The Qualitative Report

Volume 22 | Number 3 How To Article 9

3-19-2017

Challenges and Facilitators of Recruitment: Lessons Learned from Conducting a Focused Ethnography in a Vulnerable Rural Population

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Abstract

The purpose of this article is to describe the challenges and facilitators of recruitment encountered in an ethnographic dissertation study of rural women with substance use disorders during the perinatal period. While the study is being conducted in the hospital setting post-delivery, potential participants who meet inclusion criteria are identified by practitioners through a number of perinatal practices within a wide geographic area as well as by inpatient social workers. Recruitment in this vulnerable and often socially disadvantaged population has been found to be challenging with regard to ethical approval, participant eligibility and availability, practice changes, and discrepancies in the recruitment process. The authors discuss these challenges and describe the process of practitioner engagement to facilitate participant recruitment and lessons learned in the process.

Keywords

Ethnography, Vulnerable Population, Socially Disadvantaged, Recruitment Challenges

The Qualitative Report 2017 Volume 22, Number 3, How to Article 1, 818-830

Challenges and Facilitators of Recruitment: Lessons Learned from Conducting a Focused Ethnography in a Vulnerable Rural Population

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The purpose of this article is to describe the challenges and facilitators of recruitment encountered in an ethnographic dissertation study of rural women with substance use disorders during the perinatal period. While the study is being conducted in the hospital setting post-delivery, potential participants who meet inclusion criteria are identified by practitioners through a number of perinatal practices within a wide geographic area as well as by inpatient social workers. Recruitment in this vulnerable and often socially disadvantaged population has been found to be challenging with regard to ethical approval, participant eligibility and availability, practice changes, and discrepancies in the recruitment process. The authors discuss these challenges and describe the process of practitioner engagement to facilitate participant recruitment and lessons learned in the process. Keywords: Ethnography, Vulnerable Population, Socially Disadvantaged, Recruitment Challenges

Background

The first author (herein referred to in the first person) lives in a rural area in the northeastern United States identified as having one of the highest rates of prescription opiate drug misuse and neonatal abstinence syndrome (NAS) in the country (Hayes & Brown, 2012; Ko et al., 2016). As a registered nurse caring for newborns with NAS, I was concerned with this trend and sought to better understand the determinants of the issue. This interest led to a search of the evidence and subsequent focus of the current dissertation study. The second and third authors serve as my advisor/dissertation committee chair and methods expert, respectively, providing continuous consultation throughout the process.

Women with substance use disorders continue to face numerous impediments to accessing available resources for recovery and parenting support (Fraser, Barnes, Biggs, & Kain, 2007). Substance use disorder in women is associated with increased prevalence of mental illness, histories of physical and sexual abuse, and medical and social problems (Milligan et al., 2010). Pregnant and parenting women with substance use disorders have been reported to experience stigma, fear, shame, and guilt, as well as high rates of co-occurring mental health problems, trauma, and post-traumatic stress disorder (Brandon, 2014; Haug, Duffy, & McCaul, 2014). Studies have shown that rural healthcare disparities, specifically those related to poverty, further complicate access to treatment, and societal stigma and lack of resources further contribute to the negative outcomes for both mother and child (Lander et al., 2013). This is particularly concerning in light of findings that protective factors, such as caretaker involvement and family resources, may moderate the negative effects of substance use on the developing child (Bada et al., 2012).

Of newborns prenatally exposed to addictive substances, 50% to 90% will experience some degree of neonatal abstinence syndrome (NAS), a term applied to a constellation of symptoms characterized by dysregulation and hyperirritability of the central and autonomic nervous, respiratory, and gastrointestinal systems (Sublett, 2013). Symptoms are treated with

a combination of pharmacologic and non-pharmacologic therapies typically requiring specialized neonatal care with an overall mean length of hospital stay of 16 days, increasing to 23 days for newborns requiring pharmacologic treatment (Patrick, Davis, Lehman, & Cooper, 2015). Despite increasing attention on this problem and evidence-based recommendations (Dow et al., 2012; Goettler & Tschudin, 2014; Hudak & Tan, 2012; Jansson, Velez, & Harrow, 2009; Lucas & Knobel, 2012; Queensland & Neonatal Clinical Guidelines, 2010; Winklbaur et al., 2008), management remains inconsistent, hospital length of stay has not declined, and expenditures continue to rise (Patrick et al., 2015).

Perinatal substance use directly impacts two constituencies, the woman and her offspring, and therefore the problem has been examined from a variety of perspectives. Numerous quantitative studies have been conducted to identify factors regarding maternal drug use which may be predictive of neonatal outcomes, such as the type and amount of medication-assisted treatment for opioid use. Several retrospective studies associated higher doses of maternal methadone dose with higher incidence of neonatal abstinence syndrome as well as duration of neonatal abstinence syndrome treatment (Dryden, Young, Hepburn, & Mactier, 2009; Lim, Prasad, Samuels, Gardner, & Cordero, 2009). These findings contradicted those of other studies, which reported no such correlation (Pizarro et al., 2011; Seligman et al., 2008). One prospective cohort study also concluded that the incidence and duration of neonatal abstinence syndrome was not affected by methadone dose (Cleary et al., 2012). McCarthy, Leamon, Stenson, and Biles (2008) noted that infants of women who began methadone treatment prior to conception had better outcomes compared with those whose mothers began treatment mid-pregnancy.

Similar conflicting results have been noted in studies comparing maternal methadone and buprenorphine medication-assisted treatment. Several studies suggested improved neonatal outcomes, such as lower incidence and severity of neonatal abstinence syndrome, in infants exposed to buprenorphine as compared with methadone exposure (Binder & Vavrinkova, 2008; Coyle et al., 2012; Gaalema et al., 2012; Kakko, Heilig, & Sarman, 2008; Salisbury et al., 2012). Other studies found no such differences (Jones et al., 2010; Welle-Strand et al., 2013). Patel and colleagues (2013) noted no difference in neonatal abstinence syndrome expression when comparing infants exposed to buprenorphine to those exposed to illicit opiates. The concomitant use of illicit substance, as well as alcohol and tobacco, with medication-assisted treatment seems to confound the results of these studies (Blandthorn, Forster, & Love, 2011; Kaltenbach et al., 2012).

Many of the aforementioned studies have been retrospective reviews of clinical data or secondary analyses of data from larger studies. Findings of several prospective studies regarding severity of neonatal abstinence syndrome relative to type and dose of maternal substance or medication-assisted treatment have been equally conflicting. Winklbaur-Hausknost and colleagues (2013) found that maternal treatment resulting in reduced illicit drug use throughout pregnancy had no influence on neonatal outcomes in two separate studies. In a systematic review and meta-analysis, Cleary and colleagues (2010) found no clear link between neonatal abstinence syndrome severity and methadone dose. Similarly, Thajam, Atkinson, Sibley, and Lavender (2010) found no correlation between amount and type of fetal opioid exposure and neonatal abstinence syndrome expression in eight of the 10 studies they reviewed. In a systematic review of the literature, Milligan and colleagues (2010) noted that quantitative and interventional studies have yet to produce sustained, efficacious improvement in outcomes for these mothers and children. It may be concluded that a singular focus on drug type and dose fails to account for the complex array of factors contributing to neonatal outcomes.

Literature regarding care of the newborn with neonatal abstinence syndrome has been equally inconclusive (Dryden, Young, Hepburn, & Mactier, 2009; Sublett, 2013; Velez,

Jansson, Schroeder, & Williams, 2009). It appears that factors other than maternal medication-assisted treatment, such as maternal-infant bonding, have greater influence on neonatal outcomes:

- Care of neonatal abstinence syndrome infants on the postpartum unit with their mothers, rather than in the NICU, resulted in shorter duration of treatment and hospital stay (Saiki, Lee, Hannam, & Greenough, 2010).
- Infants discharged home on a methadone weaning protocol with support from a multidisciplinary team, as opposed to a traditional inpatient methadone wean, resulted in shorter hospital stays and reduced cost (Backes et al., 2012; Smirk, Bowman, Doyle, & Kamlin, 2014) .
- Substantial breast milk intake significantly reduced severity of neonatal abstinence syndrome symptoms, delayed the onset of symptoms, and decreased the need for pharmacologic treatment (Abdel-Latif et al., 2006; Dryden et al., 2009).

Early and adequate prenatal care has been shown to mitigate the negative effects of substance use disorders during pregnancy (Wright, Schuetter, Fombonne, Stephenson, & Haning, 2012). Studies of early identification, engagement, and treatment retention of pregnant women using integrated substance abuse and perinatal services are showing potential benefits in the promotion of maternal-infant bonding (Burns, Mattick, Lim, & Wallace, 2007; Mayet, Groshkova, Morgan, MacCormack, & Strang, 2008; Meyer et al., 2012; Racine, Motz, Leslie, & Pepler, 2009; Suchman, Pajulo, DeCoste, & Mayes, 2006; Taylor et al., 2012). In a recently published systematic review, Jumah (2016) identified location as a major factor in accessibility to treatment for rural, opioid-dependent pregnant women, yet she also noted that gender issues and stigma remain largely unaddressed in the literature. Studies of harm-reduction approaches in Britain, the Netherlands, and Canada have shown positive outcomes in terms of lower rates of child protective involvement and withdrawal symptoms in infants (Boyd & Marcellus, 2007). Pilot studies in the U.S. have shown similar results (Wright et al., 2012). The programs described in the literature have used a variety of interventions, including integrated prenatal and substance abuse services and motivational incentives, so it is unclear which aspects of a harm-reduction approach contribute to outcomes. A focused review of the literature, highlighting studies of perinatal substance use disorders that included health care provider-mother-infant relational perspectives within various care delivery models, concluded that published studies have yet to identify the relative contribution of multiple risk factors to adverse outcomes as well as program components most likely to improve outcomes (Kramlich & Kronk, 2015).

It would seem from this review of the literature that the voice of pregnant and parenting women with substance use disorders has been minimally included in prior studies as evidenced by the relatively limited number of qualitative studies. Woodley and Lockard (2016) noted that qualitative research methods may provide more opportunities to engage with marginalized groups through personal connections as compared to quantitative methods, therefore informing my choice of study design. My dissertation study aims to address the gaps in the literature by exploring the women's experiences and perceptions of care, leading me to ask several questions: a) What are the experiences and perceptions of women with substance use disorder regarding the care they received during their pregnancy and through their infants' hospitalization? and b) How have their experiences supported or inhibited their ability to bond with their baby? For research purposes, pregnant women, human fetuses, and neonates are identified as vulnerable populations and are afforded additional protection (Protection of Human Research Subjects, 2001). Additionally, Flaskerud and Winslow (1998)

suggest that persons who are poor, subjected to discrimination, intolerance, subordination, stigma, politically marginalized, disenfranchised, and denied human rights may be considered vulnerable. Studies have shown that women with substance use disorder, particularly those who are poor, indigenous, and members of racial minorities, "are the most vulnerable to arrest, child apprehension, and poor health outcomes" (Boyd & Marcellus, 2007, p. 14). Access to and engagement of participants from vulnerable, socially disadvantaged populations have been found to be challenging due to mistrust of research/researchers and fear of authority, public exposure, and potential harm, stigma, mistreatment, or exploitation (Bonevski et al., 2014). For the reasons noted above, pregnant and parenting women with substance use disorder may be reluctant to participate in research studies due to the perceived and real risk of prosecution and incarceration, particularly in light of the criminalization of drug use during pregnancy in several states (Miranda, Dixon, & Reyes, 2015). Gatekeepers may serve as both barriers to and facilitators of participant recruitment; the relationship between vulnerable individuals and the health professionals caring for them may potentially inhibit the recruitment process (Bonevski et al., 2014; Namageyo-Funa et al., 2014).

Study Purpose and Design

Women living in remote rural geographic areas with fewer resources who may experience greater obstacles to accessing services have been underrepresented in prior studies. An exploration of the experiences of women with substance use disorder regarding the care they received for pregnancy, parenting, recovery, and psychosocial and economic issues is being undertaken to identify unmet needs. It is hoped that results of the study may contribute to a better understanding of the determinants of the problems associated with perinatal substance use to inform development of efficacious models of care. These findings may be of particular interest to the health care and psychosocial support services professionals who care for these women, as well as policymakers tasked with addressing issues related to substance use disorders.

Ethnographic studies are designed to understand a culture by learning from the people within that culture through contextualized examination of their speech, behavior, and artifacts (Spradley, 1979). Focused ethnography, defined by Munhall (2012) as "the study of small elements of one society, group, or culture; focus on [a] distinct problem within a specific context among a small group of people" (p. 291), may be particularly suitable for the study of vulnerable, stigmatized groups and sensitive issues (Li, 2008; Stahler & Cohen, 2000). The topics of inquiry for a focused ethnography are pre-selected, and the short-term yet time-intensive nature of observations are conducive to the study of sensitive topics and complex issues such as substance use disorders in women during the perinatal period within the limitations imposed by dissertation studies.

This study is being conducted at a large tertiary care hospital serving the northern two-thirds of a state in the northeastern United States. This encompasses a relatively large geographic range, with towns located in the farthest reaches of the service region situated well over 100 miles from the hospital. The area is also identified as having the lowest population density and highest rates of poverty in the state, one of the highest rates of opiate addiction in the country, and a Native American population greater than five times the national average. These variables have previously been noted to be barriers to access to adequate resources for substance use disorder recovery, pregnancy, and parenting support. The majority of pregnant women with substance use disorders in the area deliver their babies at this hospital. Three smaller hospitals located 50 to 100 miles from the hospital provide obstetric services but do not provide care for unstable substance-exposed newborns; newborns delivered at one of those small hospitals, either anticipated or unplanned, who

show signs of neonatal abstinence syndrome in need of escalating medication-assisted treatment are transferred. Depending on the circumstances, the mother may or may not be transferred with the newborn; typically, the mother has been discharged from the hospital and must travel to visit the hospitalized newborn.

As first author, I engaged in preliminary exploration which provided background information to guide this study. Telephone conversations and personal meetings with various providers of care for these women as well as attendance at conferences and meetings where these individuals have spoken contributed to a greater awareness of the problem. These care providers identified potential sites for observation and processes for gaining access to informants in addition to anticipated challenges. The relationships cultivated with these professionals has enhanced my ability to conduct the proposed study. This pre-fieldwork yielded what Hammersley and Atkinson (2007) termed a *foreshadowed problem*, the starting point for an investigation that will evolve as knowledge is gained through inquiry and observation.

This study is currently in progress; to date, primarily due to the recruitment challenges, only 13 participants have consented to interviews, observations, and data collection. The original prenatal recruitment method, as outlined below, yielded less than half of these participants; the remainder have been recruited postpartum through the hospital social worker subsequent to protocol amendment. Data in the form of transcribed interviews, participant observation, field notes, demographic data, and artifact reviews has undergone preliminary analysis and initial coding. Deeper analysis is currently underway and will involve constant comparison to create substantive (descriptive) and theoretical (abstract) categories. Data matrices will be developed from the coding schema to organize and display categories and establish emerging themes.

Recruitment Challenges

Multiple Processes for Ethical Approval

To conduct this study, ethical approval from several Institutional Review Boards (IRBs) was required, a process that took nearly eight months. IRB members, particularly at the study hospital, were concerned about maintaining privacy of the women during prenatal recruitment since special protection is required for research involving pregnant women, fetuses, and neonates (Protection of Human Research Subjects, 2001). After multiple protocol revisions and two full hospital IRB reviews, it was agreed that a researcher-designed informational flyer would be made available to eligible women in the perinatal practices. Women interested in the study would give permission for me to be contacted by the hospital social worker after delivery to initiate informed consent, Health Insurance Portability and Accountability Act (HIPAA) Privacy release, and subsequent data collection.

The ethical approval process itself required a certain degree of gatekeeping, consistent with the findings of Walker and Reed (2011). The university IRB requested letters of agreement from the four perinatal practices to allow and participate in recruitment; the hospital also needed to provide a letter of agreement for the study to be conducted, separate from their own IRB approval process. For a variety of reasons, it took over three months to receive the letters.

As noted by Walker and Reed (2011), gatekeepers of ethical approval for research in vulnerable populations and sensitive subjects can serve as facilitators and barriers for the protection of their organizations and participants. Reviewers of the original study protocol requested that researcher-developed fact sheets for gaining verbal consent by hospital personnel and participants' family and friends for observation during data collection be

eliminated, deeming them confusing and unnecessary. The hospital's IRB, however, expressed concern with the absence of a verbal consent process for non-participant observations, so the fact sheets were reinstated. Additionally, the method of distribution of the research information flyer at the perinatal practices evolved with each IRB review. The first reviewers were uneasy with the idea that eligible participants would be identified and given a flyer by practitioners due to negative experiences reported during previous full IRB protocol reviews, the details of which were not disclosed. They suggested instead that recruitment materials with researcher contact information be placed in waiting areas and examination rooms. The hospital IRB, on the other hand, disliked that procedure and asked that practitioners hand-deliver to eligible women the recruitment flyer with a pre-addressed stamped envelope for return to me. The recruitment process, therefore, came full circle.

The extended process for ethical approval as well as the time lapse between perinatal practice site commitment, subsequent initiation of recruitment, and postpartum data collection appear to have negatively impacted recruitment. As will be noted, practitioners seemed to forget recruitment procedures, eligibility criteria, or the study itself, or lose the recruitment materials. Additionally, the reliance on busy practitioners to facilitate recruitment due to privacy concerns, rather than direct recruitment by the researcher, may also reduce the potential participant pool. Lack of time and gatekeeper bias toward participants deemed more reliable or favored in some way may also skew the participant pool. My experience is consistent with challenges noted by Bonevski et al. (2014) and Namageyo-Funa et al. (2014).

Ineligibility

One inclusion criterion for the study is a personal substance use history inclusive of opioids, whether that be past or current use of illicit substances, misuse of prescription opioids, or engagement in opioid-replacement therapy, in recovery or relapsing. Several of the women who returned flyers early in the process did not in fact have a personal substance use history. They indicated that they misread or misunderstood the criteria for inclusion in the study and thought having a friend or relative with a substance use history would qualify them.

Women to be considered for the study also need to be currently pregnant since informed consent and data collection commences once the woman delivers her baby. Several women returning flyers, when asked about their expected due dates, responded that they had delivered a number of months prior. This discovery illuminated a limitation of the study which did not allow access to women once they and their baby were discharged from the hospital.

Unavailability

Given the demographic profile of the women most likely eligible for the study (rural, higher rates of poverty, relapsing nature of substance use disorder), it was not surprising that I was never able to reach three of the women who returned flyers despite multiple attempts. This is not an unusual phenomenon (van Wijk, 2014). Wireless coverage in the northern part of the state is often unreliable. Residents turn to web-based service and prepaid phones for numerous reasons. Economic instability may cause unpaid bills and disconnected service. Lapses in judgment and avoidance of law enforcement also may result in full voice mailboxes and unreturned calls. In one case, the message on every attempt was "number unreachable." Multiple voice messages left over a period of weeks, with the other two potential participants, were never returned.

Practice Change

When the study was initially proposed, all babies born with any addictive substance exposure in the northern part of the state were automatically transferred to the large hospital where the study was approved. In the time between study proposal, IRB approval, and commencement of recruitment, practices at the smaller hospitals evolved. Substance-exposed babies not requiring pharmacologic treatment were being retained for observation at the small hospitals. One of the earliest flyers I received was returned by a woman whose first baby required transfer for observation and treatment; she was hopeful that this delivery would be different. Indeed, as it turned out, she and her baby were able to stay in their local community hospital, which was a positive outcome for them but the loss of a study participant.

Observed Anomalies

The recruitment flyers were color-coded by perinatal practice site to facilitate data collection and organization. I supplied what should have been sufficient numbers of flyers and pre-addressed stamped envelopes to each practice with the promise of more as needed. I maintained close contact with each practice to check on the status of the supply of flyers. Several months into recruitment, white flyers in envelopes not provided by me began to appear, some with stamps that had not been cancelled and appeared to have been left in my mailbox without going through the postal service. This was a bit unsettling, as I live well over 100 miles from the hospital and nearest perinatal practices. Coincidentally, all but one of those irregular returns were also from women with whom I could not connect. I again contacted the practitioners to reinforce the recruitment process, and the anomalies ceased.

Questionable Leadership Approval

After months of recruitment, I noticed that one of the recruitment sites had not yet yielded a returned flyer. This might not be unusual given that it is a small rural perinatal practice; however, the rate of perinatal substance use disorder in that county is among the highest in the state. Additionally, the senior administrator who had granted permission for recruitment was no longer at the hospital and the remaining administrators were unaware of the study, a finding that was revealed when I sought an amendment to the original study proposal. Unfortunately, this experience seemed to create enough uncertainty that the new senior administration elected to prohibit further recruitment efforts.

Recruitment Facilitators

I initially contacted perinatal practice leadership to delineate the research purpose and plan to conduct the study with women in their service area. Hammersley and Atkinson (2007) identify individuals with control over access to key informants or potential participants as *gatekeepers* and suggest that "identifying the relevant gatekeepers is not always straightforward" (p. 49). It has been noted that most health-related research studies of human participants involve collaboration with other health care professionals, and cultivating relationships with key administrative, clinical, and support staff is crucial to successful recruitment at the practice sites (Patel, Doku, & Tennakoon, 2003; van Wijk, 2014). I connected with the practice leaders through the process of community networking as described during preliminary work; often the support staff facilitated introductions with practice leaders. Leadership positions ranged from practice manager to hospital senior administration to health care practitioner. I then arranged initial meetings with the

practitioners designated to identify potential informants and facilitate recruitment. I have attempted to maintain ongoing dialogue with these practices through personal meetings, e-mail, and telephone communication to further cultivate the relationships. This relationship-building has proven to be beneficial to the recruitment and data collection process.

I was aware of the potential constraints and limitations posed by study of a vulnerable rural population, including distance, time constraints, fluctuations in women meeting inclusion criteria, their availability and willingness to participate, and attrition. The relationships fostered with perinatal practitioners have mitigated the challenges, but my willingness to remain flexible, sensitive, and responsive to practitioner and participant needs has been equally important.

Conclusions and Lessons Learned

Conversations about the recruitment challenges with my advisor and the hospital social workers led to possible strategies to improve the recruitment process. The hospital social workers suspected many eligible participants were not being identified through the perinatal practices due to practitioner time constraints and confusion regarding the process, which is consistent with other reports in the literature (Namageyo-Funa et al., 2014). They suggested direct recruitment in the hospital and were willing to act as facilitators since they were already familiar with the study and the population. Subsequently, amendments to the original study proposal were approved by the IRB, and two participants have been recruited into the study.

Qualitative research takes time which can result in changes in practice patterns (Hammersley & Atkinson, 2007) and which was certainly the case in the present study. The revelation that the small rural hospitals were changing practice and beginning to retain substance-exposed newborns for observation unless pharmacologic treatment was needed motivated me to seek an additional protocol amendment to allow direct recruitment and data collection at those rural hospitals. The IRB has approved the amendment and I have met with senior hospital leadership and the perinatal unit nursing staff to initiate the process. A parallel process was advancing slowly through the other rural hospital where a complete senior leadership turnover has occurred and the original administrative approval was in question. I have spent countless hours meeting in person and by conference calls with the current administration to establish legitimacy and regain trust so the study may advance, to no avail.

A prior study by Namageyo-Funa et al. (2014) identified recruitment challenges, including access to participants with the use of one recruitment strategy and limited interview locations. These issues have become evident in the current study. The distribution of flyers through gatekeepers at multiple sites, with diverse practices and processes, and the restriction of data collection to the inpatient postpartum setting, seem to have undermined recruitment rather than enhanced it. I anticipate that expansion of the study to the small rural hospitals may mitigate some of those constraints. I did contact a number of substance use disorder treatment practices in the service area on the advice of the social workers; they hypothesized that, although pregnant women may receive integrated services for pregnancy and substance use, some women may slip through the cracks and be more easily recruited through a substance abuse program. Those practitioners politely declined to participate, indicating that they did not feel they could add to the current recruitment efforts. In consideration of the potential participants excluded due to lack of personal substance use history but who had friends or relatives with substance use disorders, I am now offering additional flyers and envelopes to study participants to share with contacts who may be interested. As indicated by several potential participants who were excluded due to remote delivery and hospital discharge dates, the ability to collect data in the postpartum period following hospital

discharge may have further augmented informant recruitment. Although this strategy was considered in the original study proposal development, it was rejected for consideration of my safety. In hindsight, I would have contemplated other creative solutions, such as data collection at the same perinatal practices in the postpartum period rather than at private homes or other public places.

As noted by Maxwell (2013), the exploratory nature of ethnographic research requires a focused yet flexible approach to sampling and data gathering, which extends to participant recruitment and negotiating of relationships. Maxwell further asserts that "research relationships…can facilitate or hinder other aspects of the research design" (p. 91), and gatekeepers are included in the established relationships. Despite careful forethought and planning, I encountered numerous challenges in the recruitment process alone. It is hoped that through this reflection and reconsideration of methodological decisions, other qualitative researchers might avoid and be prepared for similar challenges. Persistence in overcoming barriers to inclusion of already marginalized and underrepresented populations in research studies may significantly impact their outcomes.

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Article Citation

Kramlich, D., Kronk, R., & Jakub, K. (2017). Challenges and facilitators of recruitment: Lessons learned from conducting a focused ethnography in a vulnerable rural population. *The Qualitative Report, 22*(3), 818-830. Retrieved from http://nsuworks.nova.edu/tqr/vol22/iss3/9