

PROCESS EVALUATION OF A MULTILEVEL INTERVENTION TO INCREASE RURAL,
AFRICAN AMERICAN PARTICIPATION IN HIV/AIDS CLINICAL TRIALS

Bahby Banks, MPH

A dissertation submitted to the faculty of the University of North Carolina at Chapel Hill in
partial fulfillment of the requirements for the degree of Doctorate of Philosophy in the
Department of Health Behavior and Health Education.

Chapel Hill
2012

Approved by:

Eugenia Eng, MPH, DrPH

Allan Steckler, MPH, DrPH

Suzanne Maman, MHS, PhD

Giselle Corbie-Smith, MD, MSc

Margaret Shandor Miles, PhD, RN, FAAN

©2012
Bahby Banks
ALL RIGHTS RESERVED

ABSTRACT

BAHBY BANKS: Process Evaluation of a Multilevel Intervention to Increase Rural, African American Participation in HIV/AIDS Clinical Trials
(Under the direction of Dr. Eugenia Eng)

Background: While African Americans are disproportionately affected by the HIV/AIDS epidemic, they continue to be underrepresented in clinical trial research. This underrepresentation has led to a critical gap in research and limited access to state of the art treatment for their disease. To increase African American willingness to participate in clinical trials, Project EAST conducted a multilevel intervention that targeted rural service providers and their HIV/AIDS clients. The dissertation study evaluated the implementation of the intervention.

Methods: This study conducted the process evaluation of the intervention. Data sources included: (a) session audio recordings, (b) verbatim transcripts from sessions, facilitator debriefings, and participant focus group discussions, (c) narrative summaries from participant observation, (d) recruitment tracking forms, (e) attendance logs, and (f) community advisory board (CAB) meeting transcripts. All qualitative data were managed using ATLAS.ti.

Findings: Intervention reach was 84% and 184% for clients and service providers, respectively. Mean dose delivered scores were .88 for patient sessions and .92 for service provider sessions. Attendance for each of the four client groups were .92, .86, .83, and .83, respectively and .97 and 1 for the two service provider groups. Fidelity evaluated via

facilitator debriefings was essential for identifying deviations from the curriculum. However, implementation checklists proved to be more comprehensive in capturing these deviations as they related to the quality and integrity of intervention delivery. Focus group data indicated clients had high satisfaction with: interactive activities, being in a group setting with other clients living with HIV/AIDS, facilitator characteristics, and an opportunity to discuss concerns and clarifications with a clinical trial expert. Service providers also indicated high satisfaction with: interactive activities, facilitator characteristics, and session content. These themes were convergent with facilitator perspectives on participant engagement.

Conclusions: The findings provide important insights regarding education about and accessibility to HIV/AIDS clinical trial opportunities for rural, African Americans and their local service providers. As researchers work to establish best practices in recruitment, referral, and enrollment of racial and ethnic minorities in HIV/AIDS clinical trials, conducting a process evaluation can yield essential understanding and recommendations for comparable educational interventions to be undertaken in rural regions of the United States.

For Dorothy Gaines Banks, RN, MSN, my mother and best friend.

Your love is my love. Your strength is my strength.

Your legacy is mine to carry on...

I love you and miss you.

ACKNOWLEDGEMENTS

To my mother, Dorothy Gaines Banks, I know I would not have made it this far without your sacrifice and support. You always have been and will always be my inspiration. Thank you for epitomizing what it means to be a woman of integrity and courage, and for reminding me during the toughest of times that we do not fear, nor do we succumb to the assumptions of others. You were my biggest cheerleader and I will forever thank God for giving us YOU if even for what we thought was a short window of time. You were the greatest gift and the greatest mom. Period. Thank you for reminding me of *who* I am and *whose* I am.

To my father, Robert Banks, I thank you for praising and encouraging my creativity for as far back as I can remember—and for making every opportunity a teachable moment. You sowed many of the skills that brought me to this very moment early in my life barely touch my feet to the floor at the kitchen table. Thank you for keeping every award, certificate, report card, and medal I have ever earned as tangible reminders of excellence.

To my brother Danny, thank you for picking up where mom left off and praising me far beyond what I ever deserved. Your support shined through on stormy days, as I could hear you proudly saying, “That’s my sister!” just as mom used to proudly exclaim, “That’s my baby!” I am just as proud to have you as my brother as you are proud to have me as your sister. To my brother Keith, thank you for reminding me of mom’s strength that lives on through me. To my brother Dreak, your wisdom and humor never left a dull moment along this journey! Thank you for everything. Who could have asked for a better trio of men?

To my big sister and cheerleader, Dr. Malika Roman Isler. I could not have asked for a better friend, mentor and supporter. I truly would not have made this journey without seeing your perseverance and dedication as you pursued your Ph.D. Your humor and encouragement really got me through the roughest of days and I am forever grateful to you for your selflessness. You, Victor, Jace and Miles have been such a blessing in more ways than you can imagine. God has a way of creating a path and placing the right people at the right time and place along one's journey. I'm so glad that our paths crossed.

To my little sister, Ebun Odeneye who affirmed, "I will be your third arm", as I worked through many sleepless nights, you are *incredible* and your words brought comfort in the midst of a crazy time. Your passion in process evaluation research inspired me to return the research evaluation world—my original love. Thank you for so much for your generosity and your support on everything from checklist assessments to reading numerous iterations of my paper. I am looking forward your entrance in to the sisterhood in academia!

To Dr. Yvonne Owens Ferguson and Dr. Liana Richardson, thank you for your spiritual and professional guidance along this journey. To Adina Black and Michelle Hayes, thank you both for your valuable feedback and assistance with all things on my dissertation study. Neither of you hesitated to help when I needed it, so thank you! To my friend, sister, and writing partner, Dr. Janelle Armstrong-Brown, thank you for helping to smooth out what could have been a very bumpy ride. I admire your strength and perseverance and thank you for being a role model to "Get 'er done!"

To my mentors Dr. Giselle Corbie-Smith and Dr. Margaret Miles, you both have been the best mentors I could have ever asked for. Thank you both for reinvigorating my passion for research and opening the door to opportunities that I never dreamed of having as part of

my doctoral. Giselle, I will be forever grateful to you for providing space for me to grow personally and professionally. Marge, thank you for the “straight talk” and your messages of support and encouragement. They *always* made their way at the right time! Sincerest thanks to all of my committee members: Eugenia Eng, Suzanne Maman, and Allan Steckler for their support and guidance from the conceptualization of the dissertation through the present. I am happy to now call you my research colleagues!

To my UNC brothers and sisters, you are the most amazing group of people I have met and I am truly thankful for your friendship, words of encouragement, phone calls, hugs, and your true concern for my well-being during the most difficult time in my life. It truly, truly takes a village. To LaToya White, Dr. Elizabeth King, Jameta Barlow, Stephanie Baker, Chandra Caldwell, Pamela Diggs, Stepheria Hodge Sallah, Erin Stephens, Kimberly Russell, Afabwaje Jatau, Angela Thrasher, Andre Brown, Justin Smith, Dr. Tyisanna Jones, Dr. Carmen Samuel Hodge, Dr. Deirdre Washington, and Justin Lucas, words cannot express my gratitude for each of your professional guidance and support along this journey.

To my adopted sisters and brothers from as far back as I can remember: Dr. Sabriya Scott-Caffrey, Neda Brown, Kimberly Nicholson, Keisha Ricks-Barnette, Nebulla Stephens, Lisa Carter, Raniesa Gray-Johnson, Derrick and Errick Jennings, and Brian Bradham, thank you for being my constant and ever-present cheerleaders.

To Melvin Muhammad and Garrett Bookman, your hard work made this work possible. I am inspired by your dedication and commitment of your fellow community members. Both of you are *amazing* and have redefined community advocacy. Also, many thanks to the Project EAST staff that worked long days and nights to ensure the success of the project.

To my nieces and nephews, thank you for your patience when Auntie Lisa came to town to visit and did not have much time to play. I hope you now see the fruits of hard work and faith! I believe in you more than you know, and aspire for each of you to be **extra**ordinary. This is only the beginning of many “firsts” in our family, as each of you has God-given talent to share with each other and the world. Follow your dreams, work hard, and remember as Grandma always said, “No C’s on your report card!”

To my “favorite” aunts, uncles, and cousins—of which there are too many to name—thank you for being my village. It is because of your sacrifices that I have had the opportunity to do what was unheard of just a few short decades ago. I stand on the shoulders of giants, and I thank you for sowing pearls of wisdom and purpose into my life.

Lastly, I give honor and glory to my Lord. It was His careful orchestration of time, people, places, and opportunities that made my time at UNC fruitful. This journey has been one that I never planned to unfold as it did, but I do know that all things happen in Your way, in Your time. I will forever speak of Your glory, and I know through you, ALL things are possible.

TABLE OF CONTENTS

LIST OF TABLES.....	xiv
LIST OF FIGURES.....	xv
Chapter 1.....	1
INTRODUCTION.....	1
The HIV Epidemic: From Metropolitan Areas To The Rural Southeast.....	1
HIV Treatment and Care.....	1
Minorities and Clinical Trial Research.....	3
Summary.....	4
Purpose, Specific Aims, and Rationale.....	4
Organization of this Dissertation.....	8
CHAPTER 2.....	9
REVIEW OF THE LITERATURE.....	9
The HIV/AIDS Epidemic in The Rural Southeast and North Carolina.....	9
History of Clinical Trials Research.....	11
Racial and Ethnic Minority Participation in Clinical Trials.....	14
Barriers to Clinical Trial Participation.....	15
Interventions to Increase Minority Participation in HIV Clinical Trial Research.....	19
Provider Involvement in Clinical Trial Research.....	23
Process Evaluation Research.....	24

Summary.....	26
CHAPTER 3.....	28
PROJECT EDUCATION AND ACCESS TO SERVICES AND TESTING (EAST)	28
Gaining Entrée: The Community Advisory Board (CAB)	29
Educational HIV Clinical Trial Intervention Study.....	29
Theoretical Foundation.....	30
Series Layout.....	32
Logic Model.....	37
Session Facilitators.....	39
Selection of Study Sites.....	40
Intervention Study Sample Population and Setting.....	42
CHAPTER 4.....	46
METHODS.....	46
Data Sources and Collection Methods.....	45
Recruitment Tracking Forms and Attendance Logs	47
Session Audio Recordings and Verbatim Transcripts.....	49
Observational Data	53
Facilitator Debriefing Interviews	54
Participant Focus Group Discussions.....	56
CAB Meeting Transcripts/Team Meeting Minutes.....	58
Satisfaction Surveys.....	59
Validity.....	63

CHAPTER 5.....	65
RESULTS.....	65
Reach and Recruitment.....	65
Dose Delivered and Fidelity.....	73
Dose Received.....	85
Satisfaction and Perceived Engagement.....	93
Intervention Modifications and Future Recommendations.....	95
Client Suggested Modifications.....	95
Facilitator Suggested Modifications (Client Series)	99
Service Provider Suggested Modifications.....	100
Facilitator Suggested Modifications (Provider Series)	102
CHAPTER 6.....	104
DISCUSSION.....	104
Achievement of Study Aims.....	105
Implications for Process Evaluation Research.....	115
Implications for Practice.....	118
Study Limitations.....	119
Study Strengths.....	120
APPENDIX A: Client Intervention Series.....	123
APPENDIX B: Provider Intervention Series.....	124
APPENDIX C: Client Recruitment Tracking Form.....	125
APPENDIX D: Sample Implementation Checklist.....	126

APPENDIX E: Facilitator Debriefing Guide.....	127
APPENDIX F: Facilitator Debriefing Interview Codebook.....	130
APPENDIX G: Client Focus Group Discussion Guide.....	134
APPENDIX H: Provider Focus Group Discussion Guide.....	136
APPENDIX I: Service Provider and Client Focus Group Discussion Codebook	138
APPENDIX J: Satisfaction Survey.....	145
APPENDIX K: Client Attendance Log, by Group.....	146
APPENDIX L: Provider Attendance Log, by Group.....	147
APPENDIX M: Sample Fidelity Comparison by Data Source (Client Series)	148
APPENDIX N: Sample Visual Display of Client Satisfaction, Select Sessions.....	149
APPENDIX O: Sample Visual Display of Service Provider Satisfaction, All Sessions.....	150
APPENDIX P: Client Satisfaction Compared to Facilitator Perceived Engagement, by Group.....	151
APPENDIX Q: Service Provider Satisfaction Compared to Facilitator Perceived Engagement, Session 1.....	152
REFERENCES.....	153

LIST OF TABLES

Table 1: Project EAST Study County AIDS Rate.....	11
Table 2: Types of HIV Clinical Trials.....	14
Table 3: Participant Barriers to Clinical Trial Participation.....	17
Table 4: Barriers to Physician Involvement in Clinical Trial Research.....	18
Table 5: Client Intervention Series.....	35
Table 6: Service Provider Intervention Series.....	36
Table 7: Intervention Study Site Profiles.....	41
Table 8: Process Evaluation Concepts.....	61
Table 9: Client Characteristics, by Group.....	69
Table 10: Service Provider Characteristics, by Group.....	72
Table 11: Dose Delivered Scores (Client Series)	76
Table 12: Dose Delivered Scores (Service Provider Series)	77
Table 13: Facilitator Characteristics.....	78

LIST OF FIGURES

Figure 1: Intended Schema for Intervention Study (Provider and Client Series).....	33
Figure 2: Project EAST Logic Model.....	38

LIST OF ABBREVIATIONS

ACTG	AIDS Clinical Trials Group
ACTU	AIDS Clinical Trials Unit
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
CAB	Community Advisory Board
EAST	Education and Access to Services and Testing
FDA	Food and Drug Administration
HIV	Human Immunodeficiency Virus
NIAID	National Institutes of Allergy and Infectious Diseases
NIH	National Institutes of Health
PLWHA	People living with HIV/AIDS
UNC	University of North Carolina at Chapel Hill

CHAPTER 1

INTRODUCTION

The HIV Epidemic: From Metropolitan Areas to the Rural Southeast

The HIV/AIDS epidemic in the United States was first noted in the early 1980s among homosexual White males in urban areas (Gottlieb, 2006). However, over the past twenty years the demographics of those most affected by this disease has shifted dramatically, with African Americans accounting for 52% of new HIV cases diagnosed in 2008 (Prejean et. al 2011) African Americans have accounted for approximately 12% of the total population over the same 20-year period. In 2007, the rate at which African Americans were diagnosed with HIV was 73.7 per 100,000, nearly three times higher than Latinos (25.0 per 100,000) and nine times higher than Whites (8.2 per 100,000) (Centers for Disease Control and Prevention, 2008). In recent years, the epidemic has shifted from being concentrated in urban areas in the United States to rural areas, predominantly in the southeastern part of the country. In 2000, the rate of HIV diagnosis was almost as high in rural areas of the Southeast as in urban areas of the same region (Hall, Li, & McKenna, 2005). In 2008, 67% of all rural AIDS cases reported in the United States were in the South; African Americans accounted for 62% of these cases.

HIV Treatment and Care

Prompt initiation of a regimen to treat HIV is essential in reducing one's viral load and preventing the onset of opportunistic infections brought on as one progresses from HIV

to AIDS (Department of Health and Human Services, 2011). Due to great strides in medical research, treatment regimens are evolving and becoming more effective in delaying this progression. Despite these advances, African Americans living with HIV/AIDS tend to seek treatment for HIV in later stages of the disease when their physical symptoms are more apparent. Additionally, broader environmental factors within minority rural communities, such as poverty, lead to limited availability to medical care and a limited number of service providers with specialization in HIV/AIDS care (Nguyen & Whetten, 2003). This lack of access can lead to delays in diagnosis and in seeking medical care when needed (Freeman, 1993).

As is the case with treatment and care, racial and ethnic minorities also have experienced limited access to participation in HIV clinical trials. Early in the course of the HIV epidemic, AIDS advocates were instrumental in increasing the accessibility and acceptability of clinical trials for homosexual White men (Wachter, 1992). Pressure from patient-activists and clinicians resulted in major changes in the procedures in which research protocols were initiated, the site of research trials, criteria for entry into trials, end points for trials and the definition of the overall research agenda (El-Sadr & Capps, 1992). Today, the populations most likely to enroll in clinical trials still closely reflect the demographics of those enrolled in the beginning of the epidemic rather than the rising trend of new infections among racial and ethnic minorities. Gifford et al. (2002) identified White race, male sex, a history of homosexual contact, education beyond high school, an annual income of more than \$25,000, private health insurance and residence within one mile of a center conducting a trial as factors associated with participating in a trial. Predictors for non-enrollment include non-Hispanic Black race, greater distance from medical centers conducting trials, lower

educational attainment and lack of health insurance. Clinical trials are time intensive, often requiring travel to and from major medical centers in large urban areas. Travel can be burdensome and overwhelming, particularly for trials that require visits several times a month over the course of months or years. In sum, key reasons for why minorities might not participate in clinical trials in general (Plummer et al., 2002), and HIV/AIDS trials in particular (Sengupta et al., 2000), are similar to the barriers they face for HIV care (Heckman et al., 1998a).

Minority Representation in Clinical Trials

Appropriate representation of minorities in HIV/AIDS clinical trials is important for producing results that are generalizable to the populations most affected by the epidemic. Cargill and Stone (2005) reported that in the early years of the epidemic when Retrovir (an antiretroviral therapy treatment) was widely prescribed, some African American patients experienced hyperpigmentation, or darkening of the nails and skin as a side effect. As a result, the treatments presented service providers and their minority patients with side effects that previously were unanticipated. Further, African Americans are already at high risk for some of the health problems that HIV medications are known to complicate, including hypertension, diabetes, and cholesterol. Retrovir also may cause anemia, an important concern for African Americans because of the high prevalence of anemia already in this population. Similarly, a higher proportion of African Americans are co-infected with HIV and hepatitis C as compared to their White counterparts, making liver problems that HIV medication can cause another potential problem that is very serious (Cargill & Stone, 2005).

Interventions to increase awareness about HIV/AIDS clinical trials and HIV/AIDS clinical trial opportunities among African Americans living with HIV/AIDS are limited in the

literature. Of those conducted in the United States, all have been in urban areas at, or in close proximity to, a major medical center conducting trials. No intervention studies to date have been conducted with rural African Americans living with HIV/AIDS. Of the studies that exist, the report of “minority” or “people of color” often has been broadly defined--not explicitly referencing inclusion of historically under-represented racial and ethnic minorities (i.e. African Americans or Latinos), which limits the extent to which findings can be generalized to these populations.

Summary

In summary, the persistent problem of low participation by African Americans in HIV/AIDS clinical trials has three implications for the field of public health. With regard to research, advances in treatment and innovations in care are limited in the extent to which their effects can be generalized to the U.S. population. With regard to public health practice, African Americans living with HIV/AIDS have limited access to the newest therapies and treatments that may benefit their health and provide an avenue for supplemental treatment and care of their disease. For some patients, particularly those in underserved, rural communities, clinical trials may represent their best opportunity for life-extending care. Finally, to increase minority participation in HIV/AIDS clinical trials, the field of public health needs to pilot interventions that are: (a) informed by socio-behavioral theory to elucidate our understanding of pathways through which specific factors contribute to or mitigate low participation, and (b) in addition to rigorous outcome evaluations, include comprehensive process evaluations to document the intermediate effects from specific intervention inputs and activities.

Purpose, Specific Aims, and Rationale

The purpose of this dissertation is to present the methods and findings from a process evaluation of Project Education and Access to Services and Testing (EAST), a multilevel intervention that targeted rural, African Americans living with HIV/AIDS and their local service providers. The goal of Project EAST's intervention was to increase awareness about clinical trials and clinical trial opportunities offered at the University of North Carolina at Chapel Hill (UNC); to address misconceptions related to HIV/AIDS research; to increase service provider willingness to refer eligible African American clients living with HIV/AIDS to clinical trials; and to increase African American client willingness to participate in a clinical trial. This study was funded by the National Institutes of Nursing Research (NINR), the UNC Clinical and Translational Science Award (CTSA), and the UNC General Clinical Research Center (GCRC). The Project EAST intervention was a collaborative effort among UNC Schools of Medicine, Dentistry, Nursing, and Public Health and five community health centers in North Carolina. The parent study was conducted from October 2006 through December 2011, with intervention sessions occurring May 2010 through June 2011. The dissertation study will evaluate intervention sessions that took place at two of the five community-based clinics from May 2010 through November 2010.

To date, there has not been a thorough process evaluation conducted for interventions to increase historically underrepresented racial and ethnic minority participation in clinical trials broadly, or specific to HIV/AIDS research. Thus, as a newly developed intervention, it was critical for Project EAST to examine its intervention's context, recruitment, fidelity,

dose delivered and dose received to better understand the implications for generalizability in comparable populations. Hence, the specific aims for this dissertation study were to:

1. Evaluate the implementation of an educational HIV clinical trial intervention with rural, African American people living with HIV/AIDS (PLWHA).

- a. Reach: (i) To what extent did the intervention reach the intended number of participants? (ii) What proportion of participants completed all program sessions?
- b. Context: What larger physical, social, and political factors affected implementation of the intervention?
- c. Recruitment: (i) What planned and actual recruitment procedures were used? (ii) What were the barriers to recruitment? (iii) What were the barriers to maintaining involvement? (iv) Were the set recruitment goals of clients met?
- d. Fidelity: To what extent was the intervention implemented as intended?
- e. Dose delivered: (i) To what extent were all of the intervention components provided? (ii) To what extent were all intervention materials used? (iii) To what extent was all of the intended content covered? (iv) To what extent were all of the intended methods, strategies, and activities completed?
- f. Dose received: (i) To what extent were participants present at intervention activities? (ii) How did participants react to specific aspects of the intervention? (iii) How satisfied were participants with the intervention?

2. Evaluate the implementation of an educational HIV clinical trial intervention with rural service providers.

- a. Reach: (i) To what extent did the intervention reach the intended number of participants? (ii) What proportion of participants completed all program sessions?
- b. Context: What larger physical, social, and political factors affected implementation of the intervention?
- b. Recruitment: (i) What planned and actual recruitment procedures were used? (ii) What were the barriers to recruitment? (iii) What were the barriers to maintaining involvement? (iv) Was the set recruitment goal of service providers met?
- a. Fidelity: To what extent was the intervention implemented as intended?
- b. Dose delivered: (i) To what extent were all of the intervention components provided? (ii) To what extent were all intervention materials used? (iii) To what extent was all of the intended content covered? (iv) To what extent were all of the intended methods, strategies, and activities completed?
- c. Dose received: (i) To what extent were participants present at intervention activities? (ii) How did participants react to specific aspects of the intervention? (iii) How satisfied were participants with the intervention?

This study was designed to systematically assess intervention implementation using available process evaluation data collected on Project EAST. The goal of this assessment was to

measure the extent to which the multilevel intervention was carried out as planned and to further explore what factors may have influenced implementation.

Organization of this Dissertation

Chapter 2 reviews several bodies of literature related to racial and ethnic minority enrollment in HIV/AIDS clinical trials. Specifically, it synthesizes current understanding about: (a) the HIV/AIDS epidemic in the rural Southeast and North Carolina, (b) history of clinical trials research, (c) racial and ethnic minority participation in clinical trials, (d) barriers to clinical trial participation, (e) interventions to increase minority participation in HIV clinical trial research, (f) service provider involvement in clinical trial research, and (g) process evaluation research. Chapter 3 describes Project EAST's intervention study as well as the theories used to inform the intervention. Chapter 4 gives an overview of the methodology and data sources collected for the process evaluation of the intervention. Chapter 5 details the process evaluation findings of the intervention. Chapter 6 revisits the dissertation study aims to determine the extent to which the intervention was implemented as designed, describes limitations and strengths of the dissertation study, and details implications of the process evaluation findings for public health research and practice.

CHAPTER 2

REVIEW OF THE LITERATURE

To provide the context and rationale for this study, this chapter presents a review of relevant literature on: (a) the HIV/AIDS epidemic in the rural Southeast and North Carolina, (b) history of clinical trials research, (c) racial and ethnic minority participation in clinical trials, (d) barriers to clinical trial participation, (e) interventions to increase minority participation in HIV clinical trial research, (f) service provider involvement in clinical trial research, and (g) process evaluation research.

The HIV/AIDS Epidemic in the Rural Southeast and North Carolina

North Carolina is located on the eastern coast of the United States and is home to more than 9.5 million people (U.S. Census Bureau, 2010). The state has 100 counties with the majority of its African Americans residents live in the eastern part of the state. Twenty percent of the total population is African American, nearly double the representation (12%) of African Americans in the nation. Seventy-eight percent of adults older than 25 have a high school degree, and 22% have at least a bachelor's degree. The median household income is \$44,772, with a mean of 2.5 people per household. The primary industries are: manufacturing, agriculture, textiles and retail. Twenty percent of the state's population lives below the federal poverty level.

According to the Centers for Disease Control and Prevention, during the past several years, the number of individuals with HIV/AIDS in the U.S. South has exceeded

those in all other regions despite the paucity of major metropolitan areas in the U.S South (Centers for Disease Control and Prevention, 2010). In North Carolina, the estimated number of living HIV/AIDS cases reported in 2008 was 23,356. The cumulative number of HIV disease cases reported in North Carolina was 35,346. Among the HIV disease cases diagnosed in 2007, African Americans represented 62% of the total. The HIV incidence rate for adult/adolescent cases was 78.2 per 100,000 for African Americans; 37.9 per 100,000 for Hispanics, and 10.7 per 100,000 for Whites (North Carolina Department of Health and Human Services, 2010). Rural residents were more likely to live in poverty, less likely to have health insurance, and less likely to be on antiretroviral therapy as compared to urban residents. Without insurance, rural residents are less likely to seek medical care or mental or social services. Additionally, rural areas had fewer healthcare service providers with HIV expertise (Nguyen & Whetten, 2003). In North Carolina, as is the case for many other states in the region, the counties with the highest prevalence of AIDS are rural. As the HIV/AIDS epidemic continues to burgeon in the rural Southeast, interest in prevention and research efforts has been growing in this region. In North Carolina, this research has ranged from studies exploring HIV transmission (Adimora et al., 2006), concurrent partnerships (Adimora et al., 2004), HIV prevention among adolescents (Coker-Appiah et al., 2009; G. Corbie-Smith et al., 2010), access to care for incarcerated populations (Rosen et al., 2004) and the needs of African American women with HIV (Black & Miles 2002). Project EAST was the first intervention study to conduct HIV/AIDS clinical trials outreach among rural populations in this region.

The data for the dissertation study came from two community-based clinics in a rural community in the eastern part of North Carolina. Clients resided in one of three contiguous

counties served by the clinics. The counties are among those with the highest AIDS case rates in the state, with two of the three counties ranking among the top 10 counties in the state (25.9 and 20.3 per 100,000, respectively). The third county was ranked 17th with an average rate nearly 1.5 times that of the state. Table 1 details AIDS trends in these three counties from 2007 through 2009.

County	AIDS Case Rate (per 100,000)				RANK (among all NC counties)
	2007	2008	2009	Average	
A	17.1	26.6	34.2	25.9	2
B	10.8	12.8	16.0	13.2	17
C	20.9	15.5	24.5	20.3	4
<i>North Carolina</i>	<i>9.3</i>	<i>10.1</i>	<i>10.4</i>	<i>9.9</i>	<i>n/a</i>

History of Clinical Trials Research

An important breakthrough in the treatment of HIV was the development of antiretroviral medications to inhibit replication of the virus, thus preventing clinical progression of immunosuppression and development of opportunistic infections. These medications have significantly decreased mortality among people living with HIV/AIDS (PLWHA) and clinical trial studies have been the backbone of drug development. Clinical trials are defined as studies that are developed to test the effectiveness of an intervention in treating or preventing disease (National Institutes of Health, September 20, 2007). All medications must go through at least three phases of clinical trial research prior to approval from the United States Food and Drug Administration (FDA). This process is essentially a systematic assessment to determine if drugs are safe and effective. In Phase I trials, researchers test a new medication or treatment with a small number of individuals initially to assess the pharmacologic action, metabolism, and safety of the treatment, determine a safe

dosage range, and identify side effects. Participants for Phase I trials may be healthy volunteers or people with the disease of interest. In Phase II trials, the medication or treatment is given to a larger group of people with the disease to determine if it is effective and to further evaluate its safety. If these early phase trials suggest preliminary evidence of effectiveness, the medication or treatment is then given to larger study populations in a Phase III trial to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely. After the medication has proven to be safe and effective, approval is given by the FDA and the medication is then available for prescription to the public. If a medication requires additional testing, a Phase IV post-marketing trial may be conducted to gather information on the drug's effect in various populations and to assess side effects associated with long-term use (National Institutes of Health, 2007).

In response to the growing number of HIV cases and high mortality rate in the earlier years of the epidemic, the National Institutes of Health established AIDS Treatment and Evaluation Units throughout the United States to conduct clinical trials research on treatment medications and regimens. In 1987, the AIDS Clinical Trials Group (ACTG) was established by the National Institute of Allergy and Infectious Diseases (AIDS Clinical Trials Group Network, 2010). ACTGs are composed of, and directed by, leading clinical scientists who conduct research on HIV prevention, HIV disease and treatment, HIV-associated opportunistic infections, and complications of HIV therapy. The ultimate goal of the ACTG is to identify medications and other treatment options that will result in the successful control of HIV as well as the prevention and treatment of HIV-related co-morbidities in infected persons. The UNC AIDS Clinical Trials Unit (ACTU) was established in 1987 and

continues to provide access to clinical trials to individuals living in and around North Carolina and at partner sites around the globe.

Depending on PLWHA characteristics and stage of diagnosis, there are many types of HIV clinical trials conducted by the UNC ACTU for which potential participants could be eligible. Studies are available for PLWHA who have never taken an HIV medication, those who have an acute or recent HIV infection, individuals who are successfully suppressed or those for whom treatment is failing, as well as select studies for women, persons with complications of HIV, and pharmacokinetic studies used in the early development of medication (UNC AIDS Clinical Trials Unit, 2010). Although a participant may be eligible for more than one HIV/AIDS clinical trial, he or she can usually only participate in one antiretroviral drug trial at a time. PLWHA who are recruited and interested in co-enrolling in trials on the treatment of other HIV-related or unrelated conditions are open to do so with approval and screening from research primary investigators. Table 2 details eligibility criteria for specific trials.

Table 2: Types of HIV Clinical Trials	
Trial Type	Eligibility Criteria
Treatment naïve	Participants who have never taken any medication to treat their HIV infection.
Acute and Recent Infection	Participants who have been infected recently with HIV. In the days immediately after infection, HIV replication is extremely rapid, and the virus copies itself over and over again, resulting in an extremely high amount of HIV in the blood. The period known as acute HIV infection can be referred to by different names such as primary HIV infection, acute retroviral syndrome, and acute HIV syndrome.
Treatment experienced: suppressed	Participants who are/have been on HIV medication and whose viral load is at less than 50 copies/mL of blood
Treatment experienced: failing	Participants who are/have been on HIV medication but the regimen no longer works (this can occur if the virus is already resistant to the drug the individual is taking; failure also can occur if the medication is not taken on a consistent basis).
Women's studies	Female participants, including those who are or would like to get pregnant.
Pharmacokinetic/ Laboratory Studies	These studies establish the correct dose of medication, to see how the body processes the drug, and how the drug affects people of different genders and races. Pharmacokinetic studies also look at drug concentration in other compartments such as semen or saliva.
Complication studies	Participants who have complications associated with their HIV. Examples include neurologic, metabolic, and opportunistic infections
HIV negative	Participants who are not infected with the virus (usually partners); useful for vaccine development.

Minorities and Clinical Trials

While enrollment data of racial and ethnic minorities in HIV clinical trials is limited, cancer clinical trials give insight into these trends. African American enrollment in cancer clinical trials declined from 1996-2002 in the United States, accounting for 11% of all participants in 1996 to 7.9 % of all participants in 2002. Numbers are likely to be lower in rural areas, as transportation to tertiary care centers limits the extent to which eligible participants can attend screening and follow-up appointments. Data collected by the UNC ACTU indicated that North Carolina counties with the lowest participation rate in HIV clinical trials have the highest prevalence of HIV/AIDS and are rural and are more than an hour's drive from the ACTU facilities in Chapel Hill. Furthermore, these underrepresented counties were among those with the highest levels of poverty and density of minority populations.

Unpublished data collected by the UNC Center for AIDS Research (CFAR) indicated that 31% of HIV-infected patients attending the UNC Infectious Diseases (ID) Clinic live in areas with a population of less than 50,000; 18% live in areas with 50,000. However, the major medical centers where HIV clinical care is available are located in more populated counties. The majority of rural NC PLWHA must travel a significant distance from their homes to receive care at the UNC Infectious Disease Clinic: 23% of the patients travel 31-60 miles and 39% travel 61-120 miles. In short, HIV-related clinical trials, especially trials of initial therapy, are least accessible to PLWHA who reside in the very places from which the data indicate are the least represented.

Barriers to Clinical Trial Participation

A major barrier to African American clinical trial participation is mistrust of the medical establishment, as the relationship between African Americans in the United States and the medical establishment has been challenged by racial discrimination and disempowerment (Smith & King, 2009). Perhaps the most well-known of these is the Tuskegee Syphilis Study conducted from 1932-1972 by the U.S. Public Health Service with African American sharecroppers in Tuskegee, Alabama (Brandt, 1978). Over the course of this 40-year period, researchers withheld treatment from the syphilitic sharecroppers in the study in order to observe the natural progression of the disease--despite treatment becoming available eight years after the study was initiated. While study participants received medical examinations, none were told they were infected with syphilis, and outside agencies were prevented from supplying treatment to any participants enrolled in the study. Instead, the sharecroppers were told they were being treated for "bad blood". The inducements for participation included free medicine, burial costs, and transportation to and from the hospital.

The residual unrest from the Tuskegee Syphilis Study precipitated a formal apology in 1997 from President Bill Clinton on behalf of the United States Government.

Perhaps a less well known ethical abuse is that of Henrietta Lacks, an African American who developed gynecological bleeding and sought treatment at Johns Hopkins University, the only local major hospital in the area that offered care for African Americans (Lucey, Nelson-Rees, & Hutchins, 2009). During the surgery (and while she was anesthetized), her doctor removed a small piece of her healthy cervix and a small piece of her cancerous tissue. Mrs. Lacks did not give consent for the removal of these tissues, nor was she made aware of their removal after the procedure. Instead, the samples were sent to Dr. George Otto Gey, who up to that point was unsuccessful in developing techniques to grow cancerous cells outside of the body. This was important to research at the time, as scientists needed cells that would survive long enough outside of the human body to experiment in ways that could not be done *in* the human body. Mrs. Lacks succumbed to her cervical cancer at the age of thirty-one, just a few short months after radiation treatment. On the very day that she died, Dr. Gey announced his discovery of an “immortal” line of cells (Javitt, 2010). To maintain the anonymity of the origin of the cells, he used the first two letters of Mrs. Lacks’ full name, Henrietta Lacks, thus naming the cells “HeLa” cells. HeLa cells have been the backbone of medical and biological research, with demands from all over the world for research including gene mapping, in vitro fertilization, cancer, AIDS and countless other research endeavors including the polio vaccine which was widely used in the 1950s. Federal legislation has since been developed to protect patients’ rights, but despite these protections, minority trust in medical research continues to influence enrollment in clinical trials (Corbie-Smith, 1999).

Fear of experimentation, lack of knowledge about research, language barriers and lack of access to clinical trials have been documented in the literature (Corbie-Smith, Thomas, & St. George, 2002; Corbie-Smith et al., 2003; Corbie-Smith, Moody-Ayers, & Thrasher, 2004; Powell, Fleming, Walker-McGill, & Lenoir, 2008). Concerns about stigma and disclosure also have been noted to outweigh the potential benefits from participating in clinical trials (Black & Miles, 2002). Compared to their urban counterparts, PLWHA in rural areas reported even higher constraints to clinical trials research: longer distances to tertiary care medical facilities, lack of personal transportation, and the resultant lost income from being away from work (Heckman et al., 1998b; Powell et al., 2008). Table 3 details additional barriers documented in the literature related to trial participation for people living with HIV/AIDS.

Table 3: Participant Barriers to Clinical Trial Participation
Physician/institutional mistrust
Transportation
Lack of access to research institution
Inconvenient / lack of time
Restrictive criteria
Language barriers
Side effects/risks
Lack of awareness about clinical trials
Patient fear of experimentation, placebo, guinea pig
Conspiracy against minorities
Lack of minority physician participation
Informed consent (too difficult and only protect doctors/research institutions)
No benefit for African Americans if treatment is found to be effective
Negative portrayal of community

In rural communities, physicians and other service providers in community healthcare practices may be less likely to refer patients to clinical trials because of lack of awareness of what participation entails and the increased time and effort these studies pose for already

strained medical practices (Kaluzny et al., 1993). Other service providers noted additional barriers to involvement in clinical trial research include inadequate reimbursement, lack of access to a clinical research coordinator, concerns about patient safety, and fear of patient being lost to other physicians (Powell et al., 2008). Additional barriers for service providers can be found in Table 4.

Table 4: Barriers to Physician Involvement in Clinical Trial Research
Attempted participation but denied
Lack of awareness of clinical trials opportunities
Lack of time
Concerns about patient safety
Inadequate reimbursement
Not affiliated with a major academic center
Lack of access to a clinical research coordinator
Lack of access to an institutional review board
Patient was lost to other physicians/ being removed from decision-making process
Poor communication with people conducting trials
Lack of experience in recruiting racial/ethnic minorities
Concern about potential adverse effects
Patient lacks time
Patient does not understand the need to participate

Innovations in clinical trial education and outreach to rural racial and ethnic minorities are of the utmost importance, as this population continues to be disproportionately affected by the epidemic, yet underrepresented in clinical trial research. Project EAST's intervention built upon previous intervention research by educating service providers and PLWHA concurrently. This combined approach at the local level within the rural context was a novel approach as it relates to clinical trial education, referral, and participation.

Interventions to Increase Minority Participation in HIV Clinical Trial Research

In response to low enrollment of racial and ethnic minorities in clinical trials research, many recruitment efforts have been made to increase their participation. Unfortunately, these efforts in the context of HIV are sparse in the literature. Cancer research, however, has provided an important foundation upon which HIV researchers and practitioners can begin to develop targeted enrollment strategies. A few short decades ago, people affected with cancer experienced a stigma similar to that experienced by people living with HIV/AIDS today. Discrimination against and isolation of those with cancer were prevalent, both of which were partly attributed to misconceptions about cancer and high mortality rates experienced by people afflicted by the disease. Cancer was once referred to as the “Big C” because the word itself was still frightening for most people to say. However, people with HIV have an added value attached to their disease, as much of the stigma they face is as a result of others’ perceptions of them being punished for engagement in risky behaviors (e.g., intravenous drug use, prostitution, promiscuity). The challenges that patients faced years ago very much resemble the challenges that people living with HIV face today. One researcher states, “Before the appearance of AIDS, cancer was the most dreaded disease (Stahly, 1988).”

Yancey and colleagues (2006) noted that from 1984 to 1998, an average of six publications per year targeted minority enrollment research. In the six years that followed (1999 to 2005), the number of studies nearly tripled to 18.3/year. A systematic review of research studies to increase minority participation in cancer clinical trials also shed light on these efforts (Ford et al., 2008). The review included qualitative, descriptive and cross-sectional studies, as well as randomized controlled trials. Of the 65 studies included in this

review, 23 targeted African Americans specifically, and of these, two were randomized controlled trials (one prevention (Ford, Havstad, & Davis, 2004) and one treatment with a pre- and post-assessment of intervention effects (Sears et al., 2003). An additional study was conducted from 1993 to 1996 with rural cancer patients and their local service providers in five counties in North Carolina (Paskett et al., 2002). The intervention included installation of a rapid tumor-reporting system, staffing of a nurse facilitator who kept physicians informed of clinical trial opportunities for their patients, distribution of a quarterly newsletter and lay health advisors to conduct outreach. This effort included pre- and post-assessments through surveys with service providers and hospital record data. An additional two studies (Gross & Krumholz, 2005; Randall-David, Stark, Gierisch, & Torti, 2001) in the review targeted rural populations as part of their recruitment efforts, but both were descriptive studies.

An exploration of educational intervention studies to increase the participation of minority PLWHA in HIV/AIDS clinical trials yielded a small number of behavioral and structural interventions, all of which were conducted in urban areas (Gwadz et al., 2010). The first study took place at an urban clinic designed for the initial assessment and triage of all newly diagnosed patients presenting with HIV infections and seeking primary care. The intervention consisted of a research associate providing information to each patient for five minutes about the purpose, role, and availability of HIV clinical trials (Freedberg et al., 2001). During the intervention, the research associate answered general questions the patient may have had about clinical trials, and patients who expressed further interest in trials were given a pamphlet and contact information for additional questions and concerns. The intervention helped reduce demographic differences in HIV clinical trial enrollment (when

compared to a historical cohort at the same clinic). Race was dichotomized for this study, with participants categorized as “White” or “persons of color”; the latter consisted of African Americans, Haitians, Africans and non-White Hispanics. Over the 20-month study period, 15.3% of persons of color and 13.0% of Whites enrolled in a trial, however no significant differences were found in participation rates between the two groups ($p=.71$).

The Harlem AIDS Treatment Group, a Community Program for Clinical Research on AIDS (CPCRA) center developed a multilevel outreach program that also was carried out in an urban clinic setting (El-Sadr & Capps, 1992). The focus of the study was to increase recruitment, enrollment, and adherence to study protocols among PLWHA of color and women. The program included informational materials about HIV/AIDS clinical trials, outreach workers who made home visits when needed, transportation for patients for study visits, social work services for referrals to necessary ancillary services (e.g., mental health, housing), and peer support groups to assist patients with adherence to study protocols. Findings for this study were not published.

An additional study conducted in Los Angeles consisted of a PLWHA meeting individually with a research assistant to discuss the meaning, role, and availability of HIV clinical trials at a local clinic in the city (Volkman, Claiborne, & Currier, 2009). Participants also were given brochures with brief descriptions of currently available clinical trials and information on who to contact for more information about the trials. After meeting with the research assistant, subjects completed a survey to determine their willingness to participate in an HIV clinical trial. Fifty-six percent of the study participants had enrolled previously in a clinical trial, and 50% of these individuals were enrolled in a trial at the time of the baseline interview. After completion of the brief educational intervention, 105

participants (94%) indicated they would be willing to be contacted about a clinical trial for which they might be eligible. Participant demographics were not reported in this study, except for gender, and there was a stark imbalance (male participants [n=106, 92%]; female participants [n= 9, 8%.])

The ACT2 Project consisted of a peer-driven intervention (PDI) strategy, which was developed to increase participation of PLWHA of color in HIV/AIDS clinical trials (Gwadz et al., 2010; Gwadz et al., 2011). The intervention, the ACT2 Project, was a randomized controlled trial designed to target barriers at the levels of individuals, their social networks and also social and structural impediments associated with healthcare service providers and ACT settings. The ACT2 intervention was grounded in the theory of normative regulation and social cognitive theory and used motivational interviewing for intervention participants. The primary outcome for the study was screening and the secondary outcome was enrollment in a trial.

The ACT2 intervention was comprised of three group sessions (5.5 hours total), three peer-education experiences, and a 30-minute individual session conducted at the ACTU. Participants in the control arm received a time-matched and attention-matched health education intervention. Of the 580 participants enrolled in the study, 56% were African American and 32% were Latino/Hispanic. Intervention dose was assessed in this study by calculating the number of sessions attended (range 0–2), whether the health education contact was completed (yes/no), and total intervention dose (range 0–3). Study results indicated that screening was much more likely in the peer-driven intervention than in the control arm (adjusted odds ratio=55.0; $p<.001$); about half of the participants in the intervention arm

(46%) were screened compared with 1.6% of controls (Gwadz et al., 2011). Approximately 92% of the participants received a full dose of the intervention.

Of the previous studies conducted to increase racial and ethnic minority participation in HIV/AIDS clinical trials research, none were conducted in rural communities where the HIV epidemic is increasing at alarming rates. Additionally, none of the studies mentioned the engagement or involvement of a community advisory board (CAB). While one of the above-mentioned studies used a theoretical approach to inform intervention development, the intervention did not include service providers, one of the most trusted sources for many PLWHA seeking treatment and care. Additionally, these studies lacked a multiple-pronged approach to assess the extent to which the intervention was carried out as planned (i.e. reach, context, dose delivered, dose received, fidelity and recruitment).

Provider Involvement in Clinical Trial Research

The importance of service provider involvement in the referral process of potential trial participants has been documented in the literature (Powell et al., 2008). Studies on minority recruitment in cancer as well as in HIV/AIDS clinical research have reported that service providers feel less prepared to discuss clinical trials with minority patients and therefore are less likely to inform minority patients about these opportunities. Further, Durlak and Dupre (2008) note that the four service provider characteristics most consistently related to implementation of an innovation, or intervention, involve perceptions related to the need for, and potential benefits of the innovation, self-efficacy, and skill proficiency. They found that service providers who recognized a specific need for the innovation, believed the innovation will produce desired benefits, felt more confident in their ability to do what is

expected (self-efficacy), and had the requisite skills were more likely to implement a program at higher levels of dosage or fidelity (Durlak & Dupre, 2008).

To identify community views about increasing participation in HIV clinical trials in rural North Carolina, Project EAST staff conducted focus groups with service providers prior to intervention development. Participants in these groups emphasized the importance of educating local service providers, as PLWHA were most likely to consult with these individuals when considering clinical trial participation. They further stated that outreach should include a variety of healthcare professionals (physicians, physician assistants, nurses, nurse practitioners, pharmacists, health educators, case managers and social workers) and should include a clear understanding of what clinical trials entail, what to expect if their client is enrolled, and consistent feedback and education around recruitment for ongoing studies to increase awareness and confidence in the research process. This mirrors the framework provided by Durlak and Dupre (2008) by addressing perceptions, self-efficacy, and skill proficiency as it relates to clinical trial participation.

Process Evaluation Research

Process evaluation is used to monitor and document program implementation and can aid in understanding the relationship between specific program elements and program outcomes (Saunders, Evans, & Joshi, 2005). The importance of process evaluation was conceptualized as early as the 1960s, as sociologist Suchman (1967) wrote:

An evaluation study may limit its data collection and analysis simply to determining whether or not a program is successful. . . . However, an analysis of process can have both administrative and scientific significance, particularly where the evaluation indicates that a program is not working as expected. Locating the cause of the failure may result in modifying the program so that it will work, instead of its being discarded as a complete failure

Across a variety of disciplines, there has been an increasing interest in process evaluation research to assist researchers in understanding the mechanisms by which program components are expected to influence behavior change (Linnan & Steckler, 2002; Saunders et al., 2005). Process evaluations have been conducted to target a variety of health behaviors, including: smoking, nutrition/diet, breastfeeding, cancer prevention and education, physical activity, diabetes, depression, fruit and vegetable consumption, HIV/AIDS prevention, and prevention clinical trials. Only a few of these studies were conducted in rural areas with African Americans—none with HIV or clinical trials among this population.

The increased attention to process evaluation research is due, in great part, to researcher awareness of the importance of understanding what specifically contributes to a program's success or failure. Program evaluation assists researchers in making a very important distinction between *implementation* failure and *intervention* failure (Harachi, Abbott, Catalano, Haggerty, & Fleming, 1999). This is to say, a program could be deemed ineffective if there were no significant effects associated with its outcome, but that could have been due to poor program design, poor or incomplete program implementation and/or failure to reach sufficient numbers of the target audience (Flay, 1986; Saunders, Evans, & Joshi, 2005). Process evaluation helps to avoid Type III error, drawing incorrect conclusions about the effectiveness of an intervention that was not properly implemented (Basch, Slipevich, Gold, Duncan, & Kolbe, 1985). Several studies have questioned reported ineffective outcome results of studies that lacked thorough assessments of the degree to which the program was implemented as intended (Rezmovic, 1982). Linnan and Steckler (2002) recommend a minimum of six process evaluation concepts: context, reach,

recruitment, dose delivered, dose received and fidelity, each of which was assessed for the dissertation study.

Context refers to the aspects of the larger social, political, and economic environment that may influence intervention implementation. *Reach* refers to the proportion of intended target audience that participates in the intervention; it is often measured by attendance and is a characteristic of the target audience. *Dose delivered* is the number or amount of intended units of each intervention or each component delivered or provided. *Dose delivered* is a function of efforts of the intervention service providers. Dose received refers to the extent to which participants actively engage with, interact with, are receptive to, and/or use materials or recommended resources. It also assesses the extent of engagement of participants with the intervention. *Fidelity* is the extent to which the intervention was delivered as planned. It represents the quality and integrity of the intervention as conceived by the developers and is a function of the intervention service providers. *Recruitment* details the procedures used to approach and attract participants. Each of the aforementioned components can be assessed qualitatively or quantitatively. A thorough process evaluation helps researchers to better understand how challenges, adaptations and contextual issues affect internal and external threats to validity to study design and implementation (Cook, Campbell, & Day, 1979; Glasgow, 2009). This has been a critical gap in public health research, and limits the extent to which research can interpret and translate findings to comparable populations.

Summary

Previous efforts to increase racial and ethnic minority participation in HIV clinical trials have been very limited in the literature. Of the programs developed to date, none have targeted rural populations in general or rural, racial and ethnic minorities specifically.

Interventions conducted in urban settings have demonstrated successes in increased screening among minorities (Gwadz et al., 2011), however there are not clear indicators to understand *how* or *why* the interventions were successful. This coupled with a need for researchers and practitioners to fully understand challenges, adaptations, and contextual issues as they relate to rural, African American PLWHA *and* their local service providers, demonstrates the need for this dissertation study.

The multilevel approach of Project EAST's intervention was novel, as previous HIV clinical trial efforts did include service providers as part of their outreach efforts. As this is the first study of its kind, it is important to understand *how* the program was implemented. Therefore, the primary aim of the dissertation study was use to evaluate implementation of Project EAST's educational HIV/AIDS clinical trial intervention.

CHAPTER 3

PROJECT EDUCATION AND ACCESS TO SERVICES AND TESTING (EAST)

The parent study, Project EAST, consisted of three phases focused on: (a) defining community and individual factors that influence willingness of rural, racial and ethnic minorities to participate in HIV/AIDS clinical trials; (b) refining a theory-based, culturally responsive outreach strategy to increase referral to, and enrollment in clinical trials and evaluate the acceptability of components of this outreach from the perspective of community members, service providers, and people living with HIV/AIDS (PLWHA); and (c) determining the feasibility of the outreach sessions to increase service provider willingness to refer eligible PLWHA to open HIV/AIDS clinical trials and increase eligible PLWHA willingness to participate in HIV/AIDS clinical trials.

The principal investigator of Project EAST, Dr. Giselle Corbie-Smith, is a professor of social medicine with expertise in community-based research and has published extensively on barriers to clinical trial research among minority populations (Corbie-Smith, Moody-Ayers, & Thrasher, 2004; Corbie-Smith, Thomas, & St. George, 2002; Corbie-Smith et al., 2003). The research team consisted of investigators from the University of North Carolina at Chapel Hill Schools of Medicine, Dentistry, Nursing and Public Health with wide-ranging expertise in health disparities research, clinical trials coordination and administration, rural population outreach and education, and community-based research. The author of this dissertation study served for three years as a research assistant with Project EAST and two

years as project coordinator an additional two years.

Gaining Entrée: The Community Advisory Board (CAB)

Given the legacy of mistrust in minority communities of medical research (Braunstein et al., 2008; Corbie-Smith, Thomas, & St. George, 2002) and the sensitive nature of HIV, guidance from a community advisory board (CAB) was critical for community buy-in, recruitment for the study, implementation of the intervention (Fouad et al., 2000; Michaels & Seifer, 2007; Seifer, Michaels, & Collins, 2010) and dissemination of findings (Fouad et al., 2001; Michaels & Seifer, 2007). Partnerships that include the establishment and engagement of a CAB can enable researchers to engage minority communities with high rates of HIV but not currently accessing clinical trials, build on trusting community relationships to improve minority participation in these areas, and provide a vehicle to develop and provide outreach to HIV clients and their local service providers around research participation. Moreover, the National Institute of Allergy and Infectious Diseases (NIAID), which requires researchers in its clinical trials network program to include community members as part of their efforts, has incorporated these principles since the 1980s and has provided a framework for other types of clinical trials research (Community Recommendations Working Group of Community Partners, 2009). The Project EAST CAB was charged with providing overall guidance to the study team by aiding in the refinement and translation of all research materials, participating in the development of the focus group and interview guides for formative data collection, advising on qualitative data interpretation, and assisted with recruitment of HIV advocates and peer outreach workers prior to implementation of the intervention.

Intervention Theoretical Foundation

Based on findings from interviews conducted with clients and focus groups conducted with service providers and community leaders during formative data collection, the research team guided intervention development using the intervention mapping approach (Bartholomew, Parcel, & Kok 1998). Constructs from the theory of reasoned action (TRA) and social cognitive theory (SCT), in addition to the social support (SS) framework were found to be relevant for understanding the mechanisms through which the intervention could influence referral to, and participation in, HIV/AIDS clinical trials among study participants.

Theory of Reasoned Action. The theory of reasoned action (TRA) was conceptualized by Ajzen and Fishbein in 1975 and has been used to explain a variety of health behaviors. This theory asserts that a person's intention is the strongest predictor for a given behavior, and is a direct result of one's attitude and subjective norms about the behavior (Ajzen & Fishbein, 1980). While this theory has not been used for explaining HIV clinical trial participation, it has been applied in a national study evaluating the efficacy of HIV prevention counseling in changing high-risk sexual behaviors and preventing new sexually transmitted diseases and HIV (Fishbein et al., 2001; Fishbein, Hennessy, Yzer, & Douglas, 2003; Kamb et al., 1998). TRA also has been used to explain service provider referral behaviors for emergency contraception (Sable, Schwartz, Kelly, Lisbon, & Hall, 2006).

Social Cognitive Theory. Social cognitive theory (SCT) is one of the most frequently used and robust health behavior change theories (Glanz, Rimer, & Viswanath, 2008). It explores the interactions of people and their environments, as well as psychosocial determinants of health behavior. The relationship of these three components is referred to as a reciprocal determinism, whereby each domain interacts reciprocally by influencing another (Bandura,

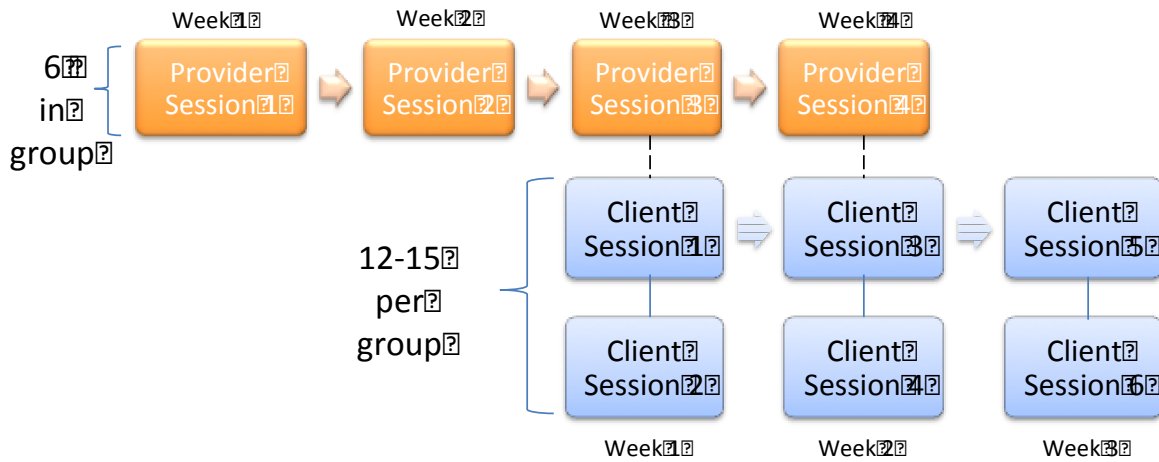
1986). It is important to note however, that the strength of influence of each concept may differ and is not necessarily equal. SCT is very complex and consists of several constructs, two of which were used for the development of the educational intervention: self-efficacy and outcome expectations. Self-efficacy is defined as one's confidence to perform a particular behavior. This construct has been described by Bandura as the most important prerequisite for behavior change (Bandura, 1977). Outcome expectations are defined as the anticipatory outcomes of a behavior. In other words, a person learns that certain outcomes occur in a given situation and expects them to occur when that situation presents itself again.

Social Support. Social support is defined as the provision of aids and services from individuals within a person's social network (Heaney & Israel, 1997). The four types of social support include: emotional, appraisal, informational, and instrumental. Emotional support is the most commonly recognized form of social support and includes empathy, concern, caring, love, and trust. Appraisal support involves transmission of information in the form of affirmation, feedback and social comparison. Informational support includes advice, suggestions, or directives that assist the person to respond to personal or situational demands. Instrumental support is the most concrete direct form of social support, encompassing help in the form of tangible aid (money, time, childcare, transportation). This framework has not been applied in the context of HIV clinical trial participation, but of the interventions targeting trial participation, two have included a peer component as a part of the dissemination of information about clinical trials. Evaluation of the HIV clinical trial interventions with peer components did not include assessments focused the type of support; rather dichotomous values were calculated to indicate whether the intervention participant received peer services or not (Volkman et al., 2009).

Series Layout

The intervention was designed so that service provider and client series could be implemented in a staggered, concurrent layout (see Figure 1). The goal was to complete half of the service provider series prior to implementation of the client series, thus affording service providers an opportunity to become familiar with concepts in the event that their client had questions regarding trial participation. This staggered, concurrent layout allowed comparable content to be covered for service provider and clients, through a variety of theory-based methods and strategies (Bartholomew et al., 1998). The intervention was developed to reach six rural service providers and 40 of their racial and ethnic minority clients living with HIV/AIDS. To ensure effective group interaction and meet the recruitment goal of 40 clients, the intervention rolled out in three consecutive groups, with 12-15 clients in each group. Figure 1 depicts the layout of one service provider group and the first client group, as intended. Subsequent client groups were scheduled to occur sequentially, with a one to two week interval between groups to allow research staff to regroup and prepare between groups.

Figure 1: Intended Schema for Intervention Study (Provider and Client Series)



Client Series. The client series consisted of six sessions that took place at a location that was accessible for all participants, including local libraries or community centers. The series was implemented over the course of three weeks, with two sessions implemented one day per week (See Figure 1). Each session ranged between 60 and 90 minutes. Each client received \$75.00 worth of Wal-Mart gifts cards for completing the series (including baseline and immediate-post survey completion) and a \$25.00 Wal-Mart gift card for completion of a six-month follow-up survey. Additionally, \$10.00 gasoline cards were provided for participants who used a personal vehicle for transportation and needed assistance with transportation costs.

Each session’s materials were informed by review of the literature on participation in clinical trial research in general and participation in HIV clinical trials in particular. Formative data from client, service provider, and community leader interviews in the parent study guided intervention development. The intervention mapping (IM) approach informed this process (Bartholomew et al., 1998). The client series provided information about the

conduct of clinical research, information about ongoing HIV/AIDS trials for which clients may be eligible, informed consent, participant rights, what to expect as part of their participation in a clinical trial and how to get support as part of their decision-making process, as well as other components raised in the client interviews the formative phases of the study (Table 5). All session materials, activities, and evaluation tools were guided by the results of the qualitative data from the first phase of the study and by the intervention mapping (IM) process. More detail is provided in Appendix A as to what activities were developed to cover the aforementioned content. If questions arose during the session that were not covered as part of the curriculum content, facilitators were instructed to place them in the “parking lot,” a flip chart used to document participant questions. Questions from the “parking lot” were then e-mailed to two co-investigators on the study who also were physicians at the UNC ACTU. The session facilitator then shared the co-investigators’ responses to these questions to clients attending the subsequent session. After completion of their series, clients received postcards every six weeks that reviewed and emphasized important concepts from session materials and presentations.

Session 1	Provide basic information on clinical trials. Participants will learn what clinical trials are, their purpose and function, the various phases of clinical trials, characteristics of randomized clinical trial research, such as: randomization, blinding and the importance of minority participation in clinical trials. Additionally, clients will learn how research fits into HIV care.
Session 2	Provide information about the different types of clinical trials. Participants will learn more about the referral process through an interactive exercise. Participants will also be equipped with necessary tools and skills for asking questions about clinical trials.
Session 3	Provide information about ethical issues related to clinical trials, including how participant rights are protected. Additionally, participants will identify ways to overcome common barriers associated with clinical trial participation.
Session 4	Focus on the importance of seeking support as part of the decision-making process. Emphasis was placed on enhancing existing social networks or creating new networks. Participants will learn about communication as it relates to seeking support for trial participation.
Session 5	Provide an opportunity to locate clinical trial opportunities and identify referral sources. Additionally, participants will learn how to effectively communicate with their service provider about clinical trial opportunities and to seek out and connect to clinical trial resources.
Session 6	Culmination of information from previous sessions to help participants understand key aspects of clinical trials. Additionally, participants will have an opportunity to communication with a referral source, an ACTU physician.

Service Provider Series. The service provider series consisted of four 60-70 minute sessions. Like clients, each session's materials were informed by review of the literature on participation in clinical trial research in general and specific to HIV, as well as formative data from the parent study. All session materials, activities, and evaluation tools were guided by formative data from the first phase of the study (clients, service providers, and community leaders) and by the intervention mapping (IM) process. In keeping with EAST co-investigator experience and existing literature, shorter, intense sessions were developed for service providers (as compared to client sessions).

Content included information about the conduct of clinical research, information about ongoing HIV/AIDS trials for which their patients may be eligible, the role of the service provider and how their relationships with HIV-positive clients may influence trial participation, what to expect if their client or patient participates in a clinical trial and how to

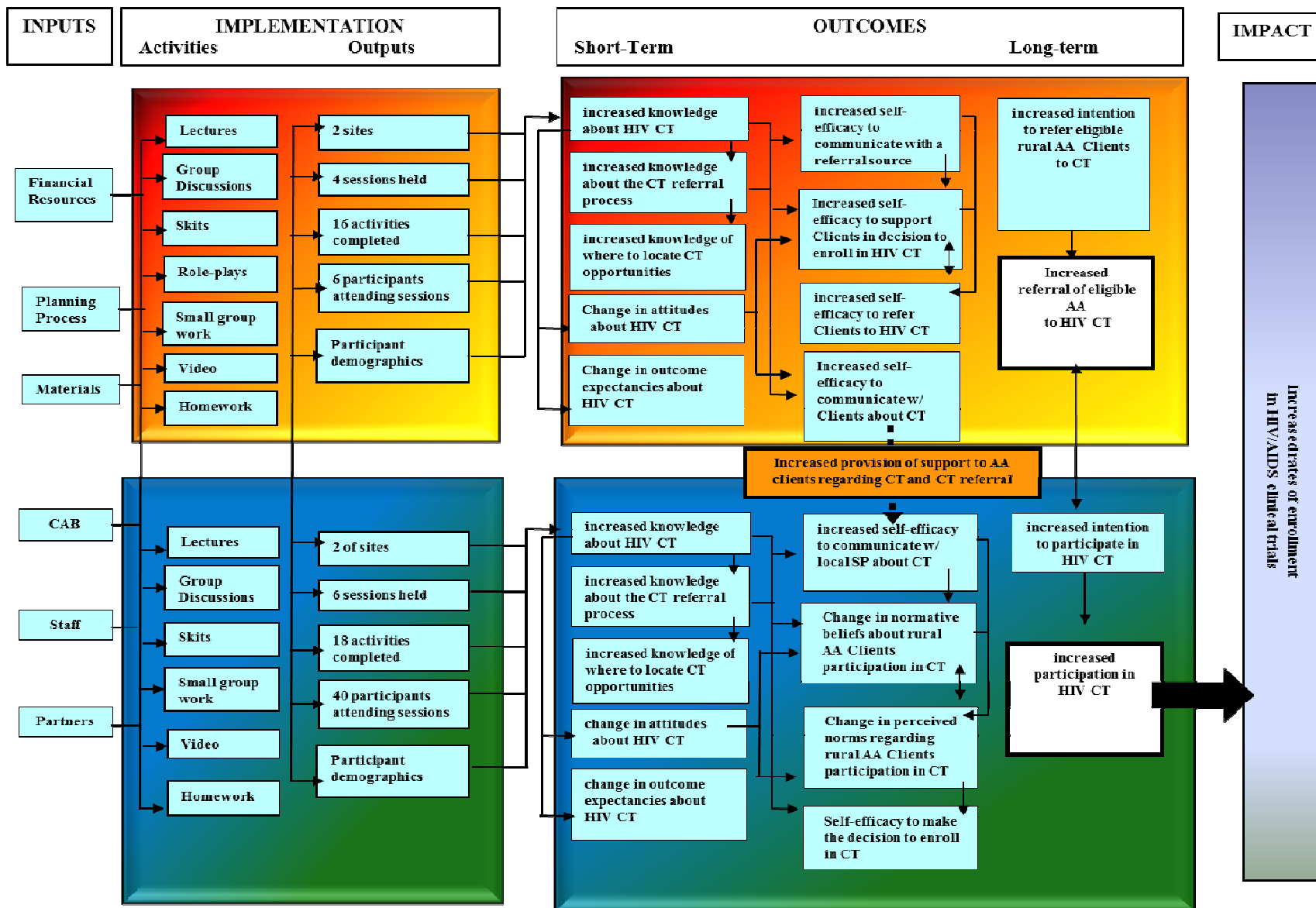
support them in their decision. Service provider sessions also had a “parking lot” to document questions that facilitators may not have been able to answer during the session. The session facilitator then shared the co-investigators’ responses to these questions to service providers attending the subsequent session. Table 6 details session specific content for service providers; more detail is provided in Appendix B regarding activities that were developed for each service provider session. Each service provider received \$75.00 for completing the series (including baseline and immediate-post survey completion) and \$25.00 for completion of a six-month follow-up survey. As service provider sessions took place in the facility in which they were employed, transportation costs were not applicable for this group.

Session 1	Provide basic information on clinical trials. Participants will learn what clinical trials are, their purpose and function, the various phases of clinical trials, and characteristics of randomized clinical trial research, such as: randomization and blinding. Will also provide information about ethical issues related to clinical trials, including how participant rights are protected. Additionally, service providers will learn how research fits into HIV care and how to support their clients in a neutral, balanced way as part of the decision making process. Finally, the session will service providers understand the importance of minority participation in clinical trials.
Session 2	Inform service providers of their role of communicating with clients in a balanced and neutral way Also, service providers will be provided with necessary tools and skills for addressing questions about clinical trials.
Session 3	Provide an opportunity for service providers to locate clinical trial opportunities and identify referral sources. It also covered the importance of establishing networks locally and at major medical centers to help enroll clients in clinical trials. Service providers were encouraged to think about where and how they can become a resource to each other and to their clients.
Session 4	Culmination of information from previous sessions to help service providers understand key aspects of clinical trials, effectively communicate with clients about clinical trial opportunities, seek out and connect to clinical trial referral resources, and to support their clients through the decision-making process. Strong emphasis was placed on skills and demonstration in this session.

Logic Model

A logic model is a pictorial representation of how an intervention is expected to work, as well as the theory and assumptions underlying the intervention (McLaughlin & Jordan, 1999). These models have been widely used in public health research across a variety of behavioral interventions (Hawkins, Clinton-Sherrod, Irvin, Hart, & Russell, 2009; Helitzer, Willging, Hathorn, & Benally, 2009; Kaplan, Calman, Golub, Ruddock, & Billings, 2006; Livingood, Winterbauer, McCaskill, & Wood, 2007; Price, Alkema, & Frank, 2009). A logic model consists of five components: inputs, activities, outputs, short-term and long-term outcomes and impacts (W.K. Kellogg Foundation, 2001). Inputs include the human, financial, organizational, and community resources that a program has available to direct toward development of intervention activities. Activities are the components of the intervention, or program (e.g., lectures, role-plays, videos). Outputs refer to the direct products of program activities and may include types, levels, and targets of services to be delivered by the program. These could include the number of people taking part in the intervention or the number of sessions offered. Outcomes are specific changes in program participants' behavior, knowledge, skills, status, and level of functioning. Short-term outcomes are typically attainable within one to three years, while long-term outcomes are attainable within four to six years. Impacts are the fundamental intended or unintended change occurring in organizations, communities or systems as a result of program activities within seven to 10 years. Due to the long duration of impact assessments, evaluation often occurs after the conclusion of project funding (W.K. Kellogg Foundation, 2001). The logic model for Project EAST can be found in Figure 2.

Figure 2: Project EAST Logic Model



The inputs for Project EAST detail the individuals (staff, volunteers, community partners and members of the community advisory board) and resources (research, travel, money, materials) that supported the development of intervention activities. Activities for clients and service providers included: brainstorming, group discussions, role-plays, skits, small group work, lectures, video, newsletters, and homework assignments. Outputs detailed the number of outreach sessions held, the number of attendees and the cumulative total numbers of hours from all sessions for each group. Short and long-term outcomes are presented in more detail in the logic model. These outcomes will not be discussed for the purposes of the dissertation study, as the assessment of the expected behavior changes are part of the outcome evaluation for the parent study.

Session Facilitators. Facilitators consisted of a combination of paid and unpaid staff on the research team. All completed the required human research ethics training through the University of North Carolina at Chapel Hill, as well as a three-day training comprised of an overview of the intervention study (including the structure and content of the client and service provider series), group management skills, and community-based research ethics. At the onset of the facilitator training, all trainees were provided with curricula covering the entire intervention study (provider and client series) including PowerPoint presentations, handouts, role-play keys with relevant probes, copies of all posters used, materials needed, and preparation for the session. Additionally, facilitators were provided with background information about the theoretical foundation of the intervention in order to assist with understanding the theoretical objectives that were to be met as part of their session. Each trainee was expected to learn all of the modules for both the provider and client series in order to understand how all of the session content

syncs together. After the culmination of the training, each trainee was responsible for facilitation of a mock session of their choice and feedback was provided by other trainees and the Project EAST research staff leading the training. The research staff then provided individualized feedback for each trainee in a private setting to further detail mastery of facilitation skills and session content. If trainees did not demonstrate sufficient mastery, they were offered remediation prior to entry in the field.

Selection of Study Sites

Two regional clinics were identified as potential study sites based on county level HIV demographics, service provider composition, number of HIV-positive clients, and the clinic's distance from major medical academic centers. Like most predominantly rural areas, residents in the study counties were generally poorer, had higher unemployment rates and were less educated compared to their urban counterparts. Site recruitment began by contacting administration at two community clinics servicing clients in Project EAST six-county region. The project coordinator provided an overview of the parent study, the intervention study (including the service provider series and client series), and also assisted with determining organizational capacity to: a) assist with recruitment and retention of service providers and clients and b) assist with transportation for clients (if needed). Sites were offered an organizational incentive to cover costs associated with recruitment of participants, securing meeting space, and tracking of participants over the course of the six-month pilot. After confirmation of interest to participate in the study, and administrative approval to participate as a site, the project coordinator sent an introduction letter to the site administrator to further explain the intervention study with their service providers and clients.

At the onset of implementation of the service provider series, one clinic had to withdraw due to severe financial and staffing constraints. Due to recruitment challenges at the remaining clinic, a partnering clinic was added to meet the recruitment goal at this study site. More information about this modification can be found in Chapter 5. Table 6 profiles each of the participating clinic’s distance from regional major academic medical centers (UNC ACTU, Duke University AIDS Research and Treatment Center (DART) and East Carolina University (ECU)) as well as the number of HIV service providers and HIV-positive clients at each clinic. Clinic names were not used for the dissertation study, as to ensure their anonymity. They were referred to as “original” or “partnering” site for narrative, descriptive purposes, or and Site A or Site B for data management and analyses in order to make a clear, simple distinction between the two sites.

Site	Proximity to major academic health centers	Status	# of HIV Service providers	# of HIV+ clients served
Original Clinic	UNC: 80.4 miles (86 min) Duke: 79.7 miles (81 min) ECU: 33.1 miles (38 min)	Public, non-profit	2 (MD and a PA)	402 (2010)
Partnering Clinic	UNC: 104 miles (106 min) Duke: 103 miles (101 min) ECU: 24.9 miles (97 min)	Public, non-profit	(HIV: 1 NP)	45 (2010)

Intervention Study Sample Population and Setting

The study population for the intervention study consisted of clients receiving HIV/AIDS care from service providers at two primary healthcare clinics in three contiguous counties of North Carolina. This section will detail eligibility criteria, recruitment procedures, and informed consent procedures for clients and providers, respectively. All consent procedures and documents were approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

Of note, “service provider” was defined broadly, so as to include clinicians and non-clinicians (e.g., physicians, nurses, nurse practitioners, pharmacists, case managers, social workers, or health educators) as part of recruitment efforts. Per the recommendations of Project EAST CAB members, and formative focus group and interview data for the parent study, non-clinicians were strongly suggested to participate in the series as they felt case managers and other non-clinicians had a considerable amount of interaction with clients living with HIV, and were among the most trusted individuals for many of these rural clients.

Client Eligibility Criteria. Clients for the intervention study had to receive HIV services from the clinic serving as a study site, be African American or Latino, HIV-positive and English-speaking. Additionally, each client had to be at least 18 years old and have sufficient cognitive functioning to allow informed consent.

Client Recruitment. Recruitment of clients began with identifying an existing HIV support at the original study site. With the guidance of the CAB, Project EAST staff was introduced to the leader of this group, an HIV-positive African American male, who later served as the site recruiter for all client series. Having obtained a Certificate of

Confidentiality from the National Institutes of Health, the Project EAST research team did not collect any identifying information from clients participating in the series. The research assistant made the site recruiter aware of this certificate and explained how clients would be tracked over time: alphanumeric identification numbers (IDs). Each client would generate his/her own alphanumeric identification number at the onset of the series (e.g., “GLH45”), which was used for all surveys for the study. Additionally, each client was encouraged to give a pseudonym in order to encourage interaction with other clients and with the session facilitator. For example, clients could give names ranging from “Sunshine” to “Mr. Z”. Because session content was built-upon material covered in preceding sessions, clients were also made aware that they could not join the series after the first session was complete.

After confirming a start date for the series with the Project EAST research assistant, the site recruiter was provided with recruitment flyers and given directives as to how to complete recruitment tracking forms as he recruited participants. The tracking form detailed the total number of clients recruited, the number who agreed to participate in the client series, the number who declined participation in the series, and the number who ultimately participated in the series (see Appendix C). Participants who declined participation in the study were asked why and assured that their decision would in no way influence their future care. Prior to the first session in the client series, the site recruiter totaled the number of individuals declining participation and reported reasons for non-participation. Participants who were absent for any individual session were also asked reasons for non-participation by the site recruiter; the Project EAST research assistant documented these reasons. To stay abreast of recruitment efforts and to assess any

challenges related to recruitment efforts, the Project EAST research assistant met weekly via conference call with the site recruiter.

Client Informed Consent. Prior to implementation of the first session in the client series, a member of the research study team obtained verbal informed consent from all participants. The team member emphasized that agreeing to participate in this part of the study did not mean that they were agreeing to be in any clinical trial and they would not receive any treatment as part of their participation in the sessions. Verbal consent was obtained from all clients prior to beginning the series.

Service Provider Eligibility Criteria. The site administrator was asked to identify six service providers that provided a considerable amount of direct services to African American or Latino clients living with HIV/AIDS. Eligibility criteria for service providers also required that providers were clinical or non-clinical employee at the study site (physicians, nurses, nurse practitioners, pharmacists, case managers, social workers, and health educators) and English-speaking.

Service Provider Recruitment. Providers were selected by the site administrator based on the number of clients each served, as well as daily interactions with eligible clients. Service providers recruited for the sessions were given information about the intervention study via e-mail from the site administrator, as well as dates for the each of the scheduled sessions. Because session content was built-upon material covered in preceding sessions, service providers were also made aware that they could not join the series after the first session was complete.

Service Provider Informed Consent. Prior to implementation of service provider series, a member of the Project EAST research study team obtained written informed consent from all providers

CHAPTER 4

METHODS

This chapter describes the methods and procedures used to assess the extent to which intervention components for service providers and clients were implemented as planned. It answers research questions for Aim 1 (Evaluate the implementation of an educational HIV clinical trial intervention with rural, African American people living with HIV/AIDS (PLWHA) and Aim 2 (Evaluate the implementation of an educational HIV clinical trial intervention with rural service providers) of this dissertation study. Chapter 4 details the data collection methods, data sources (accompanied by information on the management, organization and analysis of each source), as well as processes taken to strengthen the validity of study findings.

Data Sources and Collection Methods

Process evaluation, particularly in the context of complex interventions, requires multiple modes of data collection to assess the extent to which the intervention was implemented as planned. Further, multiple methodological approaches strengthen the validity of study findings by reducing facilitator subjectivity in interpretation of findings (Linnan & Steckler 2002). As such, this dissertation study used a variety of methods: observation, interviews, focus group discussions, memoing, and document review. A total of 2,338 pages of data and 38 hours of audio were analyzed across data sources for the dissertation study. Data sources included: (a) recruitment tracking forms and attendance logs, (b) session audio recordings and verbatim transcripts, (b) observational

data, (c) facilitator debriefing interviews, (d) participant focus group discussions, (f) CAB meeting transcripts, and (g) satisfaction surveys. A detailed overview of process evaluation concepts, data sources, tools, timing and analysis can be found in Table 8.

The next section will describe each data source, its management and organization, timing of data collection, and analysis beginning with session audio recordings and transcripts.

Recruitment Tracking Forms and Attendance Logs

The recruitment tracking form answer the questions regarding recruitment: *What were the barriers to recruiting participants for the intervention? What planned and actual procedures were used to encourage continued involvement of individuals, groups, and organizations? What were the barriers to recruiting individuals, groups, and organizations? What were the barriers to maintaining involvement of individuals, groups, and organizations?* Tracking forms were used in concert with attendance logs to assess the reach of the intervention study, thus answering the question: *What is the proportion of the intended target audience that participates in the intervention?*

The tracking form completed by the site recruiter detailed the number of clients recruited to participate in the client series, as well as the number of those who agreed or declined to participate in the client series (See Appendix C). Space was also provided for the site recruiter to document reasons for client refusal to participate. The site recruiter and a member of the Project EAST team met weekly to discuss recruitment updates for each group and barriers to recruitment. Given that service providers were identified and selected by administrators at their respective site, the tracking form was not applicable for these participants. Once enrolled in the intervention study, clients and service providers were required to sign in at the beginning of each session in their series. To maintain

client confidentiality, each client was asked to provide “signatures” consisting their self-generated alphanumeric IDs (three letters and two numbers). As two consecutive sessions were held per day for clients, two sign-in sheets were completed on each of these days. The principal investigator of this dissertation study developed an attendance log that was a compilation of sign-in sheets from all service providers and clients in the intervention study. To determine to proportion of those recruited attending each session, the total number of participants present were divided by the total number of those who agreed to participate in the series (as identified on the recruitment tracking form).

Management and Organization

Recruitment tracking forms and sign-in sheets were labeled with the group type (client or service provider), session number, and date prior to session implementation. Once completed, each form was scanned electronically and saved on a secure, password protected server. The attendance logs created for service providers and clients also were saved on the secure server.

Analysis

To determine the proportion of intended participants enrolling in the intervention series, the total number of participants beginning their respective series across all groups divided by the recruitment goal for all clients. For example, if a total of 36 clients began the client series (9 in each group), then 90% of the intended number of clients participated in the intervention series. Recall, the recruitment goal for clients was 40, therefore 36 total clients divided by 40 intended participants equals .90 or 90% of the intended goal was reached.

Attendance logs were created from sign-in sheets distributed at each session.

These further explored retention of those enrolled in the intervention study All service provider and client IDs were compiled into one document and attendance for each session was marked as “1” for present and “0” for absent. Proportions were used to determine the percentage of sessions attended by each participant (number of sessions attended/ number of sessions offered x 100%). For example, if a service provider attended three out of four sessions, he attended 75% of the sessions offered ($3/4 \times 100 = 75$). Reasons for client or service provider dropout after beginning the series were documented by the site recruiter and relayed to research staff during weekly recruitment meetings.

Session Audio Recordings and Verbatim Transcripts

Digital audio recordings and transcripts of sessions served as data sources for implementation checklists, tools developed by the principal investigator of this dissertation study to assess whether tasks associated with each session activity were completed as designed (See Appendix D). This tool also has been used in other studies to assess intervention implementation in HIV clinical trials research (Ferguson et al., 2009). Checklists also provided space for the principal investigator to note any variations in intervention delivery. These data provided a structured means to answer the following questions related to *dose delivered* and *fidelity*: *To what extent were all of the intended components of the intervention provided to participants? To what extent were the intended content, methods, strategies, and activities used? Was the intervention implemented as planned?*

Management and Organization

All sessions were recorded using digital recorders, typically two with each being placed at opposite ends of the meeting space to capture dialogue, comments and

questions during the session, and facilitator delivery of session content. After completion of all sessions for a group, the research assistant uploaded audio files from the digital recorders to a secure password-protected server for the parent study. Audio files were saved and labeled with an archival ID that included: a) group number, b) study site location (abbreviated “AA” for the original study site or “BB” for the partnering site), c) the group type (abbreviated as “SP” or “CL”), and session numbers separated by periods. For example, an audio file from sessions 3 and 4 with the second group of clients at the original study site would be identified as, “2AACL3.4.FL”. After session audio files were labeled and saved on the secure server, they were ready to be transcribed.

An experienced transcriptionist, using the Project EAST transcription protocol with strict confidentiality guidelines, transcribed session audio files verbatim. The final hard copy transcripts were redacted of any identifying information as part of the transcription process. After completion, the transcriptionist saved the electronic version of the transcript on the secure server and alerted the Project EAST research assistant. These transcripts were then printed, labeled to mirror audio file IDs, and then stored in a locked file cabinet in the principal investigator’s office. Each session transcript was verified through a four-step process: three independent listens, and a finalization.

The verification process consisted of identification and correction of text that was transcribed incorrectly, or audio the transcriptionist could not decipher (thus labeled “inaudible”). Like the transcriptionist, each reviewer was required to follow the Project EAST transcription protocol. The first verification, or “listen”, of the transcript text was conducted by the professional transcriptionist immediately after transcription. After the file was placed on the secure sever, and the Project EAST research assistant alerted of file

completion, the transcript was saved in a corresponding folder with additional data for the group. The second verification, or “listen”, was conducted by the research assistant or a project intern. If any discrepancies or errors were identified, edits were made on the hard copy of the transcript. If any additional discrepancies or errors remained after the second listen, a third reviewer (the project coordinator or the principal investigator of the parent study) would resolve these prior to finalization of the transcript. During this final step all previous edits from the hard copy were made on the electronic version of the transcript and saved on a secure server. The final version included a header that detailed the finalization date with the word “FINALIZED” following the original file name (for example “2AACL3.4.FL—FINALIZED 10/23/11”). The finalized transcript was printed and placed with the original file in the locked file cabinet.

Implementation checklist data were entered electronically, labeled with an ID corresponding with session transcript ID, and saved on the secure server by the principal investigator of this dissertation study. Additional space was provided for comments, or memos, related to implementation *fidelity* (see Appendix D). For example, if the facilitator of the session completed a task (as indicated by a “1” on the implementation checklist) but did not follow the specific directives the per the session curriculum, this variation was documented in the space next to the corresponding task (e.g., “The facilitator skimmed the handout very briefly—only read four of the seven types of HIV clinical trials”). In reality, the handout was distributed and the facilitator did read it, thus the task was complete and would be scored as such (see “Analysis” below for more detail). Reading a fraction of the handout however, is not the manner in which the curriculum directed the facilitator to read the handout. Fidelity data captured as part of

the completion of the implementation checklists were then organized into matrices to further explore patterns related to facilitator characteristics, possible intervention discrepancies or broader contextual influences on implementation.

Analysis

Session audio files were used a data source for the completion of implementation checklists. The principal investigator of the dissertation used digital software to access and listen to these files while completing implementation checklists. Session transcripts supplemented session audio files by serving as a source to resolve any discrepant issues with inter-rater reliability scores

Tasks were scored on the implementation checklist as “1” if they were completed and “0” if they were not completed. The dose delivered score was then obtained by adding the individual scores of the tasks completed in the session and dividing this value by the total number of tasks slated to take place in the session. For example, if the session facilitator completed 13 of the 19 tasks required for a particular session, his dose delivered score would be .68 ($13/19 = .68$). Dose delivered scores over .85 indicated high dose delivered for the session (Miles & Huberman, 1999). To assess reliability in scoring of the implementation checklists, every fifth checklist was also scored by a doctoral student who was part of intervention development and implementation, as well as research project staff training. Inter-rater reliability scores were obtained by determining the number of items in agreement between the principal investigator and doctoral student divided by the total number of tasks in the session. Discrepancies found to be a result of rater error were categorized as such; discrepancies due to ambiguity or unclear directives in the curriculum were categorized as scripting errors.

Observational Data

Observational data were used to assess *dose delivered*, *dose received*, and *fidelity*. This data supplemented other data sources by providing information that could not be captured otherwise, specifically non-verbal indicators of participant engagement or facilitator/participant interaction. These data were collected by a combination of paid and unpaid staff on the research team. All observers completed the required human research ethics training through the University of North Carolina at Chapel Hill, as well as four-day training comprised of an overview of the intervention study (including the structure and content of the client and service provider series), process evaluation methods, group management skills, community-based research ethics, basics of process evaluation, measurement, and observation/note-taking basics. All observers completed a one-hour, hands-on field observation exercise in which each trainee had an opportunity to expand their observation notes into a narrative summary and receive feedback from project staff.

During each client or service provider session, two members of the research team served as observers. A structured guide that included a layout out of the room and space to document issues for each session activity was provided to each observer prior to implementation of each session. Observers documented verbal and non-verbal indicators of participant engagement, interruptions (if any), and the length of session activities. This handwritten data was expanded into a narrative form within 48 hours of the session, and was saved electronically on a secure server. Narrative summaries also served as a very important source to determine whether all session materials were used, particularly if the information was not acknowledged or stated by the session facilitator or the

participants during the session, or as part of their respective follow-up discussions (i.e., facilitator debriefing interview or participant focus group discussion). For example, the observer may note the “Clinical Trial Definition” poster was not displayed during the session and the data was not captured elsewhere, this critical information could be omitted from process and outcome analyses.

Management and Organization

Structured observation guides were labeled to correspond with the session ID (i.e. “2AACL3.4”) and were scanned electronically. Narrative summaries of these data were typed and saved using the same ID from the structured observation guide, with the addition of an “.EX” suffix to identify them as expanded notes from the structured guide. All observational data was saved on a secure server in a file corresponding with the session ID.

Analysis

Handwritten notes and expanded narrative summaries from each session were read prior to the analysis of interviews and focus group discussions to gain contextual information about the session. Brief memos were written by the principal investigator and documented while completing the checklist.

Facilitator Debriefing Interviews

Facilitator debriefing interviews were conducted at the end of each session by one of the session observers. A pretested debriefing interview guide with relevant probes was used to guide the discussion (see Appendix E). The interviews gave the facilitator an opportunity to discuss overall thoughts about the session, barriers to session implementation, and suggestions for modifications to the session content. If the

completion of a task was unknown through listening to session audio (e.g. perhaps the digital recorders were turned on late, and the status of introductory tasks were unknown), facilitator debriefing interviews served as an additional source to determine the *dose delivered* or *fidelity* of the session. Unlike implementation checklists, debriefing interviews provided contextual information regarding intervention delivery, as facilitators were able to provide rationale for the modification or omission of session tasks or activities. These data were also a critical part of understanding whether theory-based objectives were met as part of the intervention delivery, as well as the receipt of and satisfaction with session content by participants.

Management and Organization

Like session transcripts, each debriefing interview transcript detailed the site location (abbreviated using two letters (for example, AA or BB), group type (abbreviated as “SP” or “CL”), group number, and session number. Debriefing files had a suffix to further identify the type of file (“.FL” indicating a facilitator debriefing). For example, a facilitator debriefing from sessions 3 and 4 with client group # 2 would be identified as, “2AAPL.3.4.FL”. Debriefing interview transcripts were verified through a four-step verification process identical to that of session transcripts (see “Management and Organization” for verbatim session transcripts). Exchange of debriefing audio files and electronic transcripts between EAST research staff and the transcriptionist took place on a secure server. Hard copies of debriefing interview transcripts were filed with the corresponding session and focus group discussion transcripts in a locked file cabinet in the project coordinator’s office.

Analysis

Qualitative themes for debriefing interviews were developed through a deductive approach in which codes were developed from the debriefing interview guides. These themes were compiled into a codebook that detailed the code mnemonic, a brief definition and a full description of inclusion and exclusion criteria (see Appendix F). The principal investigator of this dissertation study independently reviewed each transcript, and developed and applied codes to the text. If new codes emerged during analysis of transcript data, they were added to the codebook and applied to subsequent transcripts. Coded interview data was organized into visual displays to facilitate interpretation and analysis, and to further explore convergence or divergence of themes within and across groups (Miles & Huberman, 1999).

Participant Focus Group Discussions

All session participants (clients and service providers) took part in focus group discussions as part of their participation in the intervention study. These data assessed *dose received*, as they answer the questions: *To what extent were participants present at session activities engaged in the activities? How did participants react to specific aspects of the session? How satisfied were the participants with the session?* Using a pretested focus group discussion guide for each group (see Appendices G and H), one of the session observers moderated the group discussion to explore participant expectations prior to participation in the series, motivators for participation in the series, satisfaction with session content, recommendations for improvement and future application of skills learned during the series.

Client focus group discussions were conducted at the end of each day (3 days total) and covered content for the two sessions implemented earlier in the day. For example, the focus group held the first day of the clients series consisted of questions about sessions 1 and 2; the second day consisted of questions about sessions 3 and 4, etc. If the ACTU expert session (session 6) occurred during clients' lunch hour, two separate group discussions took place: one immediately before the expert arrived (session 5) and one immediately after the expert ended the discussion (session 6). Therefore, a minimum of three and a maximum of four focus group discussions were held for each client group.

Due to feasibility and time constraints, service providers were not able to participate in focus group discussions at the end of each session. Instead, one focus group discussion was held after the completion of the entire service provider series was complete. The discussion was moderated by one of the Project EAST co-investigators, and lasted approximately 60 minutes. All group discussions were audio-recorded and professionally transcribed for analysis and verified through a four-step process (see "Management and Organization" for verbatim session transcripts). Figures 2 and 3 detail data collected for service providers and clients, respectively.

Management and Organization

Each focus group discussion transcript detailed the site location (abbreviated using two letters ("AA" or "BB")), group type (abbreviated as "SP" or "CL"), group ID number, and session number. Debriefing and group discussion files had a suffix to further identify the type of file (".PD" indicating a participant discussion). For example, a client focus group discussion from sessions 1 and 2 with the third group of clients the original study site would be identified as, "3BBCL.1.2.PD". Exchange of audio files and

electronic transcripts between EAST research staff and the transcriptionist took place on a secure server. Hard copies of focus group discussion transcripts were filed with the corresponding session and facilitator-debriefing interview transcripts in a locked file cabinet in the project coordinator's office.

Analysis

Coding of participant focus group discussions occurred in the in the same fashion as facilitator debriefing data. Deductive codes were generated from the FG discussion guides and inductive codes emerged from the data. See Appendix I for the focus group discussion codebook for providers and clients.

CAB Meeting Transcripts/Team Meeting Minutes

CAB transcripts and team meeting minutes were analyzed to capture contextual issues occurring over the course of the intervention implementation. These data answer the question: *What are the external factors directly or indirectly affecting the intervention?* A total of 12 CAB meetings were held over the course of the parent study. Each meeting was considered to be a source of data; therefore each meeting was audio-recorded and transcribed verbatim. Project EAST team meetings occurred every other week with research project staff at UNC, including the principal investigator, co-investigators, project manager, project coordinator, and research assistants. During these meetings, staff discussed maintaining the integrity of the intervention, problem solving, making collaborative decisions about issues involved in the intervention, and providing support to prevent stress and burnout. Minutes were taken at each team meeting.

Management and Organization

CAB meeting transcripts were verified through a four-step process identical to that of session transcripts (see “Management and Organization” for verbatim session transcripts). Exchange of CAB audio files and electronic transcripts between EAST research staff and the transcriptionist took place on a secure server. The transcripts were then printed, labeled with the CAB meeting date (e.g., “CAB Meeting 10.15.09”), filed in a folder designated for CAB meeting data in a locked in a file cabinet in the project coordinator’s office. and then stored in a locked file cabinet in the principal investigator’s office. Team meeting minutes were labeled with the meeting date (e.g., “EAST Meeting 3.10.10”), typed by the research assistant and saved on the secure server.

Analysis

CAB transcripts and team meeting minutes were read in their entirety and the principal investigator of this dissertation study created memos throughout analyses of other data sources.

Satisfaction Surveys

All participants in the intervention study completed surveys to determine the extent to which they were satisfied with the session content, delivery and the facilitator. These data answered the question: *How satisfied were the participants with the session?* Responses ranged from “strongly agree” to “strongly disagree” on a five-point Likert scale (see Appendix J). For client sessions, the moderator of the focus group discussion read each question and response options on the survey aloud in the event there were literacy issues among clients participating in the session. Service provider surveys were self-administered and collected at the end of each session by one of the session observers.

Management and Organization

Satisfaction surveys were labeled to correspond with the site ID, group number, and participant ID (e.g., “AAG3-NGH65” for clients “AAAA1” for service providers).

The research assistant created electronic copies of surveys by scanning each survey (within a given group) and saving the document in a corresponding session file on the secure server. Hard copies of surveys were filed with the corresponding session data in a locked file cabinet in the project coordinator’s office.

Analysis

Preliminary analyses indicated very limited variation in participant responses, as a great majority of clients indicated, “strongly agree” or “agree” for survey items. Among service providers there was some variation, but none of the service providers indicated dissatisfaction with any of the session activities. As such, the primary mode of data collection to assess participant satisfaction for the dissertation study was through focus group discussions.

Table 8: Process Evaluation Concepts					
Concept	Process Evaluation Question	Data Sources	Tools/ Procedures	Timing of Data Collection	Data Analysis or Synthesis
Context	What are the external factors that directly or indirectly affect a specific session, or the entire series?	<ul style="list-style-type: none"> • Team meeting • CAB meeting 	<ul style="list-style-type: none"> • EAST meeting notes • CAB transcripts 	<ul style="list-style-type: none"> • Weekly • Quarterly (four times a year) 	<ul style="list-style-type: none"> • Memoing
Reach	What is the proportion of intended target audience that participates in the series?	<ul style="list-style-type: none"> • Project grant application • Site recruiter 	<ul style="list-style-type: none"> • n/a • Recruitment tracking form 	<ul style="list-style-type: none"> • n/a • Prior to series implementation 	<ul style="list-style-type: none"> • Document review • Document review
	What proportion of those recruited attended each session? (<i>Attendance</i>)	<ul style="list-style-type: none"> • Session facilitators 	<ul style="list-style-type: none"> • Attendance log 	<ul style="list-style-type: none"> • Each session 	<ul style="list-style-type: none"> • Percent of participants in each session calculated
Recruitment	<p>What planned and actual recruitment procedures were used to attract individuals?</p> <p>What were the barriers to recruiting individuals, groups, and organizations?</p> <p>What planned and actual procedures were used to encourage continued involvement of individuals, groups, and organizations?</p> <p>What were the barriers to maintaining involvement of individuals, groups, and organizations?</p>	COS	<ul style="list-style-type: none"> • Recruitment tracking form 	<ul style="list-style-type: none"> • Weekly recruitment meeting 	<ul style="list-style-type: none"> • Percent of those recruited and those attended
Fidelity	Was the session implemented as intended?	<ul style="list-style-type: none"> • Session observers • Session transcript • Session facilitators 	<ul style="list-style-type: none"> • Observation assessment forms • Implementation checklist • Debriefing interviews with session facilitators 	<ul style="list-style-type: none"> • Each session • N/A (secondary data analysis) • End of each session 	<ul style="list-style-type: none"> • Document review • Notes from checklist • Coding

Dose Delivered	<p>To what extent were all of the intended components of the session provided to participants?</p> <p>To what extent were all materials (written and audiovisual) designed for use in the session used?</p> <p>To what extent was all of the intended content covered?</p> <p>To what extent were all of the intended methods, strategies, and/or activities used?</p>	<ul style="list-style-type: none"> • Session observers • Session transcript • Session facilitators 	<ul style="list-style-type: none"> • Observation assessment forms • Implementation checklist • Debriefing interview with session facilitators 	<ul style="list-style-type: none"> • Each session • N/A (secondary data analysis) • End of each of each session 	<ul style="list-style-type: none"> • Document review • Count of deviations (primary) • Count of deviations (validation)
Dose Received	<p>To what extent were participants present at session activities engaged in the activities?</p>	<ul style="list-style-type: none"> • Session observers • Participants 	<ul style="list-style-type: none"> • Observation assessment forms • Participant focus groups 	<ul style="list-style-type: none"> • Each session • After completion of entire series (SP); or each day (CL) 	<ul style="list-style-type: none"> • Memoing • Coding
	<p>How did participants react to specific aspects of the session?</p>	<ul style="list-style-type: none"> • Session observers • Participants 	<ul style="list-style-type: none"> • Observation assessment forms • Participant focus groups 	<ul style="list-style-type: none"> • Each session • After completion of entire series (SP); or each day (CL) 	<ul style="list-style-type: none"> • Memoing • Coding
	<p>How satisfied were the participants with the session?</p>	<ul style="list-style-type: none"> • Participants 	<ul style="list-style-type: none"> • Participant focus groups 	<ul style="list-style-type: none"> • After completion of entire series (SP); or each day (CL) 	<ul style="list-style-type: none"> • Coding

Validity

Several strategies were used to maximize the credibility of study findings, the first of which was the creation of an audit trail (Rodgers & Cowles, 1993). This method of consistent and concise documentation assists researchers in maintaining an accurate record of decisions related to data collection, analyses and interpretation. The principal investigator of the dissertation study included four types of audit trail documentation: methodological, analytical, personal response (also known as “reflexivity”), and contextual. Specific items included: prioritization of data analyses (in order to maximize objectivity in analyses), sensitivity of implementation checklists, and pertinent conversation with Project EAST staff. The audit trail was kept on a secured electronic database that could be accessed from any remote location at any time of day. This access was critical to capturing ideas as they occurred, in order to provide as much detail and context as possible in real time.

Additionally, transcripts for intervention sessions, facilitator debriefings and participant focus group discussions were validated through a four-step process, thus strengthening the accuracy of these data prior to analysis. Minor variations in wording on transcripts had potential to completely change the context of a phrase, thus verification was imperative to ensure that terms, particularly those that related to terms associated HIV clinical trials, or regional terms used by participants, were transcribed appropriately. For example, transcription of a “can” as a “can’t” or omission of important concepts such as “clinical equipoise” due to the text being identified as “inaudible”, could have very important implications as it relates to analyses and interpretation of data.

The completion of implementation checklists *after* sessions took place, as

opposed to during the session, afforded the opportunity to triangulate this data with other sources as the checklist was completed. Finally, achieving inter-rater reliability of data ensured proper scoring for implementation checklists; inter-coder reliability assisted in ensuring proper conceptualization and application of codes.

CHAPTER 5

RESULTS

This chapter is organized into six sections: (a) reach and recruitment of study participants (clients and service providers, respectively), in addition to information about retention of participants over the course of the series; (b) dose delivered; (c) fidelity; (d) dose received, including information about participant satisfaction and engagement; and (e) client, service provider, and facilitator suggested modifications for future intervention development, implementation. Contextual data will be presented in the discussion chapter. For presentation of dissertation findings, service provider and client groups have been labeled to reflect group type (“SP” and “CL”, respectively) and the order in which the group occurred.

Reach and Recruitment

Client Reach. A lapse in communication between Project EAST research staff and the site recruiter regarding client eligibility led to the recruitment and inclusion of three participants that did not meet eligibility criteria. Two clients in CL1 did not meet the criterion for race and one client in CL2 had severe cognitive issues. The data for the client in CL2 was excluded from analyses for outcome data for the parent study. Because all data was collected anonymously, and in a group setting, process data for the two clients in CL1 was included as part of the dissertation study findings.

Baseline characteristics for clients, by group, can be found in Table 9. The

majority of the sample was African American (n= 31, 89%) and male (n=22, 65%). Approximately 25% (n=8) were diagnosed with HIV within the past six years. By group, the number of years living with HIV varied among clients, with the exception of CL3, where all four clients had lived with HIV for over 15 years. Most clients heard of HIV clinical trials prior to their participation in the client sessions (n=20, 61%) and 41% (n =14) reported previous enrollment in a clinical trial. Fifty-one percent (n = 17) of participants completed high school (or equivalent), 36% were unable to work because of a disability (n = 12), and 50% were uninsured (n = 17). Additional client characteristics can be found in Table 9.

Adherence to recruitment procedures for clients was assessed through document review of the Project EAST recruitment manual, recruitment tracking forms and weekly meeting agendas. The site recruiter completed all recruitment tracking forms, attended all scheduled weekly recruitment conference calls, and distributed recruitment flyers to eligible participants for three client groups. He was not able to fully enumerate clients recruited for the CL4, however, as the site administrator reassigned these duties to the clinic nurse based on clinic needs at the time. That said, the newly appointed nurse made clients aware of the intervention and documented the names of those agreeing to participate in the client series. The total number of clients approached by the nurse at this site is unknown, but the tracking document details confirmation of 11 participants. Site staff assisting with recruitment noted the major reasons for non-participation, which included disclosure/privacy concerns, work/school conflicts, and lack of interest in participation.

Client Recruitment. The site recruiter completed a total of four recruitment forms, one for each group participating in the intervention study. In total, 85 clients indicated interest in participating in the client series; of these 34 (40%) ultimately enrolled. Seventeen clients were recruited for CL1. Of these, 15 confirmed participation and 13 attended the first day of the series. Of the 15 clients recruited for group 2, 10 confirmed participation, and five attended the first day of the series. As a result, a make-up day (sessions 1 and 2) was offered to allow more clients to participate in the sessions. Through the recruitment efforts of site staff, fourteen additional clients were recruited. Ten confirmed participation and six attended this group. These two groups combined brought the total number of participants in CL2 to 11 clients total.

A third client group had to be cancelled altogether because one of the eight confirmed clients was present on the first day of the series. Despite reminder phone calls and pre-arranged pick-up times and locations on the day of the session, an overwhelming majority of clients no longer had interest in participation, had schedule conflicts, or were ill. One additional attempt was made to recruit clients for the last client group to occur at the study site (CL3). Twenty-eight clients were recruited for this group; 11 confirmed participation and four were present on the first day of the series. At the recommendation of the site administrator, one final group was held at a partnering site. A total of 11 clients confirmed participation in CL4; six were present on the first day of the series. Study site staff felt social desirability was a major contributor to the low participation in the client series, feeling that clients agreed to participate, but had no intention of enrolling in the sessions. If a client enrolled in the series, but was absent for a session, or a pair of sessions occurring over the course of a day, the site recruiter documented reasons for

absence and relayed this information to the research assistant during the weekly recruitment conference calls.

Client Retention. Full attendance was defined as completion of the series of six sessions over the course of three days. Appendix K details client attendance and percent of sessions completed in the series. Of the 34 clients beginning the series: 76% completed six sessions (n=26), 3% completed five sessions (n=1), 6% completed four sessions (n=2), and 15% completed one session (n=5). At the group level, the average proportion of sessions completed for each group of clients (in order of implementation) was .92, .83, .83, and .72, respectively. CL1 had the highest percent of clients completing the entire series (85%), while CL4 had the lowest percent, with 67% of clients completing the series.

Of note, CL1 clients were all members of an existing HIV support group in their county. Of the two participants in this group that did not complete the entire six-session series, one had a schedule conflict and the other relocated to another city. Likewise, a schedule conflict with work restricted one client in CL3 from attending sessions 4 through 6. Of the clients that completed four of the six sessions ($4/6 = 67\%$), both missed sessions occurring in the middle of the series (Day 2), but returned on the last day to complete the last two sessions. The client with severe cognitive issues completed 87% of the series, but was unable to complete the last session. One client in CL4 and two clients in CL2 were lost to follow-up at the close of the client series.

Demographics	CL1 (n = 13)	CL2 (n = 11)	CL3 (n = 4)	CL4 (n = 6)	Total (n=34)
Age					
Under 20	--	1 (9%)	--	--	1 (9%)
20-29	1 (8%)	--	--	1 (17%)	2 (11%)
30-39	2 (15%)	1 (9%)	--	2 (33%)	5 (15%)
40-49	5 (38%)	5 (45%)	--	--	10 (29%)
50-59	3 (23%)	2 (18%)	2 (50%)	3 (50%)	10 (29%)
60-69	2 (15%)	2 (18%)	2 (50%)	--	6 (18%)
Race/Ethnicity					
Black	11 (89%)	11 (100%)	4 (100%)	6 (100%)	31 (89%)
Hispanic	---	---	---	---	---
White	2 (11%)	---	---	---	2 (11%)
Gender					
Male	8 (61%)	9 (82%)	2 (50%)	3 (50%)	22 (65%)
Female	5 (39%)	2 (19%)	2 (50%)	3 (50%)	12 (35%)
Years living with HIV					
Less than 1	3 (23%)	---	---	2 (33%)	5 (15%)
1-5 years	1 (8%)	2 (18%)	---	---	3 (9%)
6-10 years	4 (31%)	8 (73%)	---	2 (33%)	14 (41%)
11-15 years	2 (15%)	---	---	2 (33%)	4 (12%)
16 + years	3 (23%)	1 (9%)	4 (100%)	---	8 (23%)
Education					
Less than HS	---	---	3 (75%)	2 (33%)	5 (15%)
Some HS	3 (23%)	7 (64%)	---	2 (33%)	12 (35%)
HS/GED	4 (31%)	1 (9%)	---	2 (33%)	7 (21%)
Some College	4 (31%)	3 (27%)	---	---	7 (21%)
Completed College	2 (15%)	---	1 (25%)	---	3 (9%)
Employment					
Part-time	---	1 (9%)	---	---	1 (3%)
Full-time	1 (8%)	---	1 (25%)	---	2 (6%)
Home/Family	2 (15%)	1 (9%)	---	---	3 (9%)
School	---	---	3 (75%)	---	3 (9%)
Retired	1 (8%)	---	---	1 (20%)	2 (6%)
Unable to work	3 (23%)	8 (73%)	---	1 (20%)	12 (36%)
Other	6 (46%)	1 (9%)	---	3 (60%)	10 (30%)
				*1 missing value	
Health Insurance?					
Yes	7 (54%)	5 (45%)	0	2 (33%)	14 (41%)
No	6 (46%)	6 (55%)	1 (25%)	4 (67%)	17 (50%)
			*3 missing values		
Ever heard of a CT?					
Yes	9(57%)	6 (55%)	3 (75%)	2 (33%)	20 (61%)
No	3(43%)	5 (45%)	1 (25%)	4 (67%)	13 (39%)
	*1 missing value				
Ever participate in a CT?					
Yes	3 (27%)	6 (55%)	2 (50%)	3 (50%)	14 (41%)
No	10 (73%)	5 (45%)	2 (50%)	3 (50%)	20 (59%)

Service Provider Reach. Reach for service providers was nearly double the intended goal as 11 service providers participated in the series. The addition of the partnering clinic as a study site nearly double the reach for service providers (n= 11, 184%). As providers were able to select more than one than category for their occupation on the baseline survey, three selected dual roles at their site (i.e. nurse and case manager). Nearly half of service providers were African American (n=6, 54%) and approximately three-quarters were female (n=8, 73%). Twenty percent (n =1) of providers in SP1 identified HIV as their primary specialty, as compared to 50% of providers in SP2 (n = 3). At baseline, 40% of providers in SP1 (n = 2) and 33% of providers in SP2 (n = 2) reported having referred at least one client to a clinical trial in the past six months. Additional service provider demographics can be found in Table 10.

Nearly half of the service providers in the study sample were case managers. While service provider type was not part of the intended reach *a priori*, addition of these individuals did reflect the profile of service providers suggested by the EAST CAB. Further, as transportation is a huge barrier for many people living with HIV/AIDS in rural eastern NC, access to major medical centers providing HIV care is very limited. As a result, many HIV-positive clients receive case management services from community-based organizations or local health departments or community-based organizations (Nguyen & Whetten, 2003). That said, inclusion of non-clinicians in the intervention study produced a study sample that reflected the type of service providers available and accessible in many rural contexts.

Service Provider Recruitment. Service provider recruitment was accessed through document review of team meeting notes and analysis of qualitative data from the

service provider focus group discussion occurring at the end of the series. As service providers were selected based on specific criteria by administrators at each site, recruitment tracking forms were not applicable for this group. All service providers were sent e-mail by the site administrator that detailed what participation entailed, the dates on which the sessions would be held, as well as a brief summary of the intervention study.

Service Provider Retention. Ninety-one percent of service providers completed all sessions in the service provider series (10/11=91%). A change in scheduling of the last session (due to limited ACTU expert availability) posed a conflict for one service provider who had previous travel arrangements for work out of the country. That said, all service providers completed 100% of the series, with the exception of one provider who completed 75% of the sessions. Provider attendance, by group, can be found in Appendix L.

Table 10: Service Provider Characteristics, by Group			
Demographics	SP1 (n=5)	SP2 (n=6)	TOTAL (n=11)
Age			
20-29	---	2 (33%)	2 (18%)
30-39	3 (60%)	1 (17%)	4 (36%)
40-49	2 (40%)	2 (33%)	4 (36%)
50-59	---	---	---
60-69	---	---	---
70-79	---	1 (17%)	1 (9%)
Race			
Black	2 (40%)	4 (58%)	6 (54%)
Hispanic	1 (20%)	---	1 (9%)
White	2 (40%)	2 (31%)	4 (36%)
Gender			
Male	1 (20%)	2 (33%)	3 (27%)
Female	4 (80%)	4 (72%)	8 (73%)
Education			
Technical school/training			
Some College	1 (20%)	---	1 (9%)
Completed College	---	1 (17%)	1 (9%)
Graduate Degree	1 (20%)	4 (67%)	5 (45%)
	3 (60%)	1 (17%)	4 (36%)
Profession*			
Physician	1	1	2
Physician Assistant	1	---	1
Nurse	1	3	4
Nurse Practitioner	---	1	1
Case Manager	1	4	5
Pharmacist	1	---	1
Health Educator	1	---	1
HIV Primary Specialty			
Yes	1 (20%)	3 (50%)	4 (36%)
No	4 (80%)	3 (50%)	7 (64%)
Number of clients referred to CT in last six months			
0	3 (60%)	4(67%)	7 (64%)
1-5	2 (40%)	2 (33%)	4 (36%)

**participants could choose more than one response*

Summary: Reach and Recruitment

Approximately 85 clients were recruited for the client series. Of these, 40% (n=34) ultimately participated in the sessions, and . In general, recruitment procedures were followed with the exception of tracking of clients in CL4. This exception was due to re-assignment of client recruitment to the clinic nurse by the site administrator. The site recruiter attended all weekly recruitment meetings with the Project EAST research assistant and also ensured timely completion of the recruitment tracking forms prior to the implementation of the series with each group. Overall, service provider recruitment was successful, as 11 service providers were ultimately recruited to participate in the series. “Direct involvement with clients” as recruitment criterion was somewhat subjective as nearly half of the service providers did not interact with clients on a regular basis, nor was HIV their primary specialty (see Table 10). This was not problematic for implementation of the series, but may have very important implications related to the outcome for the larger parent study: increase service provider willingness to refer eligible African American people living with HIV/AIDS to HIV clinical trials.

Dose Delivered and Fidelity

This section will begin with presentation of *dose delivered* findings for client and service provider groups, separately, then within and across groups. *Fidelity* findings will then be presented, incorporating qualitative findings from the facilitator debriefing interviews and memos captured on implementation checklists. be organized to view convergent and divergent themes among the two data sources (implementation checklists and facilitator debriefing interviews), then by group type (client and service providers).

Client Series. Dose delivered scores for all client groups, by session number are detailed in Table 11. Five of the six sessions across all client groups had average dose delivered scores higher than the .85 acceptable score. The highest average score among the client groups was .90 for CL2 make-up group and the session carried out with the highest dose delivered score across all client groups was Session 4 (“Support: What is It and Where Can You Get It”), with an average dose delivered score of .96. This session provided information about ways eligible clinical trial participants can seek out support as part of their decision-making process. The exercises in this session were guided by the social support framework and allowed clients to explore how the four types of support (emotional, instrumental, appraisal, and informational) could influence clinical trial participation. Clients also learned communication skills as it related to seeking support for trial participation.

The session implemented with the lowest dose delivered score across all client groups was session 3 (“Participant Rights and Informed Consent”). The average score for this session was .77, with the lowest scoring session occurring with the second clients group (CL2). While the majority of session tasks were delivered at or above the acceptable dose delivered score of .85, failure to distribute handouts to clients (e.g., “Key Questions to Ask Clinical Trial Staff”), compile solutions to from session activities (e.g., “Break the Barrier”), introduce the “parking lot” and/or session objectives at the onset of the session, provide responses from the previous week’s “parking lot” questions, or summarize the session’s objectives and associated activities lowered dose delivered scores considerably. The “Key Questions to ask Clinical Trial Staff” handout in session 3 was not distributed for two of the four client groups. The facilitator of the CL3 series

noted in her debriefing interview, however, that the series curriculum directed facilitators to distribute the handout in two separate sessions, but she was unclear as to why this was the case. The curriculum did not clearly indicate how to integrate the sample questions in to the content of either of the sessions, nor did it specify whether the second provision of the handout was a reinforcement for the previous activity (thus meeting the same theoretical objectives) or whether the handout stood alone within each session (thus meeting separate theoretical objectives). Facilitators who were part of intervention development were more familiar with the purpose of the handout, and why it was distributed twice during the series. Two activities for which the handout was provided as a resource: a) questions to ask as part of the informed consent process (Session 3) and b) information to consider as part of client-service provider communication regarding trial participation (Session 5).

Session	Session Content	CL1	CL2	CL2* make-up group	CL3	CL4	Average Score
1	Clinical Trials Basics	.73	.92	1	.75	.82	.86
2	Referral, Participation and Types of Trials	.93	.80	.80	.93	.87	.87
3	Participant Rights and Informed Consent	.92	.69	--	.77	.77	.77
4	Social Support and Trial Participation	1	1	--	.92	.96	.96
5	Locating Clinical Trials and Confidentiality	.92	.85	--	1	.91	.91
6	“Ask the Expert”	.80	1	--	.80	.90	.90
Average Score (per group)		.88	.88	.90	.86	.87	.88

**completed sessions 3-6 with CL2*

Service Provider Series. Dose delivered scores for the service provider series are detailed in Table 12. These findings revealed dose delivered scores for all sessions were above the acceptable score of .85, with an overall average of .92 for all sessions. The lowest dose delivered score among all service provider sessions was .88 (Session 1: “Clinical Trials 101”) with service providers at the partnering clinic. This was due to the facilitator’s failure to have participants create ground rules and failure to forecast information about overcoming barriers to clinical trial participation at the end of the series. Interestingly, the first service provider session also had highest dose delivered score among all service provider sessions implemented, with a full dose (1.0) delivered to service providers at the original study site. Both sessions were led by the same facilitator, BF1, however fidelity data from the implementation checklists provided

insight into the discrepant scores for this session: “The session began approximately thirty minutes late as facilitators arrived late—told participants they would skip ground rules in light of time and requested that participants silence their cell phones.” The facilitator confirmed this during the debriefing interview:

“... [We] got here late--took a wrong turn into [name of town]...even given our leaving two hours ahead of time. Ground rules--I completely skipped over... when I looked down we didn't have time to do a five minute 'talk about what you all want to do'...the only thing I did mention was cell phones.”

Session	Content	SP1	SP2	Average Score (per session)
1	Clinical Trials Basics and Types of Trials	1.0	.88	.94
2	Referral, Participant Rights and Informed Consent	.91	.94	.93
3	Locating Clinical Trials, Support, and Communication	.93	.93	.93
4	“Ask the Expert”	.90	.91	.91
Average Score (per site)		.94	.92	.92

Facilitator Characteristics. As facilitators varied by race, gender, education, and status of employment with the project, it was important to examine if and how facilitator characteristics may have affected the dose delivered of intervention sessions. Table 13 details demographics of facilitators, as well as the number and type of sessions each person facilitated over the course of the intervention. All facilitators completed an undergraduate degree, two of whom were currently enrolled in graduate programs at a local university. Two facilitators were not paid staff, and none of the facilitators had previous experience facilitating or taking part in clinical trial outreach efforts. Two facilitators were, however, heavily involved in the development and pretesting of the intervention, as well as the development of process and outcome evaluation measures.

Table 13: Facilitator Characteristics								
ID	Race	Gender	Educational Attainment	Paid	Number of Sessions Facilitated		Average Dose Delivered Score	
					Clients	Service providers	Clients	Service providers
BF1	Black	F	Graduate	Y	11	8	.84	.93
WF1	White	F	College	Y	2	--	.85	--
BM1	Black	M	College*	Y	2	--	.93	--
BF2	Black	F	College*	Y	6	--	.90	--
BM2	Black	M	College	N	4	--	.91	--
BF3	Black	F	Graduate	N	1	--	.87	--

**currently enrolled in graduate program*

Facilitator average dose delivered score for client sessions exceeded the acceptable score of .85, with the exception of facilitator BF1 (average score = .84). She was the primary facilitator for all service provider sessions, and her average dose delivered score was .93 for this group. The top two scorers for client sessions were black males, one paid staff member and one unpaid staff members (.93 and .91, respectively). Both had undergraduate degrees, and one was pursuing doctoral studies. There were no differences in dose delivered by race or educational attainment. In sum, dose delivered did not seem to be a function of the facilitator's race, education, or employment status with the project. The average reliability score for implementation checklists was .92 with the majority being due to coder error.

Fidelity

Fidelity, which measured the quality and integrity of intervention delivery, was assessed through analysis of facilitator debriefing interview data and a review of notes documented on implementation checklist by the principal investigator of this dissertation study. Implementation checklists provided outsider's perspective of variations in intervention delivery to session participants. Although curricula were provided for facilitators to follow, some variability in delivery was expected, as each facilitator has his own style. Some barriers to implementation were beyond the facilitator's control, such as malfunctioning equipment or late arrival of session participants, and some were a function of facilitator error, such as lack of preparation or incorrect provision of information. Two analytical approaches were used to assess intervention fidelity: qualitative coding of facilitator debriefing interviews—viewed across groups and comparative analyses between facilitator debriefing interviews and fidelity notes captured on implementation checklists. In the next section, salient factors found to affect intervention fidelity in both series are presented, followed by factors found to be specific to the client and provider series, respectively.

The principal investigator of this dissertation study created visual displays of fidelity data across and within groups. See Appendix M for a sample visual display for client sessions. Exploration by data source afforded the opportunity to determine the reliability in which data was reported by the facilitator and data captured by the principal investigator. These tables detailed fidelity findings for client and service provider sessions by group number and data source (implementation checklist and facilitator debriefing interviews). The final column detailed findings captured from both sources.

Visual displays yielded information on *why* an activity had not been carried out in the manner in which it was designed, and thereby, complemented findings from quantitative data in implementation checklists.

Delayed Implementation of Sessions. Late arrivals of project staff or clients resulted sessions beginning up to half an hour after the designated start time. At the onset of the series for each of client groups (sessions #1 and 2), research staff arrived late 75% of the time (three of the four groups). This often led to session activities being split into smaller time frames to allow participants to take lunch breaks at the designated time on the schedule. Facilitator debriefing interview data did not give context as to why research staff members were late, other than a facilitator's comment regarding the need for the team to depart UNC on time.

Technical issues also lead to late start times for client sessions, or interruptions during the sessions. While baseline survey administration was not a formal part of the client series, the audience response system used to administer the survey was problematic in three of the four client groups. This software used remotes, or "clickers", to allow participants to respond to multiple-choice questions via the remote. Solutions for this problem were to troubleshoot until the software worked or administer backup, paper copies of the survey. Both had implications as it related to beginning the session at the designated start time. Additionally, the audio quality of the clinical trial participant testimonial video led was poor in each of the four client groups. Each facilitator noted in his/her debriefing interview that the speakers projected a low, muffled sound or hearing "static" during the video. DVD compatibility was also problematic for one group, as a variety of laptops were used while staff were in the field.

Adherence to Curriculum Script. In general, most issues related to variability in intervention delivery for client and provider sessions were due to facilitator deviation from the scripted text in the curriculum. Text was sometimes paraphrased by facilitators or omitted altogether, the latter appearing to be function of the session not beginning on time or over-scripting in the curriculum. Activities associated with lower fidelity for service provider sessions were those that had heavier scripting in the curriculum. For example, in Session 1 the introductory scripting for “The CARD” (a pamphlet that lists all available HIV clinical trials offered at the UNC ACTU) was not read in its entirety by the facilitator either time the session was offered. The facilitator did not highlight this during the debriefing interview for SP1; it was however mentioned in the debriefing interview for SP2. This resource produced by the UNC ACTU quarterly, and is available for service providers to stay abreast of clinical trials for which their patient(s) could be eligible. The follow-up exercise to the introduction of The CARD required the facilitator to tie four “eligible participant” profiles to trials currently offered on The CARD. The scripting for this exercise also spanned several pages in the module, which may not have been practical for facilitators to read in their entirety.

Variations also included facilitator provision of content beyond the information provided in the curriculum, as one facilitator detailed a considerable amount of contextual information about history of Project EAST (i.e., phases of the parent study, formative data findings, the community advisory board, and the refinement of the intervention study from the onset of the parent study). Another facilitator provided analogies related to randomization, but drew examples from non-HIV clinical trials (e.g.,

breast cancer and prostate cancer). These examples were drawn in an effort to illustrate gender differences in the context of eligibility criteria for a clinical trial.

Most facilitators appropriately referenced critical information located in the speaker's notes from PowerPoint presentations, but some were omitted altogether. The use of "we" and "us" by the session facilitator was also documented on the implementation checklist, particularly in the context of clinical trial participation. For example, if the facilitator stated, "We want to ensure that every clinical trial participant is treated the same...", this had the potential to confuse clients, as the intervention study was not a clinical trial. While none of the clients mentioned being confused based on the facilitator's use of "we" or "us" during the follow-up focus group discussion, conflation between the intervention study and a clinical trial was noted by most facilitators at the onset of each series.

Clear directives. For service provider sessions, role play activities had the lowest fidelity, primarily due to time constraints and lack of adherence to introductory scripting for the exercise by the facilitator. This introduced some confusion among participants prior to beginning role plays, as stated by one of the service providers SP1 during their focus group discussion at the end of the series. The facilitator to be aware this, as it was not mentioned in either of the debriefing interviews for provider series. The facilitator did however note participant confusion when starting role-plays:

I think with role plays people always take a second to kind of figure out like, "Okay, what is this?" Perhaps given a better description but that's pretty much, I don't know what I would like for the role play--on the other hand but people definitely were kind of like, "Uh, exactly what am I?"

-Facilitator, SP2 (session 3)

Participant Involvement in Intervention Delivery. Facilitators occasionally invited clients to take part in session activities that were designed to be carried out with members of the Project EAST research staff. For example, a client in CL1 performed a skit with the session facilitator regarding patient-provider communication regarding trial participations.. While this was not identified on the implementation checklist for this session (nor was it mentioned during the facilitator debriefing interview), the session observer recorded the following information in his narrative summary:

“One of the clients participated in the role play with the facilitator. Other [participants] seemed engaged during the role play. One of the [participants] was observing and took notes. One mentioned that she liked that the service provider during the role play didn’t influence the [client participating in skit’s name] in participating in a clinical trial. [Session participant observing skit name] noticed that the service provider’s purpose was to inform and reassure [client participating in skit’s name] about clinical trials.”

Facilitators also encouraged providers and clients participating in the sessions by inviting them to read information aloud from recap PowerPoint presentation shown at the beginning of each session. These ranged from having clients read definitions of previously covered concepts to posing questions that encouraged their feedback (e.g., “Who remembers the four types of support we covered last week?”). Additionally, clients in every group were offered the opportunity to assist with the introduction to read the “Type of Trials” handout. Participant involvement in content delivery during the session was rarely noted during the debriefing interview by facilitators.

Summary: Dose Delivered and Fidelity

The dose delivered and fidelity findings above highlight a few important points. First, as pointed out by several researchers, multiple methods are essential to assess process evaluation concepts for complex interventions. The triangulation of data sources

in the dissertation study afforded the opportunity to objectively determine the extent to which intervention components were delivered as designed *and* the quality, or fidelity, of intervention delivery by session facilitators. Additionally, the variety of data sources provided a means for findings to be validated or for gaps to be filled in the event that information was not captured by other data sources. For example, observational data highlighted participant involvement in the skit in Session 1 for the first group of clients. Neither implementation checklists nor debriefing interview data captured this information.

The dose delivered scores for client and provider series clearly demonstrate completeness of sessions across groups and group types to be very high, as the average dose delivered scores for these groups were .88 and .92 respectively. Both average scores exceeded the acceptable score of .85. Each facilitator's average score also exceeded the acceptable score, with the exception of one facilitator whose average was slightly below at .84. These data in isolation would lead researchers to conclude the intervention to be implemented very well across all sites. Fidelity data however provide very important insights into *how* well session content was covered. Major deviations from the script occurred with three facilitators, all of whom were offered remediation before reentry to the field.

Facilitator exchange of terms like "luck of the draw" and "flip of a coin" had potential implications as it related to proper delivery of intervention content. These deviations caused confusion among participants and indicated a lack of mastery with session content on the part of the facilitator. Other incorrect information shared with participants included Project EAST's use of participant identifiers (participant names

were not taken), and repeated inquiries from the facilitator as to whether participants disclosed their HIV status to anyone (this was not a part of the curriculum). Lack of familiarity with session content was reflected in the delivery of sessions of facilitators, and mentioned by facilitators during their debriefing interview.

Among service provider sessions, most variations in fidelity occurred with providers in SP2. Due to the late arrival of facilitators on the first day, activities from session 1 had to be rearranged and placed in subsequent sessions. The testimonial video for session 2 was forgotten when the session was implemented, so the video had to play during the following session (Session 3) for this group. While all session activities were complete (as indicated through dose delivered scores on the implementation checklists), there was some variation in *when* the activities were implemented.

Finally, the “Ask the Experts” session for participants in CL4 and SP2 were scheduled to be implemented on the same day due to the limited availability of the ACTU expert to moderate the last session. This change meant the ACTU expert had to meet with service providers at the original study site and drive approximately 45 minutes to another site to meet with clients from the partnering study site at the local town hall. This change shortened the service provider discussion time with the expert, and also caused a late arrival of the expert for client session.

Dose Received

The following section details participant dose received for client and provider series. Qualitative data from participant focus group discussions are presented to detail participant satisfaction with session content and activities. The principal investigator of the dissertation study created visual displays that organized these group type, group

number, and session number. See sample displays in Appendices N and O for visual displays illustrating client and service provider satisfaction, respectively. Convergent themes among clients and providers were related to satisfaction with: (a) discussion with the ACTU expert, (b), facilitator characteristics, and (c) interactive activities offered during the session. Satisfaction data were also compared to facilitator perceived engagement themes for each respective group through the creation of visual displays (see Appendices P and Q for select sessions). These analyses afforded an opportunity to explore convergence and divergence between these two concepts. Like satisfaction data, visual displays were organized by group type, group number, and session number. The following section will present convergent and divergent themes among clients and service providers, followed by comparative analyses of these data with facilitator perceived engagement.

Discussion with the ACTU Expert. The last session in the client and provider series consisted of a 50-minute discussion with an infectious disease physician, or “expert” from the UNC ACTU. The two physicians were also co-investigators on the parent study, and were involved in the development of the intervention activities. Across the four client groups, participants were satisfied with the experts’ honesty and openness about the clinical trial referral and participation processes, and their use of lay terms to explain the referral and enrollment processes. Prior to the discussion with ACTU expert, participants in every group stated a desire to hear more about the negatives related to trial participation as they felt the testimonial video only showed one side of the story by highlighting benefits of trial participation. The following dialogue is from participants in CL1 regarding expectations of the “Ask the Experts” session:

- R10: *It was totally different.*
- R3: *Very different.*
- R10: *Because we had the doctor.*
- R7: *But also it was similar because he was informed and he was on top of the trials and results. He had examples of things that have been tested and, and passed but not, you know, not perfect but working towards perfection as far as curing HIV and AIDS.*
- R11: *And he had testimonials I hadn't heard before.*
- R7: *The positive and the negative. Because he said some people, some trials were given that he thought that the people passed on so, you know, so there was a positive and a negative in there with [this] conversation.*
- R11: *I just think it was too short.*
- R10: *It could have been longer.*
- R7: *It should have been. It was good though.*

Facilitators also noted this as being the most liked session overall by clients, often referring to participants “sitting forward” or “being attentive”. Previously disengaged participants also dialogued with the expert, as highlighted by the session facilitator for CL1:

I think that's the first time I've seen [identifier - name] sitting up at attention at ninety degrees. [identifier - name] as well sitting forward. Nobody was looking away or distracted by anything during those sixty minutes.

A few interesting points were raised among facilitators and observers about the nature of client questions during the “Ask the Expert” session. First, many of the questions in this group were previously answered through “parking lot” responses from the ACTU physicians. Participants were made aware that all “parking lot” questions were being sent to the physicians from the ACTU, and hard copies of the responses were distributed to participants one week prior to meeting the expert. Inquiries ranged from specific in nature (i.e. “Are there trials for non-progressors at UNC”) to general (“Do I have any rights? If so, what are they?”). The reasons for the redundancy of inquiries are unknown, as participants did not provide any information during their focus group

discussion about their rationale for asking questions a second time (i.e. validation of information, unsatisfactory responses from the Parking Lot, etc.). When asked what participants like most about session 6, however, one participant stated, “That your questions were answered directly”. Overall, the numbers of clinical trial-specific inquiries for the expert were relatively low among all client groups. Participants asked questions about medical treatment, co-infection and other general HIV transmission questions. The facilitator of CL2 stated:

Overall I, think [the session] was fine. A lot of the questions were not necessarily--besides the ones that may have been on the “parking lot”--pertaining to clinical trials participation. It was more HIV related care. I think the expert was great but I think just like I said, the questions she was asked, especially the first question it seemed like it took fifteen to twenty minutes to answer and it had nothing to do with clinical trials...we had our two people [out of nine] who were mostly doing the talking, but everybody seemed to be really engaged.

Providers, like clients, service providers liked the “Ask the Experts” session and found the information provided by the expert to be helpful. Suggestions were made, however, to integrate the expert more in the activities during the last session, perhaps involving the expert in a role-play or having the expert give feedback to service providers on mastery on communication skills.

Facilitator Characteristics. Clients and providers often referred to session facilitators as being “informative” or “personable”. One client stated that she expected the series to be led by a doctor or nurse, but was glad to see college students facilitating the sessions. This comment was mentioned in the context of facilitators being able to inform the “next generation” about HIV/AIDS so they would be knowledgeable of how to

protect themselves from HIV/AIDS. One client described facilitators as being “informative”, but also making use of the “parking lot” when needed:

Client: They were very informed, very knowledgeable and questions that were a “question mark”, they put on the parking lot and came back with an answer. So they were good, excellent, top shelf.

Moderator: So that was important to you to have good instructors?

Client: Yes. Somebody that’s teaching that knows and is aware of what’s going on.

-Female, year of diagnosis unknown, CL4

Clients also spoke about being treated with respect and not being berated or talked down to “like they were in the sixth grade” and appreciated the reciprocal learning that took place during the session, stating:

“You all keep it down to earth....you all make us feel like you are learning just like we are.”

Facilitators were trained to “use the wisdom in the room” in order to allow space to all participants to talk through any potential disagreements, value statements or inquiries or misconceptions related to HIV transmission or clinical trials research.

Interactive Activities. Clients and providers expressed satisfaction with a variety of interactive activities that facilitated an understanding of what clinical trials were, where they are offered, how to locate them, and what they should expect as part of the referral and enrollment processes in a clinical trial. Clients and providers identified the “Break the Barrier” activity as the “most liked” or “most memorable” activity in the series. In this activity, each group brainstormed a list of barriers to clinical trial participation. After this list was generated, participants were divided into small groups and competed to provide solutions to the barriers, thus “breaking them”. Clients appreciated having an opportunity to engage with one another during session activities, as opposed to having to be seated the entire time. One participant stated this form of

instruction and the layout of the series allow clients to “full view of what’s going on” instead of just being told”. After taking part in the randomization activity during the “Clinical Trials 101” activity, one session participant stated:

I liked that flip a coin deal because... like she said, when you put your hand in that bag and you take out something, you don't know what class you're going to be, A, B, C, D, or E... So it helped me understand that better.

-Female, diagnosed < 1 year, CL4

All clients mentioned skits as their “most memorable” or “most liked” part of participation in the series. One participant perfectly summarized a patient-service provider skit during the session by saying the participant was “informed, but unsure” and met with her case manager to get reassurance as part of her decision-making process.

She went on to say later during the follow-up focus group discussion:

... it was like questions that you may have in your mind and you may not know how to formulate it but...she asked the questions that I might not have put in words the way I wanted to...and it helped me to get a better idea as to how I should proceed as far as getting this information and then bringing it to my service provider to help me help myself. Basically that's what this class is about-- it's about teaching you how to help yourself and get information and that's a good thing.

-Female, year of diagnosis unknown, CL1

Like clients, the “most liked” activities were those that required a considerable amount of participant engagement. In addition to “Break the Barrier”, service providers identified the “Locating Clinical Trials” internet activity and Informed Consent Jeopardy (an activity that that familiarized service providers with the major sections of the informed consent form). When asked about suggested modifications to the curriculum during the focus group discussion, one service provider exclaimed, “Don’t do away with Jeopardy!” While facilitators and observers noted heightened energy and playfulness of service providers at both sites during the Jeopardy activity, this was an interesting

finding, as session facilitators at both sites stated they felt like they were teaching material to service providers who already knew about clinical trials at some level, thus providing elementary information. One facilitator stated during a debriefing interview:

Um, the doctor...I always wonder when you're sitting in a room with a physician teaching him stuff with handouts and colors and teaching stuff on a very elementary level how that plays out...

-Facilitator, SP2

The HIV physician in this group spoke to the contrary, as described below:

It's a tough time for any presentation because it's right after lunch or during lunch. Your attention, attention span is going down as it is, but the role play and the computer and hands on, you know, get you participating. And the Jeopardy and all those things will definitely need to stay [up]. So you stay up.

-HIV Physician, SP1

Peer Influence. Service providers described the testimonial video as an “excellent” tool for clients as it showed someone who participated in a clinical trial and “is still alive to share his story.” This mirrored some of the sentiments shared by clients regarding the likelihood of death as a trial participant, and requests to provide mortality and/or serious illness statistics to participants in the clients groups. Service providers at both sites were described as being attentive during the video by observers and facilitators in the sessions. Providers in SP1 provided a considerable amount of feedback on the video and had questions related to clinical trial participants being able to switch from one trial to another for treatment of their HIV (rollover studies). One service provider also shared concern about patients moving their primary care to UNC during trial participation.

...the apprehension with some of the service providers in the rural areas is that am I going to be [losing my patient]. Now the problem is that UNC might have the resources within the study to provide 24/7 outreach over the phone whereas local places might not and they say well, “UNC is doing more for me now that I’m participating in this study. Why would I go to my old service provider?”

-Pharmacist, SP1

Group Setting. An additional salient theme among clients was being offered the opportunity to be in a group setting with other people living with HIV/AIDS. Session facilitators observed this during CL4 where participants shared testimonials about their diagnoses, experiences with discrimination, and breaches of confidentiality by others in the community. These discussions occurred during the session, and well into their lunch break. During the follow-up focus group discussion for CL2, which was one of the most heterogeneous groups in terms of prior knowledge of one another, one participant stated:

Well you’re more relaxed and you’re able to just say what you have to say and you don’t feel uncomfortable to talk, because you’re around people that have the same problem.

-Male, year of diagnosis unknown

While clients often gave brief responses as the most liked activity during the session (e.g., “the video”), service providers described as an excellent tool for clients considering clinical trial participation, as it showed a rural, racial and ethnic minority who participated in several clinical trials at the UNC ACTU. Clients participating in the sessions did suggest, however on several occasions that a “real” person give their testimony. During the last focus group discussion for CL2, one participant explicitly requested “a real person, not the video”.

Satisfaction and Perceived Engagement

Engagement in the form of questions and/or feedback varied among client groups, with CL1 being the most engaged participants, from the perspective of facilitators and observers at both sites. Interactive activities, however, heightened participant engagement across all groups, even if engagement at the onset of the session was considered to be low by the session facilitator. All participants (service providers and clients) were attentive and engaged with ACTU expert, with the exception of service providers in SP2, where the nurse practitioner posed a great majority of the questions. This raised a broader concern of perceived disengagement of service providers at this site, as the facilitator noted stark differences in engagement of service providers across sites. During each facilitator debriefing interview for SP2, service providers were described as being “tired” or “nodding off”. A partial explanation of this disengagement could have been due to the extra work and time required for service providers in this group, as the session was held in a town hall approximately a 30-45 minute drive to the sessions. This was not the case for providers in SP1, as sessions were carried out in their clinic, a few short minutes away from their offices.

Dose Received: Satisfaction & Facilitator Perception of Engagement

There was not a formal inquiry into which session(s) were “most liked” of all the sessions offered, but across all groups a common theme was interactive activities. Among all client groups, skits, the discussion with the ACTU expert and the “Break the Barriers” activity were mentioned the most as being the most liked activity. Facilitators and observers also noted heightened engagement among participants during these activities. Among service providers, the activities identified as “most liked” were the

clinical trial participant testimonial video and Jeopardy, both of which were documented as very active activities by the facilitator, particularly service providers in PR1.

An important finding, however, was a lack of concordance in facilitator perception of engagement and participant report of satisfaction with activities in the session. This was partly due to the facilitator's: a) observation of the lack of feedback or questions from session participants, b) interpretation of body language as tired or bored, or c) perception of participant frustration of facilitator's lack of knowledge about clinical trial specific questions. One example of this disagreement was with the "Referral to Participation" presentation, as the facilitator sensed the providers in SP1 felt they were "being lectured to" and preferred to have their questions answered before moving on the next exercise (as opposed to being put in the Parking Lot to bring back at the subsequent session). Service providers stated during the focus group discussion, however, the comprehensiveness and detail of the activity was very helpful and provided a visual representation of the entire referral process.

Divergence in themes was also seen between facilitators and service providers in group SP2. The facilitator and observer noted the service providers to be attentive during the testimonial video, but were surprised at the lack of feedback during the post-activity discussion. Additionally, the facilitator noted three participants' body language still appearing to be disengaged during the locating clinical trials activity (e.g., talking on the cell phone, leaving the room for extended periods of time, engaging in side conversations) but each contributed to the brainstorm activity for this exercise. Both activities were identified as the "most liked" for service providers in this group.

Summary: Dose Received

Qualitative dose received data provided very important insights into participant engagement and satisfaction, and further illustrated the need for triangulation of data for process evaluation research. Objective data from the perspective of observers was essential in better understanding non-verbal indicators of participant engagement. For example, participant excitement, spatial arrangements, or even nodding off were important in better exploring indicators of participant engagement.

Intervention Modifications and Future Recommendations

Client Suggested Modifications

The principal investigator of the dissertation study Suggested modifications to improve the content and delivery of intervention activities were assessed through and participant focus group discussions (clients and service providers) and facilitator debriefing interviews. Additional findings for each group are presented below.

More time with ACTU expert. A salient theme for clients and providers was a desire by to have more time to interact with ACTU expert. This “interaction” varied, however, as providers wanted to incorporate the ACTU expert in session activities in order to understand how he, as an HIV physician, has overcome common barriers associated with clinical trial referral and participation. The “Ask the Experts” session for providers was designed to implement “Break the Barrier” before the discussion with the expert. As service providers brainstormed barriers on two separate occasions during the series (session 1 and session 4), they suggested that the latter brainstorm be removed altogether and instead have the expert spend the session having conversation with the local service providers. They further stated the expert could also revisit the barriers

generated during the first service provider session, and offer his advice on “breaking” those barriers. The text below illustrates service provider feedback on integrating the expert in the “Break the Barrier” exercise in the final session:

“Why not have the expert tell me how a particular group has already addressed these barriers? Why do I need to come up with ways around it when I’m really operating on a referral source format. What has UNC or any other particular group done to overcome those?”

- Case Manager, CL1

Clients liked the forum-like question and answer session and simply wanted to continue conversing with the doctor. Participants stated they could have continued the discussion for at least another hour given the additional time. Clients also proposed inviting additional physicians from UNC join the discussion, possibly in a panel format. One client stated the number of panelists would essentially reflect what they experience a part of their HIV care--multiple doctors over the course of the day. The same participant referenced wanting to see a “real doctor” that “has an office”.

Provision of session materials. Clients and providers expressed a desire to be provided with session materials (e.g., handouts) both in-session and as take home materials. As part of the informed consent activity with clients, a sample consent form was made available for participant perusal during session breaks. Some participants requested copies of sample consent forms to review on their own. Additionally, a participant in CL3 expressed the necessity of providing handouts to assist participants with retention of information to the facilitator during the second half of the “Clinical Trials 101” PowerPoint presentation that detailed the informed consent process:

Client: It’s, just something to reflect on. You know? I mean because we can’t remember everything on a blind, slide. If it’s in front of us and we want to go back and reflect on it, we’ll have it. That’s all.

Facilitator: Right. What we have done is give out notepads and pens.

Client: Well the whole point is you can't expect us to keep all this in our heads.

Moderator: I understand.

Client: And some people just can't write that quick. All this stuff you're all going over, I cannot just sit here and write everything down. It ain't going to work.

-Male, diagnosed 15+ years, CL3

Interactive Activities. Clients expressed a desire to have more interactive activities as part of their participation in the sessions, (e.g., role-play activities) and a desire to provide more challenging activities. Role-plays were not a part of the client curriculum, so as to not make any participants uncomfortable if they had any literacy challenges. Modifications for this group also included “mixing up” images for the social support poster activity to challenge their thinking during the activity. The activity consisted of participants matching paper slips containing short vignettes about a potential clinical trial participant to one of four corresponding posters that illustrated the four types of support. Vignettes and posters had identical images that conveyed people receiving picture receiving support. The majority of clients wanted the vignettes to remain the same, but for the images on the vignette to be rearranged, so that the images no longer matched or corresponded to the poster. One client group failed to observe the association between the images on the vignettes and posters, despite several probes from the facilitator.

Accessibility of Clinical Trial Information. Clients inquired about alternative ways to access information about clinical trial opportunities on the Internet, particularly those with limited computer skills. One participant acknowledged the Internet as being a “quicker” resource to locate clinical trials, but he would need assistance or training to navigate these opportunities. At the end of the “Locating Clinical Trials” Internet activity, another participant highlighted several concerns as it related to accessing

information about clinical trials offered at major medical centers, also suggesting alternative forms of dissemination. He went on to highlight challenges with Internet accessibility and availability for many other people living in rural areas:

I was just wondering if there was a forum or something you could visit or be a part of or maybe a mailing list where they mail you different things letting you know--that way you're not always everyday out there looking for these trials, they come straight to you. It looks like they would put people that are interested in clinical trials right on a mailing list...because not everybody wants to keep going to the different websites--you might not always have access to a computer. Sometimes I go months without being able to get on a computer, and when I do get on, I don't be thinking about clinical trials.

-Male, diagnosed 15+ years, CL3

Participants in CL2 also expressed a desire to visit a major medical center as part of their participation in the series. While observing the clinical trial brainstorm and Internet exercise during a client session, one facilitator noted:

We need to know where [clinical trial opportunities] are here...making [the exercise] more culturally or context appropriate--their local newspaper or whatever...because these are typically offered by major medical centers. But, I was just sitting there thinking--watching the activity like [the nurse practitioner in CL1] told us [before] they're not advertised here...

In-Person Clinical Trial Participant Testimonial. The most salient theme as it related to client suggestions for modifications was to provide an opportunity for participants to dialogue with a former or current HIV clinical trial participant. Many referenced wanting to hear the “pros and cons” of participation because the sessions provided the benefits of participation, but no information on unknown or undesirable side effects experienced by former participants. Some referenced wanting to hear a “true testimony”, “outcomes”, or “statistics” in this regard. Another important finding was related to client perspectives on the role of peer influence in the clinical trial decision-making process. During focus group discussions, clients were asked to provide thoughts

about additional information they felt was needed to make the decision to participate in a clinical trial, or what modifications they would suggest for future implementation of the client series. Most indicated a desire to have a face-to-face discussion with a former or current clinical trial participant. This was among the most salient themes across all client focus group discussions and was mentioned several times over the course of the client series.

Facilitator Suggested Modifications (Client Series)

Interactive activities. Modification themes for facilitator suggestions were consistent with client suggestions for more interactive activities. For example, one modification suggested by a session facilitator was to make the informed consent activity (which consisted of participants developing a “silly” consent form) more closely related to participants’ everyday lives in order to foster more interaction and dialogue:

...before you jump into all of this heavy duty language... what are some other things that maybe that they would have to give consent for outside the medical field or research field...something that indicates agreement between [them] and someone else? I wonder if we could do like, “How many of you guys have apartments or other things that other people have to do some sort of contract with- -and what are some things that you would have to, what are things you want to know?”

Remove activity. Facilitators questioned the utility of homework assignments for service providers and clients. Across all groups, a few participants completed the “Locating Clinical Trials” homework assignment to search for clinical trial opportunities advertised in their communities. The greatest proportion of participants completing the homework assignment was in CL1, as four of the 11 participants (36%) completed the assignment prior to session 5.

Pictorial Additions. The most salient challenge for clients, according to facilitator debriefing data, was conflation of HIV *care* with HIV *clinical trials*. Of the clients having challenges making the distinction between the two treatment options, the confusion was a result of their familiarity with terms such as “tests”, “test run”, or “trial” used in the context being switched from one treatment regimen to another as part of their regular HIV care. A few participants believed the intervention study to be clinical trial because they were “learning new things”, or because they were completing surveys as part of their participation in the research study. Given the conflation of HIV care with HIV clinical trials by some clients participating in the intervention study, facilitators noted the need for a clear distinction to be made prior beginning the intervention sessions, by offering a pictorial representation of the continuum of HIV care:

...describe how HIV fits into HIV care... I think they're still conflating the two and I think that's because--perhaps we should preface this whole exercise with, "This is HIV care. You go to your doctor for this. This is probably what all of you are doing right now in some form or fashion", and [then], "This is what a clinical trial is..."

Clients did not express this need for this distinction during any of the sessions, but questions asked during subsequent sessions, including the session with the ACTU expert, indicated a need to make these concepts clear and distinctive at the onset of the series.

Service Provider Suggested Modifications

Restructure Role Plays. For service providers, most suggestions for modifications to session content revolved around communication and skill-building. There was an overall feeling that role plays seemed to be “crammed in” at the end of sessions, and that clear directives needed to be given before service providers were expected to begin these activities. Providers also suggested role-plays incorporate observation and feedback from

facilitators or ACTU expert in order to determine if key skills to be learned by service providers were indeed mastered.

Clear expectations/directives. Service providers also noted the need to restructure the “Break the Barrier” activity, as the content seemed to overlap with the barriers they generated at the onset of the participation in the series. This led to some confusion among participants at the beginning of the activity, as they believed the session was dedicated solely to conversing with the ACTU expert for the 60-minute session. One participant stated:

We’re going to talk about these barriers again and how we can break them down and then we’ll have an expert here to address some of those barrier issues but that wasn’t how I felt it was communicated to us. So it did not seem to really flow- -or you know, it wasn’t what I expected. And I thought, “Why are we talking about barriers when we talked about that in the first session? We’re back to where we started.

-Nurse Practitioner, SP1

Restructure “Locating Clinical Trials” activity. During the “Locating Clinical Trials” Internet exercise in session 3, providers in SP1 requested that a handout detailing a list of the bookmarked CTs on the laptop computers be provided from them to use as a reference in the clinic. This was referenced again during the focus group discussion for participants after completion of the entire series. Service providers also suggested integrating the Internet activity with other session activities in the form of a case study to replace the homework assignment:

I guess maybe having a case study, a case scenario. “You have this patient. This is the criteria they fall under now go surf the Internet and find a study that they would be able to--” instead of doing [the homework].

-Nurse Practitioner, SP1

HIV Clinical Trial Referral Liaison. Finally, service providers shared the realities of their everyday work schedules: demands at work limited the extent to which they were

able to spend time engaging in dialogue with eligible trial participants. This, in addition to the challenges with the referral process caused service providers with previous referral experience to be less likely to refer other eligible clients. While they found the sessions to be helpful in learning more about clinical trials and clinical trial opportunities, they felt that provision of a liaison from a major medical center, or a direct phone number was the best way to increase referral of their eligible clients. Additionally, one service provider noted that while he fully understood the importance of the four service provider roles suggested in the curriculum (inform clients about clinical trial opportunities, listen to concerns about trial participation, address misconceptions related to HIV and HIV clinical trials, and to support clients in a neutral and balanced way), he could not serve in the capacity of a “neutral” party if he felt a clinical trial was the best option for his client.

Facilitator Suggested Modifications (Service Provider Series):

Restructure Role Plays. A salient theme for facilitators was the need to restructure service provider role-plays as participants often ran out of time to complete the activity during each session. Unlike service providers, facilitators did not suggest a modification of providing feedback to session participants. A suggestion was made, however to remove a role-play from a previous session in order to allow service providers to have more time with the expert, and to spend more time completing the final role-play in the series:

... If you had asked me an hour ago, I would have just said to keep it [solely as] a “Ask the Experts” session but I do think giving [service providers] one final opportunity to mull through everything they learned in all the sessions and what they learned from the expert being there--move “Break the Barriers” somewhere else and take out another role play...possibly the role play with the referral source because Dr. [ACTU expert] ends up being the clinical trial staff member

...

-Facilitator, SP1

Summary: Suggested Modifications

Convergent modification themes for clients and facilitators included relevance of session materials and the need for more interactive activities. Facilitators noted a need for the locating clinical trials homework/internet activity to be restructured to be relevant for service providers and clients in the study counties. While facilitators identified a need to explore where, or if, opportunities were advertised in the community, clients gave recommendations ranging from a community forum to a mailing list. Facilitators and clients also identified a need for more opportunities for clients to be involved in more interactive activities, specifically in session 3, which is the longest in the intervention study (80 minutes).

Both service providers and facilitators suggested modifications for “Break the Barrier” activity, but service providers suggested complete removal from the activity in the last session. Likewise, both groups saw a need to restructure the “Locating Clinical Trials” homework activity, as completion of the handout was minimal for each service provider group. Service providers suggested the handout be integrated with the “Locating Clinical Trials” Internet activity to afford service providers the opportunity to find trials for eligible patients. One service provider suggested that vignettes be provided from the “Referral 101” activity, so each service provider would have a sample profile from which he/she could begin the search for a trial on the web. The handout would then serve as a place to document the relevant information for the clinical trial. The facilitator simply suggested removing the homework altogether.

CHAPTER 6

DISCUSSION

The purpose of this dissertation study was to evaluate the implementation of the Project EAST intervention study, which was designed to increase rural service provider willingness to refer eligible racial and ethnic minority clients to clinical trials *and* to increase these clients' participation in HIV/AIDS clinical trials. The intervention study built upon previous educational outreach studies by using a multilevel approach to educate both of these groups concurrently, with a staggered approach. As the Project EAST intervention was the first of its kind, it is important to highlight implications of the process evaluation findings to inform intervention development, implementation, and evaluation for comparable efforts in rural contexts. This dissertation study assessed the intervention study's *reach* and the *context* in which it was implemented, as well as the *recruitment* of series participants (service providers and clients). Additionally, the dissertation study assessed the *fidelity*, *dose delivered*, and *dose received* of each series in the study independently, and comparatively across groups. This chapter will revisit the study aims to determine the extent to which the intervention was implemented as designed, provide recommendations for evaluation methodology, curriculum modifications, and staff trainings based on the relevant process evaluation concept. Context findings will conclude this section. The chapter will conclude with presentation

of the dissertation study's limitations and strengths, as well as implications of the process evaluation findings for public health research and practice.

Achievement of Study Aims

Aim # 1: Evaluate the implementation of an educational HIV clinical trial intervention with rural, African American people living with HIV/AIDS (PLWHA).

Reach and Recruitment. Overall, the client series was implemented as intended. The recruitment goal for the intervention study was 40 racial and ethnic minority clients receiving HIV services at the participating clinics; thirty-four ultimately participated in the client series. Of these, two clients did not meet the eligibility criteria for race. Additionally, research staff discovered after series implementation that an additional client had severe cognitive functioning challenges. Recruitment procedures for clients were followed in general by Project EAST research staff and the study site recruiter albeit reassignment of staff responsibilities at the original clinic prior to implementation of the last client group (CL4).

Recruitment efforts could be enhanced by providing more in-depth training for all site staff involved in recruitment of clients to ensure all session participants meet eligibility criteria prior to implementation of the series. Associations between process and outcome data for the parent study will be explored through analyses of various client characteristics linked to a variety of their respective service provider's characteristics (at baseline and across time points). That said, it is imperative for research staff to clearly communicate eligibility criteria for clients to ensure site recruiters are fully aware inclusion and exclusion criteria. While this recruitment error was negligible for process data collection and interpretation, it may pose challenges in making associations between

process and outcome data, and further exploration of these relationships through linkages of client and service provider outcome data at the site. For example, if a client does not receive his HIV care at the participating study site, his outcome data (i.e., willingness to participate) cannot be linked to any service provider outcome data (i.e., willingness to refer) at the site. Perhaps a more effective recruitment strategy is to have a member of site staff in the clinic identify eligible clients from medical and case management records based on the six service providers selected to participate in the series. These clients could be contacted by a designated member of the clinic staff associated with his care via telephone, by a peer who is also HIV-positive, or during an in-person visit. A reinforcing strategy could be to place an informational flyer about the intervention study in the client's medical or case management record to have service providers offer the opportunity to eligible clients during their clinic visit. Or, if medications are dispensed within the participating clinic's pharmacy, the flyer could be placed in the client's pharmacy bag. For quantitative process data collection and analyses, the number of:

- eligible clients (based on determination from medical records),
- clients contacted or approached (via telephone or in-person invitation)
- follow-up communication attempts were made for interested clients
- clients agreed to participate in the series,
- present at the onset of the series,
- present during each session
- peer interactions, and
- flyers distributed (distribution in-person and in pharmacy bags)

Dose delivered and Fidelity. The average dose delivered score for the entire client series across all groups was .88, which was slightly above the acceptable score of .85. While there were no major variations in dose delivered scores based on facilitator characteristics for service provider or client series, intervention delivery varied considerably. These variations ranged from provision of incorrect information about clinical trial concepts to incorrect delivery of intervention activities, both of which had implications as it related to participant process (i.e. engagement, satisfaction) and outcome (i.e. knowledge, attitudes, or self-efficacy) data. For example, if the facilitator paralleled randomization to the “luck of the draw” as opposed to the scripted reference of “flipping of a coin”, this could affect response to the knowledge item on the survey that parallels randomization to flipping a coin. Further, in this context of the former analogy, participants may interpret randomization as gamble of sorts, as opposed to an equal chance of receiving treatment. These deviations from scripting were often identified and corrected during the session or during the subsequent session, however a concept as integral has no room for variation in delivery.

There were, however, variations in facilitator delivery of the session content that appeared to be a result of some ambiguity and lack of clear directive training materials (recap presentation) and insufficient mastery of clinical trial content and curriculum, as well as A review of facilitator training materials, intervention curriculum, and session transcripts indicated the need for a few modifications. There is a growing recognition of the importance of fidelity of implementation (FOI) in intervention research, however challenges persist with conceptualization and measurement of this concept (Century, Rudnick, & Freeman, 2010).

Deviations from scripting could be better assessed through coding of session transcripts to determine the type of deviations (e.g., omission of information, rewording of scripting, etc.) to better understand if these variations were due to intervention failure or implementation failure. Qualitative fidelity data could be supplemented with quantitative fidelity data to assess the influence of fidelity on main study outcomes and provide contextual information as to what barriers were to maintaining the quality and integrity of the intervention.

Intervention developers should determine what items are considered to be core components are it relates to study outcomes, and what items can afford some variability. In other words, identify what components of the intervention will have the strongest influence on the study outcomes based on sociobehavioral theories or researcher experience. This could be a very integral part of ensuring these components are delivered as intended, by incorporating this information in facilitator training. Facilitators should be provided with indicators of acceptable adherence as part of their training to ensure readiness to enter in the field, and full comprehension of the intervention curriculum for clients and service providers. There is a recommendation to re-educate participants if more than two months have passed between clinical trial education and the actual informed consent process to enroll in a trial due to the complexity of clinical trial information (Campbell et al., 2008).

Dose Received. Another important finding for the client series was related to client perspectives on the role of peer influence in the clinical trial decision-making process. A great majority of clients suggested having an in-person testimonial from a

current or former clinical trial participant. This finding was surprising for a few reasons. First, to lessen any client fears or apprehension of involuntary disclosure of their HIV status, the research team involved in intervention development intentionally did not introduce individuals who were not participating in the series, including HIV-positive clinical trial participants. As such, the clinical trial participant testimonial video was chosen as an alternative form to convey an HIV clinical trial participant's experience at the UNC ACTU. Surprisingly, clients did not express any apprehension with the addition of in-person testimonial. This delicate balance of peer influence within client risk assessment leads to a broader question of how clients process risk as part of the decision making process. Not a great deal of formal inquiry into clinical trial basics. Does peer influence supersede provision of detailed information about clinical trials? Should both be used in concert to achieve the goals of increasing awareness about clinical trials, and ultimately participation in clinical trial research? There are not established best practices associated with normative beliefs, or peer influence with African Americans living with HIV/AIDS, or rural, African Americans living with HIV/AIDS in the context of HIV/AIDS clinical trials.

Results from the ACT2 study do however shed some light on the effect of direct peer involvement, as their study reported a 55-fold increase in screening for clinical trial enrollment when patients were given a component that included a peer discussion compared to those who did not receive a peer component (Volkman et al., 2009). This study also used respondent-driven sampling (RDS), a method that afforded participants completing the intervention to then have the opportunity to serve as peer educators for subsequent trainings. This type of sampling has been recommended where identification

and selection of participants can be difficult, such as populations that have been marginalized by society or those that have a history of mistrust from the research community (Kogan et al., 2011). Future studies should consider training former trial participants who are interested in serving as peer recruiters, or RDS “seeds” to recruit potential participants for the educational series, and ultimately, clinical trials. Clients in the Project EAST intervention study expressed interest in serving as peers in educating other people living with HIV in their communities about information learned during the series.

The majority of clients had question onset of series implementation that related to content covered in subsequent sessions in the series. Facilitators noted participants “frontloading” with questions covered in future sessions and felt there was a sentiment of “solicitation”, and therefore a “cut to the chase” response. Client inquiries at the onset of series implementation ranged from access to medication after clinical trial participation to participant rights and researcher responsibilities in the event of an adverse event. These questions were also asked of the expert, despite answers being given through “parking lot” responses the week prior. It is not clear whether there was a lack of interest in clinical trials participation a desire to use the opportunity to answer lingering questions regarding their care. The research team originally thought the name of the session “Stump the Experts” set a tone of challenging the expert to assess their clinical trial knowledge, as opposed to using the session as an opportunity thus the name was changed to “Ask the Expert”. There were still numerous of questions about HIV treatment in general, and specific questions related to a client’s particular regimen. Consideration should be given to introducing the ACTU expert at the onset of the series to give an overview of what he

does as part of his role as an ACTU researcher, what a typical participant experiences as part of the referral process, and then preface what the remainder of the intervention sessions entail for clients participating in the series.

An additional modification for the client series is to incorporate analogies provided by the ACTU physician during the “Ask the Expert” session. Pretesting of the curriculum revealed some anticipated questions, and afforded the opportunity to the research team to refine the curriculum prior to implementation of the intervention study. The ACTU expert parallel HIV and host cell receptors to a “lock” and “key” to illustrate how HIV seeks out a specific receptor on the host cell to attach and insert its genetic material (RNA) to be replicated by the host cell. Another analogy provided by the ACTU expert was the explanation of trials offered at the UNC ACTU. The expert explained that most trials at the ACTU were phase 3 or phase 4 trials, so they were essentially comparing Coke with Pepsi—two medications known to already work, just seeing which works best for a given population.

Process Evaluation Methodology. Client focus group discussions raised few concerns for collection, analysis and interpretation of data received of study participants.. First, satisfaction of each participant was difficult to assess as, a group format does not necessarily ensure feedback from each individual in the group. For example, if there was a dominant speaker in the group who answered the majority of questions, with verbal or non-verbal affirmations from others in the group, it is difficult to assess the extent to which the responses truly reflected the thoughts of everyone in the group. Secondly, brevity of some client responses regarding what was “most liked” or “most memorable” about the sessions did not provide a wealth of information, even if probed further by the

moderator of the discussion. Third, the frequency with which these group discussions occurred may have led to fatigue on the part of the clients. While it is not possible to determine if repeated questions during each focus group limited client feedback, it is a consideration for future process evaluation studies in determining the best methods to assess participant satisfaction, including the frequency of data collection. Lastly, focus group discussion guides should be modified to reflect the theoretical objectives and associated activities of each session, as opposed to general questions asked for each session. For example, clients were asked about their confidence in speaking to a referral source during *each* focus group discussion held in their series. It was not clear if the questions were related to changes in confidence *over time* given the variety of activities offered, or if change in confidence was a direct result of a specific activity from the day's session. Conversely, the focus group method to assess dose received worked much more effectively for service providers as compared to clients in terms of feedback and satisfaction with session content.

Satisfaction surveys provided very little variability for clients and providers, as a great majority of participants indicated they “strongly agreed” or “agreed” with each statement on the survey. Qualitative methods should be explored to better understand what activities were most liked and why intervention participants liked them.

A final concern in the rural context related to potential literacy issues among clients participating in the intervention sessions. A small number of clients expressed literacy challenges at the onset of their respective series by openly stating they could not read, or by requesting help from a member of the research team in completing surveys or handouts given during the session. While this did not seem to be a barrier to retention in

the series, one participant in CL4 who expressed this concern did not return after the first day of the series and was lost to follow-up. Literacy also may have played a role in the limited feedback given during focus groups discussions or during the intervention session itself, but assessing how this may have factored into participant engagement or comprehension of session content is not possible. While demographic data, including educational attainment, was collected at baseline, these data are not indicators or proxies for literacy.

Aim # 2: Evaluate the implementation of an educational HIV clinical trial intervention with rural service providers.

Reach and Recruitment. The service provider series was also implemented as intended. Fidelity was a concern for the second service provider group (SP2), as session activities were rearranged as a result of the delayed start time for the first session in the series. This modified sequence did not appear to compromise the fidelity of intervention delivery, as none of the rearranged activities (i.e., clinical trial testimonial video or patient-service provider skits) was reliant upon content presented in previous sessions.

Dose delivered and Fidelity. Average dose delivered scores for the entire provider series were slightly higher than those for client series (.92, and .88 respectively), which may be attributed to a smaller number of sessions and shorter duration of sessions (thus less opportunity for variability in provision of session content). Fidelity long scripting condense and identify what information is most salient, core components

Intervention Modifications. Service providers, like clients, also raised several concerns related to post-trial availability HIV medication for their clients, as well as expectations of local service providers in resuming the patient's HIV care, particularly if

neither is aware of treatment their client received while in a clinical trial. While blinding increases methodological rigor and ensures equal treatment for participants, it also is one of the biggest concerns of service providers resuming their clients HIV care after the trial. Service providers acknowledged having limited time available to fully engage in informing their clients about clinical trials due to their responsibilities in the clinic), yet there was consensus about the importance of understanding the comprehensive picture of what the referral and enrollment processes look like for local service providers, clients, and clinical trial staff—including responsibilities of all parties involved. Provision of practical examples of client post-trial linkages to care, including associated forms or contracts, information about the average duration of post-trial care, and alternative options beyond trial participation.

Second, intervention developers should collaborate with researchers and practitioners at ACTU prior to intervention development to discuss alternative forms of dissemination of clinical trial opportunities, particularly for rural populations who may not have access to the Internet, or limited skills to use the Internet to find these opportunities. As the epidemic continues to burgeon in rural areas, this is a very important factor in ensuring availability and accessibility of information about clinical trials to those who are most disproportionately affected by HIV/AIDS. Sharing information about the accessibility and availability of clinical trials with participants was one of the goals of the EAST series. The Internet, while useful for many may not be an ideal way to disseminate information about available clinical trials. As the epidemic continues to affect the poor and underserved, researchers should rethink efforts to recruit minorities, particularly in the rural Southeast. One participant suggested a mailing list or

forum to share information about trials with rural clients, as many people in rural areas have their mail sent to post office boxes, which would ensure their privacy. As the intervention is a multilevel effort, researchers and practitioners should provide a forum or mechanism by which providers and clients interact to discuss concerns or questions about clinical trial participation.

Implications for Process Evaluation Research

Process evaluation research, while valuable, is complex and can be very extensive for intervention research. A variety of data collection methods can be used to assess the extent to which process evaluation concepts were met, therefore evaluation researchers must be strategic in determining the most efficient way to achieve the goals of the evaluation (Linnan and Steckler 2002). The following section will highlight implications based on methods and analyses used for the dissertation study.

Dose received is perhaps the process evaluation concept that most warranted triangulation of data sources, as satisfaction or engagement from an outsider's perspective could have varied from participant report of satisfaction. Engagement is subjective and could be misinterpreted by session facilitators or observers. For example, the facilitator may interpret participant lack of response or feedback during a session activity as a lack of engagement or dissatisfaction with an activity, while participants express the contrary on both counts. This leads to a broader inquiry of the best methods to assess participant engagement and satisfaction. If multiple data sources are used (e.g. observational data, facilitator debriefing interview, and focus groups discussions, and satisfaction surveys) researchers should have well defined processes as to how discrepancies between these data sources would be resolved. The dissertation findings

speak to the need for reduction in the sensitivity of implementation checklists and exploration of session transcripts as qualitative data sources for participant satisfaction.

Intervention Context. Future studies should consider ways to fully document and measure the effect of potential policy changes on individual motivation to participate in the EAST intervention, and ultimately CTs by capturing this data as part of survey data at each time point. As stated previously, contextual data captured external factors influencing implementation. However, more distal political influences were not captured as part of the dissertation study. For example, there were fiscal changes in the state AIDS Drug Assistance Program (ADAP) which severely limited access to HIV medications for PLWHA across the state (AIDS Legal Project, 2010). A few short months prior to recruitment and implementation of the intervention at Site A, over 800 people living with HIV/AIDS across the state were placed on a waiting list for treatment as a result the loss of ADAP funding.

As PLWHA meeting the criteria for ADAP (gross income at or below 300% of interest in clinical trials may have been heightened for these individuals. Unfortunately, the extent to which this policy change may have affected client or service provider interest in the Project EAST intervention study or HIV/AIDS clinical trials is unknown, as there was no formal inquiry of this change as part of data collection. All participants in the intervention were asked during their respective focus group discussions what their motivations were for participation in the series; neither service providers nor clients mentioned the closure of ADAP, or any other contextual barriers restricting client access to treatment. This type of contextual data may have had important implications for the outcome evaluation. That is, lack of access to HIV medications due to policy changes,

such as this, could have influenced a client's participation in HIV/AIDS clinical trials, as well as service provider referral to HIV clinical trials.

Another value for documenting context relates to capturing potential threats to the outcome evaluation's internal validity. The intervention study was carried out with organizations that received state funds from Ryan White Part D, a federal program that supports public and private organizations to provide family-centered and community-based services to children, youth, and women living with HIV and their families (Health Resources and Services Administration, 2011). This program also supports activities to improve access to clinical trials and research for these populations, thus there may be an impetus for organizations to take advantage of opportunities to increase awareness about and access to this information to meet funding requirements. Baronowski and colleagues (2010) suggest documenting the number of competing programs reaching participants in a study to determine the external contamination rates (ECRs) over the course of intervention implementation. Future process evaluation studies should consider conducting interviews with site administrators and/or staff at study sites to document potential contamination threats to gain more in-depth information regarding the number of competing programs could affect implementation of the intervention. Additionally, as part of client and service provider baseline surveys, an additional item could be added to determine whether they received information about clinical trials or clinical trial opportunities from other efforts from local organizations or major medical centers. Assured this in no way affects participation in the EAST series, partnership, or care

Implications for Practice

For grassroots organizations, health departments, faith-based organizations and community-based organizations, there are two considerations for intervention implementation: staff capacity and access to a clinical trial expert. Perhaps the most important consideration is organizational capacity of the research team and the partnering sites in the intervention. The Project EAST staff consisted of a project coordinator, two research assistants, and up to six volunteers at any given time. Five members had capacity to serve in dual roles: facilitation and observation. An additional three staff served solely as observers. At a minimum, three staff persons were needed for a large group of clients (12-15 participants): one facilitator, one observer, and one person to oversee other logistics for the site (audiovisual setup, catering, transportation, etc.). As research is not the primary goal for practitioners, staff size is as not as important, particularly if the intervention is implemented in one location,

Personnel time at partnering sites included time to recruit, document, and track clients for each session, reserve meeting space, and oversee transportation logistics for clients, if needed. With all of these factors considered, practitioners and researchers should consider organizational capacity well before implementation of the intervention as well as research staff capacity to collect and verify qualitative data process evaluation data collection and analysis.

Clinical Trial Expert. Access to clinical or clinical trial expert is vitally important for the intervention, as the last session for both groups (clients and service providers) consists of a conversation with an expert. While this was carried out in-person for the Project EAST intervention, future implementers can consider using other forms of media

to allow participants to engage in a dialogue with the expert(e.g. Skype, videoconference, etc.), particularly if distance or time involved in transit to and from the site is problematic for the expert.

Study Limitations

As mentioned in Chapter 3, the principal investigator of the dissertation study also served as the project coordinator for the larger, parent study, Project EAST. In this capacity, she assisted with the development, pretesting, and refinement of the curriculum for the intervention, as well as facilitation of service provider and client sessions at both study sites. Potential biases for the dissertation study were mitigated by her memo-writing and documentation of reflexivity notes during data interpretation and analysis. Both methods have been well documented in the literature as strategies to mitigate potential biases for qualitative researchers (M. B. Miles & Huberman, 1999; Watt, 2007).

Social desirability on the part of clients may have led to favorable responses regarding satisfaction with session materials or the main outcomes for the parent study: willingness to refer to, or participate in, a clinical trial. There was very little dissent among clients as it related to satisfaction with session activities. As clients spent a considerable amount of time in the outreach sessions and interacted with facilitators and other Project EAST staff, and were compensated for their time, there is a possibility that they felt obligated to give favorable responses despite EAST staff making it clear that participants' feedback was about the "product", or the series, and that all feedback was kept anonymous and confidential. Social desirability has been documented in the literature, particularly in the context of focus group discussions where conformity pressures may lead participants to adjust their opinions to match those of others

(Hollander, 2004).

Failure to establish adherence standards for FOI limited the extent to which I could state that the fidelity was acceptable, or not acceptable, for a given session, group or facilitator. Despite this shortcoming, the PI took detailed notes from audio files and session transcripts as part of the completion of session transcripts and made note of extreme deviations from scripting or instructions in the curriculum. These findings were detailed in Chapter 5.

Study Strengths

Project EAST provided a novel approach to increase access to increase awareness about clinical trials and clinical trial opportunities through a multilevel approach with rural, African American clients and their *local* service providers. This is very important in the rural context where a client's primary care service provider may not be integrated within, or in close proximity to the site conducting the clinic trial. Further, the concurrent education of both groups (service provider and clients) ensured comparable delivery and measurement of theoretical based behavioral objectives.

The primary strength of the process evaluation was triangulation of data sources for the analysis. This method has been encouraged by several qualitative researchers to strengthen validity through the support of study findings from independent data sources (M. B. Miles & Huberman, 1999; Patton, 1999). For example, dose received data for the dissertation study was captured from two data sources: focus group discussions, and observation notes. These data allowed for validating findings by comparing two data sources. Additional methods included memoing and using a data audit trail during qualitative data analysis, and both of which have been documented in the literature as

methods to strengthen validity of qualitative findings (Mauthner & Doucet, 2003; Rodgers & Cowles, 1993). These methods have been suggested to increase objectivity of findings, by reducing potential bias of the researcher in interpretation of findings.

Community Advisory Board-Informed

The intervention was developed with the guidance and feedback of a community advisory board (CAB). The importance of community input and involvement in research has been well documented in the literature (Cargo & Mercer, 2008; Minkler, 2005). CABs ensure that intervention content is culturally appropriate and relevant for community members. More importantly they are the facilitators and drivers of engagement, buy-in, and trust for research institutions and minority communities. Despite the recognized benefits to research design and implementation, relatively few HIV interventions have been designed using participatory methods, including the involvement of a CAB.

The findings from this process evaluation provided important insights into *how* behavior change occurs by investigating the degree to which the intervention was carried out as planned. This has been a critical omission in the literature as it relates to behavior interventions in general (Linnan & Steckler, 2002) as well as those developed to increase racial and ethnic minority participation in clinical trials. Of the five studies targeting racial and ethnic minority participation in clinical trials in the literature, only one reported process evaluation measures: dose delivered scores (Gwadz, Cylar et al., 2010; Gwadz et al., 2011; Linnan & Steckler, 2002). Therefore, this dissertation study is the most extensive process evaluation to date of an intervention to increase African American participation in HIV clinical trial research. In the context of HIV clinical trial education

and outreach, which is in its infancy among African Americans in general and African Americans in rural areas, findings from this process evaluation will provide a foundation upon which future efforts can build their intervention efforts with comparable populations. The inclusion of multiple process evaluation concepts (reach, context, recruitment, fidelity, dose delivered and dose received), afforded the opportunity to fully explore factors related to intervention implementation. While this was strength for the dissertation study, researchers and practitioners should determine the feasibility of collection, management, verification, and analysis data, as these may require a great deal of human and financial resources. That said, researchers and practitioners should prioritize which components are most relevant in answering their research questions (Linnan & Steckler, 2002).

Appendix A: Client Intervention Series

Session 1: CLINICAL TRIALS 101

- **Presentation:** Overview of Project EAST
- **Discussion:** “Clinical Trials Defined”
- **Presentation:** Clinical Trials Basics Power Point -Part 1

Session 2: REFERRAL AND TYPES OF TRIALS

- **Presentation:** HIV Clinical Trial Participant Testimonial Video
- **Activity:** Exploring the Types of Clinical Trials
- **Activity:** Referral to Participation

SESSION 3: OVERCOMING BARRIERS TO CT ENROLLMENT

- **Presentation:** Clinical Trials Basics Power Point -Part 2
- **Activity:** Informed Consent Exercise
- **Activity:** “Break the Barrier”: Identifying and Overcoming Barriers to CT Participation

SESSION 4: SUPPORT: WHAT IS IT AND WHERE CAN YOU GET IT?

- **Activity:** Support: What it Means to You
- **Activity:** Circle of Connections
- **Skit:** *Seeking Family Support*
* *Homework :Locating Clinical Trial Opportunities (Scavenger Hunt Sheet)*

SESSION 5: CLINICAL TRIALS: WHAT SHOULD YOU EXPECT?

- **Activity:** Scavenger Hunt Reflections
- **Role Play:** *Communicating with Your Service provider*
- **Discussion:** Protecting Your Confidentiality
**Homework: “Ask the Experts”*

SESSION 6: CONVERSATION WITH THE EXPERTS

Discussion: “Ask the Experts” :Real Life Experiences of Clinical Trial Staff

Appendix B: Service Provider Intervention Series

SESSION 1: CLINICAL TRIALS 101

- **Presentation:** Overview of Project EAST
- **Presentation:** Clinical Trials Basics Power Point
- **Activity:** Referral 101: Exploring the Types of Clinical Trials
- **Skit:** Informing Your Client About Clinical Trials

SESSION 2: SERVICE PROVIDER-CLIENT/PATIENT COMMUNICATION ABOUT CLINICAL TRIALS

- **Video:** HIV Clinical Trial Participant Testimonial Video
- **Presentation:** Referral through Participation
- **Activity:** *Clinical Trial Jeopardy*
- **Skit/Role Play:** Communication Show and Practice
 - * **Homework:** *Locating Clinical Trial Opportunities (Research Resource Sheet)*

SESSION 3: LOCATING CLINICAL TRIALS RESOURCES: WHERE DO I GO?

- **Activity:** Locating Clinical Trial Opportunities
- **Activity:** Circle of Connections: Establishing Networks with Other Service providers
- **Role Play:** Discussion with a Referral Source
 - * **Homework:** *“Ask the Experts”*

SESSION 4: SYNTHESIS OF INFORMATION

- **Activity:** “Break the Barrier”: Identifying and Overcoming Barriers to CT Participation
- **Discussion:** “Ask the Experts”: What Happens to My Client During the Trial?
- **Role Play:** Talking with Your Client about Clinical Trial Participation

Appendix C: Client Recruitment Tracking Form



ID	Race		Date Recruited	Agree to Participate?		If no, why?
	Black	Latino		Yes	No	
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

Appendix D: Sample Implementation Checklist

Group ID: 3AACL3.4	
Date of session: 11/17/10	Facilitator ID: BF2

Session 3 Tasks	Yes =1 No = 0	Notes
1. Facilitator introduced him/herself and project staff to participants.	1	•
2. Facilitator presented Session 2 recap PowerPoint presentation	1	• Not clear if every type has to be reviewed
3. Facilitator introduced session objectives.	1	•
4. Facilitators addressed Parking Lot questions from previous sessions.	0	• Unclear as to whether they were sent to the ACTU
5. Facilitator introduced the Parking Lot for Session 3.	1	•
6. Facilitator led Clinical Trials PowerPoint presentation	1	• Did not give AZT example for DSMB slide – better scripting on all slides?
7. Facilitator introduced the “Informed Consent” activity, placed the corresponding posters on the wall and read information from each poster aloud.	1	• Didn’t read introductory script; or that headings are the same, but content varies from study to study
8. Facilitator led the “Silly Consent Form” activity.	1	<ul style="list-style-type: none"> • Facilitator states that we want equal numbers of people in each study arm. • Confusion between “cost to participate” and “compensation” • Facilitator spoke about “fear of needles” as a risk • Did not read summary text
9. Facilitator distributed the “Key Questions to Ask Clinical Trial Staff” handout.	0	• Went directly into Break the Barrier
10. Facilitator led the “Break the Barrier” activity.	1	<ul style="list-style-type: none"> • Facilitator is threading/leading with the “needles” example throughout the session. • Did not offer an example prior to exercise
11. Facilitator concluded session by reiterating session activities	1	•
12. Facilitator gave information about the upcoming session	0	•
IMPLEMENTATION SCORE	75%	

Appendix E: Facilitator Debriefing Guide

Session ___

1. How do you feel about the session? Did it go well? Why or why not?

2. What types of activities worked well? What did not work well?

3. In what way did the session flow logically?

4. Did the participants seem to easily understand the content of the session?

Probe: What did not they understand? What were some indicators that they did understand the content?

5. Did the participants seem to easily understand the activities in the session?

Probe: What did not they understand?

6. How engaged were the participants?

Probe: What were some indicators that the participants were engaged?

7. How did their participation and involvement change as you progressed through the session?

8. How well do you think the participants related to the session?

9. What interesting points/questions were raised for you (with the process or feedback from the participants)?

10. How well was the match between the amount of time allotted to teach the session and the amount of materials that you needed to cover?

11. How well was the session objectives met?

12. Was there anything unusual or awkward about the session?

13. What was challenging about teaching this session?

14. What revisions/changes would you make to this session?

15. What revisions/changes would you recommend for the remaining sessions?

16. Were there any interruptions during the session?

17. Were there other people (besides participants) present during the data collection event? If so, who and what was their role?

18. Were there problems with the layout of the room? Briefly describe the setting.

19. Were there any other logistical problems (e.g., food, etc.)?

Appendix F: Facilitator Debriefing Interview Codebook

Concept	Code	Code Name	Code comment
Barriers to Implementation	IMPLEMENTATION BARRIERS		Apply this general code to any information that is important to capture related to barriers to implementation, but does not fit into any of the sub-topical codes below.
	IMPTIME	Delayed start/Late arrival	Apply this code to any information that reflects a late start to the sessions. This could be due to late arrival or logistical problems.
	IMPMAFUNCT	Malfunctioning equipment	Apply this code when the facilitator references implementation barriers related to malfunctioning audiovisual equipment (projector, DVD, volume problems, etc.)
	IMPFORECAST	Forecasting	Apply this code when the facilitator references implementation barriers related to participant inquiries that are beyond the scope of the current session (and will be covered in subsequent sessions).
	IMPCONFLAT	Care vs. Clinical Trials	<p>Apply this code when the facilitator references implementation barriers related to participant conflation with clinical trials.</p> <p>An example statement could be, “I was in a clinical trial--I went to the doctor and he switched my medication because I was getting sick.”</p>
	IMPINTERRUPT	Interruptions	Apply this code when the facilitator references implementation barriers related to interruptions (i.e. participants entering the room, a disruptive participant, or cell phones ringing).
	IMPINCORRECT	Incorrect Information	Apply this code when the facilitator references implementation barriers related to his/her provision of incorrect information (i.e. handouts, duplicates of session materials (i.e., support slips”),) or delivery of session content(i.e. not fully reading instructions for and exercise.
			This does not apply to the <i>omission</i>

			of information; instead use “IMPOMISSION”
	IMPOMISSION	Omission of session content	Apply this code when the facilitator references implementation barriers related to his/her omission of session information. This includes omission of scripted text in the session plan. This does not apply to the <i>provision of incorrect</i> information; instead use “IMPINCORRECT”.
Modification / Future Application	MODIFICATION		Apply this general code to any information that is important to capture related to facilitator recommendations for modification of current session content, but does not fit into any of the sub-topical codes below.
	MODNONE	No modifications	Apply this code when the facilitator states that no modifications were needed to the activity and/or session. This includes the facilitator stating that the perfect amount of time was used for the session.
	MODRESTRUCT	Restructure activity	Apply this code when the facilitator states that an activity should be <i>restructured</i> . Examples include: giving feedback during role-plays, removing a picture from an exercise, making a PPT presentation into a handout, or condensing session activities. If a specific activity is mentioned, apply the appropriate code from “SPECIFIC”
	MODEDIT		Apply this code if the facilitator makes any reference to scripting that text in the lesson plan needs to be edited. This code applies specifically to wording in the curriculum (i.e. adding more or less text to the introduction of an exercise, or shuffling/condensing session objectives within a lesson plan).
	MODREMOVE	Remove activity	Apply this code when the facilitator states that an activity

			should be <i>removed</i> from a session completely, or when the activity is described as not being useful.
	MODMORE	More Time	Apply this code when the facilitator states <i>more</i> time was needed for a specific session or session activity or more time with the ACTU expert. Double code with “ACTU” if this is the case.
	MODLESS	Less Time	Apply this code when the facilitator states <i>less</i> time was needed for a specific session or session activity.
	MODLIVE	Real PLWHA	Apply this code when facilitator states an in-person testimonial from a PLWHA (currently or previously) enrolled in a clinical trial would be beneficial.
	MODINTERACT	Interactive exercises	Apply this code when the facilitator suggests an activity should be made more interactive for session participants.
	MODMATERIAL	Provision of session materials	Apply this code when the facilitator states that provision of <i>existing</i> session materials would be helpful for session participants (i.e. PPT presentations, informed consent form, etc.)
MISC.			
	ENGAGEMENT		Apply this code when the facilitator references participant engagement or disengagement, including verbal and non-verbal indicators of engagement. Apply this code to illustrate disengagement as well.
	INTERESTING		Apply this code when the facilitator references interesting points made by participants, or interactions among participants that were surprising or unusual. If this relates to their comprehension of session specific materials, double code with the appropriate “KNOWLEDGE” code.
	CHALLENGE		Apply this code when the facilitator references challenges related to group management.
	ILL EQUIPPED		Apply this code when the facilitator references feeling ill-equipped to answer participant questions. This is a function of insufficient training, not a lack of

	LAYOUT	<p>preparation.</p> <p>Apply this code when the facilitator references the layout of the room and how it may have contributed to participant engagement. Can double code with “ENGAGEMENT” when applicable.</p>
	LOGISTICALGEN	<p>Apply this code when the facilitator references logistical problems (i.e. incentives, food, meeting space, transportation, etc.). If this is stated within the context of the late arrival of participants and it affected the start time of the session, double code with “IMPTIME”.</p> <p>This does not apply to malfunctioning AV equipment, instead use “IMPMALFUNCT”.</p>
	RELATE	<p>Apply this code when the facilitator references how well participants related to the session content.</p>
	TRUST	<p>Apply this code when the facilitator references participant concerns related skepticism/mistrust of the medical establishment in general or clinical trials research.</p>

Appendix G: Client Focus Group Discussion Guide

Recruiting

I'm going to start by asking you some questions about how you got involved with this series and what your experiences were before the sessions started.

How did you first hear about the Project EAST's Client Intervention Series?

What were your reasons for wanting to participate in the sessions?

What did [recruitment source] tell you about the program?

Did you think you received enough information about Project EAST to feel comfortable starting the sessions?

Did you think you received enough information about the series to feel comfortable participating?

What did you expect the sessions to be like?

Intervention Series

Now I have some questions about the sessions themselves. Please think about the 6 sessions that made up the series.

How would you describe the sessions to a friend/colleague who is also living with HIV?

Probe: What did you do at the sessions?

How were the sessions similar to what you expected?

How were they different from what you expected?

What did you like about the sessions?

What was most memorable about the sessions?

What was the most important part of the sessions?

What new skills or information did you learn from the sessions?

What skills do you feel you need more help with?

What information do you feel you still need to be effective in being informed about HIV trial opportunities?

What information do you feel you still need to be effective in being referred to HIV/AIDS clinical trials?

What information do you feel you still need to locate HIV trial opportunities?

What information do you feel you still need to be supported in your decision to participate in a clinical trial?

What would you have liked to get out of the sessions that you didn't get?

How do you feel about the amount of information you got? What about the length of the sessions?

What would you do to improve the sessions?

Future Application

These last few questions ask about how you feel about incorporating what you've learned into your personal lives.

How prepared do you feel about locating HIV trial opportunities?

Before going through this series, did you know about your role as a potential participant of a HIV trial?

Now that you have gone through the series, do you think you consider HIV trial opportunities and tell others about trial participation?

How comfortable are you talking with your service provider about HIV trials?

How comfortable are you talking with referral services about HIV trials?

What fears do you have about communicating with your service provider about HIV trials?

What fears do you have about communicating with referral services about HIV trials?

What do you think will be most difficult about participation in HIV trials?

What do you think will be most rewarding about participating in HIV trials?

Thank you so much for your time and thoughtful comments! The information you have provided will greatly help us with future sessions.

Appendix H: Service Provider Focus Group Discussion Guide

Recruiting

I'm going to start by asking you some questions about how you got involved with this series and what your experiences were before the sessions started.

How did you first hear about the Project EAST's Service provider Intervention Series?

What were your reasons for wanting to participate in the sessions?

What did [invitation source] tell you about the program?

Did you think you received enough information about Project EAST to feel comfortable starting the sessions? Why or Why not?

Did you think you received enough information about the series to feel comfortable participating? Why or Why not?

What did you expect the sessions to be like?

Intervention: Series

Now I have some questions about the sessions themselves. Please think about the 4 sessions that made up the series.

How would you describe the intervention series to a colleague?

Probe: What did you do at the trainings?

How were the sessions similar to what you expected?

How were they different from what you expected?

What did you like about the sessions?

What was most memorable about the sessions?

What was the most important part of the sessions?

What new skills or information did you learn from the sessions?

What skills do you feel you need more help with?

What information do you feel you still need to be effective in informing your clients/patients about HIV/AIDS clinical trial opportunities?

What information do you feel you still need to be effective in referring your patients/clients to HIV/AIDS clinical trials?

What information do you feel you still need to locate HIV/AIDS-related clinical trial opportunities for your patients/clients?

What information do you feel you still need to support your clients/patients as they decide on participating in a clinical trial?

What would you have liked to get out of the sessions that you did not get?

How do you feel about the amount of information you got? What about the length of the sessions?

What would you do to improve the sessions?

Future Application

These last few questions ask about how you feel about incorporating what you've learned into your practice as a service provider.

How prepared do you feel to fulfill the key roles of a service provider relating to HIV/AIDS clinical trials?

Before going through this series, did you know about your role as a service provider relating to HIV/AIDS clinical trials (inform your clients/patients about clinical trials, refer them to available opportunities, and support them through their decision to enroll and participate in clinical trials)? Tell me more about how you saw your role.

Now that you have gone through the series, how do you foresee your future interactions with clients/patients with respect to HIV/AIDS-related clinical trials?

How comfortable are you talking with your clients/patients about HIV/AIDS-related clinical trials?

What fears do you have about communicating with your patients/clients about clinical trials?

What do you think will be most difficult about fulfilling your role as a service provider relating to HIV/AIDS clinical trials?

What do you think will be most rewarding about fulfilling your role?

Have you informed your clients/patients about HIV/AIDS clinical trials, referred them, and supported them through the decision-making process to participate since the end of the series? If so, please describe how the process went.

Appendix I: Service Provider and Client Focus Group Discussion Codebook

Concept	Code	Code Name	Code comment
Recruitment	RECRUIT		Apply this general code to capture information that is important to capture related to participant recruitment.
Motivators for Participation	MOTIVATORS		Apply this general code to any information that is important to capture related to participant motivators for participation, and does not fit within any of the sub-topical codes below.
	MOTCTKNOW	Clinical trial knowledge	Apply this code when participants reference motivators related to learning more about clinical trials knowledge. This includes correct and incorrect references regarding clinical trial characteristics (definition, phases, key terms, and availability).
	MOTPROG	Project EAST	Apply this code when participants reference motivators related to learning more about “the program” or “classes”. This includes correct and incorrect references regarding the sessions and general references about the project (i.e. wanted to learn more about why the project is taking place.)
	MOTLIVEHIV	Living with HIV	Apply this code when participants reference motivators related to learning more about living with HIV. This includes references to symptoms, treatment regimens, and side of effects medication.
	MOTINCENTIVE	Incentives	Apply this code when participants reference motivators related to financial incentives (gift cards, gas card) or transportation. Do not apply if participants reference incentives as part of their “most memorable” or “liked” part of the intervention session. Instead, use “SATINCENTIVE” .
	MOTALTERN	Alternative	Apply this code when

			participants reference motivators related to a “break” or “alternative” to their regular routine. This includes avoiding boredom, or being given the opportunity to convene with other people living with HIV.
	MOTPROVIDREC	Service provider Recommendation	Apply this code when participants state their local service provider (physician, nurse, case manager, peer coordinator, etc.) suggested they participate in the sessions to gain more information about clinical trials opportunities.
	MOTGOAL	Organizational goal	Apply this code when participants state the intervention sessions fit with their organizational goal or that they received administrative persuasion (i.e. mandatory, or “clear your calendars”) to participate.
	MOTPREVUNC	Previous relationship with UNC	Apply this code when participants state previous relationships/collaborations with UNC served as motivators for participation.
Satisfaction with Session	*SATISFACTION		<p>Apply this general code to any information that is important to capture related to participant satisfaction with the intervention sessions, but does not fit into any of the sub-topical codes below.</p> <p><u>*If a session activity is mentioned in context of participants “liking” and activity or an activity being identified as being the “most memorable” activity in the session, double code with corresponding activity from “SPECIFIC”.</u></p>
	SATAWARE	Awareness	Apply this code when participants make any reference about the sessions raising awareness or increasing knowledge about clinical trials. Also apply this code for any reference to the sessions being “informational” or “informative”.

	SATFACIL	Facilitator characteristics	Apply this code when participants make any reference about characteristics of the facilitators. This includes facilitator knowledge of content or interpersonal interactions.
	SATINCENTIVE	Incentive	Apply this code when participants make any reference to incentives being their “most memorable” or “liked” part of the intervention session.
	SATAURS	Audience response system	Apply this code when participants make any reference about the audience response system (“Turning Point”), “survey”, or “clickers”.
	SATGROUP	Other PLWHA/Group Setting	Apply this code when participants reference being happy, comfortable, or “feeling safe” with other PLWHA in a group setting.
	SATQSANS	Questions answered	Apply this code when participants give any general reference regarding their questions being answered directly, or in a timely fashion.
		SATQSANS.ACTU	Apply this sub-code when participants specifically reference ACTU experts answering questions or <i>receiving</i> “Parking Lot” responses (from ACTU experts, or in general).
	SATGENACT	Interactive activities	Apply this code when participants make any reference about “liking” or “being satisfied with” the intervention sessions <i>in general</i> . Do not apply this code if participants reference a specific activity; instead use “ SATSPECACT ” with the relevant sub-codes.
Modifications	MODIFICATION		Apply this general code to any information that is important to capture related to participant recommendations for modification of current session content—or skills they still need help with as it related to CT participation and referral
	MODNONE	No modifications	Apply this code if participants state that no modifications were needed to the activity and/or session.

	MODLIVE	Real PLWHA	Apply this code if participants state that an in-person testimonial from a PLWHA (currently or previously) enrolled in a clinical trial would be beneficial.
	MODOUTCOMES	Clinical Trial Outcomes	Apply this code if participants state that provision of statistics on clinical trial outcomes (survivorship, mortality, illness, injured by research) would be beneficial during the sessions. Also apply if participants mention outcomes being beneficial to the medical community.
	MODINTERACT	Interactive exercises	Apply this code if participants desired more interactive activities.
	MODFDBK	Feedback on activities	Apply this code if participants desired feedback on activities (i.e. role-plays--where demonstration of skills are being assessed)
	MODMATERIAL	Provision of session materials	Apply this code if participants desired copies of <i>existing</i> session materials (i.e. PPT presentations, informed consent form, etc.).
	MODREMOVE	Remove activity	Apply this code if participants state that an activity should be <i>removed</i> from a session, or if the activity is described as not being applicable or useful.
	MODRESTRUCT	Restructure activity	Apply this general code if participants state that an activity should be <i>restructured</i> , but not removed from a session. Examples include: removing a picture from an exercise, making a PPT presentation into a handout, providing more context to the introduction of an exercise, or condensing session activities.
	MODFGGUIDE	Focus group discussion guide	Apply this code if participants state the questions asked as part of their focus group discussion are redundant, or if questions/statement/complaints are made in reference to the discussion and timing.
	MODACCESS	Accessible	Apply this code if participants state the intervention study needs to be made accessible to the

	MODREFERRAL	Referral	broader community. Apply this code if participants suggest ways to streamline the referral process. An example includes setting up satellite clinics (where trials can be offered) in rural areas.
	MODSTAFF	Project staff	Apply this code if participants suggest changes to staff for the sessions. This includes the rotation of staff in roles of facilitators or note takers.
MISC.			
	ROLECONSIDER	CLIENTS ONLY Consideration of participation (before or during)	Apply this code if participants reference considering participation in clinical trials, thoughts/inquiries about participation (prior to beginning the series or during the sessions).
	SPROLE	SERVICE PROVIDERS ONLY Service provider role in the referral process	Apply this code if participants reference their roles as service providers as it relates to awareness about and referral to a clinical trial. This includes lack of knowledge about their role prior to participating in the series, or if they don't think the roles are practical with their population.
	TELLOthers	Tell other PLWHA about clinical trials	General information about what participants would tell other PLWHA about clinical trials and/or clinical trials opportunities. This should not be confused the probe for the question "What did your during the sessions", as this probe is used to assess participant knowledge. If this is the case, use the appropriate "KNOWLEDGE" code.
	PREVEXPER		Apply this code if participants reference previous participation in clinical trials. Also include and contextual information to describe their experience(s).
Specific Session Activities	SPECIFIC		
	CTBAS	Clinical Trials Basics	Apply this code to capture the facilitator's thoughts related to participant knowledge of clinical

			<p>trial basics (definition, phases, types, and key terms (blinding, randomization, placebo)), or regimen changes for a potential participant.</p> <p>Includes PPT presentations, handouts, or other associated activities (i.e. randomization activity (CLIENTS only)).</p>
	TYPE	Types of Trials	<p>Includes “Types of Clinical Trials” handout, THE CARD, vignettes (SERVICE PROVIDERS only), or posters (CLIENTS only). <i>Associated terms may include “naïve”, “failing” “HIV negative” or “suppressed”.</i></p>
	VIDEO	Testimonial Video	<p>Includes participant testimonial video. Associated terms may include “Glow” or “his story”, or “other people”.</p> <p><i>This should be a function of participant feedback and/or engagement, not malfunctioning AV equipment; instead use “IMPMALFUNCT”.</i></p>
	INFCONS	Informed Consent	<p>This includes the Jeopardy game, consent form (SERVICE PROVIDERS only), “silly” consent form and/or posters (CLIENTS only) or PPT presentations (SERVICE PROVIDERS and CLIENTS). <i>Associated terms may include “IRB”, “DSMB”, “participant rights”, “bells”, “candy” or “teams”.</i></p>
	REFERRAL	Referral to Participation	<p>Includes handouts (SERVICE PROVIDERS and CLIENTS) or posters (CLIENTS only). Associated terms may include “steps” or “walking around the room”</p>
	COMM	Communication	<p>Includes skits or role plays. Associated terms may include “communication” or “talking with” family, local health care service provider or clinical trial staff (aka “referral source”) as it relates to trial participation.</p>
	SUPP	Support	<p>Includes handouts and/or posters/slips (CLIENTS only). Associated terms may include “help”, “love”, “trust”, “care”,</p>

	LOCATE	Locating trials	“advice”, or “childcare”. Includes homework, internet exercise, and sample clinical trial advertisements. Associated terms may include “internet”, “find”, “brochure” or “flyer”.
	CONFID	Confidentiality	Includes discussion and handout. Associated terms may include “private”, “privacy”.
	BREAK	Break the Barrier	Includes brainstorm activity (participants generate barriers to clinical trial participation). <i>Associated terms may include “bells” or “teams”.</i>
	ACTU	“Ask the Expert”	This includes the “Ask the Expert” discussion and the homework that details questions to ask the expert.
	EAST	Project EAST	This includes the Project EAST brochure or PowerPoint presentation. Associated terms may include “classes”, or “program”.

Appendix J: Satisfaction Survey

Project EAST
Service provider Curriculum

Response options

- 1 = Strongly Agree
- 2 = Agree
- 3 = Disagree
- 4 = Strongly Disagree
- 5 = Not Applicable

Satisfaction

- _____ 1. The facilitator did a good job teaching the series.
- _____ 2. The facilitator did a good job teaching me new skills.
- _____ 3. The facilitator was knowledgeable about the material.
- _____ 4. Material was clearly explained during the session
- _____ 5. The session activities were appropriate for the material.
- _____ 6. I was comfortable asking questions during the sessions
- _____ 7. The facilitator did a good job answering my questions.
- _____ 8. I think other service providers would find this series helpful
- _____ 9. I learned relevant information for my professional practice through these sessions.
- _____ 10. The information presented was what I expected.
- _____ 11. I was satisfied with the series.
- _____ 12. Overall, I liked participating in the program.

Thank you for completing this survey!

Appendix K: Client Attendance Log, by Session and Group

CL1								
Session Number								
	1	2	3	4	5	6	total #	
LT8	1	1	1	1	1	1	6	1.00
AL3	1	1	1	1	1	1	6	1.00
MN2	1	1	0	0	1	1	4	0.67
AR1	1	1	1	1	1	1	6	1.00
EE5	1	1	1	1	1	1	6	1.00
DC7	1	1	1	1	1	1	6	1.00
RW8	1	1	1	1	1	1	6	1.00
IG6	1	1	0	0	0	0	2	0.33
RI0	1	1	1	1	1	1	6	1.00
AB3	1	1	1	1	1	1	6	1.00
DR2	1	1	1	1	1	1	6	1.00
UB8	1	1	1	1	1	1	6	1.00
MM5	1	1	1	1	1	1	6	1.00
AVERAGE								0.92
CL2								
	1	2	3	4	5	6	total #	
BC1	1	1	0	0	0	0	2	0.33
AT1	1	1	1	1	1	1	6	1.00
OR3	1	1	1	1	1	0	5	0.83
AP1	1	1	1	1	1	1	6	1.00
EK3	1	1	1	1	1	1	6	1.00
BW2	1	1	1	1	1	1	6	1.00
IM5	1	1	1	1	1	1	6	1.00
AM6	1	1	1	1	1	1	6	1.00
AH6	1	1	1	1	1	1	6	1.00
LM1	1	1	0	0	0	0	2	0.33
NK0	1	1	1	1	1	1	6	1.00
AVERAGE								0.86
CL3								
	1	2	3	4	5	6	total #	
LI4	1	1	1	1	1	1	6	1.00
BJ5	1	1	0	0	0	0	2	0.33
JO3	1	1	1	1	1	1	6	1.00
DG4	1	1	1	1	1	1	6	1.00
AVERAGE								0.83
CL4								
	1	2	3	4	5	6	total #	
BP97	1	1	1	1	1	1	6	1.00
LB59	1	1	1	1	1	1	6	1.00
LA40	1	1	1	1	1	1	6	1.00
LL68	1	1	0	0	0	0	2	0.33
LL55	1	1	0	0	1	1	4	0.67
AL73	1	1	1	1	1	1	6	1.00
AVERAGE								0.83

Appendix L: Provider Attendance Log, by Group

SP1						
ID	Session 1	Session 2	Session 3	Session 4	total # attended	
AAAA1	1	1	1	1	4	1
AAAA2	1	1	1	1	4	1
AAAA3	1	1	1	1	4	1
AAAA4	1	1	1	1	4	1
AAAA5	1	1	1	1	4	1
AVERAGE						1
SP2						
BBBB1	1	1	1	1	4	1
BBBB2	1	1	1	0	3	.75
BBBB3	1	1	1	1	4	1
BBBB4	1	1	1	1	4	1
BBBB5	1	1	1	1	4	1
BBBB6	1	1	1	1	4	1
AVERAGE						.96

Appendix M: Sample Fidelity Comparison by Data Source (Client Series)

Implementation Checklist Only	Facilitator Debriefing Interviews only	Both
<ul style="list-style-type: none"> • Did not ask participants what questions they have after the CT brainstorm. • Did not follow scripting after the randomization exercise (creating comparable groups) • Did not forecast upcoming information for session 3. • Facilitator gives too much info about trends in clinical trial participation when reading the EAST brochure; this information is captured as part of the PowerPoint presentation later in the session; this information shouldn't be introduced this early. 	<ul style="list-style-type: none"> • Asked participant to volunteer to read CT definition; not accounting for potential literacy issues. 	<ul style="list-style-type: none"> • Used analogy to elicit participant responses for CT brainstorm that was not scripted
<ul style="list-style-type: none"> • The facilitator did not introduce the Parking Lot. • Facilitator did not present the session 3 recap PPT presentation; read it verbally • Did not write participant feedback on the video on a flipchart. • Did not use the coin reference—this is VERY important concept! Instead used, "luck of the draw" • Went over time (72+ minutes) • Two participants made it to step 8; script calls for one. 	<ul style="list-style-type: none"> • Speakers were not working well/static • Still unclear as to what went wrong • Had participants read "Referral to Participation" Handout 	<ul style="list-style-type: none"> • Selected four participants instead of two; integrated with types of trials activity
<ul style="list-style-type: none"> • Facilitator did not read objectives at the beginning; read at the end of the entire activity • No responses during recap, facilitator reframes question as "Who is eligible for" • Did not summarize "silly consent" exercise at all; also did a test run questions before part 1 began; should have been done before part 2. • Facilitator did not summarize the "silly consent" at all. 	<ul style="list-style-type: none"> • Posters were placed ~ 20 feet away from participants, much further away than they were at other sites 	<ul style="list-style-type: none"> • Posters not put up in time • Did not follow the script for Break the Barrier
<ul style="list-style-type: none"> • Did not say: "Remember your participation is voluntary" or that the circles correspond to the pictures on the poster. • Asked participant to read four rows homework assignment; she read everything. 	<ul style="list-style-type: none"> • Facilitator gave several hints to see if participants would associate pictures on slips with posters. 	<ul style="list-style-type: none"> • Duplicate support slips
<ul style="list-style-type: none"> • Did not have participants name places first—jumped directly into what they found and information from the ad; engages in dialogue about trials not being on TV • Framing his inquiry around "has anyone disclosed their information"; this isn't the focus of this activity (e.g., "what do you tell people if they ask why you're going....") 	<ul style="list-style-type: none"> • Facilitator uses "privacy" and "confidentiality" interchangeably during this session.; unsure to what the difference is 	<ul style="list-style-type: none"> • No Internet for locating trials activity; walked through website links very slowly for participants.

Appendix N: Sample Visual Display of Client Satisfaction, Select Sessions

Session #	Client Group			
	CL1	CL2	CL3	CL4
1	<ul style="list-style-type: none"> Facilitators were personable; “broke down” [information] and provided answers to participant parking lot questions. “Clickers” 	<ul style="list-style-type: none"> Session was more than expected; great job Participant thought he would have to talk about himself; was glad he didn’t have to (“I be happy.”) 	<ul style="list-style-type: none"> Skit Interact with other CLIENTS Organization of the room (like a board room) “Clickers” (audience response system) 	<ul style="list-style-type: none"> New information (“Learning things I didn’t know about” “All of it” Participants questions were answered; received a lot of information Randomization activity
3	<ul style="list-style-type: none"> “Clickers” from previous week (ARS) Facilitators were great Break the Barrier activity (“the thing we did competing for the candy... that was challenging”) “All of it” Interactive activity from previous week 	<ul style="list-style-type: none"> How to overcome barriers (“Break the Barriers” activity) Everyone’s participation in activities (“I won’t forget how everybody participated”) Comfortable; around people who have the same problem 	<ul style="list-style-type: none"> That you all make it fun and like down to earth so that, you know, you can relate all different types of situations from n-, not having family support to having family support 	<ul style="list-style-type: none"> Receiving “vital information” Feeling comfortable (“I felt comfortable with [the people], you know, I do, you know.”

Appendix O: Sample Visual Display of Service Provider Satisfaction, All Sessions

Session #	Service Provider Group	
	SP1	SP2
1	<ul style="list-style-type: none"> • Comprehensiveness and detail of “Referral to Participation” activity; visual representation of the process • Defining the different types of trials and what different trials look at. • Honesty and upfront nature of the clinical trial participant video; participants worked issues with the CT team. • Video is an excellent tool for clients as it shows someone who has been through trial and is still alive • Facilitators were informative; kept participants attention • Knowing what research is being offered at UNC (The CARD) • Use of different media (paper, internet, skit) 	<ul style="list-style-type: none"> • Interactive • More information on how people get involved; never paid attention • Sessions flowed together; well integrated • Most memorable was testimonial video • How to reach out and where to go to get more information • RTP handout very helpful • Types of Trials new to everyone except for physician
2	<ul style="list-style-type: none"> • Informed consent activity (Jeopardy) allowed service provider to look through an ICF to find major components (“Don’t do away with Jeopardy!”) • Understanding the informed consent process, and that participation is voluntary 	<ul style="list-style-type: none"> • Jeopardy; good way to learn informed consent • Scavenger Hunt made them more aware; “they are everywhere now” • Service provider/Patient role-play was helpful; allow them to feel more equipped give more detailed information; got easier as they went through
3	<ul style="list-style-type: none"> • Learning where to go to find clinical trials (where the rubber meets the road); having facilitator navigate service providers through the website. 	<ul style="list-style-type: none"> • Don’t recall the four service provider roles handout • Circles of Connections more local in content; local HIV service providers
4	<ul style="list-style-type: none"> • “Breaking the Barrier”—what service provider thinks is a barrier may not be perceived by someone else at a barrier; challenged service provider to think outside the box • Opportunity to have a candid conversation with ACTU doctor; “real time responses” • Most memorable overall: presenters and testimonial video. 	<ul style="list-style-type: none"> • “Were we uneducated; now that we are educated, those barriers have been removed.”

Appendix P: Client Satisfaction Compared to Facilitator Perceived Engagement, Select Sessions

	CL3		CL4	
Session #	Facilitator Perspective (Engagement)	Client Perspective (Satisfaction)	Facilitator Perspective (Engagement)	Client Perspective (Satisfaction)
3	<ul style="list-style-type: none"> • First 30 minutes less lively as compared to the rest of the session activities; participant really wanted a copy of the presentation slides; facetiously said “Here’s a handout” when handouts were passed out. • “Pretty lively group” • Not as engaged and lively during the ICF activity; observer states they were glancing off, but still paying attention to the facilitator • Participants looked “drained and disengaged” after the ICF activity; facilitator took a five minute break (and a few other five minute breaks over course of the day) • 	<ul style="list-style-type: none"> • That you all make it fun and like down to earth so that, you know, you can relate all different types of situations from n-, not having family support to having family support 	<ul style="list-style-type: none"> • Female participant that was disengaged the previous week was very active during this session (taking notes, answering facilitator questions); couldn’t quite finish her responses, but spoke anyway • Older male participant is “checked out”; very quiet and doodling during the session <i>but</i>, made 2 or 3 comments! • Dominant female very engaged; first to answer every question 	<ul style="list-style-type: none"> • Receiving “vital information” • Feeling comfortable (“I felt comfortable with [the people], you know, I do, you know.”)
6	<ul style="list-style-type: none"> • Expert ask participant to pass her a note? • Participant looked “paralyzed”; very still and didn’t say anything. Expert tried to make her look comfortable by asking if she had anything to ask • Small group, pretty engaged; body language is somewhat deceiving because the participant with back turned and head down is still engaged in dialogue 	<ul style="list-style-type: none"> • Flow of entire series; doctor came in an “nipped everything in the bud” • Doctor explanation of how medication dosages are determined • Interaction in session activities; get the “full view” on what’s going on instead of just being told. 	<ul style="list-style-type: none"> • Very engaged; attentive. Male participant still doodling, but engaged otherwise 	<ul style="list-style-type: none"> • Doctor answered all participant questions (honestly and clearly) • Being able to talk their disease in a space with other clients

Appendix Q: Service Provider Satisfaction Compared to Facilitator Perceived Engagement, Session 1

Session #	Facilitator	SP1	Facilitator	SP2
1	<ul style="list-style-type: none"> • Participants are attentive and engaged; seem comfortable asking questions • Participants sitting forward during the skit; gave insightful feedback • Participants more attentive with the “Referral 101” exercise; very quick responses with the client vignettes. • Nodding in affirmation; smiling • One service provider looked fatigued; had 8 patients that morning • People getting fidgety and restless towards the end of the session 	<ul style="list-style-type: none"> • Comprehensiveness and detail of “Referral to Participation” activity; visual representation of the process • Defining the different types of trials and what different trials look at. • Honesty and upfront nature of the clinical trial participant video; participants worked issues with the CT team. • Video is an excellent tool for clients as it shows someone who has been through trial and is still alive • Facilitators were informative; kept participants attention • Knowing what research is being offered at UNC (The CARD) • Starting with the basics and building from there (not assuming that SERVICE PROVIDERS know the information • Use of different media (paper, internet, skit) 	<ul style="list-style-type: none"> • Participants spread out across the room; no table for them sit around • More engaged and attentive at the beginning and end of the session • Participants some nodding off; no questions about Project EAST • Facilitator states, “I felt like I had one cheerleader in the crowd for a while.” • One question during the CT PPT presentation • More attentive with the “Referral 101” exercise; read TOT handout very quick responses with the client vignettes. • Pretty active during the CT barriers brainstorm. Physician shared info about Guatemala; WWII • Participants read handouts that are passed out; somewhat engaged • Two participants (MD and NP) ask questions about RTP. 	<ul style="list-style-type: none"> • Interactive • More information on how people get involved; never paid attention • Sessions flowed together; well integrated • Most memorable was testimonial video • How to reach out and where to go to get more information • RTP handout very helpful • Types of Trials new to everyone except for physician

REFERENCES

- Adimora, A. A., Schoenbach, V. J., Martinson, F., Donaldson, K. H., Stancil, T. R., & Fullilove, R. E. (2004). Concurrent sexual partnerships among African Americans in the rural south. *Ann Epidemiol*, *14*(3), 155-160. doi: 10.1016/S1047-2797(03)00129-7
- Adimora, A. A., Schoenbach, V. J., Martinson, F. E., Coyne-Beasley, T., Doherty, I., Stancil, T. R., & Fullilove, R. E. (2006). Heterosexually transmitted HIV infection among African Americans in North Carolina. *Journal of Acquired Immune Deficiency Syndrome*, *41*(5), 616-623. doi: 10.1097/01.qai.0000191382.62070.a5
- AIDS Clinical Trials Group Network. (2010). *About ACTG*. Retrieved from <https://actgnetwork.org/about-actg>
- AIDS Legal Project. (2010). *ADAP*. Retrieved from <https://www.law.duke.edu/aidsproject/resources/adap>
- Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. Upper Saddle River, NJ: Prentice-Hall.
- Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*(2), 191-215. doi: 10.1016/0146-6402(78)90002-4
- Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory*. Upper Saddle River, NJ: Prentice-Hall.
- Baranowski, T., & Stables, G. (2000). Process evaluations of the 5-a-day projects. *Health Education & Behavior*, *27*(2), 157-166. doi: 10.1177/109019810002700202
- Basch, C. E., Sliepcevich, E. M., Gold, R. S., Duncan, D. F., & Kolbe, L. J. (1985). Avoiding type III errors in health education program evaluations: A case study. *Health Education & Behavior*, *12*(3), 315-331. doi: 10.1177/109019818501200311
- Black, B. P., & Miles, M. S. (2002). Calculating the risks and benefits of disclosure in African American women who have HIV. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *31*(6), 688-697. doi: 10.1177/0884217502239211
- Brandt, A. M. (1978). Racism and research: The case of the Tuskegee Syphilis Study. *The Hastings Center Report*, *8*(6), 21-29. doi: 10.2307/3561468
- Braunstein, J. B., Sherber, N. S., Schulman, S. P., Ding, E. L., & Powe, N. R. (2008). Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine*, *87*(1), 1-9. doi: 10.1097/MD.0b013e3181625d78

- Campbell, H. M., Raisch, D. W., Sather, M. R., Segal, A. R., Warren, S. R., & Naik, R. (2008). Impact of a clinical trials information handbook on patient knowledge, perceptions, and likelihood of participation. *IRB: Ethics and Human Research*, 30(1), 6-14. Available from <http://www.thehastingscenter.org/Publications/IRB/Default.aspx>
- Cargill, V. A., & Stone, V. E. (2005). HIV/AIDS: A minority health issue. *The Medical clinics of North America*, 89(4), 895-912. doi:10.1016/j.mcna.2005.03.005
- Cargo, M., & Mercer, S. L. (2008). The value and challenges of participatory research: Strengthening its practice. *Annual Review of Public Health*, 29, 325-350. doi: 10.1146/annurev.publhealth.29.091307.083824
- Centers for Disease Control and Prevention. (2008). Diagnoses of HIV infection and AIDS in the United States dependent areas, 2008. *HIV Surveillance Report*, 20. Retrieved from <http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/>
- Centers for Disease Control and Prevention. (2010). Diagnoses of HIV infection and AIDS in the United States dependent areas, 2010. *HIV Surveillance Report*, 22. Retrieved from <http://www.cdc.gov/hiv/surveillance/resources/reports/2010report/index.htm>
- Century, J., Rudnick, M., & Freeman, C. (2010). A framework for measuring fidelity of implementation: A foundation for shared language and accumulation of knowledge. *American Journal of Evaluation*, 31(2), 199-218. doi: 10.1177/1098214010366173
- Coker-Appiah, D. S., Akers, A. Y., Banks, B., Albritton, T., Leniek, K., Wynn, M., . . . Corbie-Smith, G. (2009). In their own voices: Rural African American youth speak out about community-based HIV prevention interventions. *Progress in Community Health Partnerships: Research, Education, and Action*, 3(4), 301-312. doi: 10.1353/cpr.0.0093
- Community Recommendations Working Group of Community Partners, National Institute of Allergy and Infectious Diseases. (2009). Recommendations for community involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS clinical trials research. Retrieved from <http://www.niaid.nih.gov/about/organization/daids/Networks/Documents/cabrecommendations.pdf>
- Cook, T. D., Campbell, D. T., & Day, A. (1979). *Quasi-experimentation: Design & analysis issues for field settings*. Boston, MA: Houghton Mifflin Company.
- Corbie-Smith, G. (1999). The continuing legacy of the Tuskegee Syphilis Study: Considerations for clinical investigation. *The American Journal of the Medical Sciences*, 317(1), 5-8. Available from <http://journals.lww.com/amjmedsci/pages/default.aspx>

- Corbie-Smith, G., Akers, A., Blumenthal, C., Council, B., Wynn, M., Muhammad, M., Stith, D. (2010). Intervention mapping as a participatory approach to developing an HIV prevention intervention in rural African American communities. *AIDS Education and Prevention*, 22(3), 184-202. doi: 10.1521/aeap.2010.22.3.184
- Corbie-Smith, G., Moody-Ayers, S., & Thrasher, A. D. (2004). Closing the circle between minority inclusion in research and health disparities. *Archives of Internal Medicine*, 164(13), 1362-1364. doi: 10.1001/archinte.164.13.1362
- Corbie-Smith, G., Thomas, S. B., & St George, D. M. (2002). Distrust, race, and research. *Archives of Internal Medicine*, 162(21), 2458-2463. doi: 10.1001/archinte.162.21.2458
- Corbie-Smith, G., Viscoli, C. M., Kernan, W. N., Brass, L. M., Sarrel, P., & Horwitz, R. I. (2003). Influence of race, clinical, and other socio-demographic features on trial participation. *Journal of Clinical Epidemiology*, 56(4), 304-309. doi: 10.1016/S0895-4356(03)00046-5
- Corbie-Smith, G. M. (2004). Minority recruitment and participation in health research. *North Carolina Medical Journal*, 65(6), 385-387. Retrieved from <http://www.ncmedicaljournal.com/>
- Department of Health and Human Services. (2011, January 10). Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. *Panel on antiretroviral guidelines for adults and adolescents*. Retrieved from <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>
- Durlak, J. A., & DuPre, E. P. (2008). Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology*, 41(3-4), 327-350. doi: 10.1007/s10464-008-9165-0
- El-Sadr, W., & Capps, L. (1992). The challenge of minority recruitment in clinical trials for AIDS. *Journal of the American Medical Association*, 267(7), 954-957. doi: 10.1001/jama.1992.03480070070033
- Eng, E., & Blanchard, L. (2006). Action-oriented community diagnosis: A health education tool. 1990-91. *International Quarterly of Community Health Education*, 26(2), 141-158. doi: 10.2190/8046-2641-7HN3-5637
- Ferguson, Y. O., Eng, E., Bentley, M., Sandelowski, M., Steckler, A., Randall-David, E., . . . Zim ba, C. (2009). Evaluating nurses' implementation of an infant-feeding counseling protocol for HIV-infected mothers: The BAN study in Lilongwe, Malawi. *AIDS Education and Prevention*, 21(2), 141-155. doi: 10.1521/aeap.2009.21.2.141

- Fishbein, M., Hennessy, M., Kamb, M., Bolan, G. A., Hoxworth, T., Iatesta, M., . . . Project Respect Study Group. (2001). Using intervention theory to model factors influencing behavior change. Project RESPECT. *Evaluation & the Health Professions*, 24(4), 363-384. doi: 10.1177/01632780122034966
- Fishbein, M., Hennessy, M., Yzer, M., & Douglas, J. (2003). Can we explain why some people do and some people do not act on their intentions? *Psychology Health Medicine*, 8(1), 3-18. doi: 10.1080/1354850021000059223
- Flay, B. R. (1986). Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. *Preventive Medicine*, 15(5), 451-474. doi: 10.1016/0091-7435(86)90024-1
- Ford, J., Howerton, M., Lai, G., Gary, T., Bolen, S., Gibbons, M., . . . Bass, E. (2008). Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer*, 112(2), 228-242. doi: 10.1002/cncr.23157
- Ford, M. E., Havstad, S. L., & Davis, S. D. (2004). A randomized trial of recruitment methods for older African American men in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Clinical Trials*, 1(4), 343-351. doi: 10.1191/1740774504cn029oa
- Fouad, M. N., Partridge, E., Green, B. L., Kohler, C., Wynn, T., Nagy, S., Churchill, S. (2000). Minority recruitment in clinical trials: A conference at Tuskegee, researchers and the community. *Annals of Epidemiology*, 10(Suppl. 8), S35-40. doi: 10.1016/S1047-2797(00)00199-X
- Fouad, M. N., Partridge, E., Wynn, T., Green, B. L., Kohler, C., & Nagy, S. (2001). Statewide Tuskegee Alliance for clinical trials. A community coalition to enhance minority participation in medical research. *Cancer*, 91(Suppl. 1), 237-241. doi: 10.1002/1097-0142(20010101)91:1+<237::AID-CNCR11>3.0.CO;2-U
- Freedberg, K. A., Sullivan, L., Georgakis, A., Savetsky, J., Stone, V., & Samet, J. H. (2001). Improving participation in HIV clinical trials: Impact of a brief intervention. *HIV Clinical Trials*, 2(3), 205-212. doi: 10.1310/PHB6-2EYA-GA06-6BP7
- Freeman, H. P. (1993). The impact of clinical trial protocols on patient care systems in a large city hospital access for the socially disadvantaged. *Cancer*, 72(Suppl. 9), 2834-2838. doi: 10.1002/1097-0142(19931101)72:9+<2834::AID-CNCR2820721512>3.0.CO;2-J
- Gifford, A. L., Cunningham, W. E., Heslin, K. C., Andersen, R. M., Nakazono, T., Lieu, D. K., . . . HIV Cost and Services Utilization Study Consortium. (2002). Participation in research and access to experimental treatments by HIV-infected patients. *The New England Journal of Medicine*, 346(18), 1373-1382. doi: 10.1056/NEJMsa011565

- Glanz, K., Rimer, B., & Viswanath, K. (Eds.) (2008). *Health behavior and health education: Theory, research, and practice* (4th ed.). San Francisco, CA: Jossey-Bass.
- Glasgow, R. E. (2009). Critical measurement issues in translational research. *Research on Social Work Practice, 19*(5), 560-568. doi: 10.1177/1049731509335497
- Gottlieb, M. S. (2006). Pneumocystis pneumonia--Los Angeles. 1981. *American Journal of Public Health, 96*(6), 980-981. doi: 10.2105/AJPH.96.6.980
- Gross, C. P., & Krumholz, H. M. (2005). Impact of managed care on cancer trial enrollment. *Journal of Clinical Oncology, 23*(16), 3811-3818. doi: 10.1200/JCO.2005.00.430
- Gwadz, M., Colon, P., Ritchie, A., Leonard, N., Cleland, C., Riedel, M., . . . Mildvan, D. (2010). Increasing and supporting the participation of persons of color living with HIV/AIDS in AIDS clinical trials. *Current HIV/AIDS Report, 7*(4), 194-200. doi: 10.1007/s11904-010-0055-3
- Gwadz, M. V., Cylar, K., Leonard, N. R., Riedel, M., Herzog, N., Arredondo, G. N., . . . Project ACT Collaborative Study Team. (2010). An exploratory behavioral intervention trial to improve rates of screening for AIDS clinical trials among racial/ethnic minority and female persons living with HIV/AIDS. *AIDS and Behavior, 14*(3), 639-648. doi: 10.1007/s10461-009-9539-9
- Gwadz, M. V., Leonard, N. R., Cleland, C. M., Riedel, M., Banfield, A., & Mildvan, D. (2011). The effect of peer-driven intervention on rates of screening for AIDS clinical trials among African Americans and Hispanics. *American Journal of Public Health, 101*(6), 1096. doi: 10.2105/AJPH.2010.196048
- Hall, H. I., Li, J., & McKenna, M. T. (2005). HIV in predominantly rural areas of the United States. *Journal of Rural Health, 21*(3), 245-253. doi: 10.1111/j.1748-0361.2005.tb00090.x
- Harachi, T. W., Abbott, R. D., Catalano, R. F., Haggerty, K. P., & Fleming, C. B. (1999). Opening the black box: using process evaluation measures to assess implementation and theory building. *American Journal of Community Psychology, 27*(5), 711-731. doi: 10.1023/A:1022194005511
- Hawkins, S. R., Clinton-Sherrod, A. M., Irvin, N., Hart, L., & Russell, S. J. (2009). Logic models as a tool for sexual violence prevention program development. *Health Promotion Practice, 10*(Suppl. 1), 29S-37S. doi: 10.1177/1524839908318803
- Health Resources and Services Administration. (2011). *Part D: Women and Families in a Circle of Care*. Retrieved from <http://hab.hrsa.gov/livinghistory/programs/Part-D.htm>

- Heaney, C. A., & Israel, B. A. (1997). Social networks and social support. In K. Glanz, B. Rimer, & K. Viswanath, K. (Eds.), *Health behavior and health education: Theory, research, and practice* (pp. 179-205). San Francisco, CA: Jossey-Bass.
- Heckman, T. G., Somlai, A. M., Peters, J., Walker, J., Otto-Salaj, L., Galdabini, C. A., Kelly, J. (1998). Barriers to care among persons living with HIV/AIDS in urban and rural areas. *AIDS Care*, 10(3), 365-375.
- Heckman, T. G., Somlai, A. M., Kalichman, S. C., Franzoi, S. L., Kelly, J. A. (1998). Psychosocial Differences Between Urban and Rural People Living With HIV/AIDS. *The Journal of Rural Health*, 14(2), 138-145. doi: 10.1111/j.1748-0361.1998.tb00615.x
- Helitzer, D., Willging, C., Hathorn, G., & Benally, J. (2009). Using logic models in a community-based agricultural injury prevention project. *Public Health Reports*, 124 (Suppl. 1), 63-73. Retrieved from <http://www.publichealthreports.org/index.cfm>
- Hightow, L. B., Leone, P. A., Macdonald, P. D., McCoy, S. I., Sampson, L. A., & Kaplan, A. H. (2006). Men who have sex with men and women: a unique risk group for HIV transmission on North Carolina college campuses. *Sexually Transmitted Disease*, 33(10), 585-593. doi: 10.1097/01.olq.0000216031.93089.68
- Hollander, J. A. (2004). The social contexts of focus groups. *Journal of Contemporary Ethnography*, 33(5), 602-637. doi: 10.1177/0891241604266988
- Javitt, G. (2010). Why not take all of me? Reflections on the immortal life of Henrietta Lacks and the status of participants in research using human specimens. *Minnesota Journal of Law, Science & Technology*, 11(2), 713-755. Retrieved from <http://www.ahc.umn.edu/mjlst/>
- Kaluzny, A., Brawley, O., Garson-Angert, D., Shaw, J., Godley, P., Warnecke, R., Ford, L. (1993). Assuring access to state-of-the-art care for US minority populations: The first 2 years of the Minority-Based Community Clinical Oncology Program. *Journal of the National Cancer Institute*, 85(23), 1945-1950. doi: 10.1093/jnci/85.23.1945
- Kamb, M. L., Fishbein, M., Douglas, J. M., Jr., Rhodes, F., Rogers, J., Bolan, G., . . . Peterman, T. (1998). Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: A randomized controlled trial. Project RESPECT study group. *The Journal of the American Medical Association*, 280(13), 1161-1167. doi: 10.1001/jama.280.13.1161
- Kaplan, S. A., Calman, N. S., Golub, M., Ruddock, C., & Billings, J. (2006). The role of faith-based institutions in addressing health disparities: A case study of an initiative in the southwest Bronx. *Journal of Health Care for the Poor and Underserved*, 17(Suppl. 2), 9-19. doi: 10.1353/hpu.2006.0088

- Kogan, S. M., Wejnert, C., Chen, Y., Brody, G. H., & Slater, L. T. M. Respondent-driven sampling with hard-to-reach emerging adults: An introduction and case study with rural African Americans. *Journal of Adolescent Research*, 26(1), 30-60. doi: 10.1177/0743558410384734
- Linnan, L., & Steckler, A. (2002). *Process evaluation for public health interventions and research*. San Francisco, CA: Jossey-Bass.
- Livingood, W. C., Winterbauer, N. L., McCaskill, Q., & Wood, D. (2007). Evaluating medical home constructs for children with special needs: Integrating theory and logic models. *Family & Community Health*, 30(4), E1-15. doi: 10.1097/01.FCH.0000290553.70347.8a
- Lucey, B. P., Nelson-Rees, W. A., & Hutchins, G. M. (2009). Henrietta Lacks, HeLa cells, and cell culture contamination. *Archives of Pathology & Laboratory Medicine*, 133(9), 1463-1467. doi: 10.1043/1543-2165-133.9.1463
- Mauthner, N. S., & Doucet, A. (2003). Reflexive accounts and accounts of reflexivity in qualitative data analysis. *Sociology*, 37(3), 413-431. doi: 10.1177/00380385030373002
- McLaughlin, J. A., & Jordan, G. B. (1999). Logic models: A tool for telling your program's performance story. *Evaluation and Program Planning*, 22(1), 65-72. doi: 10.1016/S0149-7189(98)00042-1
- Michaels, M., & Seifer, S. (2007). *Involving communities as partners in cancer clinical trials* [PDF document]. Retrieved from background paper for the conference series communities as partners in cancer clinical trials: Changing research, practice and policy: <http://www.researchtoolkit.org/primer/docs/ENACCT%20Report-Communities%20As%20Partners.pdf>
- Miles, M. B., & Huberman, A. M. (1999). *Qualitative data analysis*. Thousand Oaks, CA: Sage Publications.
- Miles, M. S., Roman Isler, M., Banks, B., Parker, D., Muhammed, M., & Corbie-Smith, G. (2011). Collaboration with a rural community advisory board in an HIV research Project.
- Minkler, M. (2005). Community-based research partnerships: Challenges and opportunities. *Journal of Urban Health*, 82(2 Suppl. 2), ii3-ii12. doi: 10.1093/jurban/jti034
- National Institutes of Health. (2007, September 20). *Understanding clinical trials*. Retrieved from <http://clinicaltrials.gov/ct2/info/understand#Q01>

- National Rural Health Association. (2004). *HIV/AIDS in Rural America: Disproportionate impact on minority and multicultural populations*. Retrieved from <http://www.ruralhealthweb.org/go/left/networking-and-programs/rural-hiv/aids-resource-center/>
- North Carolina Department of Health and Human Services. (2010). *2010 HIV/STD surveillance report*. Retrieved from <http://www.epi.state.nc.us/epi/hiv/pdf/std10rpt.pdf>
- Newman, P. A., Duan, N., Roberts, K. J., Seiden, D., Rudy, E. T., Swendeman, D., Popova, S. (2006). HIV vaccine trial participation among ethnic minority communities: barriers, motivators, and implications for recruitment. *Journal of Acquired Immune Deficiency Syndromes*, *41*(2), 210-217. doi: 10.1097/01.qai.0000179454.93443.60
- Nguyen, T. Q., & Whetten, K. (2003). Is anybody out there? Integrating HIV services in rural regions. *Public Health Reports*, *118*(1), 3-9. Retrieved from <http://www.publichealthreports.org/index.cfm>
- Partridge, A. H., & Winer, E. P. (2002). Informing clinical trial participants about study results. *The Journal of the American Medical Association*, *288*(3), 363-365. doi: 10.1001/jama.288.3.363
- Paskett, E. D., Cooper, M. R., Stark, N., Ricketts, T. C., Tropman, S., Hatzell, T., Atkins, J. (2002). Clinical trial enrollment of rural patients with cancer. *Cancer Practice*, *10*(1), 28-35. doi: 10.1046/j.1523-5394.2002.101006.x
- Patton, M. Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health Services Research*, *34*(5 Pt. 2), 1189-1208. Retrieved from <http://www.hsr.org/hsr/index.jsp>
- Plummer, P., Jackson, S., Konarski, J., Mahanna, E., Dunmore, C., Regan, G., . . . Millikan, R. (2002). Making epidemiologic studies responsive to the needs of participants and communities: The Carolina Breast Cancer Study experience. *Environmental and Molecular Mutagenesis*, *39*(2-3), 96-101. doi: 10.1002/em.10045
- Powell, J. H., Fleming, Y., Walker-McGill, C. L., & Lenoir, M. (2008). The project IMPACT experience to date: Increasing minority participation and awareness of clinical trials. *Journal of the National Medical Association*, *100*(2), 178-187. Available from http://www.nmanet.org/index.php?option=com_content&view=article&id=234&Itemid=363
- Price, R. M., Alkema, G. E., & Frank, J. C. (2009). California Geriatric Education Center logic model: An evaluation and communication tool. *Gerontology and Geriatrics Education*, *30*(4), 317-331. doi: 10.1080/02701960903347691

- Randall-David, B., Stark, N., Gierisch, J., & Torti, F. (2001). 'What do they know about it?' How the North Carolina public views cancer clinical trials: Implications for primary care doctors. *North Carolina Medical Journal*, 62(5), 281-285. Available from <http://www.ncmedicaljournal.com/>
- Rezmovic, E. L. (1982). Program implementation and evaluation results: A reexamination of type III error in a field experiment. *Evaluation and Program Planning*, 5(2), 111-118. doi: 10.1016/0149-7189(82)90017-9
- Rodgers, B. L., & Cowles, K. V. (1993). The qualitative research audit trail: A complex collection of documentation. *Research in Nursing & Health*, 16(3), 219-226. doi: 10.1002/nur.4770160309
- Rosen, D. L., Golin, C. E., Schoenbach, V. J., Stephenson, B. L., Wohl, D. A., Gurkin, B., Kaplan, A. (2004). Availability of and access to medical services among HIV-infected inmates incarcerated in North Carolina county jails. *Journal of Health Care for the Poor and Underserved*, 15(3), 413-425. doi: 10.1353/hpu.2004.0047
- Sable, M. R., Schwartz, L. R., Kelly, P. J., Lisbon, E., & Hall, M. A. (2006). Using the theory of reasoned action to explain physician intention to prescribe emergency contraception. *Perspectives on Sexual and Reproductive Health*, 38(1), 20-27. doi: 10.1363/3802006
- Saunders, R. P., Evans, M. H., & Joshi, P. (2005). Developing a process-evaluation plan for assessing health promotion program implementation: A how-to guide. *Health Promotion Practice*, 6(2), 134-147. doi: 10.1177/1524839904273387
- Sears, S. R., Stanton, A. L., Kwan, L., Krupnick, J. L., Rowland, J. H., Meyerowitz, B. E., Ganz, P. (2003). Recruitment and retention challenges in breast cancer survivorship research: results from a multisite, randomized intervention trial in women with early stage breast cancer. *Cancer Epidemiology, Biomarkers & Prevention*, 12(10), 1087-1090. Retrieved from <http://cebp.aacrjournals.org/>
- Seifer, S. D., Michaels, M., & Collins, S. (2010). Applying community-based participatory research principles and approaches in clinical trials: Forging a new model for cancer clinical research. *Progress in Community Health Partnerships*, 4(1), 37-46. doi: 10.1353/cpr.0.0103
- Sengupta, S., Strauss, R. P., DeVellis, R., Quinn, S. C., DeVellis, B., & Ware, W. B. (2000). Factors affecting African American participation in AIDS research. *Journal of Acquired Immune Deficiency Syndromes*, 24(3), 275-284.

- Sengupta, S., Strauss, R. P., Miles, M. S., Roman-Isler, M., Banks, B., & Corbie-Smith, G. (2010). A conceptual model exploring the relationship between HIV stigma and implementing HIV clinical trials in rural communities of North Carolina. *North Carolina medical Medical Journal*, 71(2), 113. Retrieved from <http://journals.lww.com/jaids/pages/default.aspx>
- Smith, K., & King, W. D. (2009). African Americans and HIV Research. HIV/AIDS in US communities of color, 245-260.
- Stahly, G. B. (1988). Psychosocial aspects of the stigma of cancer: An overview. *Journal of Psychosocial Oncology*, 6(3-4), 3-27. doi: 10.1300/J077v06n03_02
- Suchman, E. A. (1967). *Evaluative research: Principles and practice in public service & social action programs*. New York, NY: Russell Sage Foundation.
- The Kaiser Family Foundation. (2008). *Black Americans and HIV/AIDS*. Retrieved from <http://www.kff.org/hivaids/6089.cfm>
- U.S. Census Bureau. (2010). *Income, poverty, and health insurance coverage in the United States: 2009* [Data file]. Retrieved from <http://quickfacts.census.gov/qfd/states/37000.html>
- UNC AIDS Clinical Trials Unit. (2010). *UNC ACTU Open Studies for HIV Positive Subjects*. Retrieved from <http://www.med.unc.edu/infdis/actu/current-studies/hiv-positive>
- Volkman, E. R., Claiborne, D., & Currier, J. S. (2009). Determinants of participation in HIV clinical trials: The importance of patients' trust in their provider. *HIV Clinical Trials*, 10(2), 104-109. doi:10.1310/hct1002-104
- W.K. Kellogg Foundation. (2001). *Logic model development guide*. Battle Creek, MI: W.K. Kellogg Foundation.
- Wachter, R. M. (1992). AIDS, activism, and the politics of health. *New England Journal of Medicine*, 326(2), 128-133. doi: 10.1056/NEJM199201093260209
- Watt, D. (2007). On becoming a qualitative researcher: The value of reflexivity. *The Qualitative Report*, 12(1), 82-101. Retrieved from <http://www.nova.edu/ssss/QR/index.html>
- Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. *Annual Review of Public Health*, 27, 1-28. doi: 10.1146/annurev.publhealth.27.021405.102113