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Research Article

Cultural and Environmental Enablers and Barriers to Participation and Retention in Clinical Trials for Cancer Research

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Abstract

Background: West Virginia (WV) residents have often rejected participation in community-based cancer research studies. Nationally, 49% of eligible patients participate in clinical trials but less than 10% of patients in WV participate.

Objective: To understand issues related to recruitment and retention of patients for cancer research in Appalachian WV.

Methods: Data were obtained from 3 focus groups including: (1) 9 patients who participated in clinical cancer trials, (2) 8 cancer research nurse coordinators, and (3) 10 physicians involved in cancer research. Groups were audio-taped and transcriptions were analyzed using MAXQDA and results were verified by two co-investigators.

Results: Most enablers and barriers identified were cultural as indicated by 72% of patients; 68% nurse coordinators; and 55% physicians. Patients identified personal emotional strength as an enabler, and negative health behaviors and fears as barriers. Enablers that nurses identified were positive patient characteristics and barriers included fear of trials, randomization, and death. Physicians identified enablers as a patient's understanding of the clinical trial and motivation to help others and the inverse of these two enablers as barriers.

Conclusion: A foundation for improving recruitment and retention of participants in cancer research in Appalachia was identified. The next step will involve cancer community organizations and patients in developing a plan to enhance enablers and overcome barriers to patient recruitment in cancer studies.

Implications for Practice: Cultural influences must be considered when recruiting for clinical trials. Community organizations educating the public about cancer research may be the key to enhancing patient enrollment.

Keywords: *Cancer; Enablers; Appalachian*

Introduction

Incidence and mortality rates for cancer in WV exceed the national average [1]. The Intercultural Cancer Council reports that elders, those with low income, racial/ethnic minorities and those living in rural areas have the smallest percentage of clinical trial participation. These same populations bear a disproportionate burden of cancer morbidity and mortality" [2-4]. WV residents have often rejected participation in community-based cancer research studies in the past [5]. Nationally, 49% of eligible patients participate in clinical trials and less than 50% complete a clinical trial [6], but less than 10% of West Virginians participate in clinical trial research.

Research studies on enhancing recruitment rates for cancer clinical trials in non-Appalachian regions have been conducted [7-9], but there have been no studies to address recruitment in an Appalachian population. In a randomized cancer clinical trial in Appalachia, the challenges of recruitment and retention of an adequate sample size became obvious [5]. Cultural values of Appalachian communities included loyalty to family and desire for self-care [10]. There was also a reluctance to respond to outsiders and researchers may not be trusted. Past participants in focus groups in WV said health care information came from family members whom they trust, and they didn't like to discuss health related problems with those outside the family [11]. To improve participant recruitment and retention in clinical trials in Appalachia, understanding such cultural and environmental barriers and enablers could be used to design strategies to address them [12].

Aim of the Study

There were three aims in this study.

1. **Aim 1:** Identify the cultural and environmental barriers and enablers that support research participation from the perspective of adults with cancer living in Appalachia who completed cancer research and participants who withdrew from cancer research.
2. **Aim 2:** Identify the cultural and environmental barriers and enablers that contribute to research participation from perspectives of nurse and physician cancer researchers at an academic institution in Appalachia.
3. **Aim 3:** Identify similarities and differences among patients and clinicians/researchers to better recruit and retain participants in cancer research in Appalachia.

Methods

Following IRB exemption, three groups of informants were recruited: (1) surviving adult patients who completed or did not complete cancer research studies; (2) nurse coordinators assigned to cancer research studies; and (3) physician/researchers conducting cancer research studies. Data were obtained from three in-depth focus groups and one semi-structured interview of Appalachian participants. The first focus group included 9 patients who had participated in cancer research, including patients who had enrolled in clinical trials and then dropped out. An incentive of $25 was given plus reimbursement for travel expenses. A phone interview using the same "focus group" questions was conducted with a patient who enrolled in a clinical trial but did not complete it. The second focus group included 8 nurse coordinators and the third group included 10 physicians. Table 1 illustrates characteristics of patients in the focus group.

Number of participants	9
Ages	40 - 70
Distance to focus group discussion	1 - 34 miles
Type of cancer	1 - colon
	9 - breast
Year diagnosed with cancer	1996 - 2012
Status of clinical trial	6 - completed
	2 - did not complete and it is over
	1 - has not completed because it continues
Satisfaction with clinical trial	8 - glad about participation
	1 - not sure
Would participate in other clinical trials	7 - yes
	2 - no

Table 1: *Characteristics of patient participants in focus group.*

The focus groups and interview were guided by a set of structured questions developed using proven techniques for conducting successful focus groups [13]. The key questions included:

(1) What kind of information should clinicians give cancer patients to help them decide whether or not they should participate in a research study of patients with cancer?

(2) What do you think keeps patients with cancer from enrolling in research studies?

(3) What are some of the reasons people stop participating in a research study before it is over? and

(4) What kinds of support do people need to help them continue to participate in a cancer research study?

All three focus groups were conducted by an experienced qualitative researcher who was not involved in previous cancer research to decrease the potential for bias. Each group was audio-taped; the PI co-moderator took notes and read her summary to the participants at the end of each focus group. The transcriptions were analyzed using MAXQDA qualitative software.

Analysis of data consisted of examining, categorizing, tabulating or otherwise recombining the evidence, to address the initial propositions of the study [14]. Colaizzi's phenomenological method was used to uncover the experience of patients deciding whether or not to participate in a cancer research study [15]. The steps used to guide the research process [16,17] were (1) describe the problem of enrollment and retention in cancer research studies; (2) collect participants' description of the enablers and barriers to research participation through the use of focus groups; (3) transcribe interviews and discussions; (4) extract significant statements of enablers and barriers; (5) describe the significant statements; (6) organize and write descriptions of each enabler and barrier with associated quotes; (7) categorize patient, nurses and physician enablers and barriers occurring at cultural and environmental levels.

Results

Comments were categorized by participant viewpoint (patients, nurses, and physicians), cultural and/or environmental context, sub-categories, and designated enablers or barriers. Cultural enablers/barriers [18] included patient capabilities, knowledge, beliefs, customs, and motivations. Environmental enablers/barriers included surrounding things, conditions, and influences. In table 2 the number and percentage of coded comments are indicated by participant groups. Cultural enablers are more prominent with all three groups. The sub-categories of cultural enablers and barriers are illustrated in table 3 and those for environmental enablers and barriers in table 4. Of all of the cultural subcategories, personal capabilities was most prominent for patients; knowledge for nurse coordinators, and motivations for physicians. For physicians, however, capabilities, motivations, and knowledge were almost evenly divided. Of all of the environmental sub-categories, influences was most prominent for patients, and surrounding things for clinicians.

Targeted Group	Cultural	Environment	Total
Patients	106 - 72%	42 - 28%	148 - 39%
Nurse Coordinators	91 - 68%	42 - 32%	133 - 35%
Physicians	53 - 55%	43 - 45%	96 - 26%
Total	250 - 66%	127 - 34%	377 - 100%

Table 2: *Cultural and environmental categories with numbers and percentages of comments by target group.*

Targeted Group	Capabilities	Customs	Motivations	Beliefs	Knowledge	Total
Patients	42 - 40%	16 - 15%	9 - 8.5%	9 - 8.5%	30 - 28%	106
Nurse Coordinators	11 - 12%	4 - 4%	12 - 13.5%	14 - 15.5%	50 - 55%	91
Physicians	16 -31%	0	18 - 33%	3 - 5%	16 - 31%	53
Total	69 - 28%	20 - 8%	39 - 16%	26 -10%	96 -38%	250

Table 3: *Subcategories for cultural enablers and barriers with numbers and percentages of comments by target group.*

Targeted Group	Surrounding things	Conditions	Influences	Total
Patients	11 - 26%	5 - 12%	26 - 62%	42
Nurse Coordinators	21 - 50%	7 - 17%	14 - 33%	42
Physicians	22 -51%	21 - 49%	-	43
Total	54 - 43%	33 - 26%	40 - 31%	127

Table 4: *Subcategories for environmental enablers and barriers with number and percentages of comments by target group.*

Table 5 displays descriptions of enablers and barriers from the viewpoint of participants: For patients, personal capabilities and family traditions/customs enabled them to participate in clinical trials. Barriers identified by patients were physical and emotional limitations. They valued health professionals with positive character traits, while citing lack of communication skills as a barrier. The internet and other media sources were barriers, while information from their physician was an enabler. Environmental enablers included clinical team members and other supportive personnel and services, as well as quality insurance coverage. Environmental barriers were study variations posing obstacles to signing up or remaining in trials.

View-point	Cultural or Environmental	Sub category	Enablers	Barriers
Patients	Cultural	Patient capabilities	• Independent • Positive • Emotionally strong • Persistent • Resistant • Compliant • Humorous	• Negative health behaviors that prevent participation • Difficulty telling family members
		Health provider capabilities	• Straight talkers • Trustworthy • Understanding/caring • Supportive • Good listeners • Keep to schedules • Go the extra mile • Thorough	• Poor communication skills • Lack of respect patient's boundaries
		Customs	• Role of others in care	
		Motivation		• Fear of randomization
		Knowledge	• Information should come from physician • Information should be written down • Patients need to hear the complete truth • Need to know what to expect • Risks and benefits • Need to know about clinical trials	• Information obtained on the Internet • Confusion choosing treatment options
	Environmental	Surround-ing things	• Support groups	• Lack of support groups
		Influences	• Nurses coordinators • Physicians • Those who have gone through • trials • Friends, family • Religious groups/leaders	• Family members or friends who do not react appropriately
		Conditions	• Quality of insurance • Test results indicate need for clinical trial	• Adverse side effects

Nurse Coordinators	Cultural	Patient capabilities	• Personal strength • A sense of humor	• Disqualifying health status • Refusal to make time commitment
		Patient customs	• Religious beliefs • Expectations of care from significant others Expectations of decision making with significant others	
		Patient Motivation	• Belief it will help others • Adequate time to think it over.	• Fear of clinical trials • Fear of the unknown • Fear of being a guinea pig • Fear of randomization, • Fear of death • Anger
		Patient knowledge	• Information from a number of sources • Process information before making decisions • Topics: options, disease, side effects, clinical trials, arms of clinical trial, and second opinions	• Complexity of the clinical trial • Completion of consent forms • Reading academic materials not written to the reading level of the patient
	Environmental	Surrounding things	• The clinical team	• Being in two studies at the same time even though old study not helping • Insurance companies that won't pay • Trial protocols that require work at other institutions • Lack of financing for travel/lodging
Physicians	Cultural	Patient capabilities	• Adequate education to understand the trial • Eligibly for the trial	• Lack of adequate education or intellect to understand their diseaseor the trial protocol • Health status or disease progression • Toxicity to the pharmaceuticals • Certain demographic characteristics
		Physician capabilities	• Trustworthiness • If s/he believes in the value of the trial	
		Patient beliefs		• Fear of clinical trials in general • Fear of the randomization process • Fear of getting the placebo
		Patient Motivation	• Motivated by helping others, researchers, and themselves.	• Patients do not always see the benefit to themselves and others • Patients disinterested from the start
	Environmental	Surrounding things	• Time to tell patients about clinical trials • Incentives • Services such as a dedicated space for participants, telecare, and home health	• Lack of incentives for physicians to participate in clinical trials such as reimbursement and academic recognition for themselves and universities • Healthcare constraints on physician time • Trials are arranged before they come to the university • Patients enrolled for only one to two years • Trial protocols that include multiple visits • Trials are targeted for specific therapies • Patients remain on trial when the treatment is not medically warranted

Table 5: *Enablers and barriers from the viewpoint of participants.*

For nurse coordinators, the focus was on the patient's personal characteristics, religious beliefs, expectations of significant others and motivation for participation. Nurses also identified their responsibility for filling in gaps in patient knowledge. Cultural barriers included the patient's health status and aspects of the clinical trial itself. Nurses identified enablers as promoting new ideas or fixing things in the clinical environment.

For physicians the patient's understanding of the trial and their motivation for participation were frequently mentioned cultural enablers. Physicians identified environmental barriers as things that prevented them from accommodating patient needs.

Discussion

Identifying how to better support cancer research participation in Appalachia found cultural enablers/barriers were discussed more than environmental enablers/barriers by all three study groups; however, descriptions of both cultural and environmental factors differed among groups. Patients focused on capabilities, nurses on knowledge, and physicians equally on capabilities, motivations, and knowledge.

Cultural enablers and barriers

Capabilities: Patients believe they are capable of understanding detailed information about their disease and clinical trial. One patient stated, "Communication is the most important thing, tell us everything you think we need to know and stuff that we probably don't need to know; more is always better". One nurse noted that the emotional strength of patients should be harnessed, "I would just say that I'm amazed by the cancer patients that I have worked with -- how they still maintain a good sense of humor and a positive outlook in the face of everything they're going through". Physicians recognize the importance identifying appropriate clinical trial candidates. One physician commented, "It has been my experience that if we have identified a patient who's eligible for a clinical trial, more than likely they will go on the clinical trial. In my experience I've only had a few or a handful of patients who are eligible and then refused clinical study".

Patients focus on the capability of their clinical team. Professionalism, honesty, and caring were prominent themes. A patient noted, "I wanted my doctor to tell me if I was going to make it or not make it. I didn't want any sugar coating. I wanted to know what he thought was happening and if it (clinical trial drug) was going to be effective". When talking about a nurse coordinator, a patient said, "…what I liked about her was that she didn't have to, but (she saw me) every time I was in for chemo, even if it was just a pop by my chair. She gave me her personal contact not just her office phone. And she often would repeat the information that the oncologist told me but tweaked it in a way that made more sense to me".

Knowledge: Consent forms provided patient information. One nurse noted that "patients come back with lots of questions and a lot of times they bring their consent forms back and will have questions they wrote in the margin and they'll have underlined things". Patients wanted to get information about their prognosis and clinical trial to come from their physician. One patient stated, "I want an MD, I don't want a PA, I don't want anyone else. They are wonderful people, they do a very good job, but something this important I want it from a MD and then I check them out. I go for a second opinion to make sure that I'm not missing something or misinterpreting something that this MD, that I have great faith in, is agreeing with another MD". This confidence in physicians' advice contrasts with previous cultural studies where researchers were not trusted [19] and family members were information sources [11]. Physicians recognized that patients look to them for information: "If the docs don't believe in the trial, the patients aren't going to go on the trial. Physicians report obstacles to being the sole provider of information, lack of time and no reimbursement incentives to enroll patients in clinical trials.

Motivation: All groups suggested that patients are motivated to participate in clinical trials for altruistic reasons. One patient stated, "I never thought I would be part of a clinical trial, but I would never ever hesitate to do it because I feel like whatever I can do to help anybody else in the future, that's what I want". A nurse echoed the patient's motivational reasoning stating, "Some people don't think they could be as altruistic as they become during research…because they are facing mortality. They know that it might not matter now but it might matter in the future". A physician made a similar comment, "Actually a lot of our patients go on nontherapeutic trials…which have no benefit for the patients".

Beliefs and fears are important motivations for participating (or not) in clinical trials. A common theme among patients was fear that they might be randomized into the control group. One patient said, "One of my major concerns was if I did the clinical trial and I ended up in the group that received the placebo, how far back am I setting my treatment? Am I going to waste a year in this trial to continue to go downhill and then would there be a way to catch up?" A nurse echoed this concern saying, "I think some people get scared of the unknowns of clinical trials, especially when they're younger with kids. They want to be on the standard treatment where they have an 80% chance of remission and then the clinical trial doesn't guarantee them that they're on it. So, for some people they rather go with the odds rather than the unknown". Religious beliefs were a motivational factor for a few patients with one stating, "And just not knowing what to choose and of course prayerfully seeking God about it, I just decided that I would participate in a trial".

Along with cultural enablers and barriers, environmental enablers and barriers were identified: Surrounding things: Surrounding things included services close to home as enablers, while services at a distance as barriers. One nurse suggested that, "Patients would continue to participate if they could get treatments closer to home". Another said, "Some patients start the trial, then they get overwhelmed by how many visits they're making or they run into trouble with the snow or car breaks down". A physician stated the need "to have more available resources for patients who obviously face an extra burden to come back and forth". Insurance companies often don't support participation in clinical trials. A nurse noted, "When a patient comes in for a discussion they may not know if they want to participate in a trial, and then … the insurance company will not allow them to participate. They won't pay for things if they participate". Physicians thought that clinical environments were problematic and think that a more inviting setting might increase recruitment, such as "a VIP lounge".

A patient commented on the benefit of being in a cancer support group saying, "There was a lot of humor in the support group. It was a lot of fun". Another patient expressed regret, saying "It seemed like I never ever had a support group or ever went to any meetings or anything. It seems like I just went through it and that was it. I don't know how that loop got broken but, I did not really have a support group".

Influences: One patient stated, "My doctor wanted me to do it". Nurses noted that the entire clinical team was responsible for the success of a clinical trial and patient recruitment: "When I say the team, I mean the whole clinical team. You know, we have the nurse clinicians who are within the clinic, you have your mid-level providers that are there, and you have the people that check them in, you have pharmacy, there's a whole group of us who when it comes to the consenting process, you know, it's the provider and the coordinators but it is also the mid-level involved. It's also the nurse clinicians that are involved. It's kind of all of us together that are there to help answer questions and help support the patient's decisions".

Conditions: Conditions such as the number of treatment options come into play when patients are deciding to participate in clinical trials. A patient said, "I hadn't made a decision, a definitive decision, to actually participate in a trial until I received my test results back …I wanted to know what the percentage of the reoccurrence would be". Another stated, "I knew that the treatment (that she picked) would be covered under a clinical trial … I had several different treatment options". The rigor of the trial can be important according to a nurse: "The rigors of trials are too much travel, inconvenient times, and schedules", although support for travel costs may be "available through cancer societies and various other funded groups… and is for any patient, but our clinical trial people can apply for those".

Conclusion

The findings of this study offer important insights from patients, nurse coordinators and physicians on what helps and hinders recruitment of patients living in Appalachia into cancer clinical trials. Among the groups' unique perspectives, agreement can be found. Conclusions are framed by the key questions and future directions.

What kind of information should clinicians give cancer patients to help them decide whether or not they should participate in a research study of patients with cancer?

Findings suggest that, rather than what kind of information should be given, the key is from whom it should come. Patients want to receive information from their physicians. The consent forms, although comprehensive, are not enough. Nurses are good at giving information in layman's terms, but patients want clear explanations from physicians. If physicians and patients believe the trial is important, and the patient is qualified, patients will likely participate. Physicians are challenged to have time to invest in clinical trials to meet needs of their patients.

What keeps patients with cancer from enrolling in research studies?

Patients recognized that participation may not help them individually, but it can be important for patients that come after them. In fact, only one patient in the focus group said she participated in the trial to help herself. Nevertheless, fears about the unknown are real and recognized by both nurses and physicians. Patients worry that trial participation might delay other treatment or that their pain and distress were meaningless if the trial fails. All three groups said fear of trial randomization hinders recruitment. Informed consents need to be clear about future impact.

What are some of the reasons people stop participating in a research study before it is over?

There were only two in the patient focus group who dropped out of their trial. One dropped out because she suffered from negative symptoms caused by the trial medication and one thought her disease was in remission.

What kinds of support do people need to help them continue to participate in a cancer research study?

Supports identified in this study included a dedicated space at the hospital where research participants can receive hospitality and specialized resources, including private space for patients and their families to meet with clinical teams and support each other. Nurses and physicians involved in cancer studies in Appalachia should address barriers of time and travel. Since healthcare centers in Appalachia are often distant from the patient's home, it may be possible to coordinate with sponsors of cancer research for adapted protocols using community care centers. If education levels of potential participants are lower, a consent form in simple language such as used in assenting children could be prepared to accompany the very detailed consent form.

In summary, the data identified in this study provide a foundation for improving recruitment and retention of participants in cancer research in Appalachia. The next step will involve key community participants (families and people living with cancer) and existing community advisory groups [20] (e.g. "Mountains of Hope" in WV) in developing a plan to enhance enablers and overcome barriers to patient recruitment and support culturally sensitive protocols.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

Bibliography

1. Bureau for Public Health. "West Virginia Cancer Registry 2012 Annual Report: Cancer Incidence in West Virginia,1993-2009".
2. Appalachian Community Cancer Network. "The Cancer Burden in Appalachia" (2010).
3. Paskett ED., *et al*. "Disparities in underserved white populations: the case of cancer-related disparities in Appalachia". *Oncologist* 16.8 (2011): 1072-1081.
4. Lengerich EJ., *et al*. "The Appalachia Cancer Network: cancer control research among a rural, medically underserved population". *Journal of Rural Health* 20.2 (2004): 181-187.
5. Petitte TM., *et al*. "Feasibility study: home telemonitoring for patients with lung cancer in a mountainous rural area". *Oncology Nursing Forum* 41.2 (2014): 153-161.
6. Center for Information and Study on Clinical Research Participation (CISCRP). Clinical Trial Facts & Figures, 2013.
7. Meropol NJ., *et al*. "Perceptions of patients and physicians regarding phase I cancer clinical trials: implications for physician-patient communication". *Journal of Clinical Oncology* 21.13 (2003): 2589-2596.
8. Liu L., *et al*. "An integrative Tai Chi program for patients with breast cancer undergoing cancer therapy: study protocol for a randomized controlled feasibility study". *Journal of Integrative Medicine* 16.2 (2018): 99-105.
9. Peddle-McIntyre CJ., *et al*. "The feasibility of a pragmatic distance-based intervention to increase physical activity in lung cancer survivors". *European Journal of Cancer Care* 27.1 (2018).
10. Health Resource and Services Administration. MUA Find.
11. Coyne CA., *et al*. "Social and cultural factors influencing health in southern West Virginia: a qualitative study". *Preventing Chronic Disease* 3.4 (2006): A124.
12. Levkoff SE., *et al*. "The matching model of recruitment". In: Levkoff SE, Prohaska TR, Weitzman PF, Ory MG, eds. Recruitment and Retention in Minority Populations: Lessons Learned in Conducting Research on Health Promotion and Minority Aging. New York, NY: Springer Publishing Company (2000).
13. Guba EG and Lincoln YS. "Fourth Generation Evaluation". Newbury Park, CA: Sage Publications (1989).
14. Yin RK. "Case Study Research: Design and Methods". Beverly Hills, CA: Sage Publications (1984).
15. Colaizzi P. "Psychological research as the phenomenologist view it". In: Valle RS, King M, eds. Existential-phenomenological Alternatives for Psychology. New York, NY: Oxford University Press (1978).
16. Krueger RA. "Focus Groups: A Practical guide for Applied Research. Second edition". Thousand Oaks, CA: Sage Publications (1994).
17. Strauss A and Corbin J. "Basics of Qualitative Research: Grounded Theory Procedures and Techniques". Newbury Park, CA: Sage Publications (1990).
18. Leininger MM. "Ethnography and ethnonursing: Models and modes of qualitative data analysis". In: Leininger MM, ed. Qualitative Research Methods in Nursing. Orlando, FL: Grune and Stratton (1985): 33-72.
19. Behringer B and Friedell GH. "Appalachia: where place matters in health". *Preventing Chronic Disease* 3.4 (2006): A113.
20. West Virginia Department of Health and Human Services. Division of Health Promotion and Chronic Disease. Mountains of Hope Cancer Coalition.

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