

Community Health Workers and Cancer Clinical Trials: Experiences, Knowledge and Concerns

A report by

Russell K. Schutt, Ph.D.
University of Massachusetts Boston
& Beth Israel Deaconess Medical Center

**Jessica Santiccioli,
Jennifer Maniates¹, M.A.,
Silas Henlon**
University of Massachusetts Boston

&

Lidia Schapira, M.D.
Massachusetts General Hospital

Research funded by National Cancer Institute grant to JudyAnn Bigby¹, MD (Massachusetts Secretary of Health and Human Services, formerly Brigham & Women's Hospital and Harvard Medical School), Lidia Schapira, MD, Russell K. Schutt, Ph.D, as part of U56 project, University of Massachusetts Boston and Dana-Farber/Harvard Cancer Center.

¹Now Commonwealth Health, Massachusetts Executive Office of Health & Human Services.

Executive Summary

- Members of some racial and ethnic minority groups increasingly are underrepresented as participants in clinical trials concerning some types of cancer.
- Community health workers are key participants in the health care system who can help to understand and address disparities in clinical trial participation.
- Information was collected from Boston-area community health workers using focus groups (N=15), intensive interviews (N=11) and a structured survey (N=76).
- Survey respondents were ethnically diverse, mostly female, one-fifth spoke Spanish as their primary language, and half had completed college.
- Survey respondents rated the quality of health care in the Boston area as considerably better for white Americans than for ethnic minorities, people of low income, or gay persons.
- Interview respondents remarked that they had an important role to play in reducing health disparities and also noted behaviors and orientations of community members that undermined their health care.
- Survey respondents were very aware of the importance of cancer research, but had less favorable attitudes toward medical researchers than toward health care providers. Some were skeptical about medical research and distrusted medical researchers; some believed that researchers were not interested in community needs.
- Interview respondents perceived little interest in health care research in their communities and many were very interested in increasing that level of interest. Potential barriers to community members' research participation that were perceived as "very important" by all or almost all interview respondents included inadequate transportation, lack of understanding and fear of research, lack of trust of researchers, limited English language ability and immigration issues.
- Most interview respondents were aware of the Tuskegee syphilis study and believed this history to be a basis for distrust of medical researchers. Some suggested that distrust could be lessened through involving community members in the design and review of medical studies.
- Most community health workers felt that their level of understanding of cancer clinical trials was inadequate and that access to cancer clinical trials in their communities was even less inadequate. There were many incorrect answers in the survey on a quiz about clinical trials. Most respondents were generally aware that clinical trials test a new treatment and that the informed consent process is supposed to protect human subjects.

Table of Contents

Executive Summary	2
Introduction.....	4
Methodology.....	4
The Importance of Community Health Work.....	5
Current Medical Research.....	7
The History of Medical Research	15
Knowledge about Medical Research	16
Knowledge about Informed Consent	20
Conclusions.....	27
References.....	29
Appendices.....	30
Focus Group Guide.....	30
Interview Schedule.....	32
Survey Questionnaire.....	41

Introduction

Disparities in cancer between subpopulations in the U.S. have been documented for several decades: risk, incidence, morbidity and mortality for cancer in general and for some specific cancers are higher for blacks compared to whites, for poor persons compared to non-poor persons, and for rural residents compared to non-rural residents. Although the reasons for disparities in cancer outcomes between different subpopulations are complex, one important area for intervention is the participation of underserved populations in cancer clinical trials.

Participation of minority populations in cancer clinical trials tends to be less common than participation of whites--although this difference varies with type of cancer--and the overall trend for black enrollment declined between 1996-1998 and 2000-2002 (Murthy 2004). Community health workers (CHWs) can play an important role in reversing this decline: As increasingly important members of the health care delivery system, CHWs (also called outreach workers, patient navigators, health educators, lay case managers, health ambassadors) connect the formal health care system to underserved communities by providing critical health care information and resources. This report summarizes the results of research to investigate community health workers' knowledge of, experience with, and attitudes toward cancer clinical trials and other types of health-related research.

Methodology

We collected information from community health workers in the Boston area using focus groups, intensive interviews, and structured surveys. The instruments used for data collection with each method drew on prior research about attitudes toward clinical trials (Avis 2006; Wright et al. 2004). In addition, we used findings from the focus groups to refine interview questions and we drew on information obtained through the focus groups and intensive interviews as we designed the structured surveys. In total, 102 community health workers participated in the research. This report describes their responses to questions in all three stages of the research.

We recruited participants for our focus groups and interviews through outreach efforts to programs that employ CHWs throughout the greater Boston area. A total of 15 community health workers participated in one of our two focus groups in June 2006. All participants were female and spoke English as their primary language. Nine participants were in their 40s and seven were younger. Six participants were African American, one identified as African American and African, two said they were African American and Latino, and five identified as Latino. One participant identified as white and one as Asian. Nine participants worked reported they worked in the field of women's health, while the others focused on specific diseases—but only one specifically on cancer.

We interviewed eleven community health workers (CHWs). All participants were female. All spoke English, but Spanish was the primary language of five and Polish, of one. Two interviewees had earned Master's degrees, three had a Bachelor's degree and one an Associate's degree; the rest were high school graduates—most with additional training related to health care. About equal numbers of respondents were in their 30s, 40s and 50s. Five interviewees identified as Latina, four as Black, one as White, and one as Asian. Eight of the women interviewed lived either in or around the communities they worked in, but two traveled significant distances to get to their jobs.

We administered our survey in collaboration with the Community Health Education Center (CHEC), a training organization funded by the City of Boston's Public Health Commission for community health workers that is located at Boston Medical Center. CHEC sponsors frequent one-day workshops and longer courses for CHWs. For one month, the survey was distributed at the end of each one-day CHEC workshop to all CHWs who had not previously completed a survey. The survey was also distributed at the end of one session during a multi-week course, as well as at one monthly meeting of the 10-person CHEC advisory board. In total, 76 CHWS completed the survey at the end of these sessions. Of the survey respondents, 85% were women, 42% were older than 40, two-fifths identified as black or African American, about one-fifth were white Americans and all but a few of the rest were Latino/a—with a total of one-fifth who identified Spanish as their primary language. Half had completed college and another third had completed some college courses. 60% had worked in community health for at least three years and 38% had worked for their current employer for at least 3 years.

All procedures were reviewed and approved by the Institutional Review Boards at the Dana Farber/Harvard Cancer Center and the University of Massachusetts Boston. Participants in the focus groups, interviews and surveys were anonymous.

Our primary findings are presented in four sections: the importance of community health work, attitudes about current medical research, concerns about the history of medical research, knowledge about medical research and suggestions for training. Survey results are used to provide an overview of many attitudes; details are added with quotes from the interviews and focus groups.

The Importance of Community Health Work

The eleven community health workers who participated in interviews worked with diverse populations. Their clients were primarily black and Hispanic, but usually included some who were white and Asian. Six of the 11 had many clients who did not speak English. Many of their clients were elderly and most were poor, as reflected in participation in MassHealth. The interviewees were devoted to their clients:

I love my job, ... it's personal. This is something that I would like to stop, the breast cancer. I would really, really like to see that one day we can stop it. And so I'm very

passionate, and when I talk to a client, I'm like trying to put my mind in their minds, in making sure that they understand that this is something that we can prevent.

Educating community members about health and health care was a key commitment:

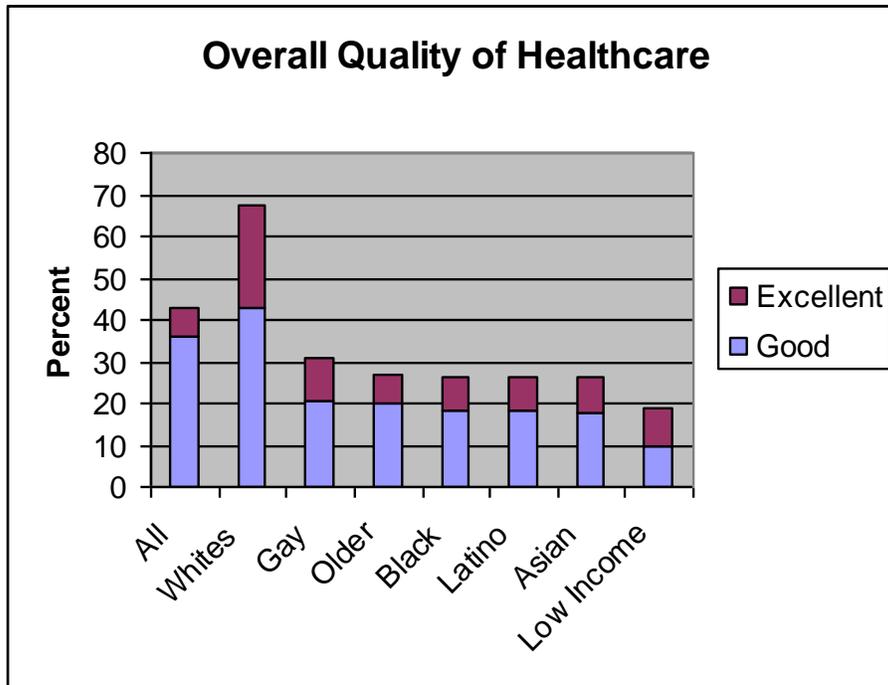
I'm sort of out there, trying to make sure that other people know more.

Many families have not even finished sixth grade, so even health itself is something that they don't know too much about.

...there are a lot of people, just the basics, they don't know. ...there were only two out of 28 women doing breast self exams. That is ridiculous. And just simple things. You know, people don't understand that they are poisoning their body by smoking cigarettes. I mean, come on?

Survey respondents perceived considerable disparities in the quality of health care in the Boston area for different ethnic or underprivileged groups. While two-thirds rated health care system performance for whites as “excellent” or “good,” only about one-quarter rated it this highly for blacks, Latinos, Asians and older persons (Figure 1). The overall quality of the local health care system for gay persons was rated slightly more positively, while it was rated as even less adequate for low income persons.

Figure 1



Some community health workers also focused attention on their role in improving communication with their communities.

I think it relates a lot to knowing the culture, coming from the culture, and the community having this certain expectation from you that you will not cross over cultural boundaries like someone who's not part of that culture.

Most of [our clients] don't speak English...sometimes they come to us and explain what they wanted or what they needed...

Other community health workers made it clear that they view the behaviors and orientations of health care recipients as contributing to inequities in health care.

It's just...let's say for some populations they don't go to get preventive care at all until they feel sick and...so we know the answer, you know, it's just trying to educate them so they can go for the preventive care.

[Clients] don't even like to take the medicine when they have a problem.

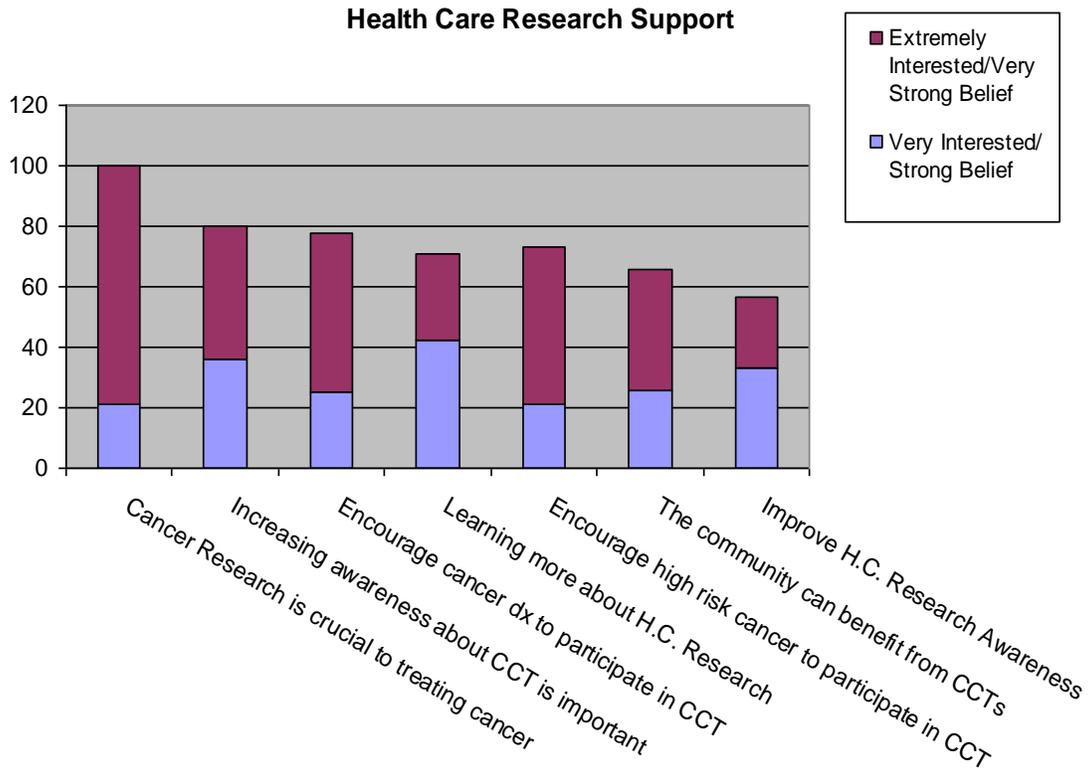
I mean, I know some of the reasons for [disparities in health] but -- public health benefits get taken away from the immigrants who are legally here. There's one reason. Then you have to access services or -- just don't access services because they can't afford to pay for it. There are some institutions that can't work with them financially or aren't willing.

Current Medical Research

Survey respondents were very aware of the importance of cancer research: all believed that cancer research is extremely or very important to finding better ways to prevent, diagnose or treat cancer and many expressed a strong interest in learning more about health care research and encouraging others to participate in cancer research (Figure 2). Specifically, between 70% and 80% rated as extremely or very important: increasing awareness about cancer clinical trials, encouraging those with a cancer diagnosis or high risk of cancer to participate in cancer clinical trials, and learning more about health care research. About 60% believed that the community can benefit from participation in cancer clinical trials and that improving awareness of health care research is very or extremely important.

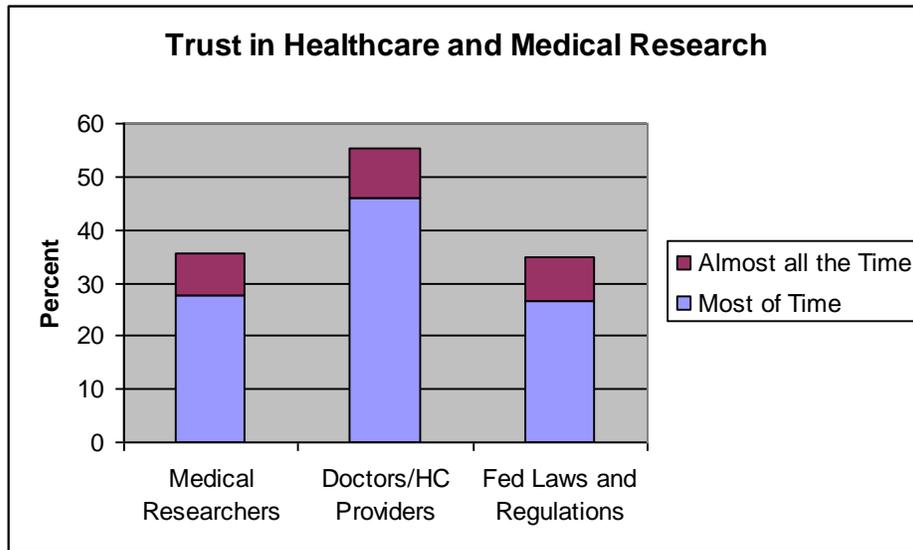
Because I really believe that in research, a lot of thought is being given to the problem, to the implementation of the planning and the implementation of it, like getting funds to do it. I think that they are very serious people, who although they might be thinking about money, like for example, specifically pharmaceuticals, but I think that they want to help people. So the benefit is more for the community.

Figure 2



In spite of this recognition of the value of cancer research, community health workers who were surveyed had less favorable attitudes toward medical researchers than toward doctors and other health care providers (Figure 3). A majority of survey respondents trusted doctors and other health care providers to protect their rights and safety” at least “most of the time,” compared to just one-third who accorded at least this much trust to medical researchers or to federal laws and regulations.

Figure 3



The interviewees reported little interest in the community in health care research. Five of the eleven interview respondents had spoken to people in the community about health care research at least three times, but only one of the interviewees reported that community members were interested in participating in health care research. Some of the community health workers expressed a strong desire to improve the level of interest.

I think this is not only for one person, this is to improve. This is when they find something, to stop a type of illness is not only going to benefit that person that is using their bodies, it's going to benefit the whole world.

A lot of patients don't have any information at all, and there's not enough work in terms of providing that information for them. There's a lot of education that needs to be done in that area, because they don't understand what research is.

They need to hear more testimony of personal experience...clinical trials are a hard sell.

The eleven community health workers who participated in interviews responded to 15 statements about health care research (Table 1). Their responses indicated that all recognized the importance of health care research but many had some level of distrust of medical researchers.

Table 1

Statement	# Agree
Health care research has led to many improvements in health care for some populations.	11
There should be more health care research occurring in minority communities.	9
Patients' rights are protected in health care research.	9
More research is needed to determine why some racial and ethnic groups have worse health than others.	9
The history of health care research in minority communities is very troubling.	8
Patients should benefit directly from participating in health care research.	8
Patients don't have enough information to decide if participating in a research study is right for them.	6
Health care researchers have no connection to community health workers like me.	5
Doctors don't know how to talk to patients about research.	5
It only makes sense to participate in health care research if you're sick.	3
Health care research benefits researchers, not the community.	2
Health care researchers are just using our bodies.	2
Patients enrolled in research studies receive better health care than other patients.	1
Most health care research is not really necessary.	1
Research funding just helps the researchers.	0

Many comments in the interviews expressed the same recognition of the value of medical research that was evident in the most commonly endorsed statements in the survey.

We need to understand that the only way for us to progress into the future is to know that what works, what doesn't work and the only way to do that is through clinical trials.

I believe that research always needs to be done. There's always something cropping up and there's always something that has not yet been addressed.

...there's just certain advances [in research] that have been able to be made. AIDS or HIV, when it first came on the scene was, for a lot of people, a death sentence. Now it's considered a chronic disease, and that's because of all the research and the funding, and the new drugs that have come out.

And they have really been making a...lot of advances with, you know, heart disease, and just cervical cancer, breast cancer. There is...significant contribution to this trial. This is like stem cell research. And I think it's exciting that we have this available for us.

Some interview respondents also focused specifically on the importance of reducing disparities in participation in medical research in order to lessen ethnic disparities in health care.

Well I know for a fact that let's say the breast cancer in Black women is more aggressive and more deadly than it is in other women. So, the research that's being done in that area is not just benefiting the researchers. It will benefit the community... I think research helps the community, and it's been more impactful in some communities than others.

It's important to figure out the variables why, you know, one racial or ethnic group is not as healthy as another, considering that overall, we have the same access to health care.

... more efforts need to be put forth. I think once you start thinking of [research] with a different population, people can get frightened of how much work it's going to be or how difficult it's going to be, and that can sometimes be discouraging and, therefore, it doesn't take place. So that's detrimental to the welfare of the diverse communities.

The majority of the studies are really based on white communities and then there are just certain ones that – there are very few that are African American, Latino, or Asian Specific...there's just minimal research, and the research that's done is just a couple of diseases like diabetes, heart disease.

Other community health workers balanced positive feelings about medical research with a degree of skepticism.

Because I have heard stories that point to telling me that patients' rights are not protected. But on the other hand, I see many advances in terms of research. So I'm kind of divided.

For the most part I think I have a very positive opinion about healthcare research because I think that there's plenty to learn and definitely we could eliminate most of this – diseases that plague us. But on the other hand, I am very skeptical about how researches are being done...Like what are the intentions behind it, what are the motives behind it, who's doing it and what – and for what reason...I don't think that most clinical trials are very inclusive.

That one I'm kind of tied between. There are some patients, like cancer patients, they go through trials and studies and if it kind of just ends there and you leave them hanging, that's wrong. So, on the other hand, just healthcare research is just taking your survey and getting some kind of – I kind of think it depends on the situation.

Success is the advantage of clinical trials, but the disadvantage is that people might be having shifty experimentation done on them for a research project's ulterior motives.

Participating in research is and isn't safe, it depends on the research.

Some accepted the value of research only in certain circumstances.

Clinical trials are only worthwhile if a new medication can do things that an old medication can't.

Especially if you have to undergo treatment or something, you can get sick rather than helping. So I, for example, if I am sick, I want to help them, but if not I think it is a risk to the person that is healthy.

They are only appropriate if something in standard care isn't functioning.

Expressions of distrust in medical researchers were sometimes quite blunt.

People don't trust that researchers will be honest, or the research isn't being done to benefit them, it is being done to benefit the researcher. That makes people not want to participate.

Sometimes I feel that this research is focused on just trying to prove something... sometimes I think that they are just using our bodies.

...the results need to come back too, and that doesn't happen...the deliverance system is bad, researchers don't bother to know the areas that they research.

...they don't trust research, that when they get to some things, they want to do it for the money that they are going to get from the medication, to be lucrative for them.

Other critical comments about medical researchers focused on medical researchers' perceived lack of concern with community needs.

Researchers don't care about what the community needs.

Health care researchers have no connection to community health workers.

I don't want to tell people to participate in research because I think that the researchers are benefiting but my community isn't.

We need to be asked what we think our communities need. It isn't right to do research that isn't needed in the community.

Researchers are ignorant and they have a lot of opinions about who they think the community is.

Interview respondents were also asked to indicate the importance of 17 possible barriers to participation by community members in health care research (Table 2). Most of these barriers were related as "very important" reasons for non-participation by at least 6 of the 11 interview respondents.

Table 2

Barrier	# Very Important
Inadequate transportation	11
Don't understand research	10
Lack of trust in researchers	9
Limited English language ability	9
Fear of participating in research	9
Immigration/Visa issues	9
Limited knowledge about health	8
Time/scheduling constraints	8
Objections of family, friends	8
Believe research doesn't help	7
Confused by consent forms	7
People don't hear about research	7
Bad experiences with doctors	6
Think their information won't be kept confidential or private	6
Doctors don't offer research to them	6
Loss of control over their health care	6
Expect inferior care	5
Other	2

Several comments explained why transportation presented problems for community members who might otherwise participate in medical research.

...a lot of people don't have transportation. You make a lot of assumptions. I mean, even though I have a car and my husband has a car and my daughter has a car, I wish they had the taxi ride program when I was doing chemo and radiation, because it was door to door. For me, it was parking your car and walking to the door, or parking your car and then getting on the bus. So even if you have transportation it's still a pain.

Transportation is a barrier, a huge barrier.

Interview and focus group respondents also explained how low levels of knowledge create a barrier to participation in research.

I don't think they understand the process and, you know, the real meaning. Like, let's say the real meaning to research... they just hear that, OK, they're using my body, and that's it...

Well, I think people just don't know enough. They don't know enough to ask – even what questions to ask.

...I think that's part of the reason why minority communities...don't participate, because they don't know about it. The other part, I think, is there's a skepticism. Some of them

are skeptical, but I think most of the time, that they don't know about it, and I think there's different reasons why they don't know about it.

It has to do with the mystification of research. I think that it's another world, and it's not linked to the regular healthcare issues. It's like oh, that's something on Mars, and we're here on Earth. So a connection is not established. When you say research, I think that most people do not link it to their health. Like I don't think OK, I will ask my doctor the next time, about if there is a research on cancer.

Interviews provided additional comments to explain problems such as fear, lack of trust, and language.

Again, I think it's because of the negative stuff that's out there, and people's preconceived notions about research or what are they going to do, and what kind of medicine am I going to be taking. Is it going to do me any good? You know, that kind of thing. I think the fear factor is a big part of it.

Well people make generalizations. They had one bad experience with a doctor or a couple of bad experiences, so anybody working in the health field was no good.

...research is like kind of separate from itself, alien to us, the providers, and to the clients too. At least that's how I perceive it.

Well the language barrier [to participation in medical research] is only part of it because it's lack of education...everyone's not at that level.

Also, the language that researchers use is ignorant. Like "African American Women" – it makes people not want to participate. I am black Latina, I am not African American, and I don't like being called African American because I am not of African descent.

Some community health workers suggested that the level of distrust could be lessened by ensuring that community members help to plan the research, receive benefits from the research, and communicate with researchers “in their own [the community members'] language.”

And after the research is completed, where do the resources go back to from your – your findings of your research. And, you know, you came in and we – we assisted in the studies that you were looking for and proving the information. But are those resources going back into that community that you just, you know, performed a study or research assistance on?

...a lot of distrust, individuals not looking like them coming in to the community trying to do research, the community not being involved in the beginning processes of research, not just when you need us – our bodies to test on. But actually being involved in planning what that research project will look like.

The History of Medical Research

Many community health workers identified the history of healthcare research as a barrier to research participation by community members. Most comments about this history referred to the infamous Tuskegee syphilis study.

Tuskegee. I don't want anybody experimenting on me and basically, they don't know enough about what's going on.

...that's one of the reasons why we have just black people in general being very wary of the government...

Just -- the population I deal with is the African-American population or people who identify as from African descent, and a lot of people have the Tuskegee experiments in the back of their mind when you say "research", they think Tuskegee. It's a lack of trust.

When you look at the African American and African community you have to look at the history of -- that medical providers have had with those communities and it's not very -- it's not positive at all. And I think that plays a huge part in not only individuals participating in research but individuals also getting care for anything.

Some of those who pointed to this problem also suggested that it could be lessened through community involvement.

The sharing of resources is an issue when you're looking at research. So I think, you know, with the African and African-American community, recognizing that there's a bad history between the medical providers and the community and seeing how -- involving this community -- involving the community can sort of lessen that.

I mean you know, people always talk about the Tuskegee thing and maybe a couple of other things, and it is troubling, but it doesn't mean you can't make it better.

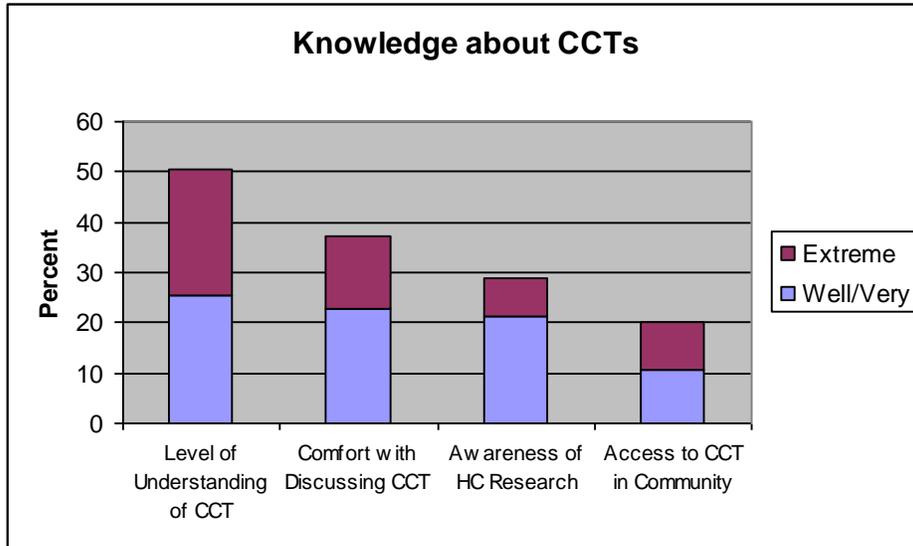
I don't need to go through the documentation of it or the history of it. But how medical so-called under the title of research has been done in Africa, and has been done here in America with black Americans. ... And not only black Americans, there's other populations. Native Americans that have undergone the same abuse and dehumanization...so looking at that and recognizing that and saying, "OK, how can we involve the community from the beginning versus bringing them in when it's time to get tested."

I mean, I think in the Black community, people are very suspicious of research studies. So you know, we have to put the past behind us and sort of start fresh and really evaluate, just like if you had a bad experience with a doctor, well that doesn't mean that all doctors are, you know, not qualified.

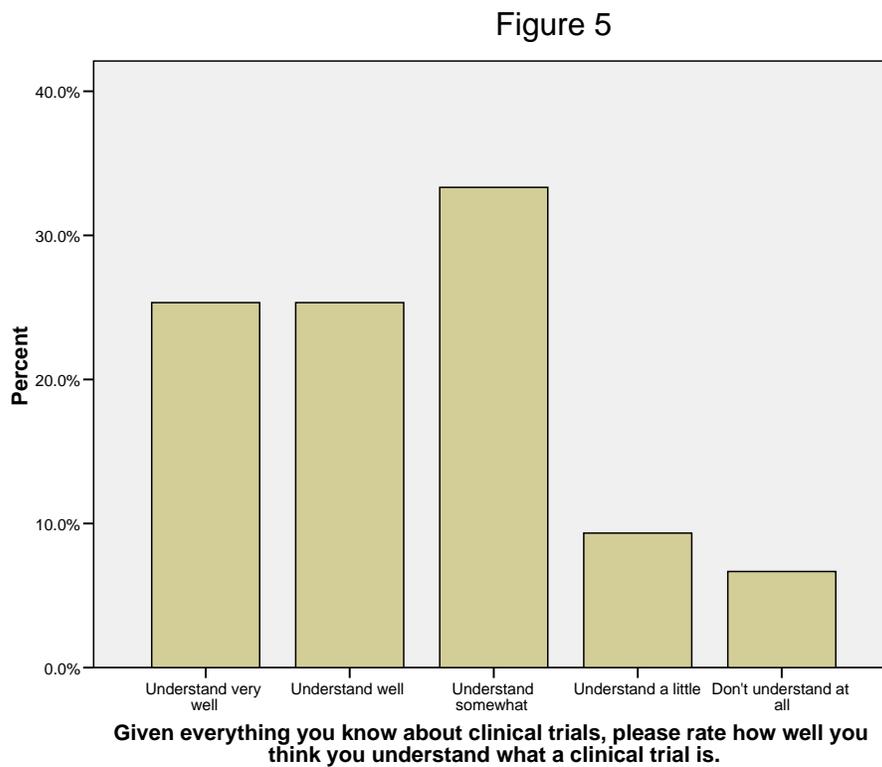
Knowledge about Medical Research

In spite of their own interest in medical research, most community health workers felt that their current level of knowledge was inadequate (Figure 4). More than half reported that they were no more than somewhat aware of medical research in their community and almost half felt that they little or no access to information about cancer clinical trials in their community (Figure 4).

Figure 4

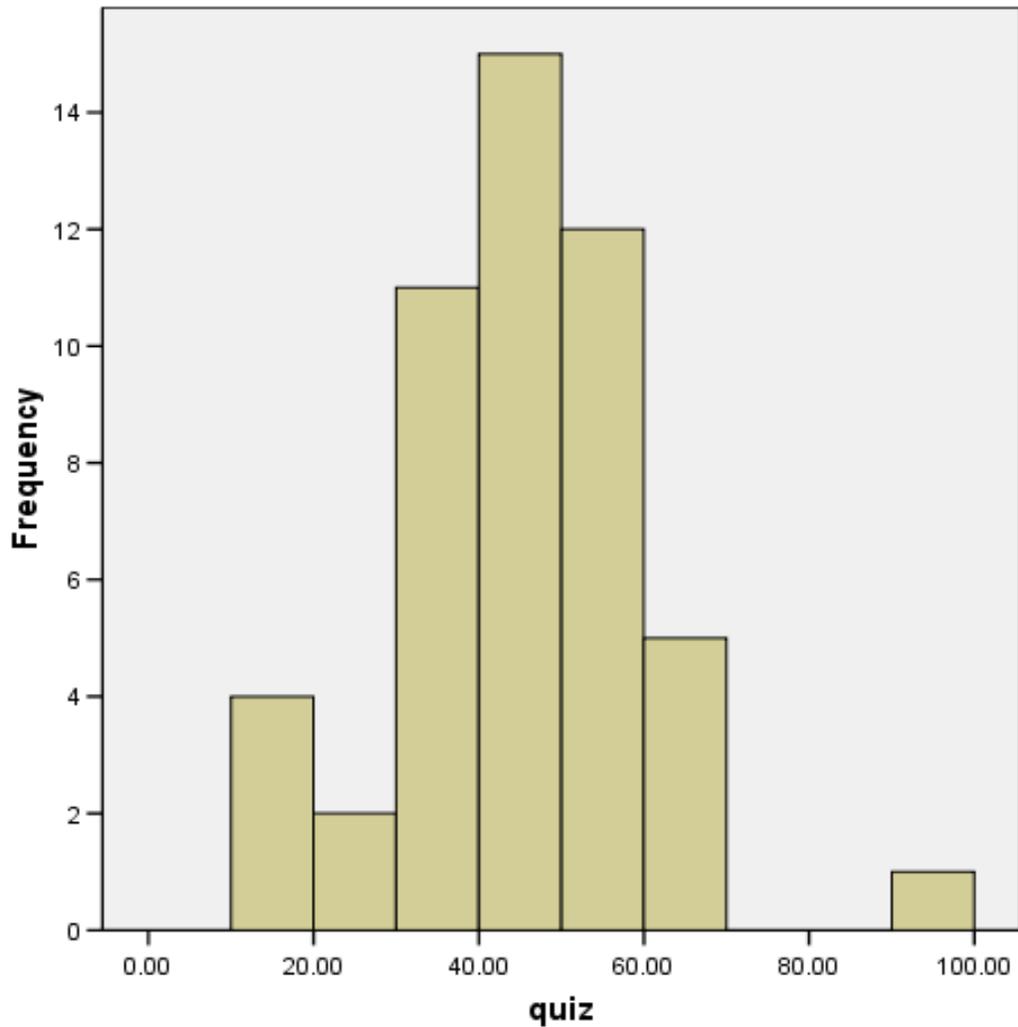


About half of the community health workers also described their level of understanding of clinical trials as only “somewhat,” “a little” or not “at all.” (Figure 5) About one-quarter felt they understood clinical trials “very well.” (Figure 5)



The average score correct on a 19-item quiz about clinical trials that was included in the community health worker survey was 50%, with many receiving even lower scores (Figure 6). Only one respondent answered more than one-third of the questions correctly.

Figure 6



Answers to questions in the interviews also reflected variable levels of understanding about clinical trials. When asked to define the term “clinical trial,” most respondents knew in a general way that this involves a test of a new treatment.

Clinical trial. Well clinical means that it's health related. It's going to be supervised by doctors. You're in good hands. And trial means that it's a test. You know, I don't think they're making any promises to you, that they can cure you. I think they can fairly well

assure you that you're not going to be any sicker than you already are, but it's a trial. It's a test to see if this particular drug or process or procedure is going to make any difference in your case.

It means trying something that hasn't fully been -- it's testing things, it's something that hasn't fully been approved yet maybe. They're still exploring the possibilities as to whether or not this is going to work. Is it going to be effective treatment? Is this going to be effective? If it's going to maybe eradicate whatever it is. So it's a time of uncertainty, unknown.

Basically it's – well for me I would say that it's something that's being tried out, to see what the benefits of it would be, in working with a particular population or with different populations.

However, many respondents also thought that clinical trials routinely involve a comparison of a new treatment with a placebo, rather than with the current standard treatment.

A trial of medication that is being tested for reliance to give it out to the general public, and while you are on that clinical trial, you can take placebos and hazardous to your health substances.

For example, if we worked for pharmaceuticals and it were a cancer patient, they would get a couple of groups going, where some get a placebo, some get the actual drugs, and they compare peoples' reactions.

For example like we do – for...breast cancer...some women might get a placebo or a Tamoxifen to reduce their cancer reoccurrence.

Some only had a general recognition that clinical trials can help to identify new treatments:

Means, hopefully, that using this type of study, we can – we can find cures for the diseases.

For me, it means the future, you know, better outcome in different diseases.

You know, sometimes I think that we use our body to try something, and sometimes that's the only way that they can find cures for cancer or any other ailment, so I think to me, it means a lot, even though I don't like to participate, but I understand that it's really important. So that's the only way that we can improve or stop cancer or any other illness.

The percentage of correct answers to the true/false statements in the knowledge quiz varied markedly between questions (Table 3). Most community health workers were aware of an informed consent requirement and of the role of clinical trials in

developing new treatments for cancer. However, at least one-third were unclear about the particular information included in consent statements, about the extent to which participants' rights are protected. Depending on the specific explanation tested, between one-third and three quarters misunderstood some aspects of the logic behind random assignment to the treatment group.

Table 3

Question	% Correct
The "Consent Form" must be signed before a patient can participate in a clinical trial	92%
Those who participate in a clinical trial are helping others with cancer	84%
People that agree to enter clinical trials have the right to withdraw from it at any time	83%
Participating in a clinical trial is a way of being involved in developing new treatments for cancer	82%
The "Consent Form" provides the Doctor's contact phone number if there are ever any problems with the clinical trial	72%
A "Consent Form" outlines the important risks and potential benefits of entering a clinical trial	68%
The random assignment of treatment ensures that the groups of patients involved in a clinical trial are as similar as possible	67%
Patients who agree to enter a clinical trial and then do not get the treatment they wanted, can usually change it	65%
If a clinical trial is about a very important clinical question, a doctor can force a patient to enter the trial	63%
A person in a clinical trial is required to complete a lot more tests or questionnaires	57%
While in a clinical trial, a patient will be informed of any new clinical information that relates to his or her cancer	57%
The treatment being tested in a clinical trial is always better	53%
Once a person is in a clinical trial he or she cannot receive other necessary treatments	51%
In a randomized clinical trial the treatment you get is decided by chance	50%
People are asked to enter clinical trials to compare the effectiveness of different treatments, or techniques of care	50%
Patients may be randomized into a clinical trial without knowing it	44%
Patients get no financial compensation for entering a clinical trial	39%
You get the best medical care when you participate in a clinical trial	38%
In a randomized clinical trial the doctor picks the best treatment to give to the patient	25%

Knowledge about Informed Consent

Explanations by interviewees about the process of eliciting informed consent revealed general awareness of the process. Some felt that this process worked well:

...research studies give enough information. They talk and talk and – what can be – what can happen wrong, what can happen right. I think they give enough information.

All information is given to the patient, basically looking out for the patient themselves, and that has been very clear within many settings and hospitals and health centers.

As a community health worker, the folks you work with, they trust you. You know, you answer their questions as best as possible and make sure they don't have anything really unanswered about the research and help put them more at ease so they could better understand the goal and the outcome and how people could benefit.

I gave the information to the patient and just let them know that this would be their decision but it's something that, going forward, they could be a part of in the future of, you know, getting better answers for the future and new drugs.

Several interviewees felt that the lack of problems they had encountered in the consent process was due to their clients simply giving their consent to research participation on the basis of trust, rather than understanding.

They will sign anything you want... many people are not well educated so that they can truly understand what's going on. They have to just trust that you have their best interests at heart. That's really what they're signing. They're telling you that they trust your best interests in their care.

Most of the people that I deal with, they really pretty much go on trust. I have them sign all sorts of forms and they could be signing their entire lives away to me (laughter) and yet they sign them because they trust what it is...the services I'm giving them and it's just that trust between me and the patient and they're trusting me and they're signing these forms and I know that they have no idea what they're signing.

Reports of problems and misunderstandings involving consent forms were more common among the community health workers who were interviewed or who participated in a focus group.

If the consent form has... too many conditions...and it has so many layers, it may be harder for some of the participants to understand... the legalese rather than down to earth as I say...If they don't understand research...they may not fully comprehend what they're getting themselves involved in, where it may be something that they are interested in.

It's a process that's not common and definitely new to them.

...you have so many papers to sign, you don't know what you're signing...if you're only a high school graduate, if you made it to high school, I mean...you go to the hospital and...you're not sure what you're signing then.

...we [CHWs] understand what informed consent is but I think the difficulty in explaining that to the community is you're signing a piece of paper, you're saying, "OK, yes," but it's something like – it's the distrust of the medical system...That's basically what it is. OK, I might say it's OK to take my organs. Or I might say it's OK for me to participate and for you shoot me with some – shoot something in my body...But like what really

happens?...What does that really mean? I think that's what we're trying to say. I mean, informed consent is what's on paper.

Half of informed consent people will not understand.

Respondents identified low literacy levels and language barriers that interfered with effective communication as special problems in the consent process.

It also has to be on the level of like the participants...For example, if you're Spanish speaking then, you know, have it in Spanish...if they're low literacy, then have it in low literacy. And this has to be meeting where they're at.

Understanding the IRB process, understanding confidentiality is very huge...that's sometimes confusing.

I feel comfortable if I knew, you know, as much information and I was comfortable and had a good understanding of it and I can articulate it back to the community that I'm serving. But if I have questions then I would be hesitant to relay that information to the community that [researchers] are trying to recruit...if I'm not fully understanding what it is that you're trying to get to the community or take from the community then I would be hesitant to pass the information on or even assist with a group.

I never talk to people directly [about cancer clinical trials]. But there are organizations that we partner with that would...mail us brochures...or flyers regarding their research and they're even calling us, letting us know exactly what it is. And I don't feel comfortable putting it on my table.

I think that we – we are, you know, we would play a good role just because we are very familiar with the community that we work with. They have trust us and we have their best concern at heart. So as long as we are provided with the right materials and we're abreast of exactly what's going on with the trial, I think that it would be o – you know, we'd do well at recruiting people if it's something that we believed in.

Several respondents highlighted the additional difficulties faced by immigrants.

If people are immigrants, they're not really 100% sure that their name and information is not going to be shared.

And especially when you're dealing with immigrants. Migration is something that's very... I mean, they move – move around.

So when you want them to stick around for six months, not saying that they're not going to be there if they have a family but you never know, you know, especially if they're undocumented. They're just going to be skipping around and just wherever they can, you know, go make money, so...

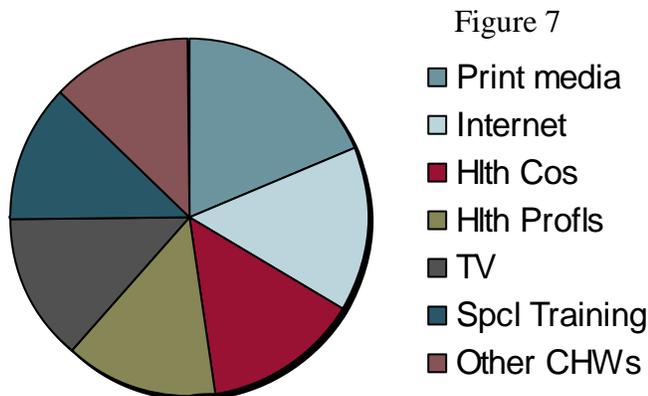
So there's questions around safety like...what are you going to do with my body. But then there's safety – there's questions around safety like the sister was saying earlier

around immigration. What does that mean? Am I going to come and sit in a focus group? OK...what's going to happen? Like do I have to sign papers and documentation? Do I have to go into a facility once a month...what type of information are you going to need from me, and then, when you get that information, where does it go?

Training Suggestions

Community health workers who participated in interviews and focus groups were eager to increase their understanding of medical research and other health issues. This interest in further training was reflected both in their frequent participation in training, in their interest in further training, and in the many suggestions they made for improving training of community members.

All of the interview and focus group participants had participated in a variety of workshops and courses, from HIV prevention to basic nutrition, to navigating the healthcare system. They had received this training through a variety of media (Figure 7).



The interview respondents described a variety of locations and methods in these training experiences.

I consider myself always a learner. So, I am constantly in workshops, training, conferences. I've taken continuing education courses at CHEC and also UMass. I have credits, and that's for me a value, to keep going.

Fairs. They [The Community Health Education Center] offer a lot of whole day conferences, workshops and you name it. It's a very intensive day in terms of health issues. And then they have a spokesperson, but it has an inspirational part too, which is very important.

My trainings usually last a day. Usually it's a day, a whole day, but it can last like two or three days. My supervisor is very in tune with that growth, professional growth.

I've had CPR training. I've had some management training. I'm taking an online class now, to become a certified tobacco cessation specialist.

Mass Law Institute, I think it was. It's in downtown Boston. They had a training on welfare advocacy, when the new welfare reform went into place. So they were training -- they did a lot of training for advocates, so that we would learn the new system

Monthly, I go to the CHEC meetings, and some of the trainings that they offer, like around substance abuse, domestic violence. The last one I went to was substance abuse.

Respondents made suggestions for training programs that ranged from regular updates and speakers to entire courses.

Just recent updates...just to keep abreast of the recent developments in Mass health and insurance laws.

...having somebody from outside the hospital coming in and speaking about for example, policy. We've found that that would be extremely helpful, you know, to save somebody from a lawyer coming in and helping as far as, you know, explaining some of the legal sort of terms, or just sort of like the legal jargon or how it applies to families and how it affects them, and how you can help them without compromising the welfare of the family...Or just having, for example, different services coming in that are available, which we may not know about. ... getting more information as far as other services that are available that we may not be aware about, sort of keeping up to date on what those might be, so that we can serve like that bridge, to help those families learn about what other services are out there. Free legal aid is also something that a lot of them are very interested in. So where can you get free legal aid.

...that they would talk about more of the actual intervention that you had yourself and, you know, you know how in some trainings they give you these scenarios that someone had like 25 years ago that don't really match up. You know, it would have been nice if some of the people had had their own scenarios, you know what I mean --to work out different situations on the personalities of people that you run into.

The only thing that's always good to have like the slides, a copy of the slides, either in paper or, you know, or by sending it to you through the e-mail...Because like that, you'll always have it there and you can back as a reference.

The only thing I would love to see is, you know, a continued refresher course because if you don't use it, you lose it, especially with languages.

...I've given them some suggestions for improvement. I think they need a glossary of terms. They've used a lot of terms that they just assume people know ...I think they should pare down the technology. I don't think it has to be that complicated. But I've

enjoyed it. I've gotten a lot out of it and I'm looking forward to it. People think I would be a good counselor.

Respondents also identified a number of content areas that should be included in training sessions.

Clinical trial jargon...Medical jargon.

...we want to know -- how -- to be -- how to interpret to them and explain to them what the benefits of their participation and what is their actual role and responsibility. How much time. Is there any kind of... I don't want to say compensation but, you know, any incentives that go –

...it would be good to see how invasive the trials could, you know, would be to the participants.

We need to be trained on what a clinical trial is.

Yeah, we need to know about the successes, the failures – the history of clinical trials. We need to know about data, databases, how to do data analysis, and the history of research. There is so much diversity.

During the interviews and focus groups we asked community health workers for suggestions concerning our planned training for community health workers about medical research. Their responses emphasized the importance they attached to improving their own knowledge as a prelude to effective training in the community.

It has to be made sure that we know all of the things going on about an issue. We need to look educated. That is so important.

Training needs to be comprehensive...It can't just be some one or two day workshop. It needs to go over everything, and they need to spend weeks and money to make sure that we have the classes and the knowledge that we need.

Clinical trials needs to have training for us, and it also needs commitment from the other end too – protocol time we need to have a copy, and the researchers need to be committed to the communities they are researching.

Our respondents suggested a range of techniques for effective training, ranging from role plays to including researchers and cancer survivors who have participated in clinical trials.

Probably do some role plays, you know, have some of the classic hecklers hanging around...and probably have people to ask them questions that are a little more technical, that maybe they can't answer, that they have to say, I've got to research that and come back to you. I've got to look into it and get back to you, because that comes up a lot, even just with regular stuff that I do, I have to tell the person, give me your name and number, and I'm going to have to look that up and get back to you.

Definitely a diversity of AV material, products. Some people are really good at learning by seeing, some people are really good at learning by doing, where you would take them out into the field, and some people, for reasons I don't know, just like books (laughter). No, it's always good to have text, I'm just kidding, but not just relying so much on the text that that's your primary tool. Definitely need visuals and hands-on for community health workers to do their work. Having them do some more independent projects too is helpful... Probably speaking you know, with professionals in the field who have done it, as well as any subjects.

As I said before, like the slides, a copy of the slides, like a nice...or, if not the slides, then printed information that has the slides in it but readable because sometimes they give it out and it's so like, black and white and small print, very tiny, that you can't even read it. Because when we have like time off, like a break, we can, you know, just use that to read and go through and study... making it convenient locations and times...

Examples and not too much written material. More, I would say definitely a video or pictures... I don't know how possible this is, but even if it's other members within their same community, other members of the same community who have participated in, almost their feeling about participating in the trial would be definitely very good for them.

The interviewees often stressed the importance of culturally sensitive training approaches and engaging community health workers as trainers.

It should include cultural barriers in it... How to talk to people when they – religion comes up, or when – that the only person that can make the decision is the male figure. How to go through that, first, to the husband, and make this other person do the research study. You know, things like that. Convince people, barriers, I think. And definitely medical terminology... interactions with the research person so we can ask questions, and pamphlets. Form groups...talk about an issue, and have the research person there answer – you know, answer these questions.

I guess you would have to be culturally sensitive to how to get your idea across to certain populations... [For example]Asian women are just not used to touching their bodies and having that breast model out there for them, you know, is quite different from, you know, Americans. That's something that shows, you know, cultural sensitivity and it's a difference and you need to expect that...

You need to think about the population, the cultural beliefs and religion beliefs and all that... health fairs in schools and churches, things like that for the community... Participating in trainings and conferences, things like that that we can learn in order to teach the community.

Training should be done by us – community health workers should help make up the training.

We need to have all of the education materials and we need to be able to bring them to our communities.

Some also emphasized the importance of training on health issues most relevant to their specific community:

Help them educate the community about healthcare research, what that training should include... Well, I think it should include maybe some relevant research that has been done that is of interest to that particular community. If you're going to be dealing with heart disease research, you know, you might want to go up to a community that has -- you know, has members of -- experiencing a lot of heart problems or heart disease, and you know, show them some research studies that have had positive results, that was done and as a result of this research being done, this is what was implemented. I think people would like to see that research has come back and had a result that was brought into their community... I think community health workers should be educated about different studies that were done, what the results of those studies were in the populations, and if they're working with those populations, to share that information with them.

Training on the things that are in the community, that are needed in the community. You know, that this community is a large community with high blood pressure and diabetes and those kinds of things would affect that community. Do you know what I mean? I mean, I'm not saying keep it in just those two things, but what's happening in that community.

Some suggestions focused on the importance of education about human subject protections and about problems in the treatment of human subjects in past research, with a particular emphasis on the Tuskegee incident.

Side effects...I think also understanding the process...that researchers have to go through in order to get a clinical trial...because I think that us, as community workers, we don't understand the IRB process. And knowing that there's supposedly this very formal, very - - supposedly, I guess, very strict process... in order for individuals to study humans. So I think as us understanding that process will sort of decrease the issue around confidentiality, around abuse, around...information.

Well, I think people have to know the history. You've got to find some good novel or good non-fiction about the Tuskegee incident and whatever else has gone on, I don't know. I think the community workers will have to know what they're up against, before they even start to try to convince someone, or a group of people, to participate in a clinical trial. And I mean, I don't know any good books. I know there was a good movie, and I don't even remember the name of it, but I remember seeing a good documentary once about it.

Conclusions

This assessment of community health workers' experiences, knowledge and concerns about cancer clinical trials and other types of health care research confirms the extent of the difficulties identified in prior research and also identifies means for lessening these difficulties. Community health workers have many concerns about cancer research, but they recognize the importance of lessening disparities in research

participation and they are eager to learn more about research so that they can provide more information to community members.

Community health workers were aware of ethical violations in the past in health care research—particularly the Tuskegee syphilis study—and tended to express less trust in medical researchers than in health care providers. They also indicated low levels of knowledge about cancer clinical trials and reported little community interest in health care research and even less community participation. However, community health workers were not satisfied with either community members' lack of trust about medical research or their own inadequate level of knowledge. Although levels of trust and knowledge varied among community health workers, all wanted to improve their understanding of clinical trials and engage more effectively about health care research in their communities.

All the community health workers we studied recognized the importance of medical research for improving health care, as well as the importance of reducing disparities in rates of participation in order to improve health care outcomes in all communities. They made many suggestions for improving trust and knowledge. First and foremost, community health workers were concerned that they be included as partners in planning and working on research projects. Although they were interested in helping to publicize clinical trials, they also stipulated that their support was contingent on believing that members of their community would receive some benefits from a clinical trial and that the researchers would inform them of the outcomes of the research.

Community health workers had learned about medical research from a variety of sources and they recommended that multiple modes be used for formal training efforts. Talks by experts, entire courses, informational booklets and videos were all suggested. Several respondents stressed the importance of cultural and community sensitivity.

Our research has identified both the potential for new training programs about cancer clinical trials targeted to community health workers and it has suggested specific content areas and methods that should be included in such programs. Further research on community health workers and cancer clinical trials should use representative samples of geographically dispersed populations. Training programs themselves should be developed by culturally sensitive educators and accompanied by rigorous evaluations of their effectiveness.

References

- Avis, N.E., Smith, K.W., Link, C.L., Hortobagyi, G.N., Rivera, E. 2006. "Factors associated with participation in breast cancer treatment clinical trials." *Journal of Clinical Oncology* 24(12): 1860-1867.
- Murthy V, Krumholz Harlan, Gross Gary. 2004. Participation in cancer clinical trials race-, sex-, and age-based disparities. *JAMA*, 291:2720-2726.
- Wright, James R., Timothy J. Whelan, Susan Schiff, Sacha Dubois, Dauna Crooks, Patricia T. Haines, Diane DeRosa, Robin S. Roberts, Amiram Gafni, Kathleen Pritchard, Mark N. Levine. 2004. "Why cancer patients enter randomized clinical trials: exploring the factors that influence their decision." *Journal of Clinical Oncology* 22(21): 4312-4318.

Appendices

Focus Group Guide

Cancer Clinical Trials Focus Group Questions Bigby, Schapira, Schutt

CHW role and work

1. First I'd like to learn about your work. Can you describe the types of things you do as a CHW?

- What things do you do most often?

CHW role as educator

2. What types of health education do you provide to the people you work with as a CHW?

- How often do you provide health education?
- Do you feel comfortable providing health education information?
- Why or why not?

Attitudes about research

3. Have you formed any opinions about health care research?

- So, what do you think about health care research?
- Do you think that participating in health care research is worthwhile?
- What do people in the community think about health care research?
- What kinds of issues about health care research have you discussed with people in the community?
- Do you feel comfortable talking about health care research? Why or why not?

Protection of participants

4. Do you think that participating in health care research is safe for the people who sign up?

- Why do you say that?
- Do you think that people are "used" in research?
- Do you think they ever benefit from taking parting in research?
- Do you talk about this with others?
- Would you say that patients' rights are protected adequately in the process of recruitment for and participation in clinical trials?

5. Have you heard about people giving "informed consent" for research?

- What does "informed consent" mean to you?
- Do you think people usually have enough information to give informed consent?

Knowledge/attitudes about clinical trials

A Clinical Trial is a research study that can answer important questions about medical care. The research can provide answers about new ways to diagnose, treat, or prevent diseases such as cancer, heart disease, and other medical problems. In a clinical trial researchers don't know if the new method will be better than the standard care that people get so the clinical trial tests the new method of care against standard care. Generally people who participate in clinical trials either get the new method of care or standard care.

6. Now, let's focus on clinical trials of health care treatments.

- Had you ever heard the term clinical trial before this focus group?
- What does it mean to you?
- What have you heard people say about clinical trials?
- Do people understand what clinical trials are and how they work?
- Do they believe clinical trials are worthwhile?

Value of clinical trials

7. Do you think there are advantages of clinical trials? Disadvantages?

- Can you say more about that?
- Do you think research like clinical trials can help people?
- Do you have any concerns about clinical trials?
- Would you ever encourage a friend to participate in a clinical trial of a new treatment?

Talking about clinical trials in the community

8. Have you ever talked to people about clinical trials of cancer treatments or other health treatments in your role as a CHW?

- Can you tell me more about that?
- What kinds of things did you discuss with people?
- How did you feel about your role in discussing clinical trials?
- How often does the issue of joining or continuing in clinical trials come up?

Educating the community about clinical trials

9. Do you think that people in the community need to better understand what clinical trials are?

- Why do you say that?
- Do you think that CHWs can play a role in educating people in the community about research and clinical trials?
- In what ways would you feel comfortable educating people about clinical trials?
- Do you think that you or other community health workers could affect peoples' decisions about participating in clinical trials? How could you do this?

10. If we design training for CHWs to help them educate the community about research and clinical trials, what should that training include?

- What would you need in order to feel comfortable providing education in the community about clinical trials?

Interview Schedule

CHW role and work

First, to get oriented, I'd like to ask a few questions about your work history.

Employment History

1. Who do you work for as a community health worker? _____
2. What is your job title at _____?
3. When did you begin this job? ____/____
Mo. Yr.
4. How many hours do you work for pay in this job in an average week? _____
5. (a) Do you work any time without pay at this job? __Yes __No
(b) How many hours in an average week? _____
6. (a) What types of jobs have you had in the past? _____
7. (a) How did you come to work here as a [CHW] _____?
(b) Can you tell me about that? _____
8. (a) What kind of training or education did you have to prepare yourself as a CHW before you started in your current position as a [CHW] _____?
(b) When did you complete that education? _____
9. Was there anything else that helped to prepare you to work as a [CHW] _____?
10. Have you had any training since you started to work here as a [CHW] _____?
 - a. Can you tell me about that training? _____
 - b. What did it involve? _____
 - c. Who was there? _____
 - d. What media were used? _____
 - e. How long did it last? _____
 - f. Was it helpful? _____
 - g. How satisfied were with you were the training? _____
 - h. Can you think of any changes that would have improved that training? _____

Work activities

11. Now I'd like to learn about your work here.

(a) Can you describe the types of things you do as a [CHW]_____?

(b) What things do you do most often?

12. How often do you engage in each of the following activities in your job as a [CHW]_____?

<i>Activities as a CHW</i> <i>How often do you engage in...</i>	<i>Never</i>	<i>Less often than once/week</i>	<i>1-4 times a week</i>	<i>About daily</i>	<i>More often</i>	<i>Can you give an example?</i>
A. Recruiting clients	1	2	3	4	5	
B. Locating clients	1	2	3	4	5	
C. Assessing client needs	1	2	3	4	5	
D. Educating clients*	1	2	3	4	5	
E. Planning services	1	2	3	4	5	
F. Coordinating services	1	2	3	4	5	
G. Monitoring progress	1	2	3	4	5	
H. Advocating for clients	1	2	3	4	5	
I. Referring clients to services	1	2	3	4	5	
J. Seeking advice about clients	1	2	3	4	5	
K. Documenting services you provide	1	2	3	4	5	
L. Developing new services	1	2	3	4	5	
M. Evaluating services provided	1	2	3	4	5	
N. Meeting with staff	1	2	3	4	5	
O. Supervising staff	1	2	3	4	5	
P. Work-related training	1	2	3	4	5	
Q. Other (specify)	1	2	3	4	5	

**If provide any education (D)...*

13. You said that you educate clients.

(a) What types of health education do you provide? ___

(b) Do you feel comfortable providing health education information?

(c) Why or why not?

Health care research

Now I'd like to focus on health care research.

14. People can learn about health care research in different ways. Can you tell me how much you have learned about health care research from each of the following sources?

<i>Sources of Information: How much have you learned about Health Care Research from...</i>	<i>Not at all</i>	<i>A little</i>	<i>Moderate</i>	<i>Very</i>	<i>How much do you trust the information from ____(this source)?</i>
A. Television	1	2	3	4	
B. Newspaper, magazine or other print material	1	2	3	4	
C. Web, internet sources	1	2	3	4	
D. Participating in health care research	1	2	3	4	
E. Special training about health care research	1	2	3	4	
F. Talking with health care professionals or researchers	1	2	3	4	
G. Talking with other CHWs	1	2	3	4	
H. Talking with community members	1	2	3	4	
I. Talking with family and/or friends	1	2	3	4	
J. Courses in school	1	2	3	4	
K. Information from drug companies or health care organizations	1	2	3	4	
L. Other: _____	1	2	3	4	

15. I'd like to read some different statements that people have made about health care research. After each statement, I'd like you to tell me whether **you** agree or disagree with the statement. Then I'd like you to tell me why you feel that way.

<i>Opinions about health care research</i>	<i>Disagree</i>	<i>Agree</i>	<i>Don't Know</i>	<i>Why do you feel this way...</i>
<i>Do you agree or disagree that...</i>				
A. Health care research benefits researchers, not the community.	1	2	8	
B. Research funding just helps the researchers.	1	2	8	
C. Health care research has led to many improvements in health care for some populations.	1	2	8	
D. There should be more health care research occurring in minority communities.	1	2	8	
E. Health care researchers are just using our bodies.	1	2	8	
F. Patients' rights are protected in health care research.	1	2	8	
G. Patients enrolled in research studies receive better health care than other patients.	1	2	8	
H. The history of health care research in minority communities is very troubling.	1	2	8	
I. It only makes sense to participate in health care research if you're sick.	1	2	8	
J. Much health care research is not really necessary.	1	2	8	
K. Patients should benefit directly from participating in health care research.	1	2	8	
L. Patients don't have enough information to decide if participating in a research study is right for them.	1	2	8	
M. Health care researchers have no connection to community health workers like me.	1	2	8	
N. Doctors don't know how to talk to patients about research.	1	2	8	
O. More research is needed to determine why some racial and ethnic groups have worse health than others.	1	2	8	

People you work with

Now I'd like to focus on the clients you work with as a community health worker.

16. What kinds of clients do you work with in the community? Of all the clients you work with in an average month ...

- | | None | Some | Many |
|---|--------|--------|------|
| (a) About how many do you contact about a specific health risk? | 1..... | 2..... | 3 |
| (b) About how many currently receive health care treatment?..... | 1..... | 2..... | 3 |
| (c) About how many have internet access at home or work? | 1..... | 2..... | 3 |
| (d) About how many are African American/black American?..... | 1..... | 2..... | 3 |
| (e) About how many are Haitian or Caribbean or African?..... | 1..... | 2..... | 3 |
| (f) About how many are Hispanic or Latino? | 1..... | 2..... | 3 |
| (g) About how many are Asian? | 1..... | 2..... | 3 |
| (h) About how many are White?..... | 1..... | 2..... | 3 |
| (i) About how many are American Indian? | 1..... | 2..... | 3 |
| (j) About how many are Native Hawaiian or Pacific Islander? | 1..... | 2..... | 3 |
| (k) About how many do not speak English? | 1..... | 2..... | 3 |
| (l) About how many are bilingual? | 1..... | 2..... | 3 |
| (k) About how many are women?..... | 1..... | 2..... | 3 |
| (l) About how many are under 18 years old?..... | 1..... | 2..... | 3 |
| (m) About how many are 65 or older?..... | 1..... | 2..... | 3 |
| (n) About how many are on Mass Health? | 1..... | 2..... | 3 |

17. How often have you talked to people in the community about health care research in your job as a community health worker?

- Never
- A few times (1-2)
- More than a few times (3-5)
- A lot (more than 5)

18. In your experience, how interested are people from the community you serve in participating in health care research?

- Very interested
- Somewhat interested
- Not very interested
- Not interested at all

19. What kinds of things have you heard people say about participating in health care research?

20. In your estimation, how important is each of the following possible barriers to participation in health care research in your community?

<i>Importance of possible barriers to participation in health care research. How important is...</i>	<i>Not important</i>	<i>Somewhat important</i>	<i>Very important</i>	<i>Why do you think so?</i>
A. Inadequate transportation	1	2	3	
B. Lack of trust in researchers	1	2	3	
C. Limited English language ability	1	2	3	
D. Believe research doesn't help.	1	2	3	
E. Limited knowledge about health	1	2	3	
F. Fear of participating in research	1	2	3	
G. Time/ scheduling constraints	1	2	3	
H. Immigration/visa concerns	1	2	3	
I. Bad experiences with doctors	1	2	3	
J. Confused by consent forms	1	2	3	
K. Expect inferior care.	1	2	3	
L. Don't understand research.	1	2	3	
M. Think their information won't be kept confidential or private.	1	2	3	
N. Doctors don't offer research to them.	1	2	3	
O. People don't hear about research.	1	2	3	
P. Loss of control over their health care.	1	2	3	
Q. Objections of family, friends	1	2	3	
R. Other: _____	1	2	3	

Knowledge/attitudes about clinical trials

A clinical trial is one type of health care research.

21. (a) Have you ever talked to people about clinical trials of cancer treatments or other health treatments in your role as a CHW?
- (b) Can you tell me more about that?
- (c) How did you feel about your role in discussing clinical trials?
- (d) How often does the issue of joining or continuing in clinical trials come up?
- (e) What does the term “clinical trial” mean to you?

In a clinical trial, researchers don’t know if a new method will be better than the standard care that people get--the clinical trial tests the new method of care against standard care. Generally people who participate in clinical trials either get the new method of care or standard care.

22. One part of a clinical trial is asking patients whether they agree to participate .

Have you heard about patients being asked to participate in a clinical trial? What have you heard?

23. When patients are asked to participate in a clinical trial, they are asked if they give their “informed consent.” When this happens, the research describes the research study. If the patient agrees to participate, the researcher asks the patient to sign an “informed consent” form.

Do you think the community members you work with are capable of giving “informed consent” to participate in a clinical trial?

24. In some clinical trials, a new treatment is compared to usual treatment. Patients who agree to participate in a clinical trial like this may be given either the new treatment or the usual treatment. The decision about which treatment patients receive is decided on the basis of chance—by the flip of a coin for example. This is so that the patients who receive the new treatment are very similar to the patients who receive the usual treatment?

How do you think the community members you work with would feel about receiving a new treatment rather than usual treatment on the basis of chance?

25. Some clinical trials result in better treatment, because the new treatment proves to be more effective than the usual treatment.

How do you think the community members you work with would feel about participating in a clinical trial that might result in better treatment options in the community?

26. Some clinical trails do not result in better treatment. How do you think the community members you would with would feel about participating in a clinical trial if it might not result in better treatment options in the community?
27. Would you ever encourage a friend to participate in a clinical trial of a new treatment? Why do you say that?

Educating the community about clinical trials

28. (a) Do you believe that people in the community need to better understand health care research?
- (b) Why do you say that?
- (c) Do you think that community health workers like yourself should help to educate people in the community about health care research?
- (d) How would you feel about providing education about health care research?
- (e) Do you think that you or other community health workers could affect peoples' decisions about participating in health care research?
- (f) How could you do this?
29. We expect to design training for community health workers to help them educate the community about health care research. Do you have any suggestions for what that training should include?
30. What kinds of approaches [or methods] do you think would be effective to train CHWs to educate communities about clinical trials and research?
31. Have you heard of Lance Armstrong or other celebrities who survived cancer? What did you think of their story? Do you know anyone with cancer who has been inspired by a story like that?
32. What could we do to help you feel comfortable about educating the community about health care research?
33. Do you have any other comments about health care research or training community members about health care research?

III. Personal Background

These last questions are about your background.

34. What is the highest level of education you have completed at this time?
- High School Diploma1
 - Hospital Diploma.....2
 - Associate Degree3
 - Bachelor's Degree.....4 -----→ What was your major? _____
 - Some Graduate Work.....5 -----→ What was your field? _____
 - Graduate Degree6 -----→ What was your field? _____
 - Other7 -----→ Specify: _____

35. What was the year in which you received your last degree? _____

36. What is your primary language? _____

A. Are you able to communicate in any other language?

Yes.....1

No.....2 If so, which language(s)? _____

37. How old are you?

- Under 20.....1
- 20-292
- 30-393
- 40-494
- 50-595
- 60 or older6

38. How do you describe your racial or ethnic background (multiple responses permitted)?

- Asian, Pacific Islander1
- Black2
- Hispanic3
- Native American4
- White.....5
- Other _____6

39. In what town or neighborhood do you currently live? _____

Thank you for your time and interest.

Survey Questionnaire

First, I'd like to learn about your level of interest in medical research in the community.

1. I am aware of different types of medical research in my community.

Extremely aware 1
Very aware 2
Quite a bit aware 3
Somewhat aware 4
A little or not aware 5

2. I am interested in learning more about medical research available to my community.

Extremely interested 1
Very interested 2
Quite a bit interested 3
Somewhat interested 4
A little or not interested 5

3. I am interested in helping to increase awareness about medical research among those I work with.

Extremely interested 1
Very interested 2
Quite a bit interested 3
Somewhat interested 4
A little or not interested 5

Now, let's focus specifically on cancer research.

4. I believe that cancer research is important in finding better ways to prevent, diagnose or treat cancer.

Extremely important 1
Very important 2
Quite a bit important 3
Somewhat important 4
A little or not important 5

5. If someone I loved learned they were *at high risk* for developing cancer, I'd encourage him/her to participate in research ("studies") about cancer treatments.

Extremely encourage 1
Encourage very much 2
Encourage quite a bit 3
Encourage somewhat 4
Encourage a little or not at all 5

6. If someone I loved were *diagnosed* with cancer, I'd encourage him/her to participate in research ("studies") about cancer treatments.

Extremely encourage 1
Encourage very much 2
Encourage quite a bit 3
Encourage somewhat 4
Encourage a little or not at all 5

*This next set of statements focuses on one type of medical research: **cancer clinical trials**. In a clinical trial, researchers don't know if a new method will be better than the standard treatment that people get – the clinical trials test the new method of treatment against standard treatment. Generally, people who participate in clinical trials either get the new method of treatment or standard treatment.*

7. I have ready access to information describing cancer clinical trials in my community.

- Extremely ready access 1
- Very ready access.....2
- Quite a bit ready3
- Somewhat ready access4
- A little or no ready access5

8. I feel comfortable discussing cancer clinical trials with people I have worked with in my community.

- Extremely comfortable 1
- Very comfortable2
- Quite a bit comfortable3
- Somewhat comfortable4
- A little or not comfortable5

9. I believe that increasing awareness about cancer clinical trials is important.

- Extremely important 1
- Very important.....2
- Quite a bit important.....3
- Somewhat important4
- A little or not important5

10. When people like me participate in cancer clinical trials, the community can benefit.

- Extremely benefit 1
- Very benefit2
- Quite a bit benefit3
- Somewhat benefit4
- A little or no benefit5

11. Given everything you know about clinical trials, please rate how well you think you understand what a clinical trial is.

- Understand very well..... 1
- Understand well2
- Understand somewhat3
- Understand a little4
- Don't understand at all5

This next section focuses on health care and medical research in Boston.

12. Now thinking about health care in general, how would you rate the overall quality of the health care system in this area for:

Excellent Good Average Poor Failing

(Please circle one number on each line)

- a. All people in general? 1 2 3 4 5
- b. Blacks? 1 2 3 4 5
- c. Latinos? 1 2 3 4 5
- d. Whites? 1 2 3 4 5
- e. Asians? 1 2 3 4 5
- f. Older persons? 1 2 3 4 5
- g. Low-income groups? 1 2 3 4 5
- h. Gays/lesbians/Trans/Bi people? 1 2 3 4 5

13. In general, how much of the time do you think you can trust **medical researchers** in this area not to expose you or your family to unnecessary risks?

- Almost all of the time 1
- Most of the time 2
- Some of the time 3
- Almost none of the time 4

14. In general, how much of the time do you think you can trust **doctors and other health care providers** in this area not to expose you or your family to unnecessary risks?

- Almost all of the time 1
- Most of the time 2
- Some of the time 3
- Almost none of the time 4

15. How much of the time do you think you can trust **Federal laws and regulations** to protect the rights of individuals who are involved in medical research?

- Almost all of the time 1
- Most of the time 2
- Some of the time 3
- Almost none of the time 4

16. After they have all the information they need about their illness and possible treatments, some patients prefer to leave decisions about their treatment up to their doctor, while others prefer to participate in these decisions. In general, *when thinking about your health care*, please indicate the statement that best describes what you believe would be ideal: (CIRCLE ONLY ONE)

- The doctor should make the decisions. 1
- The doctor should make the decisions but strongly consider my opinion. 2
- The doctor and I should make the decisions together on an equal basis..... 3
- I should make the decisions, but strongly consider the doctor's opinion. 4
- I should make the decisions..... 5

17. *The next statements are about cancer clinical trials. I'd like you to tell me whether in your opinion each statement is true or false.*

- | | | | |
|--|------|-------|--------|
| (a) In a randomized clinical trial the doctor picks the best treatment to give the patient..... | True | False | Unsure |
| (b) A "Consent Form" outlines the important risks and potential benefits of entering a clinical trial. | True | False | Unsure |
| (c) Patients may be randomized into a clinical trial without knowing it. | True | False | Unsure |
| (d) People that agree to enter clinical trials have the right to withdraw from it at any time. | True | False | Unsure |
| (e) You get the best medical care when you participate in a clinical trial..... | True | False | Unsure |
| (f) The "Consent Form" must be signed before a patient can participate in a clinical trial. | True | False | Unsure |
| (g) Once a person is in a clinical trial he or she cannot receive other necessary treatments..... | True | False | Unsure |
| (h) A person in a clinical trial is required to complete a lot more tests or questionnaires. | True | False | Unsure |
| (i) The treatment being tested in a clinical trial is always better. | True | False | Unsure |
| (j) While in a clinical trial, a patient will be informed of any new clinical information that relates to his or her cancer. | True | False | Unsure |
| (k) In a randomized clinical trial the treatment you get is decided by chance. | True | False | Unsure |
| (l) The random assignment of treatment ensures that the groups of patients involved in a clinical trial are as similar as possible. | True | False | Unsure |
| (m) People are asked to enter clinical trials to compare the effectiveness of different treatments, or techniques of care. | True | False | Unsure |
| (n) Patients who agree to enter a clinical trial and then do not get the treatment they wanted, can usually change it..... | True | False | Unsure |
| (o) If a clinical trial is about a very important clinical question, a doctor can force a patient to enter the trial. | True | False | Unsure |
| (p) Patients get no financial compensation for entering a clinical trial..... | True | False | Unsure |
| (q) The "Consent Form" provides the doctor's contact phone number if there are ever any problems with the clinical trial..... | True | False | Unsure |
| (r) Those who participate in a clinical trial are helping others with cancer..... | True | False | Unsure |
| (s) Participating in a clinical trial is a way of being involved in developing new treatments for cancer..... | True | False | Unsure |

.....

I'd like to conclude with some questions about your work experiences and personal background.

18. What is your job title(s)? (Circle all that apply.)

- Community Health Worker A
- Outreach Educator B
- Health Advisor C
- Health Educator D
- Patient Navigator E
- Health Advocate F
- Outreach Worker G
- Peer Health Provider H
- Promotor/Promotora I
- Other: _____ O

19. How long have you worked as a Community Health Worker (Health Advocate, Outreach Educator, etc.)?

- Less than 1 year A
- 1 – 2 years B
- 3 – 5 years C
- More than 5 years D

20. How long have you been in your **current** job?

- Less than 1 year A
- 1 – 2 years B
- 3 – 5 years C
- More than 5 years D

21. How many **different** “Community Health Worker” jobs have you had? _____

22. On average, how many hours do you work each **WEEK** as a “Community Health Worker”?

- Less than 5 hours A
- 5 – 10 hours B
- 11 – 15 hours C
- 16 – 20 hours D
- 21 – 25 hours E
- 26 – 30 hours F
- 31 – 35 hours G
- 36 – 40 hours H
- More than 40 hours I

23. What activities do you **currently** do as a Community Health Worker? (*circle all that apply*)

- | | |
|--------------------------------------|--------------------------------------|
| A. health education/information | N. assessment |
| B. make referrals | O. case management |
| C. follow up to referrals | P. counseling |
| D. home visits | Q. health screenings |
| E. support groups | R. office work |
| F. case finding/recruitment | S. translation/interpretation |
| G. clinical services | T. provide transportation to clients |
| H. teach classes | U. community organizing |
| I. health fairs | V. fundraising/grant writing |
| J. collaborating with other agencies | W. other, specify: _____ |
| K. peer education/mentoring | X. other, specify: _____ |
- L. presentations in schools, community centers, etc.
- M. health plan enrollment (MassHealth, CMSP, insurance, etc.)

24. On average, how many clients do you serve in any given month? _____

25. What is the ethnicity of up to three of the groups of people you **most often** work with? (**circle up to 3**)

- | | |
|-----------------------------------|--------------------------|
| A. African | L. Portuguese |
| B. African American | M. East European/Russian |
| C. White American | N. Other European |
| D. Haitian | O. Middle Eastern |
| E. Brazilian | P. Laotian |
| F. South American (not Brazil) | Q. Asian Indian |
| G. Cape Verdean | R. Pakistani |
| H. Dominican | S. Chinese |
| I. Caribbean Islander/West Indian | T. Vietnamese |
| J. Mexican or Central American | U. Cambodian |
| K. Puerto Rican | V. Other, specify: _____ |

26. What is the race of those people (from question 24 above)? (circle all that apply)

- America Indian/Alaskan Native..... A
- Asian B
- Black or African American C
- Native Hawaiian or other Pacific Islander..... D
- White..... E
- Other F

27. Which population(s) of people do you **most often** work with? (circle up to 3)

- Men A
- Elderly B
- Minorities C
- Women D
- Pregnant Women/New Parents E
- Gay/Lesbian/Bisexual F
- Adolescents G
- Families H
- Other: _____ O

28. What age group do you **most often** work with? (circle up to 3)

- Under 20 A
- 20 – 25 B
- 26 – 30 C
- 31 – 35 D
- 36 – 40 E
- 41 – 45 F
- 46 – 50 G
- 51 – 55 H
- 56 – 60 I
- Over 60 J

29. Where do you do **most** of your work? (circle one)

- Individual Homes, Apartments A
- Group/Transitional Homes B
- Community Centers C
- Work Sites D
- Shelters E
- Clinics/Hospitals F
- Schools G
- Religious Centers H
- Street I
- Other: _____ J

30. What kind of training did you receive **when you began your current job**? (circle all that apply)

- I received no training when I began my job A
- Health Issues (AIDS, Cancer, Domestic Violence, etc.) B
- Techniques for Health Education C
- Counseling/Mentoring Techniques D
- Making Referrals E
- Cultural Competency/Health Issues F
- First Aid/CPR G
- Safety H
- Leadership Training I
- Management/Organizing Skills J
- Fundraising/Grant Writing K
- Other: _____ L

31. What ethnicity do you consider yourself? (please circle only one)

- | | |
|-----------------------------------|--------------------------|
| A. African | L. Portuguese |
| B. African American | M. East European/Russian |
| C. White American | N. Other European |
| D. Haitian | O. Middle Eastern |
| E. Brazilian | P. Laotian |
| F. South American (not Brazil) | Q. Asian Indian |
| G. Cape Verdean | R. Pakistani |
| H. Dominican | S. Chinese |
| I. Caribbean Islander/West Indian | T. Vietnamese |
| J. Mexican or Central American | U. Cambodian |
| K. Puerto Rican | V. Other, specify: _____ |

32. What is your race? (circle all that apply)

- | | |
|--|---|
| America Indian/Alaskan Native..... | A |
| Asian..... | B |
| Black or African American..... | C |
| Native Hawaiian or other Pacific Islander..... | D |
| White..... | E |
| Other _____..... | F |

33. What is your primary language? _____

Are you able to communicate in any other language?

Yes..... 1 -----→ If so, which language(s)?

.....

No 2

34. How old are you?

- | | |
|---------------|---|
| Under 20..... | A |
| 20 – 25..... | B |
| 26 – 30..... | C |
| 31 – 35..... | D |
| 36 – 40..... | E |
| 41 – 45..... | F |
| 46 – 50..... | G |
| 51 – 55..... | H |
| 56 – 60..... | I |
| Over 60..... | J |

35. What sex are you?

- | | |
|-------------|---|
| Male..... | A |
| Female..... | B |

36. What is the last level of school you attended?

- No formal education A
- Grammar school (up to 8th grade) B
- Some high school C
- High school degree/GED D
- Some college/university E
- College/university degree F
- Vocational school G

37. Are you an RN, LICSW, or other certified professional?

- Yes 1 (Please specify _____)
- No 2

38. Have you ever been diagnosed with cancer?

- Yes 1
- No 2
- Don't Know/Not Sure 3

39. Have you ever been a participant in a cancer clinical trial?

- Yes 1
- No 2
- Don't Know/Not Sure 3

40. Have you ever been a participant in a clinical trial other than one related to cancer?

- Yes 1
- No 2
- Don't Know/Not Sure 3

41. How many close relatives and friends of yours have been treated for cancer?

- None 0
- One 1
- 2-3 2
- More than 3 3
- Don't Know/Not Sure 4

42. How many close relatives and friends of yours have died from cancer?

- None 0 → SKIP THE LAST QUESTION
- One 1
- 2-3 2
- More than 3 3
- Don't Know/Not Sure 4 → SKIP THE LAST QUESTION

43. How often are/were you involved in their care?

- Daily 1
- Weekly 2
- Monthly 3
- Rarely 4
- Never 5
- Don't Know/Not Sure 6

Thank you for taking the time to complete this survey.