

Invited Commentaries:

Involving Communities as Partners in Cancer Clinical Trials

Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy is a 3-part conference series designed to explore the potential of employing community-based participatory research (CBPR) principles in therapeutic cancer clinical trials and to define an agenda for research, practice and policy.

Convened by the Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH), with core funding from the Agency for Healthcare Research and Quality and the National Cancer Institute, the conference series will a) explore the potential links between incorporating CBPR principles into therapeutic cancer clinical trials and b) define an agenda for research, practice and policy for this field. The priorities developed through this conference series have enormous potential impact to change the way in which cancer clinical research is conducted at the local level and how it is funded.

A background paper, *Involving Communities as Partners in Cancer Clinical Trials*, co-authored by Margo Michaels and Sarena D. Seifer, lays out a vision for applying CBPR approaches to cancer clinical trial research and makes recommendations for implementing that vision. Respected representatives of key stakeholder groups were invited to write commentaries on the paper, to enrich discussion at the first conference. This document is a compilation of these commentaries.

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Inclusion of communities of color is an ethical and equitable means of conducting therapeutic clinical trials in the 21st century and beyond. This is particularly true for members of the African American community, who are dying from cancer at alarming rates. Inclusion of minorities in cancer clinical trials is not only a means of exploring better prevention, detection and treatment options, it is a matter of social justice.

Every newly diagnosed cancer patient deserves access to clinical trials. However, African Americans and other minorities are seldom approached and/or recruited successfully for participation in traditional research trials.

CBPR is not a new concept to practitioners in the scientific arena, yet it has not been fully embraced by traditional clinical researchers. As a result, traditional ways of conducting therapeutic trials have not provided solid answers to research questions that may explain the cancer related disparities people of color face on a daily basis.

In order to decrease the disparities associated with cancer and advance the science of cancer research to the next level, there has to be a change in the way clinical research is conducted.

More minorities have to be successfully recruited and retained in research trials, and that requires a working relationship between researchers and the community. Michaels and Seifer did an exceptional job of explaining the meaning of community, the role of CBPR and its principles, as well as the challenges and barriers that may impact the minority community's ability to participate in therapeutic cancer clinical trials.

After reviewing the background paper, I concluded that overall, the community based therapeutic model was feasible and realistically achievable, but there is a lot of work that needs to be done. This work would require open mindedness and the cooperation of researchers, the community and all other stakeholders involved in the process.

It is my hope that the upcoming conference will provide a platform for Federal funding agencies, researchers and community representatives to have a rich dialogue and sharing of experiences, as we work together to implement a change in the way minorities are represented in clinical research.

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The Wellness Community of Greater Boston is a non-profit agency providing support, education and stress management services, free of charge, to adults with cancer and their families. Through a partnership with Beth Israel Deaconess Medical Center and Dimock Community Health Center, we provide these services to the communities of Roxbury, Dorchester and Mattapan, Massachusetts, which have large pockets of underserved African-American people.

It is with great excitement and hope that I read this paper and anticipate the work of ENACCT and CCPH in forwarding the partnership of communities in clinical trial design and implementation. Through our work in the city of Boston, we have become well aware of the injustices, both real and perceived, in the delivery of quality medical care to a range of populations within a city rich with medical resources and teeming with clinical trials. This work has the potential to make a significant impact on the health status of many individuals and families.

The model is comprehensive in its design. Care has been taken to address each step of the clinical trials paradigm and consider where community participation could be integrated. Of particular significance is the attention paid to gaining input on the actual needs as perceived from within the community, considering quality of life issues in the design of studies, making all materials accessible to people with a range of reading levels, and promoting continued participation of the community representatives throughout the entire clinical trial process. The attention to the language of trials is also an important contribution of this approach. To identify people who engage in clinical trials as “partners” or “participants” rather than “patients” or “subjects” can go a long way toward making people feel they are respected and valued.

Of note in the paper is the recognition of the misconceptions that often get in the way of involving diverse communities in a range of medical and research activities. Assumptions about mistrust, while having a historical context and arguably a consideration, have too often been held up as reasons for the lack of involvement of participants of color in research protocols. Little consideration has been given to the power of education, the healing process of time, and innumerable ways to overcome that legacy. Not making the effort required to procure the involvement of participants of color perpetuates historical inequities, leaving us in a cycle of medical discrimination.

When The Wellness Community set out to provide support programs for people of color in the Boston area, we were told not to bother, that the community was not interested; that they found support in their families and the church and did not want support groups. The truth is far from that prediction – underserved people of color with cancer find as much support, hope and friendship in groups as do white, middle class people. The problem was that nobody had taken the time to involve them in the design of such programs.

There are barriers to the implementation of the model, all of which will take a great deal of work to overcome. Chief among them is the identification of the “right” representatives of any given

community. Historically, when such “representation” was engaged, it was achieved through the involvement of more educated members of the community, who had become comfortable in the mainstream world of academia and medicine. Their color or heritage alone was considered sufficient to make them a credible representative of the community. While involvement of such people continues to be critical, the reality is that involvement of people living within the community, faced daily with the realities and challenges of life on the margins of our society, is the only way to truly get a pulse for the needs and the means of entry into the community.

Identifying leaders from within the community is one way to reach others in the community. Through clergy, neighborhood leaders, and grass roots advocates, others can be accessed and engaged. The trust placed in community leaders is significant for all populations, and it is essential for those looking to encourage people to become involved with any aspect of clinical trials to work with those leaders. What is even more critical is to go beyond those chosen representatives to find people who have the potential to be representatives of their communities and to get them involved. Only the leaders on the inside can help to identify those potential partners. In addition, such leaders can begin to educate researchers about the diversity within any given community, so that sweeping assumptions about the community are not made that could then misguide research.

The time necessary to succeed in this effort is an important consideration. There is no quick fix – it takes time and patience to gain the trust and involvement of communities that have felt marginalized. It is imperative that a careful time line is in place that reflects the reality of this and of the necessary training to create committed partners who feel that the effort is one that will sustain itself, and not be abandoned like so many other initiatives that are brought into communities with great promise and hope and are then withdrawn for lack of funding or commitment to what the process will involve and how much time it will take.

The Wellness Community of Greater Boston can be an effective partner in this process and can benefit greatly from it. Having identified access points into the communities of color and collaborated with representatives of people with cancer in those communities, we have an audience and partners who will be interested in participating in this effort. We also can be a portal to those communities, through educational programs that we can offer to participants in our programs that can inform them of both how they can gain access to clinical trials and how they can be part of the process of increasing access for their communities. We see this project as something we would and could benefit from, both in our programming and in helping our participants to gain access to better medical care.

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This CBPR model would be ideal for implementation of cancer clinical trials. The feasibility of this model will depend on bringing in the many stakeholders who could benefit from this new concept, and convincing them to change existing models of clinical trials.

Community representation in trial design is a key component of the model. There must be training for all community members who participate in this new model, as well as systems for identifying those community members who can most enhance trial implementation, from the beginning of the protocol design to accrual and monitoring of the trial.

With a CBPR model, it is important that during the planning for clinical trials, all stakeholders demonstrate commitment to the research plan. Also, whoever presents a research plan to the community, should be a community member who knows the research institutions well.

Training community members and researchers in this new model is a potential challenge. One recommendation is to conduct regional trainings at centrally located sites, which would include all stakeholders (health professionals, advocates, IRB members, etc.).

Another challenge is identifying who from the community (i.e., leaders, advocates) would be involved in this project. To make sure that this project is inclusive for all cancer clinical trials, a possible solution would be to send out information into the community via email or list serves about the program, and those chosen would be interviewed through several processes that would make them eligible for this program. Since training is provided for the program, what is most necessary is having broad community representation. Other considerations include what role the existing patient advocate community will have and the special needs of very rural or small communities.

The implementation of this project would truly increase the dialogue between the community and the health professionals involved in clinical trials. Also, this model can develop partnerships that do not currently exist in every community, which will help build community trust in the clinical research process. It is also important to point out the benefits of this model to researchers and clinicians, such as enhancing research protocols, accrual rates, quality of life and survivorship outcomes for patients.

This is a much needed program that should have happened many years ago, and my hope is that this will move forward as a working model for clinical trials outreach, planning and outcomes.

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The purpose of the background paper is to provide an overview of CBPR approaches in therapeutic cancer clinical trials. The paper raises several very pertinent issues. My commentary addresses these issues and also suggests areas needing clarification.

Traditional Research that attempts to use Smoke and Mirrors (SM) to camouflage itself as CBPR.

Clearly, this background paper is attempting to follow Israel's CBPR principals. In reviewing multiple applications that are currently called "CBPR," because that is the language specified within RFAs, it is clear that many academic and research institutions are using the CBPR language to mask a traditional research approach. The following are a few of the several "give-away" indications that CBPR approaches are being manipulated and marketed via smoke and mirrors (SM), but are actually falling back into the designs of traditional research. Please note that the background paper clearly states that CBPR is not appropriate for every study, and this author agrees. If that is the case, then the research protocol should not refer to it as CBPR.

SM Issue #1. If the clinical trial design is planned and then the community is invited to join as a partner, this is not CBPR. The latter processes require that the community be a partner in every step of the research process, including "planning".

SM Issue #2. If the community is involved in "selected" steps of the research project, but not all, this is not CBPR. For example, if cancer centers and academic settings have community organizations involved in recruiting cancer patients, but not in designing the protocols or interpreting the findings, this is traditional research, not CBPR.

SM Issue #3. Monies need to be comparably allocated among all partners of the project. The primary recipient may receive a small amount for administrative tasks and the clinical setting needs a bit more for direct service-related costs, but the rest of the budget should be split equally among the partners. Because recruitment within medically under-represented populations requires multiple conversations with the patient and the family members, at least 1/3 of the total budget should be shared with the partner community groups. The community's voice for decision-making is drowned out when they have no money with which to barter, when sitting at the table with the institutions.

SM Issue #4. The definition of community may need to resort back to an older one from the 1970's: "community of solution." This definition is relevant to clinical trials. If the clinical trial is to be therapeutic or a treatment based, then the "community of solution" is cancer patients and their families. If it is a prevention trial, then the family members are the community of solution. Such a definition keeps academic and cancer centers from falling into the trap of partnering with inappropriate community-based organizations for this process (e.g., for true CBPR design to be used, the local cancer support groups may need to be the partners, rather than a community hospital or clinic). Thus, the type of trial determines who comprises the "community of solution."

SM Issue #5. “Community-driven”, “community-based”, and “CBPR” refer to different components and the distinctions must remain clear. If the outcome is to be CBPR, then the community is involved in every step of the research (from planning through dissemination of findings); has a leadership and decision-making role for every step of the clinical trials process; and receives comparable and/or equal payment for the work performed on every step of the research process. In contrast, “community driven” means that the community identified the idea or concept for the trial and may help with selected steps in the process, but not all of them. “Community-based” means that part of the project (the easiest is “recruitment”) initiates from community clinics, programs and patients. These terms are not inter-changeable, but a CBPR clinical trials project may include all three aspects. These terms are somewhat confusing in how they are used within the background paper.

How feasible is the CBPR model, related to therapeutic clinical trials?

It is feasible and practical for long-term solutions for CBPR to drive the clinical trials process for many scientific questions. However, the five SM issues listed above need to be addressed. Also, the CBPR model needs to focus on a protocol and processes that result in a “win-win” project (i.e., good science is conducted while respecting local cultural and geographic issues of the communities).

To improve the likelihood of the CBPR model succeeding, the author strongly suggests that the table of Conduct of Clinical Trials Research add two columns, similar to the following:

Clinical Trial Research Component	Research Institution’s Role (How will they earn their money for this step in the research process?)	Community Organization’s Role (How will they earn their money for this step in the research process?)
1. Oversight community established	1a. Which members from the research institution have the power and ability to make decisions on behalf of the institution? 1b. How are these individuals held responsible for assuring the scientific integrity of the subsequent design?	1a. Which members from the community organization have the power to make decisions on behalf of the organization? 1b. How are these individuals held responsible for assuring the respect and cultural appropriateness of the subsequent design?
2. Research question(s) identified/ concept developed	2a. How will findings related to this research question contribute to the science? 2b. How do/es the research question(s) phrasing extend inclusiveness rather than exclusiveness (e.g., are co-morbidities such as high blood pressure or diabetes implied as excluding participants for eligibility criteria?)	2a. Where does the research question(s) integrate with the local communities’ health priorities? 2b. How is the research question translated into easy-to-understand language for local community leaders to obtain their guidance and reaction of appropriateness and respect for the community?

Is there value in implementing such a model in your work?

Native American Cancer Research (NACR) incorporates community-driven, community-based, and CBPR projects. The community has actively requested that clinical trials protocols involve them in the planning phase. For example, almost every Native community wants to have a prevention phase cancer clinical trial that addresses environmental (not behavioral) contamination and its potential relationship to cancer prevalence and incidence. Likewise, most of our communities are interested in improving access to care. This relates to all types of cancers and is not limited to those few types for which there are early detection tests. For example, childhood leukemia is escalating throughout

Indian Country, yet few of our children ever make it into the Children's Hospitals. For those few Native children who do make it to a Children's Hospital, they receive state-of-the-art care and access to clinical trials. However, most of our children are misdiagnosed (typically as early stage diabetes because the symptoms appear similar) and by the time the child is diagnosed, the cancer is advanced.

The "community of solution" for childhood cancers includes parents, family members and providers who work in clinical settings that serve Native patients (i.e., focusing on, but not limited to Indian Health Service / Tribal / Urban clinics). To date, most of the adult Native cancer patients who work with NACR locally or nationally (through our toll free number and support services) have been receptive to clinical trials once they understand what they are (versus the misconceptions about clinical trials that are very prominent in our communities). Of note, the clinical trials development, implementation and dissemination partnerships need to delineate the differences between conducting clinical trials research and investigating a "cancer cluster" (i.e., the invasive nature of cancer cluster protocols is disrespectful of most Native cultures even though there is interest in learning why certain types of cancer are increasing in their local region).

How would this model affect our work?

We already use this model and have been using it since 1987. The model works. Almost every member of our local Native Cancer Survivors' Support Circle made informed choices about clinical trials participation. The majority selected to learn more and attempted to enroll in a clinical trial. Some had to travel back to their home reservation to do so rather than enroll in the local setting. Likewise, at times it is necessary to negotiate with the research institution on how and why protocols need to be adapted to be culturally acceptable. For example, for a recent breast cancer prevention trial, the tribal leadership prohibited participation in the genetic specimen collection. With the assistance by Dr. Wortia McCaskill-Stevens from the NCI, the clinical trials protocol was modified to allow tribal participation in all phases of the research study except the genetic specimen collection and analysis.

Conclusion

CBPR does take more time and effort to initiate and implement, but it works. Through appropriate use of the processes (i.e., note the five Smoke and Mirrors common errors), science can move forward in culturally respectful and inclusive manners. Both cancer science and the community members affected by cancer "win". The funding research body needs to allocate sufficient funds to allow for culturally respectful recruitment, retention and continued support from the community organizations' navigators or patient advocates.

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This conference series is being convened to examine the impact of employing CBPR principles to the conduct of cancer clinical trials (CCTs). Commentary from key opinion leaders is being sought to assess the feasibility of implementing the various components that comprise the CBPR model and identify the potential value to be derived, weighted against the challenges and barriers that will be faced in implementing such a model. We provide this commentary, individually drawing on more than 25 years' clinical, operational, and executive experience in oncology clinical research, in comprehensive cancer centers, a cooperative group, and an umbrella organization devoted to increasing public awareness of the importance of clinical trials.

Performing clinical trials provides physicians and the public with the data necessary to establish the accepted evidence-based practice standards of care. Regrettably, the accepted practice standards for many types of cancer remain palliative, at best. Well-designed, adequately accrued trials are the necessary link if we are to continue to make advances in prevention, detection and treatment. Recruiting volunteers to participate remains one of the most difficult and costliest aspects of the clinical trials process. Reducing the length of a clinical trial by just several months by improving the rate of accrual could not only save lives, but also improve efficiency and reduce the cost of conducting trials in a system already suffering from gross under funding.

This Background Paper provides a broad perspective on the accomplishments of more than a decade of efforts to develop partnerships that bring researchers together with patient advocates and other community members in worthwhile collaborations. In the scheme of the clinical trials enterprise, these are viewed as activities both important and necessary. Yet those attending the three-part 2007-2008 conference series face a clinical research climate that perhaps can best be described as "uncertain" in respects such as these:

- More than a decade of high-level committee deliberations and recommendations has resulted in little positive movement to bring either program or support integration among the competing cancer research arenas.

- An 80% increase in the NCI's budget stimulated widespread research achievements, broadened and modernized both the physical and human research infrastructures, and generated hopes for more of the same in the years ahead – only to find a Federal budget climate that has resulted in reduced budgets and grant award levels for virtually all oncology research.
- Hundreds or even thousands of basic and clinical researchers are considering abandoning their research commitments because of the dismal prospects of having their work funded adequately.

Feasibility of implementing CBPR components to the conduct of CCTs

Many of the collaborative activities proposed over the years, and well described in the Background Paper, could theoretically be accomplished and provide significant gains in various aspects of the clinical research arena, but only at substantial costs. Several components of the model being proposed have already been adopted into the current publicly funded cancer clinical trials research system and are recognized as essential elements while other components, such as the CBPR approach to expanding the involvement of local IRBs, may prove to be more problematic to the system.

In the areas of trial development, design and implementation, the investigator/community partnership is critical to the success of any project. CCTs are performed to resolve, or diminish, uncertainty concerning the relative merits of comparator interventions. With respect to the design and conduct of a particular trial, uncertainty should be considered at three levels: the community of expert clinicians, which includes investigator-trialists; individual physicians, who have to decide whether to conduct a trial at his/her site and whether to offer participation to particular patients; and the patient, who has to decide whether to accept the offer. As we begin to test new interventions earlier in the disease process such as adjuvant treatment regimens, there is both scientific and ethical justification for the design of the ideal trial to include a “no treatment” observation arm as the comparator to the intervention being tested. When presented to multiple focus groups, including patient representatives, it became clear that a no treatment arm would be unacceptable. With meaningful participation from all the stakeholders, alternate trial designs may be considered to find an acceptable control arm for these trials without sacrificing the objectives of the study.

As we begin to better understand the molecular basis of cancer, these diseases will no longer be limited to the anatomical and histopathologic classifications currently used. Trials evaluating new interventions will become more selective, using molecular sub-classifications of what was previously classified as one form of cancer. More trials will be required to selectively address each of these subclasses with treatment tailored to the qualitative differences of the disease process. Innovative designs will be required to meet this demand. Community input into these decisions will be essential to the success of these trials.

Regarding the CBPR approach to expanding the IRB's role, the current shortcomings of the nation's IRBs are well documented and solutions have been widely discussed; it is difficult to estimate the cost of improving all IRBs' ability to reflect the input of community partners, and few, today, are even developing pilot efforts of this sort. The tenet of maintaining local IRB oversight of multi-center clinical trials is based on the assumption that IRBs possess adequate knowledge of

community attitudes, information on conditions surrounding the conduct of the research, and the continuing status of the research to assure fulfilling their regulatory requirements. The FDA and OHRP regulations require all IRBs to have membership sufficiently qualified to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects. By rule, IRBs need to consider the local context and be knowledgeable about the community from which the subjects are drawn, to ensure that subject rights will be protected and that the consent process is appropriate for the subject population involved. The current IRB structure should be sensitive to community laws and mores because state and local laws and community attitudes pertaining to research may be more restrictive than Federal regulations or the prevailing standards of the community where the IRB is located. To expand this process would result in additional layers of review delay in implementing the trials.

In the area of educational programs, there was a general recognition for the need to improve education programs for all participating in the human subjects protection program. This includes IRB chairs, members, administrators, investigators and research staff, institutional officials, students and the community of research subjects. Besides inadequate funding for educational programs at both the national and institutional levels, a related issue is that minimum training needs, for each of the participants noted, have not been developed. The Coalition of Cancer Cooperative Groups recently presented the results of their assessment of barriers to CCT participation¹. Although there are myriad reported barriers to CCT participation, the findings concluded that the physician is overwhelmingly the most important source of CCT awareness and his/her perceived attitude is the most important factor in a patient's decision to participate in CCTs. Increased CCT participation hinges upon physician commitment and communication; conversely, a lack thereof may be the greatest barrier to increased CCT participation. The sustained progress in cancer treatment through CCTs is dependent on the commitment of physicians to offer CCTs to their patient for consideration.

The broad goals proposed, both in the Background Paper and in the growing literature of collaborations of communities and researchers, are necessary. However, "in the trenches" of clinical research, we respectfully suggest to the conference planners and conferees that it may be more beneficial, in the short term, to focus on what can be achieved now, with limited resources, such as prioritizing what can realistically be achieved in the short term; developing pilot or demonstration projects to determine best practices for the issues and areas of potential improvement that appear to offer the greatest real-world payoff; and deciding on a research agenda (as suggested at pp. 5 of the Background Paper) for the next few years.

¹ Comis RL, Colaizzi DD, Kimmel LG, Miller JD: Barriers to Cancer Clinical Trials Participation: We have met the enemy and he is us. Proc. Am. Soc. Clin. Oncol., 2007 (Abstract No. 6567)

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Practical approaches to greater community involvement in cancer clinical trials are long overdue. Michaels and Seifer should be commended for taking on such a large and complex problem of the role of CBPR in cancer clinical trials. Their overview of cancer clinical trials and CBPR illustrates how divergent the two research methods are. They provide concrete examples of how communities can become more involved in the process of clinical trials. The recommendations are straightforward and provide a platform by which community could have a substantive role in the decision making of clinical trials. In light of their recommendations, several points bear mentioning.

Community involvement is not equivalent to the methods of CBPR. The outlined approaches to community involvement are based on the principles of CBPR and, taken as a whole, may be an important step toward community participation in the clinical trials process. However, without acknowledging that this is an integrated approach and all steps are essential to maximize community participation, the possibility remains that trial investigators will choose among the recommended approaches, as if a menu, to include those that may seem best suited for the current trial infrastructure. If less than the full complement of recommendations is taken up by trialists, community influence would obviously be lessened, whether intentional or not. The full potential of a community perspective being integrated into the process of producing clinical trials would not be realized.

The recommended approaches also seem unidirectional, that is, the recommendations as written seem to be an attempt to insert community perspectives into the trial process. Fundamental to CBPR is recognition that all partners have much to give to the process and much to learn - the principle of co-learning. The current recommendations do not clearly acknowledge the need for capacity building among investigators involved in cancer clinical trials. If these recommendations were to be implemented in the current structure in which cancer clinical trials are conducted, investigators would need to be supported in this endeavor, as many are unlikely to have had this kind of training.

To ensure that investigators who are conducting research have the skills to work respectfully and effectively within local settings, investigators would need to develop skills in community based research methods. Such skills include understanding the steps and range of methods for engaging community members in a study; authorship, publication and community dissemination of study findings; the process for building a collaborative community team; and the community structure and ethical considerations in community-academic partnerships. In addition, investigators would need to be able to articulate the full spectrum of community participation (i.e. from community as advisors through community as partners), the goals of community participation, the benefits of a chosen method of participation and potential pitfalls of participation that falls short of true partnership and engagement. Only when investigators are armed with this knowledge will the current recommendations have the greatest chance of leading to changes in the conduct of cancer clinical trials that reflect community decision-making power.

Another important consideration is the need for supporting the capacity of partners to work together with a shared vision and goal -- building partnership capacity. Funders of this approach could play a key role in setting the tone for this new model and supporting it during the conduct of the trial. For example, the request for proposals or applications could clearly articulate the expectation of community involvement, and reference the Michaels and Seifer recommendations. Funding agencies could also fund research in innovative approaches to clinical trial design and analysis, which take into account the ethical issues of conducting randomized trials in community settings. Planning grants or planning phases of larger grants devoted to partnership development could be a requirement prior to trial funding (see recent NCMD CBPR planning grants). During the conduct of the trial, funding agencies could require site visits and larger meetings of grantees – both academic and community partners- devoted to issues of collaboration and partnership to promote learning from other sites. In the application of a new model, the combination of capacity building, innovation in research methods and support for substantive involvement of all parties would maximize the impact of these recommendations.

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This paper outlines a “new model” for ensuring meaningful community participation in the conduct of cancer clinical trials specifically, but more significantly clinical trials of all sorts given the range of diseases being studied with extramural grant support from the various institutes and centers of the National Institutes of Health (NIH). The paper addresses a timely and central topic, as the Director of NIH, Dr. Elias Zerhouni talks of the 4P’s of clinical and biomedical research in the 21st century being, predictive, personal, preemptive and participatory; but more importantly issues RFAs calling for community participation in research; places value on community engagement in the NIH Clinical Translational Science Awards; and announces a new NIH Roadmap, which changes the traditional research paradigm that has existed as the hallmark of NIH scientific inquiry for decades.

The paper provides an excellent grounding in the principles and values of CBPR, as well as a thorough overview of the cancer clinical trials research system and makes a strong case for the how and why of integrating the two. It is an invaluable resource for those of us proposing strategies and policies for changing the research enterprise as we know it. The authors correctly note that CBPR is slowly taking hold as a credible model in the areas of health services and public health research, particularly in research on disparities with vulnerable populations. However, the real challenge lies in integrating the same level of participation into therapeutic clinical trials, which are most often national in scope, with multiple sites, varied settings, and “meticulous scientific rigor.” Can CBPR and therapeutic clinical trials be integrated? Yes, under the right circumstances.

Is CBPR a model or a set of principles? In this case of therapeutic clinical trials research, I would argue that CBPR is best used as a set of principles. In the more applied model of CBPR in health services and public health research, there is an emphasis on building relationships between researchers and communities, and researchers becoming a presence in the community for the long haul. In therapeutic clinical trials, I’m not certain the community desires a relationship with many of these scientists. Furthermore, I believe the notion of a “new model” evokes an inherent resistance to change among clinical researchers. As advocates for change, we would do better by talking about principles of participation that can be adopted by the clinical trials system, without making researchers feel they are compromising the reliability, validity and generalizability of their scientific research with a “messy” model.

The Center for Community Health Education Research and Service, Inc. (CCHERS) is comprised of a network of fifteen “academic community health centers,” serving the racially, ethnically and socio-economically diverse populations of the central city neighborhoods of Boston, in partnership with Boston Medical Center, the Boston Public Health Commission, Boston University School of Medicine, and Northeastern University Bouvé College of Health Sciences.

For the proposed model to be successful in Boston - the U.S. city with the most NIH dollars invested in clinical and biomedical research and the center of a clinical research enterprise resistant to change - the focus would need to be on implementing specific individual components of the

model and infusing principles of participation in the academic medical research community. In this case, the sum of the parts can certainly be greater than the whole.

It is quite feasible to incorporate public/community participation in clinical trials research through existing structures such as oversight and advisory committees of the institutes and centers of NIH; community advisory boards; data safety and monitoring boards; institutional review boards, etc. However, the commitment to community participation in the forms of training, education and compensation is critical to any measure of success. The background paper model goes further by suggesting ways of incorporating public/community participation into the research effort as well. Again, this is highly feasible and also recognizes the valuable contribution that can be made by public/community representatives.

The work of CCHERS focuses on making the work of the “research extensive” and “research intensive” institutions in Boston more meaningful and relevant to the health of the city’s residents. Those served by our community health centers are those who have historically been left out of research, including racial and ethnic minorities, the poor and uninsured, and women and children. Exclusion occurs either explicitly or implicitly due to research protocols, eligibility criteria, or other exclusionary factors. CCHERS helps to develop partnerships between academic researchers and communities of color. Promoting the principles of CBPR in these partnerships is the essence of what we do. NIH policy and institutional policy that would require diverse public/community participation in all types of research and at all levels of research would certainly us help in our work.

The most significant challenges and barriers for implementation of the proposed model, or the principles of public/community participation, lie in the structure and process of clinical trials research, as well as the values and attitudes of those conducting the research. The complexity of clinical trials research that is national in scope, involving multiple sites, investigators, etc., is a challenge for many to understand. It is even more difficult on a local level, where such research appears so distant and disconnected from local issues and priorities. Research has dispelled the myth that people are reluctant to enroll in clinical trails. Most often their lack of participation is based on lack of awareness and misinformation. People would probably be more inclined to engage in clinical research that is built on true participation and partnership, and preferably with people who look like them.

If implemented, this model would positively affect the work of CCHERS. As the leading city in academic medicine and research, Boston’s efforts to increase community participation in research would have major implications for change nationally.

According to the AHRQ report on CBPR, the evidence indicates that employing CBPR improves the quality of the research being conducted, builds community capacity and improves health outcomes for populations. For clinical trials research, this could mean improved accrual and retention, particularly for minorities and women; a faster rate of scientific discovery and clinical translation; attention to issues of access, equity, justice and health needs of the local community; and improved overall treatment and health outcomes of vulnerable populations. These alone are compelling enough reasons for promoting principles of participation in clinical trials research. However, I would add these additional benefits: cost savings from fewer failed recruitment efforts; expanding the pool of beneficiaries of clinical and biomedical advances; and improving the quality of healthcare delivery in this country.

GlaxoSmithKline

Introduction

GlaxoSmithKline (GSK) supports the concept of CBPR in oncology clinical trials. We are interested in exploring the use of this concept in our oncology clinical trials. Upon review of the background paper, *Involving Communities as Partners in Cancer Clinical Trials*, we have provided the following feedback on the model.

Community Representative Committees

We support the concept of community representative committees in the development and implementation of oncology clinical trials. We believe that their input in study design, materials, and processes will be beneficial. However, we are concerned with the additional time required to establish these committees, and decision making among the various partners, throughout the life of the study. We believe that the development of stream-lined processes, timelines and decision-making rules/guidelines would be absolutely essential to ensure success of partnerships and trials.

Research Question and Trial Design

Though we believe that valuable feedback would be obtained regarding research question and trial design, the overall scientific integrity of the study could not be compromised by these objectives. It would be important to communicate this understanding between all parties involved.

Consent Forms and Process Development

Health literacy is essential in writing and updating informed consents and other patient/study materials. Therefore, we agree with these elements of consent form writing and do not anticipate any significant barriers with incorporation.

Qualifications for Local Research Team Development

We believe that having a core group of individuals who can relate to individual communities and their beliefs will contribute significantly to the success of oncology clinical trials. The focus for these individuals should be community core competencies and their readiness for change.

We believe that a recruitment board is a good idea and would be interested in providing additional input as this process is defined. However, we do not believe that they should be associated with the IRB. In addition, timelines might be at risk if these types of systems are not coordinated within an appropriate timeline. We believe that the development of stream-lined processes, timelines and decision-making rules would be absolutely essential to ensure success of partnerships and trials.

Trial Submitted for Approval and Funding/Peer Review for Scientific Merit

Though we value the input and expertise of community leaders regarding community trial specific objectives, the overall scientific integrity of the trial should not be compromised by these objectives. It would be important to communicate this understanding between all parties in involved.

Funding received/funds distributed

Additional funding would be necessary to support these community-based initiatives. Individual proposals would be submitted and approved on a study-by-study basis; and would include an initiative funding impact assessment. Further input from within our organization would be needed to provide feedback on this aspect of the model.

Institutional Review Board (IRB)

This element of the model would not be feasible. Having an IRB involved in trial material development and any type of financial incentive is considered unethical by regulatory agencies.

Data Collection Protocols Implemented

Though we believe that valuable feedback would be obtained through committee input and partnerships, the overall scientific integrity of the study could not be compromised by these objectives. It would be important to communicate this understanding between all parties.

Communication of Trial Availability

We believe that this element of the model would be extremely beneficial, and support it. We do believe that this would pose some logistical challenges which should be examined, including contracting of community leaders, training, volunteer retention, tracking and management and other related issues. We are also concerned with the additional time required to establish this communication process. We believe that the development of stream-lined processes, timelines and decision-making rules/guidelines would be absolutely essential to ensure success of these education activities.

Recruitment and identification of potential participants

We fully support the creation of a recruitment plan. We value the input of the community members in its development and implementation. With these additional decision makers, timelines, however, might be at risk. Development of stream-lined process, timelines and decision making rules/guidelines would be absolutely essential for success of the plan. Additionally, these processes should impose accountability on partners, which can be tracked and measured across community and site activities.

Screening, Initial Consent and Accrual

We agree with the concept of additional consent training and principles stated within this model. We recommended conducting an informed consent workshop with potential role play during the training.

Ongoing Informed Consent and Communication

We support the idea of ongoing, informed consent and communication of study progress to the IRB and DSMB. However, we believe that the actual submission and follow up of these reports to the IRB would be a site responsibility. We believe that this process may be cumbersome for the sites; and possibly be a site deterrent from participating in the clinical trial.

Participant retention

We fully support the creation of a retention plan. We value the input of the community members in its development and implementation. With additional partners in the development of the retention plan, timelines might be at risk. Development of stream-lined processes, timelines and decision making rules/guidelines would be absolutely essential for the success of the plan. Additionally, these processes should impose accountability on partners, which can be tracked and measured across community and site activities.

Data safety monitoring board (DSMB) monitoring

We support the idea of having patient advocates sit on DSMBs. We also support sending yearly progress reports to these committee members.

Data analysis and interpretation

We would need to assess further the legal and regulatory implementation of allowing data to be reviewed. Further research from our internal resources would be needed to provide more valuable feedback on this aspect of the model.

Dissemination of findings

We support the dissemination and review of findings with patients. However, we would need to assess further the legal implementation of allowing data to be reviewed. Further research from our internal resources would be needed to provide more valuable feedback on this aspect of the model.

Translation of positive findings into standard care provision

We support the concept of “translation of positive findings into standard care provision.” GSK currently has departments that disseminate positive findings to the public; and would be a willing partner with community leaders to ensure the message is disseminated within all communities.

Conclusion

Logically, implementing this model could prove challenging. The specific barriers are listed above. However, we believe that this concept could be beneficial in helping to enroll diverse ethnic populations and thus delivering new therapies to these populations. Therefore, we recommend that a pilot program be considered so further evaluation of this concept within oncology clinical trials can be explored.

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Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy is an ambitious, aspirational document – ambitious because the document proposes a complete reinvention of how we currently conduct clinical trials to include broad community representation; aspirational because achieving the goal of comprehensive CBPR would have to be achieved incrementally over an extended period of time to avoid a potentially catastrophic upheaval in our already beleaguered current trials system.

The document lays forth a proposal for the universal involvement of community representation in the development, implementation, analysis, and results dissemination of cancer clinical trials. From my perspective as the leader of an imaging (and hence most often “diagnostic”) clinical trials cooperative group that has fostered patient advocate perspectives in the group’s operations, this seems a logical extension of that activity to improve the acceptance and pertinence of cancer clinical trials. The development by the Patient Advocate Committee of the American College of Radiology Imaging Network’s (ACRIN) Project IMPACT (Improving Participation by Advocates in Clinical Trials)[Roach et al] – which integrates advocates into every phase of the clinical trials process - has greatly improved the appeal of our trials to potential subjects and, I believe, helped accelerate subject accrual. It seems to me that broader community participation could only enhance this effect.

However, Project IMPACT, which is now being promoted as a model for better patient advocate participation in other cooperative groups, occurs in the context of ACRIN’s timelines and budgets. No accommodations are made to extend deadlines, nor are advocates compensated for their participation. This is in distinction to what is proposed in *Communities as Partners*, where it is acknowledged that start-up phases might be prolonged in order to recruit community involvement and where the document supports fair compensation for community representatives’ efforts.

Both time and money are problematic. The usual time to bring up clinical trials is already prolonged well past what is desirable and resources are short. Compensation is a particularly knotty problem. A best estimate is that the National Cancer Institute (NCI) funds roughly 40% of the real costs of performing a clinical trial. Researchers’ salaries are capped at an NCI maximum that is often below the salaries institutions must pay their faculty, particularly physicians. Whereas previously these institutions could rationalize research participation as providing marginal revenue, the increased demand for better paying clinical services has depleted their “slack” resources. As a result, many participating institutions are beginning to take a harder line on whether losing money on clinical trial participation is something they can continue to afford.

Clearly, in this environment, if clinical trials were to cost more in order to compensate community representatives, additional funds would need to be found. The NCI seems an unlikely place to look for this funding. The NCI has suffered cuts in its spending capabilities for four years in succession and is unlikely to see a reversal of this trend for at least 2-3 more years [NCI Director, John Niederhuber, MD, to the NCI Clinical Trials Advisory Committee, 2006]. The NCI cooperative groups - the principle engine of multi-center clinical cancer research - were threatened this year with

cuts of greater than 10%. While they were made whole in May 2007, much of the damage in abandoned trials and lost opportunity already had occurred. The cooperative groups - as well as the cancer centers and Special Programs of Research Excellence (SPOREs) - continue to operate under a cloud of uncertainty. Whether CBPR will be sufficiently appealing to private funding to supersede concerns of time and money is to be determined.

The rationale for proposing CBPR is undeniable. Many of the reasons that scientifically sound clinical trials are slow to accrue or fail to achieve their full subject subscription are traceable to community apathy, a lack of incentives for participation, and the absence of support from community leaders. What is uncertain in my mind is the extent to which involving community members in the process can consistently overcome these problems. Inevitably, representation from the community is what is possible, not the involvement of the full community itself. The likelihood that including selected community members will be successful in improving the clinical trials process is clearly related to how well the community feels it actually is being represented, and perhaps more significantly, the extent to which the community educates itself and truly acts as a community to support clinical trials.

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CBPR is an entreaty to do what is both common sense and scientifically necessary for advancing our medical knowledge. For example, outright exclusion of Limited English Proficiency (LEP) people from a study can limit the generalizability and therefore utility of findings.¹ Michaels and Seifer (2007)² make a compelling case for why this is so and offer a CBPR model for all involved in the conduct of research.

Including Latinos as full participants in each phase of cancer research—from conception, design, implementation, analysis, interpretation, conclusions, and communication of results³—is a clear case in point. Latinos suffer a high cancer burden. Cancers with a higher incidence among Latino men compared with white men include stomach, liver, and gallbladder cancers. Latina women suffer disproportionately high incidence of uterine, cervix, stomach, liver, and gallbladder cancers when compared with white counterparts.^{4,5} Participation in cancer clinical trials by ethnic and racial minorities, including Latinos, however, is disproportionately low and in some cases has declined over time.^{6,7} Enrollment in clinical trials by Latinos, moreover, is far below our representation of the total U.S. population.^{8,9,10} In 2004, we represented an estimated 14.1% of the population and accounted for 49% of the nation's growth from 2004 to 2005.¹¹ In short, the number of individuals at risk for cancer will increase over the coming decades.¹²

There is a reason why we and other Latino medical professionals continue to underscore the critical obligation to assure that health education materials and medical protocols are “culturally appropriate” and “linguistically accurate.” A recent focus group study by Ellington et al.¹³ provides an illustrative example of the substance behind the meaning of these concepts. Researchers in this study identified factors that influence English- and Spanish-speaking participants' decision to enroll in a clinical trial. English-speaking participants valued physician competency and an autonomous decision-making process, expressed hesitancy in conveying emotions in medical encounters, felt they would not take emotional concerns into account when making a decision about whether to enroll in a trial, and had the acquisition of knowledge about all treatment options as their medical encounter goal.

Spanish-speaking participants with higher levels of education shared a similar perspective to English-speaking participants about the importance of provider competency and comprehensive information. However, regardless of education level, Spanish-speaking participants placed more value on the interpersonal style of the physician as an influencing factor. They expressed the need to tell the story of their cancer experience (involving both medical and emotional concerns) and for their physician to acknowledge the salient aspects of their narrative. This finding is supported by our own research.¹⁴

Ellington et al.¹³ study participants said they could trust that a doctor's discussion of clinical trials was based on a full understanding of their cancer experience when the doctor acknowledged their concerns, offered reassurance, and took time to listen. If they felt a personal connection with the doctor who introduced them to a trial, Spanish-speaking participants said they would be more likely to consider participation. Many participants shared they believe providers form ethnically based assumptions about patients (e.g., related to citizenship and socioeconomic status as well as cultural stereotypes). Because of this, they expressed skepticism that physicians would even recommend a trial to them, or if they did recommend a trial, they would be suspicious of motives.¹³ In our own work, we have seen how fear of deportation and unfamiliarity with cancer clinical trial terms serve as difficult hurdles as well.

Many Spanish-speaking participants in the Ellington et al. study (2006)¹³ revealed a fatalistic attitude (that disease is a matter of chance or “God’s will” and therefore fate), and incorrectly associated clinical trials with aggressive, last effort treatment and randomization with “uncertainty.” They viewed the family as integral to treatment decision-making and identified faith as playing a dominant role in health decisions (these findings have been corroborated by other research^{15,16}).

Other than attitudes towards the Western medical system influenced by cultural beliefs, logistical obstacles to trial participation by Latinos are innumerable. The predictable ones include cost, time, and disruption of family and work responsibilities.¹⁷ Despite the instances when the aforementioned barriers are removed, the initial step of signing a consent form is a window into how the clinical trial system is fraught with systemic problems for LEP patients. Informed consent does not end when a subject signs a consent form even if the form has been translated—informed consent is a communication process that should continue throughout a study. Study participants need to understand information exchanged during research so that they can decide whether to answer survey questions, take medications, participate in procedures, or withdraw from a study.¹⁸

At least 60% of people who speak a language other than English at home speak Spanish..¹¹ A sizeable and growing percentage of people who may participate in research studies does not speak English well or does not speak it at all.¹⁸ Researchers might decide to exclude LEP people from enrollment because of difficulties translating study documents and problems with recruiting, training, and paying bilingual staff.¹

We agree with Resnik and Jones' (2006) assessment that intentionally excluding LEP subjects is unethical and illegal.¹⁸ For their safety, participants must receive accurate and understandable (related to language and literacy level) written instructions for: taking medications; recording or reporting symptoms; using medical devices; and completing questionnaires. Not translating documents can undermine the integrity of a study's data if LEP subjects fail to follow directions appropriately or do not understand how to answer survey questions.¹⁸

It is important for Michaels and Seifer² to clarify the barriers extant in concentric circles rippling outwards from the individual—from the community clinic and academic cancer center levels to the “ivory tower level” that includes the National Cancer Institute. For example, it took 5 years to shift DC-area community clinics' perspective of research as a clinical distraction and paperwork burden to one of self-serving access to useful data that can help improve services and secure funding (e.g., a random, cross-sectional pre- and post- medical chart review helped clinics assess use of mammography, Pap tests, FOBT, sigmoidoscopy, and colonoscopy after 4.5 years of activity).¹²

Today, cancer control coordinators who have daily contact with patients and staff initiate ideas for investigations. Such best practices from the Special Populations Network (SPN) and the Community Network Program (CNP) experiences^{12,19} could be included in more detail in Michaels and Seifer's paper.²

Michaels and Seifer's CBPR model² is only feasible if research sponsors and institutions earmark funding for: translating and validating translated documents; recruiting and retaining bilingual/bicultural professional translators and interpreters; and drafting clear IRB guidelines for dealing with LEP research participants. We have seen how with funding, discipline, time, and patience, Latinos can genuinely become part of research design process.^{12,19}

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Introduction

Based on my 20 years in academia (prior to joining NCI in 2000), and having served as the CCOP Research Base Coordinator at Memorial Sloan-Kettering Cancer Center (MSKCC), having conducted over 25 peer-reviewed cancer prevention and control community based projects (with varying degrees of community participation) at MSKCC and the Lombardi Cancer Center at Georgetown University, and having served on multiple NCI and NIH grant application review panels, including chairing the NIH Community Prevention and Control Study Section (now Community-Led Health Promotion), I found the proposal to integrate CBPR with cancer treatment clinical trials both novel and conceptually challenging.

The novel elements center on how broader community participation in clinical trials design, development, implementation, analysis, and dissemination of findings would be organized and implemented. As noted in the background paper, community involvement has usually been limited to representation on Community Advisory Boards, IRBs, and in some circumstances, peer-review of research proposals. Conceptually challenging is the proposition that the adoption of a CBPR approach to cancer clinical treatment research would lead to increased patient participation in clinical trials and improved quality of care for historically underserved communities.

Is there value in implementing a CBPR model for cancer clinical trials?

The simple answer is I don't know. While the barriers to minority participation in clinical trials have been relatively well articulated, few strategies have been tested or evaluated.² Thus, a small pilot of a CBPR model for cancer treatment research might be in order, to explore the challenges and opportunities of this novel approach. If such a pilot were to be mounted, I would propose comparing CBPR accrual vs. regular clinical trials accrual focused on some cancer sites where incidence disparities are high and conventional care is largely ineffective (e.g., pancreas and liver cancer), as well as cancer sites where incidence disparities are not so large and where conventional care is relatively effective for early stage disease (e.g., breast and colorectal cancer). I would posit that the CBPR approach might work better in the former versus the latter context, because where unequal access to efficacious conventional care limits the treatment choices of underserved populations, and where there are limited disparities in the incidence of the disease, the perception that minorities are being used as "guinea pigs" in research may unintentionally be reinforced.

How feasible/realistic are the various components of the model?

¹ The opinions in this commentary are solely those of the author and do not represent the positions or the policies of the National Cancer Institute, the National Institutes of Health, nor the US Department of Health and Human Services.

² Ford JG, et al. (2005) Knowledge and access to information on recruitment of underrepresented populations in cancer clinical trials. *Evidence Report: Technology Assessment No. 122* Rockville, MD: AHRQ Publication No. 05-E019-2.

A key overarching issue is the very low (2-3%) overall adult cancer patient participation rate in clinical trials. It is unclear how a CBPR approach could overcome the system barriers to broader participation and more rapid accrual to clinical trials. Thus, with the largest number of published studies focusing on opportunity barriers to participation in clinical trials (e.g., logistics, co-morbid conditions, costs),³ CBPR approaches may help to address barriers of awareness and barriers of acceptance, but may have little impact on system factors limiting opportunities for participation. In addition, given the relatively slow and deliberative nature of CBPR planning processes (e.g., to build community trust), a CBPR approach might be perceived as slowing the pace of cancer treatment research to such an extent that, even if accrual were to increase, the time to develop and clear a protocol might dramatically reduce the pace of cancer treatment innovation. Particularly within the time pressured environment of academia (e.g., publish or perish), there may be little enthusiasm for this more time consuming approach.

What do you see as the most significant challenges and barriers to implementing this model? How might these be overcome?

I have described a number of implementation barriers above. Key to a good CBPR approach is the a priori time investment needed for all the stakeholders to get to know each other, learn from one another, and learn to trust each other's motivation even when perspectives differ. Assuming these relationships are in place, and CPBR clinical protocols are successfully initiated, the analysis and dissemination of study findings may lead to new sources of conflict. For example, in a period where more cancer clinical research is moving towards a heavy reliance on biotechnologies for characterizing tumors and individually tailoring treatment protocols, how will these innovative but extremely expensive approaches to cancer care be made available to all patients irrespective of their ability to pay? In the absence of a healthcare system that guarantees access to high quality care for all cancer patients, participation in clinical research may be viewed with growing skepticism. What's in it for the broader community to help establish the efficacy of new intervention approaches that ultimately will be inequitably made available based on a patient's ability to pay? CBPR may serve to highlight this question as communities learn more about the inner workings of cancer clinical research and they become more aware of the gaps between the haves and have-nots in terms of patient care.

If implemented, how would this model affect your work?

The ultimate economic impact of adopting a CBPR model for clinical research in cancer will be to make protocol participation more expensive. Given that NCI only funds its cooperative groups and CCOPs at \$2,000 per patient accrued to cancer treatment trials, versus \$5,000 - \$15,000 per patient from the private sector, increasing the expense of participation without increasing reimbursement could pressure an already strained system to sustain an active government-sponsored clinical research enterprise. In the absence of a significant increase in NCI's clinical research budget (about 15% of the total NCI budget),⁴ if a CBPR approach to clinical research were to be adopted broadly by NCI, new investment priorities may need to be developed to more fully fund fewer clinical trials. If NCI were to consider this shift in funding priorities, I would propose that NCI invest its limited clinical research dollars in those cancer sites where disparities in incidence are relatively high, where

³ Ford JG, et al. (2005) Knowledge and access to information on recruitment of underrepresented populations in cancer clinical trials. *Evidence Report: Technology Assessment No. 122* Rockville, MD: AHRQ Publication No. 05-E019-

⁴ National Cancer Institute. 2005 Fact Book. NIH Publication No. 06-512, March 2006

case fatality rates are high, and where the private sector has made a relatively smaller investment given the more limited market potential. In this fashion, the NCI's public investment in cancer clinical research would better complement the larger investment of the private sector, could accelerate progress for cancers where conventional care has had a limited impact to date, and would reduce cancer health disparities in terms of cancer treatment outcomes.

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Research Culture and CBPR

One of the greatest challenges to CBPR is that it requires power sharing. Specifically, CBPR requires researchers to share control, money and credit for what gets accomplished.

In their background paper, *Involving Communities as Partners in Cancer Clinical Trials*, Michaels and Seifer identify some of the barriers to such power sharing within research institutions and culture. These include limited funding for community participation and the additional time requirements for genuine partnership. However, a more basic barrier is the tenure and promotions process within many research universities.

At my own institution, Washington University School of Medicine (WUSM), the importance of *independent* and *original* contributions for achieving tenure is critical, and there lies the dilemma. This focus on independence and originality creates a fundamental tension with the principles of *interdependence* and *inclusion* essential to CBPR.

The following information comes from WUSM's Appointments and Promotions Guidelines and Requirements (APGAR) document and pertains to the granting of tenure. They are revised standards that have been in place since November 2, 2005¹:

Appointments and promotions to Associate Professor on the Investigator Track are based primarily on the original, independent scholarly contributions of the faculty member, and are evaluated by the following criteria (listed in the typical order of importance):

1) Investigation and Other Scholarly Accomplishments

In order to be promoted to Associate Professor on the Investigator Track, a faculty member must be responsible for an outstanding body of original basic biological, biomedical, or clinical research. Elements of this achievement typically include formulation of original research ideas, setting up the research methodology, recruiting necessary personnel, obtaining funding through peer-reviewed mechanisms, analysis and interpretation of the results, presentation at significant scientific meetings, and publications in high-quality peer-reviewed journals in which the faculty member is typically the first or senior author.

One of the revisions in this document, compared to the prior policy, is that it opens a door for valuing collaboration. It acknowledges that some investigators make unique contributions across a number of projects and are less likely to be first or senior author. This type of collaboration is defined as follows:

¹ <http://aladdin.wustl.edu/medofa/ofa.nsf/WV/9E990FC6A1A0592A8625723A0074B3FA?OpenDocument>.

In cases where a major component of a faculty member's research accomplishments depend [sic] on collaborations with other investigators, it is essential that the quality and originality of the faculty member's individual contributions to the design, analysis, and interpretation of the published studies be carefully documented. These contributions should meet the high standards expected of faculty whose research is not collaborative in nature.

Unfortunately, from a CBPR perspective, this view of collaboration still emphasizes collaboration *within* the walls of the university and *among* researchers.

Other criteria for granting tenure in “typical order of importance” are: teaching, evidence of regional and national recognition, assessment of clinical excellence (where applicable) and finally “service to the Medical Center, University and Community.” Specifics under this last category are: administrative roles in medical school, hospital, departmental, or divisional activities; service on medical school, hospital, departmental, or divisional committees; and important contribution of service to a basic science research or clinical laboratory program.

Once again, the kinds of “communities” essential to CBPR are left out of the equation.

Michaels and Seifer rightly point out that part of the reluctance about CBPR in the research environment is the assumption that community participation “comes at the price of scientific rigor, reliability and validity.” This same set of attitudes clearly influences tenure and promotions policies. Science is seen as a specialized and sufficient process where outside influences only cause contamination. Advancement of scientific knowledge is also seen as an essentially *individual* process, and the incentives are aligned to reward *individual* productivity.

Changing Culture and Increasing Accountability

Recognition of the tension between CBPR and research values is not new and has been particularly well documented by Campus-Community Partnerships for Health in their *Community-Engaged Scholarship Toolkit*.²

For individual academics, this toolkit has a wealth of survival strategies with ample, concrete information about navigating and negotiating career advancement within research institutions. However, as a broader community of people who want to improve health outcomes, we have the responsibility and opportunity to challenge research culture and the assumptions that drive the tenure and promotions process.

This challenge should take place through two avenues: “scientific” debate and public advocacy. The science of the issue is that clinical trials as currently designed are inadequate for addressing the needs of the population. The major issue is generalizability, and in many ways we seem to have remained in the pre-1993 era, prior to the passage of the NIH Revitalization Act. Michaels and Seifer make this argument, and it needs to be made repeatedly in the cancer literature. Specifically, we need to document the failure of current trials and trial designs to generate relevant treatment information for populations that experience the worst cancer outcomes. One might tackle this topic cancer by cancer or take on a cross-cutting issue like exclusion criteria around co-morbidities.

² Calleson D, Kauper-Brown J, Seifer SD. Community-Engaged Scholarship Toolkit. Seattle: Community-Campus Partnerships for Health, 2005. <http://www.communityengagedscholarship.info>.

Public advocacy is something that can be achieved through this conference series. It is important to remember that NIH money is public money, and we have the right to demand that NIH funding create meaningful incentives for individual researchers to use CBPR principles and for research universities to recognize and reward such work.

Some might say that it's too hard to change research culture, but cultures are dynamic. They change all the time. In particular, they change in response to external pressures. Participants in this conference have a strong voice that will be heard. This is an opportunity we cannot pass up.

Edith A. Parker, Dr.P.H.

**Associate Professor, Health Behavior & Health Education
Associate Dean for Academic Affairs of the School of Public Health
University of Michigan School of Public Health**

I found this concept paper to raise several provocative issues around the role of participation of lay persons in cancer clinical trials. While I support the suggestion of increasing community and lay person participation in the implementation of cancer clinical trials, I believe we must consider and answer the following questions before we can decide if a CBPR approach is feasible for cancer clinical trials.

What is the rationale for adopting a CBPR approach?

In this concept paper, the rationale for changing the current structure of clinical trials mentions “accrual rate,” “enrollment” and “enrolling required number of patients on time” and thus focuses on the need for new strategies for clinical trial recruitment and participation. Does an emphasis on solving the challenge of enrollment in clinical trials automatically lead to a CBPR approach or instead, to greater participation in some aspects of the clinical trial design and implementation?

Is CBPR appropriate for cancer clinical trials?

If indeed the rationale for change to the current structure of cancer clinical trials is driven by concerns about enrollment, then perhaps it is a less participatory approach than CBPR that we should consider. Participation of lay persons in research can be thought of as the following continuum, with basic research being the least participatory and CBPR the most participatory.

One can increase lay participation in clinical trials design and implementation in ways that, while not a CBPR approach, would move the study towards the more participatory end of the continuum. For example, the sponsoring agencies of the National Children’s Study, while placing a high value on the necessity of community engagement in the study, acknowledge that, due to a standardized core protocol with collection of data from multiple sites across the U.S., it is not possible to follow a strict CBPR model. The NCS is still committed to adhering to principles of community-based research when feasible and requires each participating center to establish a plan for community involvement and engagement.

It may seem strange for such a strong proponent of CBPR to be questioning the use of CBPR. Because I am not convinced that a true CBPR approach can be used with cancer clinical trials, I worry that we will be promising more than we can deliver to communities by suggesting we will take a CBPR approach and allow them more power and control than they will actually be granted. Consider the following two key aspects of CBPR: a) the involvement of all partners in all stages of the research process, including defining the initial problem and the research questions for the research and; b) a focus on the local relevance of the problem that pays attention to individuals and the larger contexts in which the individuals and their families and networks exist (including consideration of the biomedical, social, economic, cultural and physical and environmental factors that influence health and disease).

Can clinical trials fully engage community members in defining the problem, given that, as the authors note, “clinical trials help to move basic scientific research from the laboratory into treatments for people?” This suggests that the problem has been pre-defined at the basic scientific research stage, before the clinical trial has begun and thus, before community partners have become involved. Additionally, by their very nature (a mechanistic, laboratory based finding leads to development of a medical treatment to be tested on populations who exhibit the disease or risk factors for the disease), I am unclear how therapeutic clinical trials, at least those focused on medicines or procedures, could consider the multiple determinants of disease and health throughout the entire research process. [Note: I acknowledge possible differences between types of clinical trials that may make one more suitable for CBPR than the other. For example, behavioral based prevention clinical trials, which must consider myriad social and other factors influencing behavior, may be more appropriate for CBPR than drug or procedure therapeutic trials, which can still benefit from increased community involvement without being a true CBPR approach].

Who is the community or communities that will be the focus of the CBPR efforts (or engagement efforts) in clinical trials?

The authors have used the following definition of community as the basis of their discussion: “community as a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.” It is not clear how other lay persons and groups mentioned, such as “advocates,” “survivors” and “patients/clients,” fit with this definition of community. Are the intended communities the patients who might benefit from the therapeutic treatments or the advocates and/or survivors who have a strong interest in the role of clinical trials or the geographical locations from which cancer patients come? If this last definition, will those communities embrace “cancer clinical trials” as a priority activity when they might have other issues, such as safe and affordable housing or other chronic diseases, that are of greater priority?

Another issue involving the definition of community is the issue of who will be engaged in a CBPR effort. A CBPR approach often engages community organizations in addition to individuals and institutions. For community engagement in therapeutic clinical trials, who would we want to engage: individual clients/patients/advocates or community institutions or broader community organizations or some combination of all of these? And if we are interested in engaging the organizations, what would be the benefit to them in engaging in this partnership if the focus is more on clinical trials of individual treatment than community prevention or intervention?

The definition of community is particularly important to this discussion because without it, we run the risk of suggesting that individuals or groups (e.g., cancer patients, advocates) or communities of survivors can be engaged in similar ways as geographical communities. While cancer patients, advocates and survivors may be and probably are communities in terms of their shared experiences and perspectives, they may not fit the geographically bounded definition of community used by the authors.

Conclusion

In sum, while I do support the call for greater participation of lay persons and communities in clinical trials, I am not sure that a CBPR approach is feasible or appropriate, given the challenges I have identified above. Thus, instead of “How can we conduct cancer clinical trials with a CBPR

approach?” the question may instead become “How might we increase participation of lay persons in clinical trials and what strategies will help us to increase engagement of the organizations, agencies and institutions that can help us to realize that greater participation?”

Nancy Roach
President and Chair, Board of Directors
C3: Colorectal Cancer Coalition

Involving Communities as Partners in Cancer Clinical Trials lays out an idealized and idealistic approach to cancer clinical trials through CBPR. As an advocate involved with the development and implementation of cancer clinical trials, and with the dissemination of research results to the patient community, my experience is that strong community involvement in all aspects of research strengthens and improves the research process and product.

At the same time, my experience leads me to believe that large-scale implementation of CBPR is almost – but not quite – impossible. CBPR proposes significant changes to the existing clinical research system. There is an old saying: “when you are up to your ass in alligators, it’s hard to remember that your original objective was to drain the swamp.” Today, alligators run throughout the system, and I believe that two of them must be corralled before we can turn our attention to our original objective: great research that yields better patient outcomes.

Alligator 1: Bureaucracy

The bureaucracy of public research is dense and relatively un-studied using standard process evaluation techniques. The required research is finally beginning to occur. Dilts et al¹ applied standard process evaluation techniques to an analysis of thirteen phase III studies in a national cancer cooperative group. The completed process map measured 20 by 3 feet in 8-point font, illustrating the complexity of just one aspect of a much larger system. Problems with the system are well-known and numerous attempts are underway to ‘fix’ them, including the implementation of the NCI Clinical Trial Working Group recommendations².

In my non-cancer life, I was a systems analyst and saw first-hand the difficulties involved with changing a complex system. One challenge in the publicly-funded clinical research bureaucracy is the presence of multiple organizations with competing agendas, making it difficult to define who can lead the way in corraling this alligator. Leadership is critical. Dilts, in a response to a comment on his article, echoes this concern:

Finally, one of the purposes of our article was to ... "to light a fire" under those with the authority and the responsibility ... If not, we fear that oncology clinical trials in the United States as we know them today may be following the same path as that of the United States automotive industry (ie, swamped by international competition, historical complacency, and dissatisfied customers).³

¹ Dilts DM, Sandler AB, Baker M, et al: Process to activate phase III clinical trials in a cooperative oncology group: The case of cancer and Leukemia Group B. *J Clin Oncol* 28:4553-4557, 2006

² Clinical Trials Working Group <http://integratedtrials.nci.nih.gov/>

³ In Reply David Dilts and Alan Sandler *JCO* 2007 25: 1148-1149
<http://jco.ascopubs.org/cgi/content/full/25/9/1148-a>

Alligator 2: Resources

Change without resources is tough. The real cost of public research is not covered by public funds⁴. In addition, public funding is shrinking. The doubling of the NIH budget in the early 2000s led to a ramp-up of NCI's budget. However, since 2004, Congressional appropriations have not kept up with biomedical inflation, which has resulted in very real cuts to the clinical research system⁵ and to cooperative group activities.⁶

The funding gap has resulted in increasing reliance on funding from industry, in the form of charitable donations to entities such as the NCI Foundation and cooperative group foundations. While all involved have processes in place to ensure that industry funding does not unduly influence public research, I join Peppercorn and his colleagues who concluded, after reviewing ten years of breast cancer research, that "Pharmaceutical involvement in published clinical breast cancer trials may affect study design and likelihood of reporting a positive result."⁷

Clearly, the lack of resources is an alligator that keeps attention from draining the swamp.

Draining the swamp

Will CBPR help drain the swamp? Will the theory of CBPR help us reach the reality of our objective of great research that yields better patient outcomes? I think it could. CBPR proposes the involvement of consumers ('community') in the product ('treatment') development cycle, a concept that is shown to add value in other product areas⁸. At the same time, I suspect that turning theory into reality will be challenging, especially given the two alligators. The public research system is both inefficient and under-funded, making change difficult.

My gut feeling is that the aspects of the CPBR model that will support accrual most directly in the existing system and infrastructure are: development of accrual and retention plans in conjunction with the protocol; and patient contact about trials at first physician visit. I believe that these would be relatively simple to implement if appropriate resources and expertise are applied to the public research system (largely cooperative groups).

The larger issue – creating a true partnership between the community and researchers – is much more complex because the theory of CBPR assumes that the community is educated, trained and engaged. In my opinion, today's reality is quite different.

⁴ C-Change, The Lewin Group, Lovett-Collins: A Guidance Document for Implementing Effective Cancer Clinical Trials Version 1.2 http://www.c-changetogether.org/about_ndc/newsroom/reports/GuidanceDocument.pdf

⁵ Goldberg, Kirsten B: NCI Anticipates 60% Decline In Number Of New Trials By Cooperative Groups. The Cancer Letter Vol. 33 No. 1 Jan. 12, 2007

⁶ Schilsky, R: Message from the Group Chair. CALGB Spring 2007 Newsletter Vol. 16 No. 1, page 2 <http://www.calgb.org/Public/publications/calgabs/2007/spring2007.pdf>

⁷ Peppercorn J, Blood E, Winer E, Partridge A: Association between pharmaceutical involvement and outcomes in breast cancer clinical trials. Cancer 109:7 1239-1246, 2007

⁸ Consumer involvement in product development is common in the business world, and discussed extensively in business literature. For example, see Identifying the Key Success Factors in New Product Launch, C. Anthony Di Benedetto, 1999 and EXPERIENCE: The Invisible Success Factors in Product Innovation, Robert G. Cooper

The reality I see is that while advocates represent the community in public cancer research venues such as cooperative groups, those advocates are not generally true partners. I have seen many situations where an individual advocate has impacted a research project in a positive way; however, I've seen more situations where advocate feedback has been missing, ignored and/or inappropriate. We are at the table because we or someone we love got sick, not because we have any particular expertise around representing our communities effectively, or because our input is critical to the product. Our roles depend largely on our personal presence and the willingness of individual researchers to hear our message.

Feedback from both advocates and researchers has shaped my conclusion. For example, C3: Colorectal Cancer Coalition provides annual training for GI research advocates. At the January 2007 training, twenty-one participants,⁹ including cooperative group, SPORE and FDA advocates, were in attendance. Discussions during the training indicated that while all advocates were eager to add value to the process, few understood how to make it happen. Similarly, in conversations with researchers, I've been told that advocates should support research by: helping to accrue trials through outreach in their 'cancer' community; and; increasing funds through lobbying Congress. My conclusion is that the concept of research advocates being involved in the development and implementation of research is novel to many in the clinical research arena, and not generally understood by either advocacy groups or institutions.

Why is this so? I think it's because the function of 'community' (patient, consumer, advocate) input is undefined – while we may be at the research 'table,' neither we nor the researchers have a good understanding of why we're there and how we can do our job. In general, advocates lack roles and responsibilities, training, and opportunities to provide input.

Developing the 'community' and incorporating us meaningfully into the process is a significant effort, which will require time and resources. The two alligators are also significant barriers. These barriers, however, can be breached. One example is Project IMPACT¹⁰ (Involving More Patients in Clinical Trials), developed by the advocate committee of the American College of Radiology Imaging Network (ACRIN)¹¹. Part of IMPACT is a review template that incorporates many of the elements defined by the CBPR model. Fundamental to the concept of IMPACT is that advocates

⁹ Specific breakdown of advocates was: cooperative groups – 13; SPORES – 5; FDA Patient Consultant – 3; affiliated with cancer-related nonprofit – 10. Nancy Roach chairs C3's Board of Directors

¹⁰ <http://www.acrin.org/ProjectImpact.html>

IMPACT is a review template which incorporates many of the elements defined by the CBPR model including:

- Consumer perspective on the research question
- Accrual and retention plans developed in conjunction with the protocol
- An informed consent which results in an informed patient

The IMPACT review is required in ACRIN's protocol development process. Reviews have shaped several ACRIN protocols, and use of the template has eased the introduction of new advocates to ACRIN. ACRIN leadership has fully supported advocate efforts with both staff and funding. Evaluation of IMPACT is underway; anecdotal feedback indicates that through IMPACT, advocates provide a consistent and substantive impact at all stages of ACRIN's research

¹¹ Nancy Roach is a member of the ACRIN patient advocate committee

are involved from the birth of the concept to the approval of the protocol. ACRIN provided the time, resources and leadership to make IMPACT possible; in return, advocates have clearly defined roles and are held accountable for their performance.

At the end of the day

Advocates are advocates because they want to make a difference. In the CBPR model, Michaels and Siefer lay out specific components of where and how advocates can make a difference in their community in substantive ways. Both leadership and resources are required to implement such efforts. The swamp can be drained, but the presence of those two big alligators makes it challenging.

Mary Jackson Scroggins
Co-Founder and President
In My Sister's Care
Washington, DC

Overview

Involving Communities as Partners in Cancer Clinical Trials focuses on CBPR as a model for cancer clinical trials. It is both a primer on CBPR and the clinical trial research system and the draft of a policy statement supporting broader, more meaningful implementation of CBPR as perhaps a bedrock component. The current paper is more useful as a primer than as a policy document.

Background and Context

In setting the context for a discussion of CBPR, the paper highlights (1) the low national clinical trial participation rate—3% out of an eligible pool of 20% of cancer patients—and the even lower rate for medically underserved groups; (2) the discrepancy between the percentage of people who report a willingness to participate in clinical trials and the percentage who actually do; and (3) the findings from a 2005 Agency for Healthcare Research and Quality report. Missing from this discussion is a strong statement on physician and/or investigator bias or selectivity as a significant factor in low accrual rates. The Wendler et al article (2005), in part, addresses this issue: “We found that racial and ethnic minorities in the US, particularly African-Americans and Hispanics, are as willing to participate, and in some instances more willing to participate, in health research than non-Hispanic whites, when eligible and invited to participate.”

In making the case for CBPR in cancer clinical trials, the paper does not address points such as the fact that (1) although the NIH mandates inclusion of vulnerable groups, enforcement is weak; and (2) equal access is not “less a matter of scientific necessity than of social justice.” Equal access—a precursor to equitable representation—is a matter of good science and also a matter of social justice. It would be ideal for the issue of social justice alone to be sufficiently persuasive to dictate change. Clearly, it is not.

Application to Cancer Clinical Trials

At the heart of meaningful expansion of CBPR is appropriate community representation. The paper does not emphasize the difficulty of achieving such representation, especially in underserved communities. Authentic representatives from such communities are rarely at the table. More often, they are “represented by” others—usually well-meaning and sometimes well-informed individuals thought to be better able to work and maneuver within the research community. Identification and recruitment of authentic community representatives, respect for what they know rather than disdain for what they have not yet learned, and ongoing training and interaction with the key players are essential to successful and genuine CBPR.

Examples described as evidence of broad community support for engaging as clinical trial “partners”—meaning being more than participants or enrollees—are not always evidentiary as opposed to being suggestive. Although my personal belief, supported by anecdotal evidence, is that

communities do support increased and meaningful engagement, portions of the discussion do not directly demonstrate such support. For example, the paper reports a finding that most U.S. adults value clinical research and would consider a clinical trial if needed; however, this finding provides evidence on U.S. attitudes about clinical trials rather than of the desire to become true partners in research.

Barriers

The barriers to community-based participatory cancer clinical trials are considerable but not insurmountable. Respect for, authority of, and integration of community members within research activities are uneven, and this unevenness is a tremendous challenge to the widespread integration of CBPR. The commitment to ongoing training—for community members, physicians, researchers, and other medical personnel—is essential to changing perceptions and enhancing proficiencies. This will be costly.

A related significant challenge is receiving and maintaining sufficient funding to support community members as equal partners—rather than as “window dressing.” The perception that it is unseemly and/or unnecessary to fund advocates and survivors is widely held, despite the fact that nearly all other advocacy and research participants are funded in some way. This reluctance to fund advocates and survivors—and by extension perhaps community members—has many effects, not the least of which is ensuring that only an exclusive group will be able to participate significantly. Socioeconomics, race and ethnicity, gender, education, and zip code as well as other factors that place one at increased health and medical disadvantage, also exponentially decrease one’s likelihood of active engagement in advocacy and research. The same will certainly be true for CBPR participation, especially given the need for sustained engagement and meaningful work.

Clear emphasis on these and other barriers must be included in the final version of the background paper, along with mechanisms for addressing them.

Background Paper Recommendations

Perhaps because the paper was developed partially to stimulate discussion among participants in the upcoming Conference Series, the recommendations are insufficiently specific, lacking language that guides change as opposed to simply suggesting it. Each recommendation should link to at least one specific strategy for achieving it.

The second and third recommendations for practice should emphasize the importance not only of building relationships before accrual begins, but also before the community is ever approached about engaging in a clinical trial. In other words, the relationship should long precede the invitation to partner in a trial.

For research, recommendations have not been provided, but questions to be addressed before developing and proposing a specific CBPR model are listed. The questions seem appropriate as starting points. It would be instructive to add questions for other recommendation sections to enhance specificity and breadth.

The recommendation to improve funding to build capacity within communities is essential; it will be a significant challenge to convince policy makers, and perhaps the public, of the importance of such

funding, especially in the current funding atmosphere. Additionally, contracting as equals with different areas of expertise and functions is preferable to a subcontract arrangement. Historically, underrepresented populations and the institutions that serve them have not fared well in such arrangements, gaining little in infrastructure development and fiscal or fiduciary stability. Developing more equitable contracts and more robust relationships will be another substantial challenge to the existing system.

Conclusion

This background paper is a work-in-progress relative to developing practice, research, and funding and policy recommendations for shifting to a CBPR approach to cancer clinical trials. The scope of the Conference Series for which the paper is preparatory is broad and ambitious, and the need for more representative, meaningful participation in the cancer research system is tremendous, both as a matter of good science and as a matter of social justice and medical equity. With only about 3% of eligible cancer patients participating in clinical trials and the health disparities gap gaping, broad, ambitious moves are required. The challenges are daunting, and strong resistance is a given.

Mary Lou Smith
Co-founder, Research Advocacy Network
Co-chair, ECOG Patient Representative Committee

How feasible/realistic are the various components of the model?

The feasibility of this model and its various components are dependent upon having a thoughtful implementation plan. The model would be enhanced by a discussion of how this model would be implemented. For example, the report states, “All protocols should demonstrate evidence of meaningful community involvement.” The definition of meaningful participation in the narrative talks about a role in approving protocols but needs to explain that role and who and how the meaningful participation will be evaluated.

The report also states, “Sufficient funds are made available at the local level for CABs and recruitment and retention initiatives.” How would this be achieved on an ongoing basis in a climate of diminished funding? Grant sources of funding are unpredictable. Developing a model dependent upon grant monies could be difficult to sustain, creating a program that could not be maintained over time. Setting up a program without sufficient long-term funding would raise unrealistic community expectations and could destroy rather than build relationships between the research community and the partner communities.

There needs to be a clear definition of community representation for a national cooperative group system. Since the cooperative groups are multi-centered and geographically disperse, the immediate community surrounding each research site will differ. Different cultures require their own representatives. The sheer numbers of community representatives may present a recruitment and retention problem. The cooperative groups currently have patient advocates who may or may not meet the definition of community representative. There must be a clear delineation of roles and responsibilities to ensure a uniform understanding of how the community representative fits within the system.

If the community representative will also represent different types of cancers, it may require a greater effort to recruit community representatives for cancers such as lung, pancreas and brain. Some of the cooperative groups are disease and modality specific, which would need to be taken into consideration in recruitment.

There is little detail about recruitment, training, retention and evaluation of the community representatives. The community representatives will need to be recruited and, in some instances, trained to be effective in understanding and influencing the clinical trial system. Some baseline understanding of the science, the process and the system will increase their acceptance and the outcomes of their activities.

The NCI has been studying the issue of underserved participation in clinical trials and has targeted the recruitment of the underserved for their patient advocate programs, e.g., Directors Consumer Liaison Group (DCLG) and Cancer Advocates in Research and Related Activities (CARRA). Their experience in recruitment, training and retention may be helpful in understanding “best practices.”

From your perspective, is there value in implementing such a model in your work? If so, what would it be? If not, why not?

Most people involved in cancer research through the cooperative group system acknowledge the poor representation of underserved populations in clinical trial enrollment. The cooperative groups have underserved or special populations committees initiated to address this problem. These committees could be a source of information and support for this model. At least one of these committees has already tried to bring a community representative into its deliberations. ACOSOG has several community representatives as standing members of its committee. This committee has also invited community representatives as ad hoc members to bring their community's perspective to the table.

Trust is an important component of relationships with communities. Having documents and processes that reflect the community and its diversity would enhance trust between the research and patient communities and increase accrual to clinical trials. The cooperative groups have been slow to provide informed consent documents in other languages, limiting accrual by non-English speaking people. A lower reading level would open clinical trials to low literacy participants. The consent process would be improved by addressing cultural and racial differences.

What do you see as the most significant challenges and barriers to implementing this model? How might these be overcome?

Funding will be a critical issue for recruiting, training and compensating the community representatives and for coordinating the development of a functional model. All cooperative group members including patient advocates, except for the central office staff, are volunteers. Paying the community representatives may give an unintended message that more is required of them.

A second challenge will be articulating realistic and clearly defined expectations for community representatives. How do community representatives differ from the patient advocates who are currently members of the groups?

Integrating this model into the existing cooperative group system could be a challenge. The cooperative groups meet face-to-face one to three times per year. Some committees have monthly conference calls, which are limited to an hour and are focused on advancing specific clinical trials. There is not much opportunity for interaction and relationship building. Establishing functional working relationships may take years instead of months. It would be important to have a well-thought out implementation plan to assuage any concerns that this initiative might take time and money away from designing and completing clinical trials. Slowing trial activation and completion would be counterproductive.

Using the NCI-designated cancer centers instead of the cooperative group system might be more feasible without the concerns about funding, volunteerism and expectations. Individual cancer centers have a defined population, including minorities and underserved. Most of the NCI-designated cancer centers do not have the same level of formal advocacy involvement and adding community representatives would not interfere with established relationships. The lack of an established organizational structure to support center-wide advocacy could allow a greater level of

involvement and creativity in providing input from the community. NCI-designated comprehensive cancer centers are required to do community outreach.

If implemented, how would this model affect (negatively or positively) your work?

If this model can be successfully implemented, there should be an increase in the number and diversity of people involved in research advocacy. Since our mission is to improve patient care by providing the patient perspective to the research process, this model would support our mission and its community representatives could use our Advocate Institute to support their efforts.

The Research Advocacy Network has worked for a number of years to increase the number and effectiveness of community members on IRBs. Increasing the awareness of this opportunity for service in the community would increase the number of community members involved in the process, enrich the research and build greater trust between the institution and the community it serves.

Robb Travers, PhD
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Involving Communities as Partners in Cancer Clinical Trials proposes a model of sustained community engagement/partnership to overcome the challenges currently facing the field, namely:

- Participation in cancer clinical trials (particularly racial and ethnic minority groups, those on the lower end of the income disparity spectrum, and the medically uninsured in the U.S.) is low.
- Effective approaches to engaging minority communities in cancer clinical trials are not well-understood.
- Best practices in community engagement, trust-building, and knowledge transfer and exchange are not well understood.

Taken together, these factors significantly impede the quality of research and scientific advancement.

An increasing body of literature (well-cited) concludes that sustained community engagement in all stages of research (in the form of community-academic-policy partnerships) is urgently required to improve the challenges facing cancer clinical trials. Drawing on the principles of CBPR, a well-conceived model of community engagement across input (research design and question identification), process (data collection, analysis and interpretation) and outcomes (dissemination) stages of research is recommended. Within this model, the authors also propose strategies to redress some of the current challenges related to ‘community ethics’ in research.

One flaw in the literature review occurs on page 15, where the authors overlook the uneasy distinction between the community’s desire to ‘participate’ in research and ‘partner’ in research (there are at least four examples of this oversight on that page).

The proposed model of community engagement/partnership is well-conceived and it is obvious that the authors have gone to considerable lengths to address the complexities of community engagement in research. I offer the following feedback for the authors to consider.

How feasible/realistic are the various components of the model we have presented?

My first question relates to broader community capacity. The same social determinants that fuel disparities in health have direct impact on the abilities of communities to effectively address their own health concerns. My assumption is that relative poverty and access barriers to medical schools as well as public health and research disciplines, have left many communities ill-equipped to participate as full partners in research. As such, is there a set of developmental or capacity-building initiatives that will have to be put in place before such partnerships can occur on a sustained basis? Moreover, what kind of policy work is needed to encourage medical, public health and research disciplines to train professionals from these affected communities?

My second concern about capacities is directly related to the training of the community individuals needed to populate these research partnerships. While the proposed model is theoretically sound in covering input, process and outcome stages of research initiatives, such participation hinges on individuals who can ‘equitably play’ in these partnerships. Do these capacities exist? If not, a plan for building them over time is required. In Canada’s HIV sector, there has been a tendency to rely on the same pool of leaders in the field when developing CBPR partnerships. A recent Ontario-wide study¹ examining barriers to meaningful participation of people living with HIV in all aspects of the local HIV sector, shows that ‘burnout’ is common when the same pool of talent is consistently drawn upon.

From your perspective, is there value in implementing such a model in your work?

Clinical trials are a serious concern for people living with HIV/AIDS and much advocacy work has been done with resulting changes in community engagement. Lessons learned from this initiative will serve to further develop efforts in other areas (such as HIV/AIDS).

What do you see as the most significant challenges and barriers to implementing this model? How might these be overcome?

Significant challenges will emerge if the concerns laid out about capacity-building are not addressed. Directly linked to this barrier is the question of how ‘meaningful engagement’ of community partners will be defined and measured. Community partners without adequate training will cease to participate in such partnerships, feeling intimidated by jargon, the credentials of more academically-trained partners, and resulting feelings of inadequacy. Realistic roles (and the corollary training to meet their expectations) must be identified and built into this model for it to be successful. Training in research methods, ethics, and knowledge transfer and exchange will be crucial to the success of this model. While it is admirable to state that community partners will be engaged across all phases of research, it is another to put in place the capacity-building plan to ensure its success.

If implemented, how would the model affect (negatively or positively) your work?

As an organization committed to engaging community in all of our initiatives, we will learn from the successes and challenges of this endeavor.

¹ http://www.ohtn.on.ca/pdf/living_serving_report_April07.pdf

JoAnn Tsark
Research Director, Papa Ola Lōkahi
Program Director
ʻImi Hale – Native Hawaiian Cancer Network
Honolulu, HI

The various components of the background paper model are comprehensive and the table comparing current and proposed CBPR approaches highlights key steps and strategies. The question, “How feasible/realistic are the components?” is difficult to answer. Much depends on the willingness of current players and funders to acknowledge the value of community participation and their willingness to share power and resources with the community, as well as the willingness of current institutions to adopt and enforce CBPR processes. From the community perspective, the question is not one of feasibility. Instead, the operative question is: “What is the right thing to do and the right way to do it?” however feasible or unfeasible it may seem.

Also, feasibility and reality can be affected by the parameters/requirements that funders put on research. If RFAs require CBPR processes and demonstrated community involvement at all phases, amazingly, researchers respond to that requirement. If the criteria is explicit and the review process adequate, the sincere and committed respondents will be identified and funded, and the less sincere, “I’ll write what the funders want, but I have no clue how to operationalize CBPR,” will not be funded. As money is a big incentive, there is a need to identify mechanisms to fund researchers interested in CBPR approaches.

As a community-based, NCI funded Community Network Program (CNP), implementing such a model would be consistent with how we do business. We have used CBPR principles successfully in the cancer prevention and control research developed and conducted through our CNP. It is also applied to our cancer prevention and control programming that we support and conduct with other community based entities.

Current processes and philosophies are clearly unsuccessful in meeting the recruitment needs for clinical trials. CBPR has shown success, but current funding mechanisms are counter intuitive to CBPR, which requires more time and longer relationships based on trust. Other problematic issues include data ownership, control of the research process and compensation vs. volunteerism. There is also the issue of who ultimately benefits from the research.

Significant barriers to implementing this model include funding mechanisms that are counter intuitive to CBPR; insufficient time for meaningful relationship building and quality community involvement; insufficient resources for the training and capacity building needs of community members (in conducting research) and of scientific/medical staff (in community organization/mobilization).

A possible solution is to work collaboratively with the NCI and pharmaceutical companies to fund pilot CBPR recruitment grants, which provide incentives, resources and opportunities for community-based organization to conduct the recruitment, provide the education and facilitate the informed consent process.

Another barrier is the denial and arrogance of current researchers and cooperative groups about the contribution and value of community involvement at all phases of research. Clinical research RFAs reflect a paternalistic paradigm. Therefore, asking current researchers to share power and decision making for rewards that are often a long time in coming is difficult. Researchers are often better equipped to deal with low recruitment, rather than two years of relationship building with a community, which often involves addressing historically negative research events and subsequent distrust. In addition, researchers are not supported by their parent institutions to engage in CBPR.

The current clinical trial infrastructure has no room at the table for community representatives (except as subjects). Some researchers may be willing to consider community members in the “recruiter role,” but it is unlikely that community representatives are envisioned or desired at the decision making forums. Conversely, if the invitation was extended, there is a need for training and capacity building, to prepare community members for this role. Getting a seat at the table is hard enough. Having the confidence to participate with physicians and researchers requires more support and time. It would be unfortunate to have community members in a token role where they are consistently out voted.

If this model is implemented as proposed, a community-based program such as ours would be a significant partner and leader. A CBPR program would fit well with our network of indigenous professionals and paraprofessionals, all of whom have increased capacity to reach into the community and have higher degrees of trust with community members. Such a model would be considered a strength-based approach that community members could embrace, because the community’s ability to engage, participate and problem solve is valued.

Negatively, one concern would be inequity in compensation. Addressing this would require clear stipulations that a proportion of the funds/resources go to support community roles and functions.

For our community IRB (currently 40% community members and 78% Native Hawaiian), it would be refreshing to review research protocols that already adopt and incorporate CBPR principles.

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I appreciate the opportunity to respond to the background paper, which portrays a broad vision of a new model for cancer clinical trial implementation across the United States. This new model is founded upon the proposition that cancer clinical trial design, funding, approval, infrastructure, implementation, completion, analysis and conclusion will all be enhanced with the incorporation of many more individuals across the nation into all the steps listed above. The result intended is a newer generation of studies, which are to be more relevant to all population groups and will be completed faster because of the enhanced participation and trust the public will have in an enterprise with such broad national involvement.

The proposed new paradigm does have some attractive features. New studies are to have broader eligibility criteria, so accrual will be faster because a higher proportion of patients will be eligible. The paradigm implies that work, which has traditionally been voluntary, such as IRB membership, will be compensated fairly. The new model suggests that because there will be representation from the “community,” that patients will not view clinical trials as a unusual invasion of the doctor-patient relationship but will instead consider participation a manifestation of quality cancer care.

The new proposal, however, is based on an interpretation of information gleaned from past studies of barriers to clinical trial accrual. In those reports, patients regularly stated that the most important factor in deciding if they should participate in a research study was what their oncologist recommended. This fact underscores the importance of the doctor-patient relationship. Our new information age has transformed medicine, and the roles of both physicians and patients. Today, patients and their physicians have the difficult task of not only knowing the data, but interpreting it correctly in the context of the entire patient’s universe of illness, health, family, job, and environment. This new CBPR model ignores this critical relationship. If the CBPR model is to succeed, the doctor-patient interaction at the time a trial is an option needs to be strengthened and the extra time needed to discuss a study must be recognized.

The new proposal is based on the supposition that clinical trials are readily available for all diseases, and that the slow progress in improving cancer therapy is because of poor and unrepresentative accrual. The new reality is actually quite different. The dramatic drop in clinical trial accrual from 2006-2007 is not because the mechanism for accrual is weak. On the contrary, the accrual network of hospitals, clinics, physician investigators and cancer centers was at its peak during 2005-2006. Over the last twenty years cancer physicians across the country have developed multiple networks of cooperative groups, CGOPs, CCOPs, UCOPs, Cancer Centers, SPORES and regional networks to implement high quality studies, while being reimbursed at an inappropriately low payment level. Accrual was rising and the percent of patients entering trials was increasing, even with more complex studies, which incorporated biologic correlative studies.

The new drop in accrual this year is because there is no funding. The National Cancer Institute is reducing the funding for the nation’s clinical trial program and this has resulted in dramatic cutbacks in the cooperative group trial development activities and far fewer studies have been allowed to

open by the NCI. The new barrier to improving cancer care is, ironically, the National Cancer Institute. Obviously this is not by design, but is the result of a decade of building a much larger NCI infrastructure. This infrastructure requires a much higher budget for ongoing maintenance coupled with appropriations that, when adjusted for inflation, are actually less than budgets from five years ago. There will be no progress in clinical trial design or implementation until a national stable funding mechanism is implanted, which that covers the total true costs of clinical research.

The new CBPR plan suggests that trials will answer better questions (such as quality of life), be more relevant, accrue faster, and change medical practice faster if community members are intimately involved at all levels. The background paper implies that only through broad community involvement will the most important questions be identified, and that trial design will change to afford all patients at some point (i.e. crossover design) the benefits of the new intervention under study. The progress in cancer treatment is built on the foundation of testing, questioning, and retesting hypothesis. It is inappropriate to assume that any intervention holds an advantage over the current standard of care. The recent negative studies incorporating targeted therapy into non-small cell lung cancer treatment are excellent examples of how new ideas must be tested. I can understand that many patients desire the newest treatment, but it isn't always the right treatment. Critical questions in cancer must be tested thoroughly with studies that are designed clearly and powered adequately to answer the question. The new knowledge thus gleaned will then truly help the next decade of patients do better, rather than remain in doubt.

Broader community awareness of how studies should be a part of the fabric of medical care will be an outstanding achievement of the ENACCT-CCPH initiative. Hopefully, the NCI will again recognize the critical role that clinical trials have played in developing new therapies and in improving our understanding of the biology of neoplasia. When that renewed commitment occurs, real progress against cancer can again be made.

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As a community oncologist, I have comprehensive experience in the conduct of community clinical research as well as serving in leadership roles for educating other community investigators. Additionally, I have initiated/authored my own clinical trials as principal investigator and served as the community co-investigator for Phase II and Phase III trials. Therefore, the following commentary should be considered in context of this background.

In approaching this commentary, I first reflected on what I consider to be the most important principles as they apply to the conduct of clinical research. Very simply, I hold paramount to all else, that the rights, safety, well-being and confidentiality of clinical trial participants be held in highest regard. Just as important, I believe the results of all clinical trials must be valid and be available to guide further research and treatment algorithms. These principles should apply to all phases of research and all research sites.

85% of oncology patients are treated in the community setting. Thus efforts to improve community trial participation must address issues relevant to community oncology practice. The barriers at the community level have been identified and include lack of awareness, sub-optimal insurance coverage, complicated logistics, strict eligibility criteria, and negative patient beliefs. Acknowledging the barriers, as well as appreciating where patients seek their care, certainly supports the Communities as Partners in the Cancer Clinical Trial system model.

The model proposed, in part, is feasible/realistic. Portions of the model have been and currently are already implemented and serve as examples of where community partners have enhanced the system. As an example, consider how the Research Advocacy Network (RAN) has influenced research in a productive manner. RAN conducted focus groups and changed the design of the TailorX trial, although they did not change the research question. RAN has also developed the Gilda's Club Program, interpreted clinical trial results and disseminated effective and understandable patient education materials (for example, in explaining the results of MA-17), and is involved in patient advocacy mentoring programs.

However there are portions of the model that elevate the role of the community partner beyond their current expertise and training. As an example, community oncologists must be knowledgeable in evaluating and treating many different oncologic and hematologic conditions. Therefore, community oncologists rely on the expertise of academic and disease specific specialists for the initial work in translating laboratory discoveries into clinical trial research. The complexity of this process is beyond the training of the general oncologist, positioning the academic scientists as the most appropriate group to define the research question and efficiently design/implement early trials with the necessary scientific rigor. This in turn results in the generation of valid results, which subsequently serve as a basis for advanced clinical trials (Phase II/III). Although community oncologists are considered "team members" in the clinical trial system, identifying limitations and strengths has resulted in optimal utilization of our contributions. I would suggest that the

community model honestly define strengths and limitations and identify opportunity within the model to optimally apply these skills.

From my perspective there is absolute value in implementing parts of the model in my work. The strength of the community approach lies in the implementation of the clinical trial process ranging from development of the informed consent process, to participation as a member in the local research team, IRB, recruitment (supporting patients by listening and sharing experiences as well as supporting decision making), marketing (increasing awareness in the community), as well as lobbying and advocating for enhanced insurance coverage and research funding. Community participation would also assist the patient community by enhancing the interpretation and dissemination of study results. As clinical trial results are incorporated into standards of care, the community partner could also advocate for reimbursement of these newer interventions. Our local experience in partnering with the community has proven effective, supporting the value of this partnership.

There are two significant challenges and barriers to implementing this model:

Compensation for community partners

These are difficult financial times for the community oncology practice; the conduct of clinical research trials is not immune to this problem. Due to reimbursement changes at the government level, and subsequently, third party payer level, community oncology practices are closing and/or shifting patients to hospitals that in turn are also closing their doors.

Additionally, within the community research model, IRB members and investigators contribute many hours on a weekly basis, without compensation. There are instances when physician investigators actually lose practice revenue when patients participate in certain clinical trials. There have been some situations where physician investigators have donated money in order to sustain research at their site.

To make matters even more challenging, NIH funding for clinical trials is shrinking, with the full impact at the community level not fully known at this time. Therefore, if “community participants” want compensation, sources other than currently assigned NIH funding and community level resources will need to be found.

My recommendation is that compensation issues need to be re-analyzed; and additional resources for community partner compensation need to be developed and systematically allocated in a fair manner.

Training of community partners

Training of community partners is not currently defined in the model. However, at a minimum, there may be some roles the community partnership assumes, which must be held to the same standard as others serving in that capacity. This may include OHRP testing. Additional training, such as familiarizing oneself with good clinical practice guidelines and local standard operating procedures, may be necessary to fulfill other roles, which will take time and study. The resources necessary to accomplish this are significant, and there must be commitment on the part of the community partnership to justify the expenditure of already limited resources.

Clearly as discussed in the context of the above comments, the community model, in part, would have (and already has had) a positive effect on the clinical trial process at the community level.

Conclusion

In closing, I suggest developing:

- An inventory of other potential partners who are currently implementing portions of the proposed model. Consider inviting them to the table for purposes of combining resources, thereby avoiding duplication of effort and efficiently utilizing resources. In other words, do not “re-create the wheel,” but instead develop a clearinghouse of existing resources.
- A metric to measure the success and limitations of the model as it is implemented. This would allow the model to be appropriately modified to maximize impact.
- A strategic approach to implementing the model. Incorporate work already being done. Identify strengths, prioritize implementation and develop a timeline (and stick to it!).