

Chapter 2

Qualitative Methodological Approach

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Introduction

Many large-scale studies and clinical trials, particularly those with biological endpoints, require the enrollment of hundreds, if not thousands, of participants across multiple sites (HPTN, 2012). There is a growing interest in large-scale, multisite qualitative data collection, as this approach has the potential to provide valuable insight into the broader social and structural factors that influence behaviors but may not be captured using quantitative data instruments. However, the collection of qualitative data in large, multisite trials presents challenges, such as determining what, how much, and where data will be collected, coded, and analyzed; ensuring stakeholder involvement throughout the process; standardization of study procedures across sites; managing large volumes of qualitative data; identification and training of staff with qualitative research skills; and, in some settings, translation of transcripts. While these challenges are not unique to qualitative research designs,

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they are often magnified in the clinical research context and may hinder widespread use of qualitative methods in the setting of large trials (Guest & MacQueen, 2008). In this chapter, we describe approaches to collecting, managing, coding, and analyzing qualitative data, as well as lessons learned, in the HIV Prevention Trials Network (HPTN) 064 (the Women's HIV SeroIncidence Study), a large, multisite observational study in the USA.

Study Methods

Study Design

As described in Chap. 1, HPTN 064 was a multisite, prospective cohort study designed to estimate HIV incidence among 2099 women living in communities with prevalent HIV and poverty in New York (the Bronx and Harlem), New Jersey (Newark), Maryland (Baltimore), North Carolina (Durham and Raleigh), Georgia (Atlanta and Decatur), and Washington, D.C. (Hodder et al., 2013). Study

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Table 2.1 HPTN 064 qualitative component key activities, contributors, and timelines

Study phase	Phase 1: Pre-implementation	Phase 2: Implementation	Phase 3: Qualitative coding and analysis		
			Stage 1: <i>Structural coding</i>	Stage 2: <i>Member checking</i>	Stage 3: <i>Advanced systematic analysis</i>
Key activities	• Site selection	• Study management	• Structural coding and codebook development	• Review of structurally coded data	• Constant comparative content coding and analysis (see Fig. 2.1)
	• Instrument development	• Data collection • Transcription	• Intercoader agreement assessment	• Preliminary data summary and theme generation	
Key contributors	• Protocol team	• Central data-coordinating center	• Central data-coordinating center	• Central data-coordinating center	• Central data-coordinating center
	• Community working group	• Protocol team	• Protocol team	• Protocol team	• Protocol team
		• Community working group	• Community working group	• Community working group	• Advanced systematic analysis team
		• Study sites • Qualitative working group	• Study sites • Qualitative working group	• Study sites • Qualitative working group	• Qualitative steering committee
Activity time-frame	2 years	1 year	9 months	1 year	2 years

participants were self-identified women aged 18–44 years who reported unprotected vaginal or anal sex with a man in the past 6 months and who resided within a geographic area with prevalent HIV and poverty. In addition, women reported at least one additional personal risk within the past 6 months (e.g., illicit substance use) and/or male partner within the past 6 months with characteristics associated with greater risk of HIV acquisition (e.g., HIV infection) (Haley et al., 2014). Women were recruited from community venues (e.g., shopping centers, well-traveled streets) using venue-based sampling (Haley et al., 2014; Hodder et al., 2013).

Our study design included a substantial qualitative component. Four study sites (the Bronx, NY; Washington, D.C.; Raleigh/Durham, NC; and Atlanta/Decatur, GA) conducted semi-structured interviews and focus groups between June 2009 and August 2010 designed to explore social, structural, and contextual factors related to HIV risk among participants. In this chapter, we describe the activities for each of the three phases of the qualitative research process: (1) pre-implementation, (2) implementation, and (3) coding and analysis (Table 2.1). These study activities spanned from May 2007 to September 2013.

Phase 1: Pre-implementation

Site Selection. We selected the four study sites (the Bronx, New York; Washington, D.C.; Raleigh/Durham, North Carolina; and Atlanta, Georgia) because they had existing expertise in qualitative research methods and represented a geographically diverse sample of HPTN 064 study sites.

Instrument Development and Stakeholder Involvement. We developed semi-structured interview and focus group guides with suggested probes, which aligned with the qualitative aims of the study, with input from study investigators (including several with expertise in qualitative research) and community members. The majority of questions/topic areas in the interview and focus group guides were the same. Interviews focused on individual-level experiences or perspectives, whereas focus groups explored community perspective and norms. Highly sensitive questions about personal experiences (e.g., trauma or victimization) were included only in the interview guide. We developed the qualitative guides in parallel with the quantitative behavioral audio computer-assisted survey instrument (ACASI) to allow for both quantitative and qualitative exploration of constructs.

Phase 2: Implementation

Sampling. We conducted a total of 120 interviews (30 per site) and 32 focus groups, based on prespecified age and race/ethnicity strata (Table 2.2). This total number of interviews and focus groups was determined to ensure saturation, explore geographic variation, and allow for additional analysis within and across sites (Guest, Bunce, & Johnson, 2006; Guest & MacQueen, 2008; Onwuegbuzie & Leech, 2007).

We used sequential sampling to identify potential interview participants and quota sampling for the focus groups. For interviews, women with an odd participant identification number, beginning with the first participant enrolled, were invited to participate in an interview. After completing the interviews, each site moved on to quota sampling for focus groups, inviting 8–12 women who were not enrolled in the individual interviews and met the predefined age and race/ethnicity focus group strata.

We chose this approach to sampling in an effort to balance representativeness of the interviews and minimize the possibility of bias that could be introduced from ongoing participation in the HPTN 064 study. To reduce such bias, we conducted the interviews and focus groups as close to enrollment as possible. Pre-enrollment random selection of women was not feasible because focus groups included predefined race/ethnicity and demographic strata. A comparison of the overall study cohort and the qualitative interview and focus group cohorts on select characteristics (Table 2.3) indicated that women participating in a semi-structured interview or focus group tended to be slightly younger, more likely to be financially responsible for a child under 18, and more likely to be living with friends or family, but less likely to be homeless than women who did not participate in the qualitative component of the study.

Table 2.2 HPTN 064 focus groups and participants by site

Strata	Geographic location				
	The Bronx, NY	Washington, DC	Raleigh, NC	Atlanta, GA	Total
<i>Black Women 18–24 years old</i>					
Number of focus groups	2	2	3	2	9
Number of participants per group	6, 5	6, 4	6, 4, 5	4, 9	—
Total number of participants	11	10	15	13	49
<i>Black Women 25–35 years old</i>					
Number of focus groups	2	2	2	2	8
Number of participants per group	6, 7	6, 8	5, 5	6, 4	—
Total number of participants	13	14	10	10	47
<i>Black Women 36 years plus</i>					
Number of focus groups	2	2	3	2	9
Number of participants per group	4, 3	7, 4	6, 4, 4	5, 4	—
Total number of participants	7	11	14	9	41
<i>Hispanic Women 18–24 years old</i>					
Number of focus groups	2	N/A	N/A	N/A	2
Number of participants per group	9, 6				—
Total number of participants	15				15
<i>Hispanic Women 25–35 years old</i>					
Number of focus groups	2	N/A	N/A	N/A	2
Number of participants per group	6, 3				—
Total number of participants	9				9
<i>Hispanic Women 36 years plus</i>					
Number of focus groups	2	N/A	N/A	N/A	2
Number of participants per group	5, 3				—
Total number of participants	8				8
Total number of focus groups	12	6	8	6	32
Total number of participants	63	35	39	32	169

N/A: Insufficient number of enrolled HPTN 064 participants at sites in specified strata for focus group

Study Management. We formed a Qualitative Working Group (QWG) to provide ongoing oversight and input on study implementation, structural coding, and preliminary data analysis (e.g., codebook development, prioritization of data analysis topics). HPTN 064 investigators with behavioral science expertise and experience in qualitative methodologies as well as community representatives comprised the QWG. We reviewed the progress of the qualitative component during bimonthly site team meetings and monthly QWG meetings.

To maximize consistency and quality assurance across sites, we managed the qualitative component activities and data through a central data-coordinating center. The data-coordinating center employed a number of steps to ensure standardization of

Table 2.3 HPTN 064 participant baseline characteristics, including a comparison of participants who did and did not participate in the qualitative component

Variable	Did not participate in qualitative component (<i>n</i> = 1811)	Participated in qualitative component (<i>n</i> = 288)	<i>p</i> -value
	<i>n</i> (%)	<i>n</i> (%)	
	Median (IQR)	Median (IQR)	
Age (years)	29 (23–38)	27 (23–36)	0.0407
Black race	1601 (88 %)	250 (87 %)	0.4350
Hispanic ethnicity	201 (11 %)	44 (15 %)	0.0402
Relationship status			0.9650
Single/Widowed/Divorced/Separated	1086 (60 %)	172 (60 %)	
Married or living as married	552 (30 %)	86 (30 %)	
Other	130 (7 %)	22 (8 %)	
Missing	43 (2 %)	8 (3 %)	
Household income			0.2614
\$10,000 or less	799 (45 %)	134 (47 %)	
\$10,001–\$20,000	191 (11 %)	34 (12 %)	
\$20,001 or more	166 (9 %)	31 (11 %)	
Don't know	536 (30 %)	80 (28 %)	
Missing/Refused	119 (7 %)	9 (3 %)	
Financially responsible for at least one child	934 (51 %)	175 (61 %)	0.0147
Missing	14 (1 %)	2 (<1 %)	
Food insecurity	841 (46 %)	130 (45 %)	0.2659
Missing	26 (1 %)	1 (<1 %)	
Drug and alcohol use			0.1001
No use	424 (23 %)	71 (25 %)	
Non-frequent use (as less than weekly use of illicit drugs and/or	662 (36 %)	121 (42 %)	
Frequent use (daily to weekly use of any illicit drug and/or weekly	689 (38 %)	92 (32 %)	
Missing	36 (2 %)	4 (1 %)	
Symptoms of depression ^a	608 (36 %)	84 (31 %)	0.8698
Missing	141 (8 %)	16 (6 %)	
Symptoms of PTSD ^b	515 (28 %)	85 (29 %)	0.1097
Missing	50 (3 %)	2 (1 %)	
Social support			
Number of people that provide financial support	3 (2–4)	3 (2–4)	0.3869
Missing	30 (2 %)	1 (<1 %)	
Number of people that provide emotional support	4 (3–4)	4 (3–4)	0.6024

(continued)

Table 2.3 (continued)

Variable	Did not participate in qualitative component (<i>n</i> = 1811)	Participated in qualitative component (<i>n</i> = 288)	<i>p</i> -value
	<i>n</i> (%)	<i>n</i> (%)	
	Median (IQR)	Median (IQR)	
Missing	21 (1 %)	1 (<1 %)	
Housing			0.0071
Place participant rents/owns	733 (40 %)	119 (41 %)	
Place male partner rents/owns	159 (9 %)	19 (7 %)	
Place friend/family rents/owns	608 (34 %)	120 (42 %)	
Homeless ^c	266 (15 %)	28 (10 %)	
Missing	45 (2 %)	1 (1 %)	
No condom used at last vaginal sex	1468 (81 %)	230 (80 %)	0.8320
Missing	22 (1 %)	3 (1 %)	
Self-reported sexually transmitted infection	198 (11 %)	34 (12 %)	0.8804
Missing	29 (2 %)	4 (1 %)	

^aA score of ≥ 7 out of 24 was indicative of psychological distress or depressive symptoms (DiClemente et al., 2001)

^bA score of 3 or greater on the Primary Care PTSD Scale (Prins et al., 2004)

^cLiving in shelter, on the street, motel, boarding house/single-room occupancy unit (SRO), half-way house

procedures across the sites, such as file-naming conventions, milestones and tracking of each step of the process (e.g., time from interview to transcription), and outlining these processes in study procedural manuals.

Focus Group and Interview Conduct. Site research staff conducted interviews and focus groups in settings that ensured adequate privacy and confidentiality, such as the study clinical site, a mobile van, local community-based organizations, or another appropriate public venue (e.g., library). Trained interviewers and focus group facilitators were matched to interviewees by race, ethnicity, and gender when possible. We compensated participants for their time and effort, and all participants provided written consent for participation.

Transcription and De-identification. Interviews and focus groups were recorded and transcribed by research staff at each study site. Each site reviewed transcripts for accuracy and removed geographic and personal identifiers. All transcripts were then reviewed by the central data-coordinating center for quality assurance (e.g., confirmation of de-identification, consistency with tracking logs) prior to upload into NVivo 8 software (QSR International, Australia) for coding.

Phase 3: Qualitative Coding and Analysis

As depicted in Table 2.1, coding and analysis of study transcripts took place in three stages: (1) structural coding, (2) member checking, and (3) advanced systematic analysis.

Stage 1: Structural Coding

All transcripts were structurally coded by the central data-coordinating center using NVivo 8 software. In qualitative research, structural coding is generally intended to identify text associated with a particular question in the interview/focus group guide. We selected this approach because it allowed for quick identification of text associated with questions in the interview and focus group guides, and was a helpful method for coding and organizing large data sets generated from semi-structured guides (Guest & MacQueen, 2008).

Structural Coding, Codebook Development, and Intercoder Agreement Assessment. Structural codes were based on each of the questions and associated prompts in the interview and focus group guides. Through this process, we developed one structural codebook for the interviews and one for the focus groups. In the codebook, each code included a definition, when to use the code, when not to use the code, and dates of any changes to the code. The conversational nature of the interviews and focus groups meant that structural coding was not a straightforward linear process clearly aligned with the structure of the guide, but rather required attention to conversational shifts in the ordering and overlapping of guide questions and topics. Coding was conducted as an iterative process. First, all coders independently coded one interview transcript and one focus group transcript from each site. Next, the coding of these transcripts was reviewed and compared line by line; discrepancies were discussed and resolved until consensus was achieved by both coders. We designated one person as the primary coder of transcripts for each of the four study sites. Throughout the structural coding phase, all of the coders met weekly to review findings and revise the codebook as needed based on group consensus. We selected 20% of all transcripts to assess the intercoder agreement between the two independent coders for each structural code using the NVivo 8 intercoder reliability (ICR) function. For codes with an ICR below 90% agreement, the designated primary coder for that transcript reviewed, resolved discrepancies, and recoded the transcript. The structural codebook was revised as needed with updated definitions and examples.

Stage 2: Member Checking

After we completed structural coding, HPTN 064 investigators from each of the four study sites, members of the HPTN 064 Community Working Group (CWG), and QWG were invited to review a randomly selected subsample of interview and

focus group transcripts in preparation for future analysis. This “interpretative community” was constructed in order to facilitate active participation in qualitative data interpretation by those who were most familiar with participants, community, and data at each site (Guest, MacQueen, & Namey, 2012).

Review of Structurally Coded Data. Preliminary data summarization and member checking took place over two in-person meetings. The first 4-h meeting involved group discussion of text from a randomly selected set of transcripts. This meeting was followed by a 5-day member checking meeting. In preparation for this 5-day meeting, the QWG identified structural codes to be explored using the HPTN 064 study objectives as a framework for prioritization of topics for exploration.

To facilitate review of massive amounts of data in advance of the 5-day meeting, we assembled four teams approximately four months before the meeting. Each team was responsible for reviewing and summarizing data from one site. Each site team consisted of site representatives, at least one member from the protocol team, community members from that site, a coder, and content experts. One person from each site served as the site team facilitator and each team member was assigned at least one structural code. Each site team member reviewed the interview and focus group data associated with the assigned codes, summarized these data, and suggested emerging themes using a standardized presentation template. The site team facilitator presented this information to their team in advance of the meeting to ensure that each member arrived at the meeting well informed. Site team facilitators attended an in-person, half-day training on presentation skills. Prior to receiving any data, all of the team members completed human subjects training and signed data confidentiality agreements.

Preliminary Data Summary and Theme Generation. During the 5-day meeting, the site team facilitator and a community member representative copresented on each of their assigned structural code topic areas. Meeting participants collectively reviewed data for each of the structural codes across all sites, described themes, and developed corresponding conceptual frameworks within and across structural codes. Following this meeting, we agreed that the richness and depth of the data merited additional content coding of the interviews and focus group data. The themes generated from this process were used to inform the advanced systematic analysis.

Stage 3: Advanced Systematic Analysis

Due to the large number of transcripts collected in HPTN 064 and the extensive time and resources required for advanced systematic analysis, we randomly selected 30 % of interviews ($n=36$), and 50 % ($n=16$) of focus group transcripts for this Stage. For the interviews, we enumerated the transcripts, and randomly selected 9 per site. For the focus groups, we randomly selected one focus group per stratum per study site. In addition, we randomly selected one additional focus group from a study site that had a large number of focus groups. We selected the constant comparative technique (Boeije, 2002) for advanced systematic coding and analysis (Table 2.1, Step 3) because this approach was compatible with both the systematic team-based structural

coding already applied to the transcripts (Guest et al., 2012; Guest & MacQueen, 2008) and a grounded theory approach. Grounded theory approach utilizes an iterative, inductive, and deductive process, and places great emphasis on simple systematic procedures to allow emergence of theory (Strauss & Corbin, 1998).

We conducted the advanced systematic analysis in four steps as depicted in Fig. 2.1. During the initial coding phase (Step 1), analysts reviewed transcripts to develop and identify codes, and emerging themes, building on previous structural codes. We applied open coding to code larger segments of text to codes. Next, we noted possible relationships between codes and groups based on geographical location, and developed descriptive subcodes and categories, also known as axial coding (Step 2). We then conducted selective coding (Step 3), to further define and develop the subcode. This step involved reviewing the code categories and coding specific information relating to that category. Steps 1 through 3 were highly iterative; analysts constantly revisited and refined codes until saturation was reached. Saturation was assessed in real time, and was defined as the point in the coding process where new codes or themes no longer emerged. In Step 4, we conducted our final analyses by reviewing code clustering and performed axial analyses to develop theoretical models.

The advanced systematic process was conducted centrally at a study site with expertise in qualitative data analysis, with support and oversight from the central data-coordinating center and the Qualitative Steering Committee (QSC). The QSC was first developed in November 2011 to provide scientific oversight throughout the advanced systematic analysis process. The team was carefully selected to ensure a range of perspectives and experience, including community expertise. The QSC convened by conference call on a monthly basis between January and June of 2012. During this time, the advanced systematic analysis team generated coding status reports and shared them with QSC weekly for feedback.

As depicted in Fig. 2.1, advanced coding analysis occurred in four iterative steps. Codes were organized hierarchically using the structural codes developed in previous

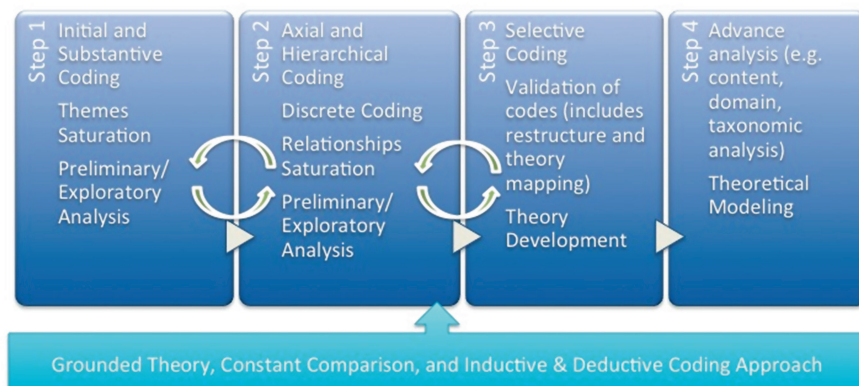


Fig. 2.1 HPTN 064 advanced systematic analysis process

stages as the parent node. This facilitated rapid assessment of source and reference frequencies for each code. To allow for emergence of themes, we developed the content codebooks separately for the interviews and focus groups. We later then compared the content and structural codebooks, and harmonized the codes and definitions across codebooks.

Initial and Substantive Coding (Step 1). We coded the interview and focus group transcripts in parallel. We randomly selected three interview transcripts and three focus group transcripts for initial codebook development. For both the interviews and focus groups, the initial transcript was used primarily for codebook development, the second for identifying additional themes, and the third for assessing analysts' comfort and clarity with the codebooks. After the codebooks were developed, we ensured alignment with the structural codebook and themes generated from the member checking process. We then independently coded remaining transcripts. During this step we openly coded large segments of the text to codes, and continued to identify inductively and add codes for emerging themes. Each transcript was independently coded by two analysts. The codes and themes for each codebook were reviewed for consensus and updated accordingly through out this inductive process. One analyst, who coded both interview and focus groups, led codebook harmonization.

Axial and Hierarchical Coding (Step 2). The intent of Step 2 was to further develop codes and emerging themes within the data, including relationships within and across codes. This axial coding process involved a combination of inductive and deductive thinking to allow for emergence of codes based on the data and based on logical top-down approach, respectively. We reviewed code definitions and used the NVivo cluster analysis procedure to assess relationships between codes, and codes to demonstrate those relationships. For each structural code, we further segmented data into similar categories (hierarchical codes), and distinctly coded descriptive information (discrete coding). The items were then grouped together (chunked) based on similar characteristics. All of these new codes were added to the existing interview and focus group codebooks. During the coding process, we discussed the addition of codes during weekly meetings, and revised the codebook with updated codes, definitions, and categories based on consensus.

Harmonization of interview and focus group datasets. At the end of Step 2, the NVivo databases for the interview and focus groups were combined so that additional axial coding could be conducted across all of the data. We used vigorous constant comparative techniques to synchronize the interview and focus group data in the combined dataset (Boeije, 2002). We reviewed each group of codes, merged similar codes, and grouped associated codes as appropriate. The interview and focus group codebooks were then compared and synchronized by combining codes that had the similar definitions. We then reviewed the coded data to further identify relationships, distinct items, and similar items. We added and refined codes as necessary, and applied the codes. We further reviewed and repeated the axial, hierarchical, and discrete coding described above. We completed a final review of the codes to ensure that the lowest level (most discrete) code was included in its hierarchical code (larger category), and that the hierarchical code was further coded into discrete codes. Any

additional codes were added to the final codebooks. As part of this harmonization process, we refined definitions and rules for each code, resulting in the more refined codebooks for the focus group and interview as well as a combined codebook. As discussed previously, because the interview and focus group guides varied, some codes were not applied to both the interviews and focus groups, but were included in all of the codebooks to allow for future analysis.

Selective Coding (Step 3). We assigned each of the major categories in the combined dataset to an analyst for selective coding. The analysts independently reviewed each code to ensure that the coded texts in each codes fit the definitions, and that they were appropriately applied to other relevant codes. The team further refined the code definitions and parameters in the final codebook as needed to make them more clear and operational for further analysis, especially those who have not been a part of this advanced systematic analysis process. The combined database was separated into an interview dataset and a focus group dataset to generate frequencies of codes, assess intercoder agreement, and resolve any discrepancies. All of the codebooks were updated as needed. The final datasets were then merged into a final combined dataset, and all of the datasets and codebooks were locked and stored for further analysis and synthesis. The dataset included a total of 1139 codes (10 structural and 1129 content). Coding saturation was assessed in real time, and was achieved in Step 3 (Selective Coding) of coding and analysis, and by that time 90 % of the data were coded, indicating that limiting this phase of the analysis to a subsample of transcripts was appropriate.

Intercoder Agreement Assessment. All of the transcripts randomly selected for advanced systematic analysis were coded independently by two analysts. Intercoder agreement was randomly assessed throughout the constant comparative coding process for 20 % of transcripts using the NVivo 8 ICR function. Using percent agreement and disagreement generated by NVivo 8 ICR function, we calculated the final ICR manually using traditional calculation methods. For transcripts with a Kappa below 0.80, the two analysts who coded them reviewed, reconciled, and revised any coding discrepancies. The final ICR was a combined average Kappa score of 0.91 for the random sample of the focus groups and the ICR for the random sample of interviews was a combined average Kappa score of 0.92.

Focused Qualitative Analysis (Step 4). The aforementioned process resulted in a systematically coded dataset. We analyzed data using conceptual mapping of the research question accompanied by a review of the thematic domains and categorical codes, and systematic descriptive analyses, e.g., matrix queries of the codes of interest.

Lessons Learned and Considerations for Future Research

The processes described in this chapter resulted in a richly coded dataset that will contribute to a broader understanding of the social and structural factors which contribute to women's health behaviors in the USA, and provided the foundation needed

for the chapters included in this book. This success is clearly a reflection of significant time and effort across many stakeholders, to include the funders, sites, and the participants themselves. Based on our experience, we present our successes, challenges, and recommendations for collecting, managing, coding, and analyzing qualitative data, as well as lessons learned, for a large, multisite clinical trial in the USA.

Multisite Study Management. The multisite nature of HPTN 064 necessitated the development of a number of manuals and standard operating procedures to ensure consistency across sites prior to study implementation. Documentation in all stages of the process was necessary to ensure that all contributors were informed and that the research process was clearly outlined. In addition, geographic variation necessitated the development of additional tools for use in coding, analysis, and interpretation. For example, each site created its own local “terminology list”; some sites had similar terms with different meanings.

Advance Resource Planning. As described, we developed the quantitative and qualitative data collection instruments in parallel, allowing for triangulation of data to validate our findings and for mixed-method analysis. However, we did not adequately anticipate the sheer volume and richness of data and the amount of subsequent advanced systematic analysis that would be needed to analyze these data. A number of strategies could be implemented in future studies which would streamline the process going forward, including using one institution for all coding and analysis, data reduction strategies, and planning for analysis support during the manuscript development process. Although we benefited from the insights of many team members and advisory committees, we would have benefited from the formation of the QSC earlier in the planning process. The QSC consisted of both internal and external members with expertise in multisite, large, mixed-method approaches and provided a number of insights, which may have focused analyses and reduced timelines.

Timelines and Staffing. As with many elements of clinical research trials, each step of the qualitative component was contingent on completion of previous steps. As a result, any delays resulted in trickle-down effects for the overall timeline. Qualitative data coding is labor intensive and, for a project of this size and complexity, required multiple analysts. Staffing was also an important consideration; coders needed to be team-oriented, well versed in qualitative methods and software, and the topic area under study. Coders and analysts worked on the study on a part-time basis. Disruptions in timelines made staff planning difficult (e.g., some staff were pulled into other projects during initial delays which resulted in time conflicts for later coding). Future studies might consider hiring full-time coders if funding allows. It may be advisable to identify and contract with a group to code and analyze all data up-front to the point of focused qualitative analysis, both as a means to enhance efficiency and because groups which exclusively manage qualitative data may be better able to adapt to changes in timelines.

Software Selection and Data Sharing. Software selection was an essential component of qualitative data management and analysis, as some software packages are more suitable for large quantities of data than others. The multisite nature of HPTN 064 introduced additional software considerations, to include the pur-

chase of licenses across institutions and compatibility of software versions. While NVivo offered capacity to conduct in-depth coding of large volumes of data, it was provided by few participating institutions free of cost and licenses were subsequently purchased by each site. Future studies should consider not only the capacity of the software package, but also preexisting availability across sites, how often licenses will need to be renewed over the course of the study, the potential for negotiating bulk pricing, and version compatibility. In addition, multiple data collection sites introduced the need for additional data security measures and software environments for sharing and storing these data. This may be particularly relevant for qualitative data, since transcripts include distinct, rich “stories” which cannot be entirely de-identified. In addition to each institution’s own data security policy, we implemented a number of measures to securely share and store data, to include the development of a password-protected portal for registered users.

Community Engagement. It may be difficult to engage community members and other stakeholders in the data interpretation process remotely, particularly when making connections within and across data, and in developing theoretical frameworks to describe these connections. We found the face-to-face member checking meeting a successful and relatively efficient approach to identify themes within the data and generate increased understanding of the data among a large and diverse group. More regular, shorter meetings discussing less data may facilitate early and ongoing discussions; however, these meetings will need to be budgeted for accordingly. Alternatively, other technologies for remote review and discussion may be explored.

Recommendations

Based on the lessons learned described above, we recommend the following:

1. Develop standardized study procedures for all study elements.
2. Develop detailed research questions and manuscript development timelines utilizing qualitative data early in implementation.
3. Develop contingency plans to address delays likely to occur in implementation and results dissemination.
4. House all coding and analysis within one institution and select coding and analytic strategies conducive for both the research aims and large data sets.
5. Integrate community feedback into the analysis process (member checking).

Although each research study presents its own unique challenges, we hope that our experience can inform future implementation of qualitative research in clinical trial settings and help ensure a rich qualitative data that will contribute to a broader understanding of the social and structural determinants of women’s health.

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