decision-making process, women may instinctively fall back upon this mode of engaging emotion rather than cognition when faced with a decision about what to do when their trials end. Women appeared to cling even more tightly to the trial lifeline when thinking about the future.

Receiving primary care from the trial clinicians may feed into the women’s dependence on the trial and make it doubly difficult for her to envision a future without it. Most women in this study either had no regular care when enrolled or replaced their primary care with that offered by trial staff. Only a few had health insurance, which limits their other health care options. While it is more convenient for women, it also may reinforce their blinders and obscure other options.

This data also speaks to the issue of trial benefits being so numerous and important as to be coercive. If one has no health care and has been diagnosed with a disease about which one knows nothing, as was the experience of most of these women, can one reject participation in a clinical trial? Interviewee 3 reported that she “couldn’t say no” to participating in another trial after hers ended; she had no other options.

The idea of staff’s implicit understanding of this emotional decision-making process is intriguing. If clearly presenting information in a way that “forces” women to engage cognitively is not rewarded by increased accrual, recruitment staff members may unconsciously shift their strategies to focus on affect rather than thought. Llewellyn-Thomas et al. (1991) found that people who refused entry in a clinical trial demanded a greater amount of treatment benefit and more active participation in decision-making; they also noted the possible negative effects of fully informed consent on accrual. It could be that when cognitive engagement by the potential participant is high, recruitment efforts are also high, thus placing more demand on staff members and increasing the likelihood that participants will choose not to join.

As this study only included women who chose to join clinical trials, data do not speak to whether women who chose not to join do or do not see clinical trial participation as a lifeline. This raises other issues, such as where women not in a trial access care, whether they react emotionally or cognitively or both to their diagnosis, and how they located other treatment options.
Summary

Overall, women appear to be satisfied with their clinical trial experience; it met their needs. They were able to successfully integrate the trial into their lives. The provision of care in a trustworthy and comforting manner may be part of the reason women decide to stay in clinical trials. It appears difficult and possibly artificial to extract the clinical trial experience from women’s life stories. The context of her life is critical; it is doubtful quantitative research would have captured many of these findings.

Hypotheses Generated

The following hypotheses about HIV+ women’s experiences in a clinical trial are generated by the data:

- Trial participation is a positive experience for HIV+ women.

- The decision to stay in a trial involves weighing pros and cons.

- African-American women disclose their HIV/AIDS to fewer people than Caucasian women.

- Spirituality and religiousity impact how well one deals with a positive HIV test result.

- Trial participation can become a lifeline for women who do not know of any other programs providing free HIV-related health care and medications; women may repeatedly participate in trials potentially providing them with sub-optimal care because the trial system becomes familiar and comforting.
Implications and Recommendations for Practice

Both explaining and understanding HIV/AIDS clinical trial information are very complex tasks (Katz, Dutcher, Toigo, Bates, Temple, & Cadden, 2002). The amount of information women take in at their initial consultation and subsequent visits overwhelms them. Going over the details of the trial, their other options for treatment, and the consent paperwork slowly and repeatedly and encouraging questions at every trial visit in case the woman forgot something important may help them gain a better understanding of their trial. Work by Schwartz and Clore (1983) implies that if women discuss their fear in the initial information session, they might be able to make participation decisions more clearly.

An HIV-related pilot study has demonstrated successful retention of knowledge and increased understanding of the protocol process (Coletti, Heagerty, Sheon, Gross, Koblin, Metzger, and Seage, 2003). Coletti et al. (2003) used a protocol with verbal and written consent, an informational booklet, and discussion of the concepts with a staff member. Their protocol resulted in a statistically significant and substantial increase in participant knowledge of key concepts, such as double blinding and the possible effects of the trial vaccine. Videotapes like *HIV/AIDS clinical trials: Knowing your options* could be watched during the information session or given to participants with TVs and VCRs to take home (AIDS Clinical Trials Information Service, 1996).

The HIV+ women interviewed did not focus on the experimental nature of their clinical trials. They each seemed to fully expect personal health improvements. Perhaps more focus ought to be placed on this at the beginning of the information session. Indeed, they held out their improvements in T-cell and viral load counts as validation of their decision to join the trial!

Some women feel very comfortable and safe within a more traditional, paternalistic model of care (Charles, Whelan, & Gafni, 1999). Without discounting that, it is also necessary that staff give a woman every opportunity to be more involved in her own care. Because women report a strong rapport with their trial nurses, the nurse is in a position not just to be a patient advocate, but to teach female participants who are
interested to advocate for themselves (Sadler, Lantz, Fullerton, & Dault, 1999). It is also noteworthy that another study of HIV+ women discovered that female patients’ lack of assertiveness and agency was due to feared retribution, such as care refusal, from health care providers (Misener & Sowell, 1998). While there is no evidence this is the case with these women, it cannot be ruled out as a conscious or unconscious fear.

As trial staff members are often the woman’s main or only source of health care, a wide range of responsibilities fall upon them outside the trial itself. Nurses especially are called on to be experts in a number of areas outside strict clinical care (Sadler et al., 1999). Nurses are able to reassure women and provide education when necessary. A little education on some basic health topics and social interaction could make a big difference in some of these women's fears. These women, who have the best HIV/AIDS care in Ohio, lack some basic knowledge like knowing the difference between HIV and AIDS. Other research has shown that providers may give health information in general, but provide limited information about HIV/AIDS (Misener & Sowell, 1998).

Because women and their families do rely on her counts to track her health, more education about what the numbers mean would be valuable to them. Also, the faster the results can be processed by the lab and reported back to the woman, the better. Along the same lines, periodic reminders about trial details like how much longer their trial is scheduled to stay open along with providing options for their care and access to medications after the trial ends may decrease client fear and uncertainty. Staff should also be clear and consistent about whether participants can continue to receive free care at the unit after the trial ends; women had conflicting ideas about this during the interviews.

Reiter et al. (2000) provide a list of topics they believe patients should be taught before beginning any antiretroviral therapy. This list includes: how HIV is transmitted; how HIV replicates and affects the immune system; how CD4+ cell counts demonstrate immunosupression; how antiretroviral medications affect viral load, CD4+ cells, and disease status and survival; what commonly performed laboratory tests are and what they mean; and the time necessary to have laboratories process the tests (Reiter et al., 2000). Women in this study often lacked knowledge of some or most of this fairly basic
information. Incorporating it into short intervals spread out over the first several sessions, using the woman’s own information as a teaching tool, would benefit clients.

Role plays and problem-solving skill building exercises might be a creative way to continue helping women overcome adherence challenges (Johnston-Roberts & Mann, 2000). It may also be of use in discussing disclosure issues.

Providing patient education about disclosure to non-trial related staff and coming up with non- or less threatening ways to disclose is important. Trial staff also should remember to tell balanced stories about disclosure when counseling, to talk about the positive and negative aspects of disclosure to family and friends. Women here report being very afraid to disclose based on some stories health care providers told; while disclosure is ultimately a woman’s decision, she can be swayed by what she hears. Sowell et al. (2003) recommend health educators assist women to realistically appraise stigma and base disclosure information appropriately.

Moneyham et al. (1996) recommended support groups for women with HIV to discuss stigma and disclosure issues with their peers and a counselor. This would also seem to be useful for women in Columbus and Cincinnati. Empowerment training, in conjunction with peer and provider support, may increase quality of life and improve coping skills for female trial clients (Squires, 2003).

Women reported being very stressed, both by beginning the trial and by other life issues. High stress levels have been associated with more rapid progression to AIDS (Squires, 2003). Routine referrals to existing stress management resources might help those women who are overloaded and need some help. One woman was thrilled to have the list of mental health resources provided to Columbus participants so she would know where to go if she wanted some counseling.

A number of aspects of the clinical trial experience were found to be very positive and might be useful in other trial unit locations. Staff worked with women to improve adherence; the importance of adherence is commendable and appears to have been impressed upon the women interviewed. Much of the data wound up concerning factors that influenced their decisions to remain in the trials, which may be pertinent for trials with high drop-out rates.
Almost without fail staff were spoken of as being friendly, concerned, accessible, and involved with women’s lives in general. A few women spoke of their trial staff almost reverently. There can be no doubt that relationships with staff are one of the reasons women chose to stay in their trials; women said staff members would go out of their way to make things with the trial easier for them. Staff encourage family and friends to come to clinic visits also; this not only gave the women the opportunity to have support during the visit but friends and family had the opportunity to ask questions and be reassured. One of the highlights of women’s appointments was their chats with their nurses near the end of the visit.

As the findings indicate, women interviewed were very satisfied with their clinical trial experience. Almost all women interviewed said they would recommend joining a trial to other HIV+ women without hesitation. Women currently in HIV-related clinical trials could be trained to be peer counselors for women considering entry into a trial; women who have joined a trial might be able to impart new information slowly. Peer counselors would have less conflict of interest than initial nurse or physician recruiters.

A policy implication of this research is that women need other options and more awareness of existing programs in order to make clinical trial participation truly voluntary and informed.

Reflections/Limitations

This section explains lessons learned for future research. While all of the changes mentioned below reflect an ideal research project, many of the processes actually used in this research are routinely used in the field.

Limitations of this study include the strictly informal data analysis that occurred during the data collection period, the interviewer’s rough interviewing skills, tape-recording equipment issues, sub-optimal number of reflections and field notes, and transcription procedures. There are also limitations due to the study design.
Grounded theory, as well as other qualitative designs, relies heavily on the interplay between data collection and analysis (Strauss and Corbin, 1998). Preliminary data analysis informs the future structure, focus, and wording of the data collection protocol for future interviews (Strauss and Corbin, 1998). In this study only informal analysis was conducted during the data collection period. The interviewer reflected on the interview, what misunderstandings occurred, what surprised her, what new information was learned, and which themes from previous interviews were repeated. None of this was documented as data analysis, and no written changes were made to the protocol as a result of previous interviews. Interview probes may have changed, but again, this is only documented in the transcripts.

The interviewer had limited experience in interviewing using a semi-structured questionnaire protocol, and she made mistakes while asking questions. Many dichotomous questions were asked. Leading probes were used. Many biased and non-neutral comments were made to interviewees; most were used to express sympathy or admiration for the interviewee. Control of the interview was lost at times, although during all interviews the 90 minutes allotted left time for both the interviewer to ask about each question domain and for the interviewee to just talk to someone about a sensitive topic like their HIV and focus on what they needed to express.

I did not realize how much tension I would feel between collecting this data and trying to comfort and empower the women interviewed. Also, I was not aware of how difficult it was to stay neutral throughout the interview without violating the social norms of a regular conversation. After discussing this issue with committee members, I decided to tell them how strong they were at the end of each interview, rather than feeling I needed to constantly jump into the conversation and reassure them.

Many tape-recording errors were made, which limited the usefulness of some data. Interview 1 was taped using a back-up tape recorder, as the interviewer did not check her primary recorder until the day of the interview, when she discovered it was not working. The sound quality was not good, and despite fairly comprehensive after-the-fact field notes, some data was lost. Another tape recorder was borrowed until the interviewer could purchase a new tape recorder specifically for this project. After about 15 minutes
into interview 4, the batteries in the recorder died; the interviewer did not understand what the blinking light meant. However, the tape was checked after the interview, and again, ‘salvage’ field notes helped to piece together the information shared.

Some data was also lost when the tape recorder purchased automatically flipped over. Occasionally, respondents would hear the tape flipping and stop talking for a few seconds so little conversation was lost. More often, about 5 to 10 seconds worth of data was lost per tape.

Reflections and field notes were not done for each and every interview, or if they were done they were not always filed appropriately, resulting in a loss of reflections and notes for some interviews. The interviewer is still learning how to focus on the interviewee and jot down field notes at the same time, and the quality of field notes taken during the interview, when made at all, varied wildly. Usually, at the very least, demographic characteristics, the interview number, and the names of the interviewee’s medications were jotted down. Probably no interview was represented by comprehensive field notes. On several occasions the interviewer would do two to three interviews in a day and not have time to take more detailed notes down after an interview; that night, the interviews often would blend together in her mind. Writing up notes as soon after an interview is completed allows both the recording of details while still fresh in the interviewer’s mind; it also allows for the beginning of analysis, as one can identify new and relevant probes, unclear issues, and discrepancies and similarities between interviews.

Ideally, all the interviews would have been transcribed either by the professional transcriptionist or the interviewer instead of the piecemeal approach taken when the interviewer realized she was too busy to transcribe them all herself and gave some interviews to the professional transcriptionist. Also, the delay in transcription was problematic and hindered the repetitive nature of data collection and analysis as discussed above. Some interviews were transcribed several months after the interview took place, which is clearly less than ideal.

The lines between an interview and a therapy session were unclear during many interviews. This can be confusing for a novice interviewer who has no formal training in
counseling or psychology. Many transcripts show the presence of biased remarks by the interviewer attempting to comfort or cheer the interviewee, especially in the beginning of this study.

Likewise, it was very difficult for me to separate my interviewer self from my health educator self. Eventually, I settled on a system where I would only answer questions about HIV/AIDS when directly asked by the interviewee; after the interview, I often answered questions that had been voiced earlier in the interview, such as what the difference was between HIV and AIDS.

Asking each respondent if she would be available by telephone later on to verify information in the interview, in event of losing data or not being able to understand a particular section of the tape, would have been enormously helpful during and after the transcription process. Also, clearly and directly communicating with trial staff who assisted in recruitment about what characteristics made a woman eligible would have been helpful, although the opportunity to talk to women who received care without being in a trial added a different perspective to this research.

In addition to methodological and procedural limitations, there are also more traditional limitations to this research. While attempts were made to recruit the entire population of HIV+ women enrolled in antiretroviral clinical trials in Columbus and Cincinnati, it is possible that respondents differed from non-respondents. While the data were similar to the non-eligible women, the results do not apply to women enrolled in other types of trials, nor women receiving non-trial care at study sites.

Due to the need for confidentiality during the recruitment process, the interviewer was unable to recruit women directly. Nurses at the clinic site recruited participants instead. The advantage of this approach to recruitment was that it gave the interviewer credibility by being sponsored by the trial staff; it also preserved the participant’s confidentiality. It is unknown if the nurses implied the interviewer was associated with the clinic or if they chose specific women with whom to discuss this study. The interviewer did get a few comments about ‘Oh, So-and-So, she’ll be a good one for you to talk to.’ Thus, these women may inherently differ from other women in clinical trials
at these same sites. Women who were very satisfied may have been chosen by nurses to participate in this study more often than women who were less satisfied. Results may be biased in a more positive way due to the recruitment procedures.

Likewise, findings from this group of women may not represent the experiences of women in trial elsewhere. As a result of the eligibility criteria, these results are only applicable to women enrolled in antiretroviral clinical trials. It is also worth noting that selection bias may affect results, as only women who had decided to join a trial were interviewed. Women who decided not to join a trial may have had very different contexts and experiences.

Qualitative research of this type has some limitations. This data is based on interviewee perceptions and recollections and may be subject to recall bias and social desirability bias. The data consists entirely of self-report data, which is appropriate for perceptions and attitudes; however, corroborative data for actual behaviors was not collected. Missing from this data are the providers, an important group in the patient-provider interaction, which made up a large amount of the data. While the interviewer has a basic understanding of clinical trials, her deliberate naivety during the interview process may have resulted in less optimal data, as probes were very general.

Feminist research suggests the interviewer’s class, gender, race, and culture may have shaped these interviews (Harding, 1987). It is unknown exactly what effects the white, upper-middle class, Anglo-Saxon female interviewer may have had on the interview process and content. The interviewer was similar in ethnicity and background to about half the respondents; African-American women or economically disadvantaged women may have restricted the information they shared, figuring the interviewer could not relate to their situation.

Another area of interviewer effects is age. The interviewer was 27, which may have facilitated a dynamic where the interviewees, all older than the interviewer, felt free to correct her and switch conversation topics to something that interested them more. This did not seem to be detrimental to the data gathered, and it may have been advantageous by allowing the interviewee more power to guide the interview and more “permission” to state her thoughts and feelings clearly.
This research is based on a single interview conducted at each woman’s stage in trial participation. While this was useful in gaining an understanding of the general flow of the trial experience, it also means this study is subject to the standard limitations of cross-sectional research. However, respondents represented different groups in terms of race/ethnicity, age, transmission status, length in a trial, previous trial experiences, and education. That common themes were found in all interviews added credibility to the findings.

Findings were based on the women’s reports of their decision-making processes and of their lives in general; interpretations of these data and conclusions ought to take the subjective nature of one’s reality into account. Data analysis was based on the assumption that women meant what they said; detailed hermeneutical analysis was not performed, although it could be in the future, due to the inexperience of the investigator with this technique. Only the obvious “not-said” was analyzed.

There is also the possibility of recall error, as time had passed since many of the women interviewed made the decision to join a trial. Following women throughout their trial experience would limit recall error in future studies. Use of triangulation would be desirable in future studies of this topic, as would interviews with trial health care providers for a more complete view of the trial experience. Using case study methodology might have been more appropriate and useful, although it would probably have meant fewer, yet more in-depth interviews.

**Suggestions for Future Research**

If women know about their options, deem them too troublesome (as one woman did with her Bactrim), and opt to join a clinical trial because it is somehow less trouble, is that an informed decision? What if women never really hear their options in the first session? They may be burnt out; they may be too scared to pay close attention; they may well make up their minds as soon as they hear the word “free.” This is troublesome for
investigators. Discussion of this topic would prove beneficial, as the ethical implications of informed consent violations are very important to the HIV/AIDS scientific community at large.

Conducting a focus group of trial staff to investigate their ideas about the role of affect in trial recruitment and their strategies would add greatly to the current research. Trial staff members were one of the most important facets in the decision-making of women who received pre-trial care; more knowledge about their referral mechanisms, information sessions, and means of rapport building would add to the perspectives of the women in this study. Investigating their needs to support all their roles, like nurse, social worker, and health educator, would provide a better means of understanding the critical role staff members play in holding a trial together.

Conducting a case study of one to three women through their trial experience to examine in-depth the decision-making framework would perhaps negate time as a confounder. Recall bias would be lessened as well; this would elucidate if women’s decision-making narratives were retrospective re-constructions justifying their decision or if factors in the framework were the most important elements in deciding to join a trial. Furthermore, significant others could be interviewed to determine if trial participation truly does not impact a woman’s social network, as the results of this study suggest.

Qualitative research with men and women in clinical trials to investigate decision-making differences and commonalities in emotion-based versus cognition-based decision-making is necessary. As most of the literature is based on the experiences of men, it is possible that men and women make decisions about joining trials differently. Conversely, it may be that men just have never been asked much about their feelings regarding entry into a clinical trial.

Factors influencing an HIV+ woman’s decision to disclose or not to naïve health care providers has potential prevention implications. Also, this was a source of uncertainty and stress for many women in this study, and guidelines about when and how to best disclose to other providers could remove this piece of uncertainty.
Summary of Key Dissertation Findings

While the decision to join a clinical trial may have been framed in previous research as a cognitively-based decision, this study provides evidence that affect may influence this decision more than the information provided to potential participants. Furthermore, the information provided to women joining clinical trials may not be processed at all, due to high negative arousal, lower educational levels, and high levels of trust in the trial providers. This leads to questions about the validity of informed consent procedures meant to protect participants in experimental research.

Many of the women interviewed, who receive the best HIV-related care Ohio’s public sector has to offer, were still ignorant about many of the basic facts about their disease. Most had no idea what HIV/AIDS’s symptoms were. This implies educational campaigns designed for women, urban and rural, are either non-existent or ineffective. Public education is a necessity, not only for prevention, but also for the edification of women living with HIV/AIDS already.


Sherer, R., Stieglitz, K., Narra, J., Jasek, J., Green, L., Moore, B., et al. (2002). HIV multidisciplinary teams work: Support services improve access to and retention in HIV primary care. AIDS Care, 14(suppl. 1), S31-S44.


Appendix A
Glossary

IDC: Infectious Disease Clinic

ACTU: AIDS Clinical Trial Unit

ADAP: AIDS Drug Assistance Program, a program to help economically disadvantaged HIV/AIDS patients get their medications.

ARV: Anti-retrovirals, a class of drugs that inhibit HIV replication.

HIV: Human Immunodeficiency Virus

AIDS: Acquired Immunodeficiency Syndrome

Viral load: Measures the amount of the HIV virus is in the blood.

T cell: Immune cells particularly susceptible to HIV.
Appendix B
Interview Protocol

Note: Questions that aren’t indented at all indicate content areas that I want to cover during each interview. Questions that are indented are possible probes. Women will be in different stages of the clinical trial experience, so questions will be framed in terms of each woman’s stage. Content area(s) that the question is intended to get at appear bolded and in parentheses.

Thank you for agreeing to participate in this interview! The purpose of this interview is to learn more about HIV-positive women’s experiences in clinical trials. This interview will last about an hour to an hour and a half. You do not need to respond to any question that makes you feel uncomfortable.

I will be audio taping our conversation and taking brief notes as we speak. By agreeing to participate in this interview, you are also consenting to this interview being taped. Written records of the interview will not have your name attached to it. No one will be able to identify who was interviewed. The tape will be erased after I listen to it to make sure I’ve written down our conversation correctly.

I want to assure you that your participation in this interview is completely voluntary, that you can choose not to answer any question, and that you can end the interview at any time. If you do agree to participate, please complete this consent form. You will receive $30 for participating in this interview.

Do you have any questions before we begin?
I want you to know that I really appreciate you sitting down with me so that we can talk about HIV and your experience being in a clinical trial. I know that HIV is a very personal thing to talk about, so as we begin I’d like to remind you that you don’t have to answer any question that makes you uncomfortable.

1) Why don’t we begin by talking a bit about your HIV? How did you first find out you had HIV?
   - What year did you test HIV+?
   - Do you know how or when you were infected?
   - Do you have symptoms from HIV?
   - Tell me about your health in general.
   - Have you been diagnosed with AIDS?

2) Why do you come to the OSU ACTU/UC IDC?

3) Let’s talk for a bit about your experience at the OSU ACTU/UC IDC…
   - How did you find out about the ACTU/IDC?
   - When did you start going here?
   - What medication are you taking?
     - For the trial?
     - And apart from the trial?
   - How often are your appointments here?
   - How long have you been in this trial?
   - How much longer will the trial last?
   - Why are you in this trial instead of other trials they have here?

4) How did you decide to come to the OSU ACTU/UC IDC?
   - How did you find out about the trial?
   - What things or people made you think about being in a trial?
   - What were the good things about participating?
How does the staff make participating easier for you?
What were the bad things about participating?
Whose opinions did you think about?
Have you been in a drug trial before?

5) How have your religious or spiritual beliefs played into your decision to be in a trial?

6) When did you make the final decision to participate?

7) In your opinion, what is a clinical drug trial? I’m most interested in your definition.
   What comes to mind when you think of a clinical drug trial?

[In case they ask me, this is the most user-friendly definition of clinical trial I’ve found. An HIV/AIDS clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective (ACTIS, 2001).]

8) Let's talk for a bit about the trial drug...can you describe how you take it?
   Do you take it with food?
   How often do you take it?
   Does it have a taste?
   What side effects have you noticed?
       How disruptive are those side effects?
   How convenient is the regime?
   Are you able to take the meds the way people tell you to?
   How has it affected your health in other ways?
   Could it be a placebo or non-active pill?
9) What do you think about your personal information being kept at the ACTU? Do you worry it might be misused?

10) What are some good things about coming to a clinic just for people with HIV/AIDS?

11) What are some bad things about coming to a clinic just for people with HIV/AIDS?

12) Let's talk for a minute about your family and friends…who are the people that you're closest to?
   
   Who knows you have HIV?
   
   Who do you take care of?
   
   Do you want to have more children?

13) Can you tell me how your family and friends feel about you participating in this trial?

14) How do you think participation in this trial has changed or will change your relationships with family and friends?

15) How many of your friends or people you know have been in a trial?
   
   Sometimes people tell stories about things like being in a trial. What stories had you heard like that?
   
   What kind of information did you and your friend(s) share about trials?
   
   Who do you talk to about the trial?
   
   What kinds of things did you say to them?

16) If an HIV-positive friend asked you if she should be in a clinical trial, what would you tell her?
   
   Why?
17) I’m really interested in what it’s like for you to participate in a clinical trial? Can you describe that to me in your own words?

   How does it fit into the rest of your life?
   Describe to me how it affects your daily life?
   Is being in a clinical trial a big part of your life?
   Are you able to do everything you need to do during your day?

18) Where do you usually go for health care when you're sick or need a check-up?

   Do you see the same doctor and nurse?
   What do you think of those people/that place?
   Do they communicate with the people here at the clinical trial unit about your medications or general health?

19) How do you think participation in this trial has changed or will change your relationships with your regular doctors and nurses?

20) BEFORE you started this trial, were you feeling well enough to do everything you needed to?

   How did your health then compare to your health now?

21) Can you tell me how you make an appointment to be seen here?

   Can you usually make it to your appointments here?

22) Can you share with me a time when you just really wanted to drop out of the trial?

   Imagine a time or an event that might make you want to drop out of this trial.
   What would that be?

   Why did you choose to remain in the trial?

   If you ever have dropped out of a trial, what was that like for you?
23) Pretend I could give you a magic wand that would change one thing about your experience being in this trial so far. Tell me about what you would change.
   Why?

24) Would you participate in another clinical trial?
   Why or why not?

Lastly, I'd like to ask you some questions about yourself…
   How old are you?
   What is your marital status?
   What is your racial/ethnic background?
   What was the last grade in school that you finished?
   Are you currently employed?
      Full or part time?

[Summarize basics points of interview.] How accurate was my summary? What did I leave out? What else might be helpful for me to know about or ask about next time?

Thank you for being a part of this research! I really appreciate it!
A Priori Coding Scheme

Patient characteristics
  Substance use
    Alcohol use
    Alcohol frequency
    Illegal drug use
  Sociodemographics
    Age
    Education
    Employment status
    Racial/ethnic group
  Disease status
    Symptomatology
      Type of symptom
    Immunologic status
      Diagnosed with AIDS

Other psychosocial factors
  QOL
  Religious/spiritual beliefs
    Affect on trial participation
  Self-efficacy/Adherence
  Reproductive decision-making
Patient’s social network

Quality

Demands

Caregiving responsibilities

Supports

Undermining

Stigma

Accidental disclosure

Components

Family

Friends

Clergy

Trial support

Patient’s perceptions of the clinic, trial, & treatment regime characteristics

Regime duration

Regime complexity

Side effects

Type

Frequency

Perceived efficacy of treatment

Knowledge of trial regime

Intent/ability to adhere

Perceived costs of regime

Incorrect dosages

Drug resistance

Convenience

Toxicity

Perceived benefits of regime

Improvements in personal health
Sense of well-being
Incentives
Types
  Free therapy
  Free health care
Value/meaning
Transportation
Child care
Clinical environment
  Description
  Feelings
Scheduling
Confidentiality
Fertility management
Feelings about trial

Patient-provider relationship (with trial staff and/or primary HEALTH CARE PROVIDER)
  Patient's perception of HEALTH CARE PROVIDER's technical skill
  Affective tone of relationship
  Communication
  Overall satisfaction
  Referral process
Appendix D
Revised Coding Scheme

Coding Structure

*Items to sort interviews by (don’t use to code)*

**Admitted former substance abuse**

**Sociodemographics**

- Age, romantic relationship status, education, employment status
- Racial/ethnic group (African-American or Caucasian)

**Immunologic status**

- Diagnosed with AIDS
- Number of years since HIV diagnosis
- Number of years since AIDS diagnosis

**Codes (and abbreviations)**

**Interviewee characteristics (PC)**

- Community type (comm).
- Medical insurance (med ins)
- Disease status (ds)
Other psychosocial factors (OPF)

Stress
Religious/spiritual beliefs (rsb)
Death (dt)

Interviewee’s social network (PSN)
Privacy/disclosure

Perceptions of the trial
Regime
Side effects
Strategies/adherence
Change in counts
Fear/anxiety/uncertainty
Transportation and scheduling
Clinical environment
Confidentiality
Care provided
Technical skill
Communication
Trust, comfort, and affection
Referral process
Overall satisfaction
Improvements

Decision (D)

Other (O)
Appendix E
Revised Codebook

Codebook (26 codes)

Interviewee characteristics – anything related to patient characteristics not mentioned in codes below nor age, admitted former substance abuse, relationship status, education, employment, racial/ethnic groups, or trial site; must be important to research questions. Use also when women discuss their infection and diagnoses stories. For example, this code would be used when a woman talks about her children driving her to the trial unit.

Community type – used when interviewee mentions the type of community she lives in (physical or otherwise) in reference to the experience of being in a trial. For example, this code would be used when a woman talks about stigma and driving to a unit away from her rural community to get treatment.

Medical insurance – this code should be used when a woman refers to whether she has medical insurance, what it covers, and uncertainty about what her insurance covers. For example, this code would be used when a woman talks about having to disclose to her insurance company that she’s HIV+ to get benefits.

Disease status – used when her HIV or AIDS is discussed, except in reference to specific symptoms and side effects of medication. Do not use for counts. For example, this code would be used when a woman talks about her HIV symptoms.

Other psychosocial factors - anything related to psychological factors not mentioned in codes below or that are covered by social network codes; must be important to research questions. Use when a woman discusses depression. For example, this code would be used when a woman talks about readiness to change her behaviors once she joined the clinical trial.
Stress – anything related to the demands in a woman’s life that she has trouble meeting or is unable to meet. Also use when a woman specifically mentions she’s feeling stressed or something is stressing her out. For example, this code would be used when a woman talks about how thinking about how much she’d have to spend on meds once her trial ended stressed her out. Re-code most of QOL data here.

Religious/spiritual beliefs - anything related to a belief, whether positive or negative, in a higher power, like God; must be important to research questions. For example, this code would be used when a woman talks about how God helps those that help themselves (by taking medicines and being pro-active about her health).

Adherence – use whenever a woman talks about being able to take or not being able to take her trial drugs (or any HIV meds for the 2 non-eligible women) the way health care providers instruct her to. For example, this code would be used when a woman talks about what she specifically does to get her meds down her throat.

Death - anything related to death from HIV/AIDS or suicidal thoughts as a result of having HIV or AIDS. For example, this code would be used when a woman talks about how sick she was from AIDS-related infections and how close she thought she was to dying.

Interviewee’s social network – anything related to interpersonal relationships and/or the people of importance to or social structures that affect the HIV+ woman except trial staff. Use this code for information important to the research questions and when the code below are too specific or don’t apply to the construct/information being coded. This code may be used to gain a general understanding of the woman’s social network in general as well as how it may relate to the trial experience. For example, this code might be used when a woman talks about how she doesn’t have a minister to talk to about her HIV meds.

Privacy/Disclosure – Use this code when women talk about how they decided to tell people or not tell people they are HIV+, have AIDS, in a clinical trial, or are taking
HIV meds. Also use for experiences and/or consequences they relate or anticipate about disclosure. *For example, use this code when the interviewee talks about hiding her meds from her family. Re-code undermining here.*

Interviewee’s perceptions of the trial – anything related to the clinic site, trial components, or medicines. Use this code for information important to the research questions and when the codes below are too specific or don’t apply to the information being coded yet relate to the research questions. This code may be used to gain a general understanding of the trial in general as well as how each woman experiences it. Use when a woman describes what happens at her trial visit. *For example, this code might be used when a woman talks about how she fits her life around what’s required of her by trial participation.*

**Regime** – use for specific medication, duration, perceived efficacy of treatment, perceived costs of trial participation, perceived benefits of trial participation, and complexity of taking medications. Also use for whether or not meds may be placebos. *For example, use when a woman talks about how many times she takes Sustiva each day.*

**Side effects** – use for side effects (physical and mental) of trial medications. *For example, this code would be used when a woman talks about how Combivir gave her a rash.*

**Strategies/adherence** – use whenever a woman talks about being able to take or not being able to take her trial drugs (or any HIV meds for the 2 non-eligible women) the way health care providers instruct her to and what she specifically does to remember to take them and how she takes them. *For example, this code would be used when a woman talks about what she specifically does to get her meds down her throat.*

**Change in counts** – use when women talk about their viral loads or T cell counts – whether due to medication or before beginning therapy. *For example use when a woman says her viral load was a million and now is undetectable.*

**Fear/anxiety/uncertainty** – emotions that a woman experiences and reports as a result of her trial experience or imaging a future without trial access. *For example, use when a woman says ‘not being in a trial – the thought terrifies me.’*
**Transportation and scheduling** – how the woman gets to the trial or treatment site and how long it takes her to do so, as well as how often the woman comes to the trial site or makes contact with a trial staff member. Also refers to how appointments are made. *For example, use when the woman talks about the bus trip to the clinic. For example, ‘I make my appointments with my trial nurse Irene after she draws my blood.’*

**Clinical environment** – how the woman describes the physical set-up of the trial or treatment areas as well as anything relating to her comfort level being in that environment. *For example, use when the woman discusses how she feels about being in a waiting room with other HIV/AIDS patients.*

**Confidentiality** – any reference to the comfort or discomfort of the woman with any aspect of the trial or treatment experience in terms of accidental disclosure of her HIV/AIDS status. *For example, ‘One of the nurses called my boss and told him I was HIV+.’*

**Care Provided** – anything related to health care providers not mentioned below. Restrict use to trial staff or to disclosure of HIV status to other Health care providers or communication between trials staff and other Health care providers. *For example, use when a woman talks about how trial staff find out when she’s in the ER.*

**Technical skill** – how the woman feels about the trial nurses and doctors in terms of how well they treat her HIV/AIDS and manage her meds (study and others). *For example, use when a woman talks about leaving her GP to come to a trial site for specialized care.*

**Communication** – availability of Health care providers as well as level of communication, ie, lay versus technical jargon. *For example, ‘Sometimes they draw me pictures when I have questions.’*

**Trust, comfort, and affection** - use this code specifically for any mention of how the trial staff is or is not a part of the woman’s social network. *For example, use this code when a woman says she loves her research/trial nurse.*

**Referral process** – how the woman found out about the trial or treatment site. *For example, ‘My ER doctor told me they had free meds here.*
**Overall satisfaction** – how the woman sums up her trial experience (or the treatment site/staff for the 2 women not eligible). *For example, ‘It’s OK there.’*

**Improvements** – use for suggestions a woman makes about how the trial experience could be more positive and/or enjoyable for her. *For example, use when a woman suggests a call-reminder system for appointments.*

**Decision** – use this code when a woman talks about her decision to enter the trial. *For example, ‘I talked to my sister-in-law who told me trials are OK.’*

**Other** – anything not covered by above codes and that is important to research questions. Examples of issues that I have coded as other so far include: disclosure, uncertainty about their future after the trial ends, monetary incentives, placebos, hope for a cure, drawing blood, Children’s Hospital in Columbus (care and treatment), HIV symptomology attributed to age/menopause, legal issues about disclosure to other health care professionals, media, and medical education provided by the trial.
Recruitment script for research nurses

"Hello!

I'm inviting you to participate in a face-to-face interview about your experiences in a clinical drug research trial and how you decided to join one. I’d like to speak with you for a minute or 2 about that interview.

We are asking you to provide information and feedback that will help researchers understand how women like yourself feel about being in a trial and how it affects the rest of your life. Participation involves answering questions about yourself, your social circle, the trial you're in, and the health care staff at this Adult AIDS Clinical Trial Unit.

The interview will take between 1 to 1 1/2 hours of your time and will be audiotaped so the interviewer can go back and listen to the interview to make sure your comments are correct. You will receive $35 for participating in the interview. You can refuse to answer any question, and you can stop the interview at any time. Participating or not participating in this study will not affect your medical care in any way.

The interviewer, Beth Canfield, is not employed by this Adult AIDS Clinical Trial Unit. She will keep your personal information confidential. It may be included in a report that summarizes information from all the interviews and will not use your name or any other information that will identify you.
Are you interested in participating? Great! Let me give you her name and phone number so you can call her!"
Appendix G
Recruitment Flyer

*Ever sit and think about the trial you are in or ones you have been in?*

*Drug trials for HIV+ women…*

Want to share those thoughts with someone else?

Are you an HIV+ woman and are in a drug trial now or have finished one within the last 3 months? If so, you can earn $35 for talking to a female researcher from public health about how you decided to join a drug trial and about your experience in your current or most recent trial!

Please ask your study nurse for more information about this interview.
Appendix H
Pros & Cons of Trial Participation

Pros:
- flexible scheduling
- no more decisions to make
- bringing family/friends to appointments
- information kept confidential
- altruism/service
- friendly trusted staff
- personal health benefits experienced
- education
- primary care - better than regular Dr.'s care
- specialized care
- free meds
- free care
- getting away from area

Cons:
- waiting for counts
- placebos
- surveys
- possible inconvenience
- side effects
- adherence/dosing
- initial fear/uncertainty
- frequent appointments
- blood draws

seeing other HIV+ people
Mental Health Resources

**OSU HIV Mental Health Clinic**

614-293-8112

Radu Saveanu, MD, OSU Clinical Psychiatry

Appointments for mental health evaluations and counseling

Counseling is available on site in the Infectious Disease Clinic

Eligible patients receive free services through Ryan White “HIV Early Intervention” funding

For information on Ryan White Funding, contact Columbus AIDS Task Force 299-2437

**Netcare Mental Health Services**

614-274-7000

24 hour phone or walk in emergency services

Fees based on ability to pay

**Southeast Incorporated**

614-444-0800

Individual, couple, or group therapy for individuals

Infected or affected by HIV

Fees based on ability to pay
Appendix J
Consent Form for University of Cincinnati Participants

UNIVERSITY OF CINCINNATI
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

“HIV-positive women’s experience and decision-making processes.”

OSU Dissertation Study, Version 1.0
Date: August, 16, 2001

Institutional Study Number
Sponsor Study Number

INVESTIGATOR INFORMATION

Judith Feinberg, M.D. (513) 584-6977
Principal Investigator Telephone No. 24 hr/day-
work

INTRODUCTION

I am being asked to take part in this research study because I am infected with human immunodeficiency virus (HIV). This study is sponsored by Ohio State University scholarship money provided from the investigator. The doctor in charge of this study at this site is: Judith Feinberg, M.D. Other professional persons who work with her as study staff may assist or act for her. Before I decide if I want to be a part of this study, I will be told about the study.
This is a consent form. It gives me information about this study. The information will include explanations of the research being done and why, what procedures will be done, and the benefits, risks, discomforts and precautions of the study. The study staff will talk with me about this information. I am free to ask questions about this study at any time. If I agree to take part in this study, I will be asked to sign this consent form. I will get a copy to keep.

WHY AM I BEING ASKED TO BE IN THIS STUDY?

Inclusion Criteria
- 18 years of age or older
- women currently enrolled in a clinical drug trial or have completed a drug trial in the past three months at the University of Cincinnati Infectious Diseases Center or the Ohio State University Hospital

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 30 women at the University of Cincinnati Medical Center or the Ohio State University Hospital will take part in the study.

HOW LONG WILL I BE IN THIS STUDY?

I will be in this study for a total of one visit, which will last between 60 and 90 minutes.

WHY IS THIS STUDY BEING DONE?

The purpose of the study is to explore HIV+ women’s experiences when participating in clinical trials, focusing on perceptions, iterative decision making, and impacts on their personal life stories. Three research questions guide the study. What are the major decision points in considering participation in a therapeutic clinical trial? What is the nature of the experience of participating in a therapeutic clinical trial for HIV+ women? How do women interpret this experience and incorporate it into their lives?

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

I will be interviewed and the interview will be audio taped and transcribed word for word by the researcher. Immediately after the interview has been conducted, the researcher will transcribe the data, write up filed notes, and reflect on the experience of data collection. The first few interview transcripts will be submitted to the dissertation committee to solicit feedback. The research will also keep an audit trail, a paper or computerized record of the recruitment and data analysis processes as they evolve.
Interviews will be conducted behind closed doors in an available room in the research clinic.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If I take part in this study, there may be a direct benefit to me, but no guarantee can be made. It is also possible that I may receive no benefit from being in this study. Information learned from this study may help others who have HIV.

I may benefit from the therapeutic value of discussing my experience with the interviewer and from any improvements in trial management that may result from the findings of this study. This research is based on the specific perspectives and experiences of HIV-positive women and is expected to be of interest to advocates, health care providers, and policy makers in the U.S. and in other developed countries. This research will add to the published literature by increased understanding of women’s decisions to participate in a clinical trial and by the addition of HIV-positive women’s voices describing their trial experiences.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

I have a choice not to participate in this study. My care will not be affected if I choose not to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep my personal information confidential. We cannot guarantee absolutes confidentiality. My personal information may be disclosed if required by law. Any publication of this study will not use my name or identify me personally.

I consent to audiotapes to record my interview. I understand that this is used to help the interviewer accurately recall the details of the interview. The tapes will be destroyed at the end of the study.

My records may be reviewed by the U.S. Food and Drug Administration (FDA), University of Cincinnati IRB, study staff, and study monitors.

WHAT ARE THE COST TO ME?

There are no cost for me to participate in this study.
WHAT HAPPENS IF I AM INJURED?
If I am injured as a result of being in this study, I will be given immediate treatment for my injuries. The cost for this treatment will be charged to me or my insurance company. There is no program for compensation either through this institution. I will not be giving up any of my legal rights by signing this consent form.

The University of Cincinnati Medical Center follows a policy of making all decisions concerning compensation and medical treatment for injuries occurring during or caused by participation in biomedical or behavioral research on an individual basis. If I believe I have been injured as a result of research, contact Judith Feinberg, M.D. at (513) 584-6977 or the IRB Chairperson at (513) 558-5259.

WILL I RECEIVE ANY PAYMENT?
I will receive $35 for participating in the interview.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?
Taking part in this study is completely voluntary. I may choose not to take part in this study or leave this study at any time. I will be treated the same no matter what I decide.

I will be told about new information from this or other studies that may affect my health, welfare, or willingness to stay in this study. If I want the results of the study, I will let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OF PROBLEMS?
For questions about this study or research-related injury, contact:

   Judith Feinberg, MD

   513-584-6977

For questions about my rights as a research subject, contact:

   Peter Frame, M.D. University of Cincinnati Medical Center, Institutional Review Board Chairperson

   513-558-5259
SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

___________________  ________________________________
Participant’s Name (print)  Participant’s Signature and Date

________________________  ________________________________
Participant’s Legal Guardian (print)  Legal Guardian’s Signature and Date
(As appropriate)

____________________________  ________________________________
Study Staff Conducting Consent Discussion (print)  Study Staff Signature and Date

____________________________  ________________________________
Witness’ Name (print)  Witness’ Signature and Date
(As appropriate)

OSU dissertation study, sem 12/12/01
Appendix K
Consent Form for Ohio State University Participants

CONSENT FOR PARTICIPATION IN SOCIAL AND BEHAVIORAL RESEARCH

Protocol title: Participating in a clinical trial: HIV-positive women’s experiences and decision-making processes

Protocol number: 01B0150

Principal Investigator: Dr. Cathy Heaney

I consent to my participation in research being conducted by Dr. Cathy Heaney of The Ohio State University and her associate, Beth Canfield.

The interviewer, Beth Canfield, has explained the purpose of the study, the procedures that will be followed, and the amount of time it will take. Possible benefits of the study have been described to me.

I know that I can choose not to participate without penalty to me. If I agree to participate, I can withdraw from the study at any time, and there will be no penalty. I have the right to skip any questions that make me uncomfortable. Should I choose to participate in this study, I will receive $35 for my time.

I consent to the use of audiotapes. I understand how the tapes will be used for this study and that they will be erased during June of 2002.

I have had a chance to ask questions and to obtain answers to my questions. I can contact the investigators at (614) 293-5575. If I have questions about my rights as a research participant, I can call the Office of Research Risks Protection at (614) 688-4792.

I have read this form or I have had it read to me. I sign it freely and voluntarily. A copy has been given to me.
Print the name of the participant:

______________________________________________________

Date:                                                                 Signed:

______________________________________________________  (Participant)

Signed:

(Principal Investigator or his/her authorized representative)

Signed:

(Person authorized to consent for participant, if required)