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BRIEF REPORT

Acceptability of a Mobile Health Unit for Rural HIV Clinical Trial Enrollment and Participation

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Abstract Few rural minorities participate in HIV clinical trials. Mobile health units (MHUs) may be one strategy to increase participation. We explored community perceptions of MHU acceptability to increase clinical trial participation for rural minorities living with HIV/AIDS. We conducted 11 focus groups (service providers and community leaders) and 35 interviews (people living with HIV/AIDS). Responses were analyzed using constant comparative and content analysis techniques. Acceptable MHU use included maintaining accessibility and confidentiality while establishing credibility, community ownership and control. Under these conditions, MHUs can service rural locations and overcome geographic barriers to reaching major medical centers for clinical trials.

Keywords Mobile health unit · HIV/AIDS · Clinical trials · PLWHA · Rural · Minority

Introduction

HIV/AIDS disparately impacts communities of color, yet racial and ethnic minorities continue to be underrepresented in HIV/AIDS clinical trials, particularly drug trials [1]. Lack of minority representation in such trials could lead to research findings that are difficult to generalize to ethnically diverse populations, impede development of more effective prevention, diagnosis, and treatment strategies [2] and inhibit access for minorities living with HIV/AIDS to the potential benefits of clinical trial participation, including therapeutic innovations, free medical care, and a sense of hope and altruism [3].

Barriers to minority participation in HIV/AIDS clinical drug trials include concerns about changes in medical regimens [4, 5] burdensome study participation [4, 5] misinformation or lack of knowledge about clinical trials [1, 5], fear and mistrust [1, 4, 5], stigma [1, 4], and a

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history of medical and research abuses [5]. Minorities in rural communities also face geographic isolation [5] and the challenge of transportation, as they are remote from major medical centers where most clinical trials take place [6]. The substantial cost and time required to travel such long distances is difficult, if not impossible, for rural participants.

Bringing clinical trials to rural communities might be one solution to improving access. However, HIV drug trials generally are conducted only at approved sites, traditionally a tertiary care hospital; [7] therefore, obtaining approval for community-based sites can be arduous. Additionally, many rural HIV care networks have limited services, few specialized clinicians, and lack the resources to participate in clinical research [6]. Mobile health units, as an extension of academic research health centers and approved alternative sites for clinical trials research, might be one solution to overcoming geographic isolation as they can reach individuals in sparsely populated rural communities [8]. MHUs have been used for sexually transmitted infection screening and treatment, [9] HIV testing and referral [10], mammography [11], cervical cancer screening [12], immunizations [13], prenatal care [14] and primary care [8, 12]. Although demonstrated as an innovative strategy for increasing access to health services, little is known about MHU use for recruitment and participation in HIV drug and treatment trials.

MHUs could not only overcome the geographic and logistical barriers of distance and transportation, but when implemented using community-informed strategies, can overcome socio-cultural barriers to HIV clinical trial participation. The rural South is characterized by poverty, lower educational attainment, fewer healthcare providers, limited access to health services, pervasive stigma, higher unemployment, and historical discrimination [15]. All of these characteristics not only make living with, and receiving care for, HIV/AIDS a tremendous challenge, but they also inhibit rural minority participation in clinical trials.

Introducing MHUs into rural communities to conduct HIV trials requires understanding community views and conditions for acceptability. Acceptability has been defined as the probability that a method (HIV/AIDS trial enrollment and participation) will be used in a specified population (individuals living with HIV/AIDS), as influenced by the service delivery system (MHU) and the socio-cultural context (rural) in which potential users live [16]. In this descriptive study, we explored the views of rural HIV/AIDS service providers, community leaders and people living with HIV/AIDS (PLWHA) about acceptance of an MHU as a way to participate in HIV trials and the unit's ability to overcome some of the geographic and socio-cultural challenges to participation that are present in southern, rural communities.

Methods

This was a qualitative descriptive study using data from a larger, community-based study, Project Education and Access to Services and Testing (EAST). The aim of Project EAST was to define and address individual, provider, and community factors that influence participation of rural racial and ethnic minorities in HIV/AIDS research. The ultimate goal was to work towards developing community interventions to increase participation in research. One possible approach is through a community-based MHU, therefore we explored the views of this option by rural minority community members.

Location and Participants

Project EAST is situated in six rural counties, divided into two communities in eastern North Carolina that experience a significant burden of HIV/AIDS. Investigators and staff worked in collaboration with a community advisory board to develop the interview guide, conduct recruitment, and perform data analysis. Eleven focus groups (10 English, 1 Spanish) were conducted with service providers and community leaders and 35 individual interviews (30 English, 5 Spanish) with PLWHA. Focus group participants were recruited by a Community Outreach Specialist (COS) and included formal and informal leaders from several community segments including political, education, grassroots, religious, and social welfare. For provider focus groups, we recruited physicians, nurses, case managers, health educators, and other clinical practitioners. PLWHA were recruited for individual interviews through local HIV/AIDS case management and clinical care programs in each county.

Data Collection

Trained staff members collected the data using a semi-structured guide, followed by a debriefing session to discuss any process issues or emergent themes. All participants provided informed consent and completed a brief demographic survey. Sessions were audio-taped and professionally transcribed for analysis. Focus group and interview guides included intentional overlap to allow for triangulation of findings. A professional, certified translator translated the guides from English to Spanish and the bilingual, bicultural interviewer reviewed them for accuracy. Audio files from Spanish-speaking data collection were transcribed, and translated into English by a professional translation service in a two-pass process to ensure data accuracy and integrity [17]. The interview guide included questions about how to bring clinical trials into the local community, and of using an MHU as a specific strategy. Focus groups and interviews lasted an average of 88 and 46 min, respectively.

Data Analysis

Two coders independently reviewed each transcript, developed and applied codes to the text, and reconciled the development and application of the codes. To develop the codebook, six coders met weekly to review and compile codes for arriving transcripts. Coders used the final codebook to manage text data using ATLAS.TI v.5.2. For this study, we analyzed the text data using Glaser and Strauss's constant comparison technique, which included a back/forth approach between discovery and verification of findings, and compared sets of respondents to look for points of convergence and divergence [18, 19]. Each emerging concept was examined to determine its full descriptive range and was compared to other concepts to examine relationships. We analyzed community perceptions of contextual and logistical factors critical to the acceptability of implementing an MHU.

Results

The demographic characteristics of PLWHA interviews and focus group respondents (service providers and community leaders) are summarized in Table 1. Most focus group respondents were black, female, and with at least some college training. Among PLWHA respondents, the majority were black, male, and unable to work.

Respondents viewed MHUs as an acceptable venue for HIV clinical trial enrollment and participation *if* the unit also attends to: balancing accessibility with maintaining confidentiality, establishing credibility, and allowing for local ownership and control.

The Intersection of Accessibility and Confidentiality

Respondents noted a striking contrast between the need for easy access to services and maintaining confidentiality when using an MHU to introduce and conduct HIV/AIDS clinical trials. Regarding accessibility versus confidentiality, respondents viewed the provision of a range of health services on an MHU as a way for PLWHA to mask their participation in HIV-related services and avoid the possibility of unintentional disclosure of sero-status. One focus group respondent indicated that "this bus can hold say three different clinical trials and we don't know that you're going for the one in HIV."

Respondents described persistent and prevalent HIV-related stigma in small, rural communities, and noted including blood glucose testing or blood pressure monitoring would provide other socially acceptable and less stigmatizing reasons for using unit services. Respondents saw the provision of multiple services as a strategy for extending the range of health care services within their community. Though HIV/AIDS was identified as a significant health concern, respondents noted the importance

Table 1 Study Participant Demographics

	PLWHA ($n = 35$)	CL ($n = 40$)[b]	SP ($n = 36$)[c]
Age (years)	42.9 (24–65)	43.4 (22–68)	40.6 (23–64)
Race/ethnicity			
White	0	5	11
Black	30	26	21
Hispanic	5	7	4
Multi	0	2	0
Gender			
Male	21	11	10
Female	14	29	26
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
Segment of community[a]			
Grassroots	–	5	–
Social welfare	–	11	–
Religious	–	4	–
Community individual	–	10	–
Community group	–	13	–
Media	–	4	–
Health	–	15	–
Economic	–	5	–
Political	–	2	–
Profession[a]			
Healthcare provider	–	–	9
Social services	–	–	6
Case management	–	–	6
Outreach	–	–	5
Health educator	–	–	6
Program planner	–	–	1
Director	–	–	2
Not specified	–	–	1

[a] Participants could select more than one response

[b] Groups, $n = 7$. One focus group was combined community leaders and service providers

[c] Groups, $n = 5$. One focus group was combined community leaders and service providers

and obligation of researchers to provide a continuum of services to increase care for the full range of community health needs and in particular to address co-morbidities of PLWHA.

The location of the unit could also facilitate confidentiality while maintaining geographic accessibility. While most respondents agreed that situating the MHU in places associated with HIV/AIDS-related services would inhibit PLWHA's ability to maintain confidentiality, there were varying perspectives about the types of locations that would best guarantee privacy. Some respondents suggested community locations providing several non-HIV specific medical services such as near doctor's offices, hospitals, or pharmacies; while others preferred the accessibility of general community locations such as grocery stores, community colleges, and churches. Some respondents felt that varying the location over time would help to avoid stigmatization of a location or disclosure of the unit's purpose. However, accessibility outweighed confidentiality for communities respondents perceived as high-risk and most in need of care, including those that are socioeconomically disadvantaged, have a high proportion of minorities, are affiliated with illicit drugs and commercial sex transactions, and are near migrant farm worker camps.

Selective marketing strategies were another way to balance service accessibility and confidentiality. Respondents noted that any marketing should refer to general health services rather than HIV/AIDS specifically since any advertising of HIV/AIDS services in a setting with prevalent HIV-related stigma could limit use of the unit's services and inhibit the very access the unit was intended to provide. Community leaders and service providers saw traditional marketing campaigns (e.g., printed materials, public service announcements) and word of mouth as the most effective ways to publicize the unit, while PLWHA preferred one-to-one communication relying on social networks and trusted sources, including other sero-positive individuals. Built upon the trust existing within the social networks, these methods were seen as a way to lessen confidentiality concerns and fear of disclosure.

Establishing Credibility

In addition to confidentiality and accessibility, respondents noted the importance of establishing local credibility within the community as part of acceptable implementation of an MHU for HIV/AIDS clinical trials. Credibility was described as the product of having built appropriate relationships, using staff deemed appropriate by the local community, and having demonstrated the effectiveness of the unit. Each of these points was seen as a bridge to establishing trust and increasing the acceptability and likely use of the unit.

All respondents noted the need for gaining community acceptance of the MHU through affiliation with local institutions. By connecting with positively perceived local entities, the MHU would garner local trust and credibility. Affiliations could be with a variety of community-based organizations ranging from those with a human service focus to those that are faith-based. One community member stressed the importance of local affiliation:

> You can't just walk up in here being a stranger and expect to get some results. You have to partner with somebody who's already established and know what's going on … They'll have to come in and partner with the right organization … faith-based or whether it be grassroots and they're going to have to be well known and respected in the community.

For PLWHA, trust and credibility were also described as built upon the developed interpersonal connections between MHU staff with unit users, as well as with the community. Respondents cited positive rapport could be established between staff and MHU users through one-to-one discussions, and among users through testimonials by unit clients as essential for creating a credible presence within the local community. For service providers and community leaders, an organized, established and continued presence in the community was also critical. One community member stated that "as long as it's a regular, consistent service … if you give me something today and not tomorrow—I'm not gonna trust you."

Staff characteristics were also vital to building trust, credibility and acceptance within the community. Respondents indicated that showing accountability by keeping promises, being honest, dressing professionally, respecting confidentiality, exhibiting caring attitudes, reflecting the racial and ethnic composition of the community, and demonstrating expertise in HIV/AIDS were important characteristics. Focus group participants offered varying opinions on whether staff should be local. Some community leaders indicated that PLWHA would connect with local staff members who share their culture and ideals, while others stated that it is more important to have non-local staff to address concerns about potential breaches in confidentiality that could exist in small rural communities with overlapping social and professional networks. Non-local staff affiliated with major medical centers, were thought to facilitate credibility based on the center's reputation, while also able to address confidentiality concerns. Finally, service providers indicated a desire to know about MHUs that had been used in other communities or with other health conditions to demonstrate their utility and credibility.

Time, or duration of presence within a community, was also a component of establishing credibility and generating opportunities for use. Specifically, respondents noted the need to allow enough time for the unit to be well-received and services accessed by the community. A service provider exemplified this by stating “it’s not going to happen overnight and then I don’t want to see it exist for 6 months, ya’ll say it didn’t work … sooner or later they (community members) gonna come around.”

Providing for Community Ownership and Control

Many of the conditions of acceptability were shared across the respondent groups, but service providers and community leaders also emphasized ownership and control of the unit within the local community. Much of this discussion was about the unit’s implementation plan and fiscal negotiations. Service providers felt strongly that funding for a unit should be local and autonomous from larger major medical centers outside of the local community. They felt that local funding would [1] increase the sense of ownership and local control over how the MHU was implemented in the community [2], validate local expertise in determining how community needs should be met, and [3] shape implementation of the unit in ways most responsive to the community. There was also a strong sentiment among community leaders that the responsibility of ownership and control of the unit includes generating local economic benefits through employment opportunities for community members and opportunities for existing local health initiatives to engage in MHU implementation. Finally, collaboration with local organizations increases buy-in and was viewed as a strategy for increasing local partnerships and alleviating any financial strains associated with implementation through cost-sharing.

Discussion

In this study, we found that successful MHU implementation for HIV/AIDS clinical trials in rural minority communities requires three conditions for community acceptance and use: balancing accessibility and confidentiality, establishing credibility, and facilitating community control of MHU implementation. Given the continuing need to find innovative ways to increase representation of rural minorities in HIV/AIDS clinical trials, this study offers strategies for HIV clinical trial researchers to consider as they plan recruitment and retention strategies.

The scientific literature is saturated with descriptions of barriers to clinical trial participation for racial and ethnic minorities; however, few reports have offered specific strategies for overcoming those barriers, particularly for minority patients with a highly stigmatized disease living in rural communities. Previous suggestions for recruiting minorities have focused on location [20], investigator communication and relationship building [21] with both participants and rural health centers [22], social marketing, and referral recruitment [23]. Other successful strategies for engaging rural communities in clinical research have included multi-pronged public education, grassroots outreach campaigns, education targeting local health care providers, and basic infrastructure and resources needed to conduct the trial [2]. To our knowledge, this study is among the first to investigate the possibility of using an MHU as a strategy for recruiting and conducting HIV/AIDS drug clinical trials, particularly in rural areas. Our findings build on the strengths of other models by introducing the use of an MHU as a means to reduce geographic barriers to participation in clinical trials while also addressing the conditions of acceptability—confidentiality, accessibility, credibility, and community control. Satisfying these conditions when implementing an MHU in a rural minority community likely will increase its utility, as community acceptance was predicated on the value of these conditions as a comprehensive whole, not as individually isolated factors.

As demonstrated in other studies, research acceptability increases when PLWHA believe staff or research partners are credible and trustworthy, i.e., staff take their work seriously and appreciate community challenges to research participation [24]. The rapport between patients and providers has also been demonstrated as critical to HIV medication compliance and medical management [25]. In examinations of PLWHA engagement in community-based research, mistrust of researchers and an inability for researchers to appreciate and understand the subjective experience of PLWHA hindered acceptability and participation in research efforts. Credibility, trustworthiness, rapport and empathy are important considerations for MHU implementation, and were echoed in participant’s sentiments and other research contexts.

Participants in this study also asked researchers to consider sharing ownership and control of the MHU, underscoring the need for more community-engaged research. This request echoes community members’ demands for a greater role in research conducted in their communities, and national community engagement initiatives, such as those supported by the NIH’s Clinical and Translational Sciences Awards, which have created an infrastructure and a cultural shift that promotes community-partnered research. By acknowledging, valuing, and encouraging community partnership, implementation of the MHU as a strategy for recruitment, enrollment, and participation is an example of applying community-partnered research principles to the traditional clinical trial structure. Community respondent’s conceptualized ownership of the MHU in three interrelated dimensions: physical, psychological, and financial. Physical ownership includes having the MHU be located in the local community; instead of solely operating as an external entity that brings services into the community. A physical presence in the community also has psychological implications, as it helps community members to identify with and trust the unit's services as an integrated part of the local culture. Ownership in the financial sense arises from the entity that fiscally supports the unit. Control, by comparison, can result from ownership and but also addresses the amount of decision-making authority that local community members have over the unit's implementation and administration. Instilling some sense of community ownership and control would increase the likelihood that the MHU can be effectively implemented or used within local communities for HIV/AIDS clinical trials.

Even if all three community concerns– balancing accessibility and confidentiality, establishing credibility, and facilitating community control of MHU implementation—are met, implementation of HIV clinical trials, particularly drug treatment studies, requires full understanding and adherence to the clinical trials process, including the scientific rigor required for trial administration. Currently, most clinical trial protocols limit funding, control and administration of trials to tertiary care centers and research facilities with staff who have expertise in the disease, treatments, and research methods being studied. The call for more engagement and input into the development, design and conduct of research by local residents and communities creates a tension between the necessary rigor needed in trial design and administration and finding innovative strategies to address the conditions of research acceptability in underserved areas [7]. However, one approach for increasing community involvement is working with a community advisory board (CAB). CABs, or other consultative bodies, have become standard practice for research worldwide, particularly vaccine and drug trials, and studies that are community-based.(26) CAB members generally are representative of the community, including people living with HIV/AIDS. CABs help guide the overall research process and can be critical for implementation of rural MHUs for recruitment into clinical trials.

Participant interest in the provision of health services, in addition to clinical trials on the MHU, raises an ethical consideration for researchers. To avoid conflation of research and care, as well as the perception that access to services is contingent on clinical trial participation, researchers must consider how to circumvent explicit or implicit coercion for individuals to enroll in clinical trials. This is particularly salient in rural communities in which individuals have limited social and economic resources, as well as access to clinical care. Some opportunities for balancing these concerns include a well-articulated informed consent process that explains the conditions and expectations for trial participation, a service disclosure statement by MHU staff, and community-based education about the unit services and clinical trials.

MHUs have demonstrated utility at extending clinical services for a variety of health problems [8, 9, 12, 14]. In addition to the current findings, clinicians and researchers must weigh the factors for practically initiating MHU services depending on function, governing regulations, licensing, maintenance requirements, and funding considerations. Researchers must consider the local and federal guidelines or codes that allow for the services they intend to provide, the requirements for the physical unit to accommodate those services, and the costs required to outfit and service an MHU. Additionally, an on-site visit to the manufacturer can help researchers more fully determine the suitability of the unit to the research and service needs.

Limitations—Strengths

Our study has two potential limitations. One, while the study is strengthened by its emic exploration of a largely unexamined inquiry, our findings could be enhanced by inclusion of more racial and ethnic minority perspectives, for example, those of more Latino or American Indian participants who increasingly live in the rural South and are part of the emerging epicenters of new HIV infections. However, the concepts reported in our study are invaluable as they define acceptable strategies for clinical trial recruitment and participation for communities most in need but least represented in current trial efforts. Two, given that only five participants had ever participated in clinical research, their views of research and clinical trials in particular might not have taken into account the protocol requirements necessary for research to achieve scientific merit.

Despite these limitations, our findings are among the first to describe the necessary conditions for introducing an MHU as a strategy for HIV/AIDS clinical trial recruitment, enrollment, and participation of rural minority communities. The MHU is not only a strategy for increasing rural minority participation in clinical research, but also is an opportunity for community-academic partnerships to facilitate the conduct of clinical trials in diverse communities. Further research is needed to evaluate the processes and outcomes of bringing MHUs to the rural South to recruit and conduct clinical trials research, including the best ways to integrate development of sustainable community linkages and partnerships with clinical trial development and administration. Further implementation research might validate innovative and responsive use of MHUs as a successful and sustainable strategy for conducting equitable, responsible, and far-reaching clinical research.

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