Community-Based HIV Clinical Trials: An Integrated Approach in Underserved, Rural, Minority Communities

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Abstract

Background—Although racial and ethnic minorities have disproportionately high rates of HIV infection, these groups are underrepresented in HIV-related clinical trials. This illustrates the need for more innovation in attempts to engage underrepresented populations in calls for interdisciplinary and translational research.

Objectives—Eleven focus groups and 35 interviews were conducted with people living with HIV/AIDS (PLWHA) to explore the perspectives of rural community leaders, service providers, and PLWHA about bringing HIV-related research, including clinical trials, into rural communities.

Methods—Over a period of 3 months in spring 2007, we collected qualitative data from three sources: Community leaders, service providers, and PLWHA. Text data were analyzed using the constant comparative method and content analysis techniques of theme identification.

Results—Respondents want an integrated approach to HIV research that builds trust, meets community needs, and respects their values. They conceptualize HIV research as part of a broader spectrum of HIV testing, prevention, and care, and suggest integrating HIV trials with existing community services, organizations, and structures, engaging various segments of the community, and conducting research using a personal approach.

Conclusions—These findings support calls for more relevant, translational, and engaged research. An integrated approach may be an important innovation to transform the research enterprise to meet these goals and more directly improve the health of individuals.

Keywords

HIV/AIDS; rural health; HIV clinical trials; African Americans

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Although racial and ethnic minorities have disproportionately high rates of HIV infection, these groups are underrepresented in HIV-related clinical trials. Early in the course of the disease, AIDS advocates were instrumental in increasing the accessibility and acceptability of clinical trials for gay White men.[1,2] However, the populations with the highest rates of

new infections are now women and minorities. These populations are concentrated in the rural Southeast.[3,4] Despite this shift, populations most likely to enroll in clinical trials still reflect the demographics of early phases of the epidemic rather than the growing trends of new infections. Participants in HIV/AIDS trials still tend to be overwhelmingly White, of higher socioeconomic status, and from larger urban centers.[5–7]

The lack of demographic parity in HIV clinical trials reflects a continued problem in HIV and other conditions where minorities are overrepresented. The need for more innovation in attempts to engage underrepresented populations is reflected in calls for interdisciplinary and translational research. The Clinical and Translational Science Awards, for example, require applicant organizations to describe efforts to more effectively engage communities in the research process. Greater generalizability of findings, more effective recruitment of participants, and faster translation of research findings to improve health underpin these calls.

However, the literature to guide engaging rural populations in HIV/AIDS clinical trials is sparse, especially studies involving minority populations. Much of the research on rural communities and HIV/AIDS has emphasized HIV prevention efforts or described barriers of access, geography, and stigma for people living with HIV.[8] In the scientific discourse that could guide investigators in their effort to engage diverse communities, we have limited data about approaches to effectively engage minorities in HIV/AIDS trial participation in rural communities, the current epicenters of the HIV epidemic.[8]

Unfortunately, the same factors that may limit clinical trial participation also limit our understanding, through other empirical investigation, of factors that contribute to underrepresentation of rural minorities in HIV research. Thus, research on engagement of rural minority communities in increasing access of persons with HIV in research is of high importance. As a prelude to development of an intervention to increase rural minority HIV trial participation, we explored the perspectives of rural community leaders and health care and service providers as well as African Americans and Latinos living with HIV/AIDS about bringing HIV-related research, including clinical trials, into rural communities.

Methods

Project EAST Overview

The overall goals of Project EAST (Education and Access to Services and Testing) are to define individual-, provider-, and community-level factors that influence participation of rural racial and ethnic minorities in HIV/AIDS research, and to develop and test interventions to increase rural minority participation in HIV clinical trials, including the use of a community-based mobile health unit. We are working in 6 counties in rural North Carolina that experience a significant burden of HIV/AIDS and other sexually transmitted infections. We present here analyses from the formative stage of our study. The study and all procedures were reviewed and approved by the UNC-Chapel Hill Institutional Review Board.

The 6-county region of Project EAST is divided into two communities in eastern North Carolina. Each county experiences a poverty level at or exceeding the state average, average county income is below the state per capita income, and all counties are below the state average for individuals who have graduated from high school.[9] Each county experiences a burden of HIV and AIDS above the 50th percentile for the state with significant racial and ethnic disparities in HIV incidence and prevalence.[10] To ensure the relevance and validity of our findings and intervention design, we worked closely with our Community Advisory Board (CAB), composed of local AIDS service providers, PLWHA, and community leaders.

The CAB advised the research team on all elements of the study design, the development of the areas of inquiry in the qualitative collection, the recruitment of the Community Outreach Specialists (COS) and study participants, interpretation of the study findings, and plans for dissemination of findings.

Participant Recruitment and Data Collection

Over a period of 3 months in Spring 2007, we collected qualitative data from three sources: community leaders, service providers, and PLWHA. We defined community leaders as those who could have influence on engaging the community around the issues related to HIV/AIDS and HIV research participation, and service providers as those who provide direct care or services to PLWHA. We conducted 11 focus groups (10 English, 1 Spanish) and 35 PLWHA interviews (30 English, 5 Spanish). Each focus group and individual interview was audiotaped and followed by a debriefing session to discuss any process issues or key emergent themes; all audio recordings were professionally transcribed.

Focus Groups—COS—lay individuals who both live and hold primary work positions within the local community—led all recruitment for service provider and community leader focus groups. The COSs were identified through our CAB, trained on the study protocol by the project coordinator, and compensated commensurate with similar university-based positions. Each COS created a master list of potential participants for the community leader groups reflecting various community segments, including political, education, grassroots, economic, media, religious, and social welfare.[11] A similar list was compiled for service providers that included physicians, case managers, health educators, and other AIDS service providers. We included providers or leaders who work in one of the target counties and recruited a purposive sample to ensure representation across community segments and provider types. All focus groups took place in a community location, were moderated by trained research staff members using a semistructured guide and lasted an average of 88 minutes (range, 67–109). Participants provided informed consent before the group interview.

Individual Interviews—We recruited PLWHA through local HIV/AIDS case management and clinical programs, who resided in one of the 6 target counties, self-identified as African American or Latino, and spoke English or Spanish. We purposively sampled participants to reflect national data on the proportion of PLWHA currently "in care" (55%),[12] which is defined as participants who have been adherent to medical appointments within the past 6 months. The case manager or COS contacted each participant to explain the study and followed up with reminder phone calls just before each interview. We conducted interviews in a private room in the local care facility on days that participants had scheduled appointments to avoid multiple trips to the facility. Trained interviewers from the research team obtained informed consent and conducted the interviews using a semistructured guide; interviews lasted on average 46 minutes (range, 20–104). Given the vulnerability and sensitivity of the target population, the interviewers and moderators completed training on maintaining confidentiality and human subject protections before data collection.

Description of Interview Guides—The interview guide included the following topics: Perceptions of HIV/AIDS research and clinical trials, positives and negatives to participating in HIV/AIDS research and clinical trials, perceptions of a mobile unit for conducting trials, stigma and confidentiality, and potential community collaborators for introducing HIV/AIDS clinical trials to their community. We developed the guides collaboratively with the CAB, which included intentional overlap between the focus group and the PLWHA interviews, to allow for triangulation of findings.

Guides used for Spanish data collection were translated from English to Spanish by a certified translator, compared with the English version, and reviewed for accuracy by the Spanish interviewer and other members of the research team.[13] A bilingual and bicultural Spanish speaker conducted the focus group and individual interviews for Spanish speakers. Audio files from Spanish-speaking data collection were transcribed, and translated to English in a two-pass process to ensure accuracy and integrity of the work by a professional translation service.[13]

Analytic Strategy

For this study, we analyzed text data across respondent types on perceptions of HIV clinical trials and methods to bring HIV trials into communities. Our analysis used the constant comparative method and the content analysis techniques of theme identification.[14–16] Glaser and Strauss's method of constant comparative analysis[14] requires the data to be reviewed in light of an initial conceptual formulation and reviewed and coded repeatedly. To develop the codebook, three rotating teams of two coders from the research team (six total coders) independently reviewed transcripts of each interview as they were conducted and developed and applied preliminary codes for the text data. To ensure consistency in the coding approach in this iterative process, the complete team of six coders met weekly to review, compile, and refine the codes, resulting in a final iteration of the codebook. In an iterative process, we used subsequent coding team meetings to reconcile differences and reach consensus in application of codes and emerging themes that were identified. In this form of analytical triangulation, important insights can emerge from the ways different analysts look at the same set of data, and also provides a means to ensure internal validity.[16] Written definitions for each code were developed and revised based on input from all research team members. Examples and directions of when to use the code and when not to use it were detailed in the codebook. We used ATLAS.ti version 5.2 (Atlas.ti Scientific Software Development, Berlin, Germany) to facilitate organization, management and analysis of the qualitative dataset. In the current analyses, three analysts reviewed the final codes, selected coded text, and compared the text data within and between interviews and respondent types. We sorted participants' comments by content areas, selecting quotes illustrative of each domain and those that were exemplars of various perspectives within that area. We presented preliminary analyses in the form of thematic findings to our CAB, as an accuracy check for interpretation and clarification of terminology and dynamics described by study participants. This feedback process helped to enhance the validity and eventual trustworthiness of the data included in this specific set of analyses. Additionally, an outline of the final findings presented in this paper were reviewed and approved by the CAB.

Results

A majority of community leader and service provider focus group participants were ethnic minorities, female, and had at least some college education (Table 1). In contrast, individual interview participants were primarily male and most had educational attainment of high school or less.

All respondents described the need for HIV research and clinical trials to be thought of as one point on a continuum of HIV care and services. For the PLWHA and community leaders, research was one end of a spectrum in HIV testing, prevention, and access to care. In our analysis, effectively engaging rural minority communities in HIV clinical trials went beyond the logistics of recruitment; research teams were expected to use a comprehensive approach that addresses, in some way, all points along the continuum of HIV care. An integrated approach to research would result in building trust, sharing power, and more effectively address the needs and values of the community. Elements of an integrated approach would include (1) integrating HIV trials with existing community services,

organizations, and structures, (2) engaging various segments of the community, and (3) conducting research using a holistic, personal approach (Table 2).

Integrating HIV Trials With Existing Services and Outreach

Respondents noted that HIV researchers need to partner with existing services, organizations, and structures in the community to build trust and more effectively address the needs of a given community. They suggested a number of ways that a new research endeavor might integrate with existing community entities. One strategy included partnering with other local organizations and agencies to offer comprehensive health related services, including HIV clinical trials, as a way to conduct both HIV and non-HIV research and other health outreach. They also suggested working with other entities that are currently doing HIV outreach to leverage their existing, trusting relationships. The conduct of HIV research could support existing outreach to communities and also would be another opportunity to increase awareness about HIV primary and secondary prevention efforts as well as HIV research.

Comprehensive and deliberate attention to integrating HIV clinical trials with other HIV and non-HIV related health efforts was also thought to be important to leverage financial and nonfinancial research resources for supporting the HIV care and services continuum. Such integration was viewed as a key aspect of future success of community-based clinical trials that sought to engage underserved groups owing to facilitated trust, shared ownership of research products, shared power, demonstrated concern for community, and responsiveness to local needs, concerns, and values.

Integrating HIV clinical trials with existing services was also noted as a way to gain a more comprehensive understanding of the structure and values of a community. By working collaboratively with existing entities, study staff would be able to see and acknowledge a broader view of the problems facing a community and thus create opportunities to demonstrate willingness to address the issues of concern in the community in the context of a research agenda. Through these professional affiliations study staff could come to "know the community" and thus would be able to make decisions that are consistent with community values. Past experiences with research teams were described as "sitting high and looking low," that is, making decisions at a distance and with disdain or lack of attention to community concerns.

Engage Various Segments of Communities

Respondents noted the importance of engaging the community in learning more about the importance and need for research. Service providers, in particular, confirmed the importance of engaging them as partners in research. They highlighted the vital role AIDS service providers and clinicians play in helping PLWHA manage and interpret complex information. Working with service providers in rural communities to integrate clinical trials with what they offer to clients and patients would build on the trust and rapport that service providers already have with their clients. However, there was a clear need and call for more information and increased awareness of and access to clinical trial information for "front-line" providers. Respondents stated that it would be essential for research personnel to "go to the service providers with an attitude of humility and respect to influence them to influence the people they serve." As eloquently noted by one service provider,

> I'm going to have to be convinced that this is good for the people I am talking with because they trust me…if I would say it is okay they would be more likely to do it. But for me to say it's okay or even suggest that this is a choice they might make, I'd have to be convinced.

In addition, both service providers and community leaders pointed out the need to engage a wide range of community and faith based organizations in the research process. The importance of engaging a variety of segments of society in HIV research was compared to antiretroviral therapies—"just like the HIV drugs; you have a combination of drugs to help the virus, we have a combination of people [to address the problem]". Broad engagement of various segments of the communities was identified to be both a multipronged approach to increase HIV trial participation, and also a means of underscoring the need for research teams to work with local community leaders and service and health care providers to make the continuum from testing, prevention, treatment, and research seamless. For example, to close the loop and ensure participant safety and retention, respondents stated the need to ensure that local hospitals were included in the research efforts, because local health care centers, rather than more distant academic centers, are where many participants go if they have a study-related emergency.

Holistic and Personal Approach to Research

The call for a more integrated approach to HIV clinical trials in communities paralleled the sentiments of PLWHA who called for a more holistic and personal approach to research participation in clinical trials. There were multiple pleas to "know the person"—understand where they are in terms of their current regimen as well as the challenges they face in their daily lives. This was similar to the calls for greater awareness of the social structure and needs of the larger community. There was a clear and recurrent concern for research teams to engage with individuals beyond the research.

> [B]esides the medicines, what are they doing? Who don't have insurance or any type of healthcare? What are they going to do to help those people? What are they doing to get those that are scared to be tested?

In addition, respondents noted research staff also need to be prepared to deal with psychological distress and the unmet mental health needs of participants that may be particularly acute in underserved areas "the people that are administering these trials will need to be trained for the psychological aspect of people living with HIV and AIDS."

Discussion

In this study, community leaders, healthcare and AIDS service providers, and PLWHA all called for a more integrated approach to engaging underserved communities in HIV research. Respondents saw HIV research as part of a broader spectrum that included HIV testing, primary and secondary prevention, and HIV research. This integrated approach required partnerships with organizations along this spectrum and with trusted entities that provided health related services beyond HIV. Currently, academic centers are charged with going beyond the walls of the health center to engage communities.[17] The results from this study are timely in the setting of these calls for more relevant, translational, and engaged research and scholarship. In addition, an integrated approach may be an important innovation in thinking about how to truly transform the research enterprise to meet these goals so that research can more directly improve the health of individuals.

An integrated approach to HIV trials would require a paradigm shift for many clinical trial programs. Respondents in our study expected more from HIV research than opportunities to enroll in clinical trials. This expectation is a notable shift from the advocacy efforts early in the epidemic for increased access to experimental therapies. Respondents in this study had expectations that were closely aligned with the principles of participatory approaches to research, where the expectation is that the process and products of research will lead to direct benefits in communities.[18–22] To meet these expectations would require researchers moving beyond collaboration with community organizations as a means to increase study

enrollment, and entail long-term partnerships that are synergistic in the goals of outreach for clinical trial enrollment and prevention and treatment. In fact, others have demonstrated the advantages of this type of integrated approach. For HIV/sexually transmitted infection prevention services, combining testing with treatment services has been shown to have both clinical and cost benefits.[23–25] In non–HIV-related conditions, screening for hypertension and diabetes have also demonstrated similar benefits.[24,25] Combining HIV prevention and treatment services, including HIV clinical trials, have also been shown to mitigate stigma and other barriers to case recognition and entrance into care.[23]

A more integrated approach to HIV prevention, care, and research may be especially salient in rural communities, where residents are often clinically underserved. Providing a continuum of integrated health services may combat current barriers to care including access to trained and available clinicians, limited service coordination, and poorer overall health status experienced by many rural residents.[23,24,26] In fact, academic health centers are well equipped technologically to meet the request for engagement across the spectrum of HIV prevention, care, and research. However, this approach would require substantive realignment of resources to increase access in rural areas to HIV specialists, testing technology, and state-of-the-art care. In addition to real-time collaborations, innovations like telemedicine and mobile health units may be ways to decrease the geographic and psychological distance between communities and academic health centers and create bridges across the spectrum of HIV testing, care, and research.

Because of the social and historical context of HIV and HIV clinical trials, and the close alignment of research and advocacy in the disease, HIV trials programs and staff may be key "early adopters" of an integrated approach to conducting HIV clinical trials.[27] Advocacy around entry to HIV clinical trials in the early phases of the epidemic led to a shift in research ethics from protecting those considered vulnerable to laying emphasis on more equitable distribution of research benefits among groups previously excluded. In fact, the importance of community input in the conduct and design of research is arguably strongest and most clearly defined in HIV research.[28–32] For, example, AIDS Clinical Trial Units and Centers for AIDS Research each have strong and active CABs.[33] With this backdrop of advocacy and strong community input, moving toward an integrated approach to conduct clinical trials may be most feasible in HIV research.

Nevertheless, an integrated approach to research as described by our participants raises possible ethical issues that would also need to be addressed. Because our respondents suggested increasing interagency collaboration between academic research and community service providers, there may be an increased possibility of therapeutic misconception—an ethical dilemma where the purpose of a clinical trial is misunderstood as being to provide care rather than conducting research.[34,35] The therapeutic misconception is well described in a variety of conditions.[36,37] In fact, for a substantial minority of respondents in this study, the line between research and HIV treatment was murky at best. In resource-constrained communities, the urgent need for care could be met through enrollment in a clinical trial, where control arms are most often standard of care. However, the integration of HIV trials with other services may increase the possibility of participants not understanding they are enrolled in research or overestimating the direct medical benefits of participating in a clinical trial. The negative consequences of this misconception may actually undermine the trust built in this type of research collaboration.

As in all research, our findings should be considered in light of the study limitations. First, our respondents were primarily rural minorities; these findings may have less relevance in urban areas. Nonetheless, the national research agendas reflecting more participatory and action-oriented research resonates with the views expressed by our respondents. While we

provided descriptions of HIV clinical trials, our respondents had limited understanding of the structural and logistical factors that are necessary for conducting HIV trials. In fact, during some of the interviews, respondents moved between HIV research in general and HIV clinical trials. Greater knowledge of the conduct of research could have tempered their views on integration of HIV trials with other services or may have led to some distinctions between the conduct of HIV-related research in general and the conduct of HIV trials.

Despite these limitations, our findings argue for more innovation as we consider engaging underserved communities in research. Realignment of the research enterprise to a more integrated approach that includes research as part of a spectrum of prevention and care in HIV could not only increase enrollment in trials, but more importantly foster relationships that lead to more effective translation of research findings. An integrated approach raises important logistical and ethical issues, which would need to be addressed. However, a less fragmented approach to prevention, care, and research may be an important element of ensuring research results are effectively translated into improved health for communities and populations.

Acknowledgments

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Table 1

Study Participant Characteristics

Demographic Variable	PLWHA (*n* = 35)	CL (*n* = 40)[a]	SP (*n* = 36)[b]
Age (yrs)	42.9 (24–65)	43.4 (22–68)	40.6 (23–64)
Gender			
Male	21	11	10
Female	14	29	26
Race			
White	0	5	31
Black	30	26	58
Hispanic	5	7	11
Multi	0	2	0
Years in HIV work	—	—	6.6 (17–24)
Education			
Less than HS	8	—	—
Some HS	11	—	—
Graduated from HS/GED	11	2	1
Technical school or training	1	1	1
Some college	3	12	7
Completed college	1	9	15
Some graduate school	—	7	2
Graduate degree	—	9	10

[a]Groups *n* = 7. One focus group was combined community leaders and service providers.

[b]Groups *n* = 5. One focus group was combined community leaders and service providers.

Table 2

Representative Quotes

Theme	Implications	Representative Quotes
Integrating HIV trials with existing community services, organizations, and structures	Build trust Address community needs more effectively Provide comprehensive HIV and non-HIV research and other health outreach Leverage existing relationships Support existing outreach Increase awareness about HIV primary and secondary prevention efforts and HIV outreach Gain comprehensive understanding of community structure and values Avoid making decisions at a distance or lack of attention to community concerns	A tie in from the health system that's here…if there's a crisis they end up at the hospital before they make it to East Carolina University or Duke or Carolina sometimes. I would say the local hospital needs to be on board. —*Service provider* … we already do a little of that as far as prevention is concerned… collaborate with somebody's that's already probably doing it…— *Service provider* R1: Partnering with local grassroots organizations and other faith based organizations. R2: The church rules…if you go into a neighborhood if you find the matriarch or the mother of the neighborhood and get her on board— Then you've got more success rate to getting stuff done. —*Community Leader* The community gatekeeper has to be involved. Find out who your gatekeepers are and educate and inform them and then you'll be more apt to get a positive outcome…—*Service Provider* R1: … our consumer advisory boards might be a wonderful place to start… R6: Along with support groups. R5: They'll [CAB members] report to their support groups and talk about what's going on and so that would definitely be a good strategy to get information in there. —*Service Provider*
Engaging various segments of the community	Engaging service providers to learn more about importance and need for research More information and increased awareness of clinical trials for providers More access to clinical trial information Use of multi-pronged approaches to trial participation Ensure patient safety and retention	… we're trying to find a way to get the ministers in. We're trying to find a way to get some business leaders in. We're trying to find a way to get some politicians in. All these people…just like the HIV drugs, we have a combination of drugs to help the virus and then we have a combination of people. —*Service Provider/Community Leader* …if we could get all the interested parties together…and kind of explain what's going on…cause among the service providers sometimes they don't even know the resources themselves…you can kind of educate them about what's going on…so if they come in contact with someone they can let them know. —*Service Provider/ Community Leader* Get the buy in from our state level. The HIV/STD Prevention and Care branch…when stuff comes down from them sometimes it's more valid to providers—Or if it comes down from the medical director it's a little more valid to some people. They tend to pay more attention. —*Service Provider* If you're talking not just getting information to them [service providers] but convincing them that it's [clinical trials] a good idea, if you want to go beyond even convincing them it's a good idea but influencing them to influence the people they serve, you would have to take me through the motions. I'd have to be convinced that this is good for the people I'm talking with because they trust me… —*Service Provider* The HIV/AIDS counselors at the health department…support programs, make sure that all of them are kept up to date with the clinical trials that are out there. —*Community Leader* R5: …they have centers in the rural areas…I just think it would be an ideal partnership for something like clinical trials, to have the universities work with these. R4: Rural health centers. —*Community Leader* R5: Churches. R2: Beauty shops.

Theme	Implications	Representative Quotes
		R5: Barber shops.
		R5: Corner mom and pop stores, sororities, fraternities…
		R5: I think you need to get who's who in the age groups because we listen to who's who and get that person to be your spokesperson to get other individuals to take part.
		R1: To go out and help you with your work in terms of getting people on board. —*Service Providers*
Conducting research using a holistic, personal approach	Know the person	…that research would be trying to reach out to get a better service that could empower us for those that has HIV —*PLWHA*
	Greater awareness of the social structure ad needs of larger community Engage with individuals beyond the research	I'm going to say this in total respect- -To people with education. It's not all about what's in the books. It's about how you treat somebody… a hug, a gentle hand, warming conversation. How are you doing today? Just one conversation. —*PLWHA*
	Prepared to deal with psychological distress and unmet mental health needs of participants	…that's where I think research should start, if you can understand those different people how they relate every day because unless somebody can ever come and tell you, I don't care how much research you do, that you're HIV positive, there is no understanding. —*PLWHA*
		…what are they doing, besides the medicine…for people who don't have insurance…who don't have any type of health care. What are they doing to help those people… What are they doing to get these ones out here that's scared to be tested…and even ones that's got it that's on drugs…not taking medications and stuff… —*PLWHA*
		…if people see that you actually care and if you come to their house and talk to them one-on-one you're providing them with that support that they may not have and that makes them more eager to want to do more. You're like well how can I help or let me know rather than just sending them something and just handing them something. Handing them something and talk to them at the same time… —*PLWHA*