Ethical Issues in Community-Based Participatory Research: Balancing Rigorous Research With Community Participation in Community Intervention Studies

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Abstract

Problem: Concerns have been raised that community participation might compromise scientific rigor in community-based participatory research (CBPR).

Purpose: The purpose of this paper is to identify potential sources of tension between the values of scientific rigor and community participation in CBPR.

Key Points: CBPR lies at the nexus of two major underlying ethical concerns—respect for community autonomy and the fair allocation of limited public resources—which have generated considerable controversy about appropriate criteria for evaluating CBPR grant proposals. The complexity of evaluating CBPR proposals is compounded by the multiple purposes that it serves: (1) an ethical function of demonstrating respect for community autonomy; (2) a research method for eliciting ideas for interventions to improve population health; and (3) an intervention in itself, seeking to enhance the capacities of community participants.

Conclusions: Growing use of CBPR raises two new ethical issues that deserve greater public attention: first, the problem of securing informed consent and demonstrating respect for community autonomy when the locus of research shifts from the individual to community level; and second, fair distribution of scarce public resources when practical constraints make the most rigorous research designs for assessing the effects of community interventions virtually impossible. In light of recent federal initiatives, it is critical to achieve a common understanding of appropriate ethical and scientific standards for assessing the merits of CBPR.

Keywords

Community intervention research, ethical analysis

A convergence of interests has raised questions about a potential tension between scientific rigor and community participation in health research. In this paper, we show how this tension can be traced to two major underlying ethical concerns: (1) demonstrating respect for community autonomy (including procedures analogous to obtaining individual informed consent); and (2) determining fair procedures for allocating scarce federal health research resources across different research designs. The paper examines how these two issues may have become conflated in controversies surrounding the increasing attention to CBPR. CBPR advocates are advised to attend to these underlying ethical concerns in responding to potential criticisms of this new research methodology.

From the outset, it is important to distinguish CBPR from community participation and from community health research. First, although a standardized definition of CBPR has not yet been formulated, proponents point out that community participation per se does not necessarily qualify a project as meeting nascent standards of excellence in CBPR. If community participation is seen on a continuum, then CBPR can be understood as an orientation to research that aims at maximum feasible community participation in all phases of the research. Thus, in principle, CBPR can be used with any research design, from epidemiologic studies to clinical trials. In this paper, we focus on randomized controlled trials (RCTs) to test community health interventions, because there are increasing calls for "evidence-based" public health and RCTs

are considered the most rigorous research design. Second, in contrast to individual health, community health research seeks to discover new knowledge to improve population health. As such, community health intervention research does not necessarily have to use a CBPR approach, and traditionally, it has not. With these distinctions in mind, this paper examines the ethical issues raised by the use of CBPR to test community health interventions.

The article opens with an analysis of two new ethical issues raised by public health interventions. Unlike previous case studies[1–4] that have examined ethical dilemmas internal to the conduct of particular CBPR projects, this paper addresses issues that are generic to the conduct of community health intervention research. We start with a discussion of the ethical challenges encountered when the locus of research shifts from the individual to the community level, specifically with regard to the issue of demonstrating respect for the community's right to self-determination. Next, we identify several "structural impediments" that make assessing the effectiveness of public health interventions in standard RCTs virtually impossible. This analysis raises the question of how research proposals aimed at the community level can be evaluated fairly, when it is infeasible to use research designs widely acknowledged as the most robust.

The paper then shows how these two concerns have converged in discussions about the merits of CBPR. We argue that these discussions have become bogged down because CBPR proponents and critics have failed to distinguish the distinct purposes of CBPR. These three distinct purposes are (1) an ethical function of demonstrating respect for community autonomy; (2) a research method for eliciting ideas for interventions to improve population health; and (3) as an intervention itself, seeking to enhance community capacities.

Based on this analysis, the paper concludes with two recommendations for achieving a sound balance between scientific promise and community responsiveness in public health research. First, we propose a model standard for respecting the community right to autonomy, and second, we present a process for allocating the limited public resources designated for health research fairly. In light of the recent federal investment in CBPR initiatives, it is critical to achieve a common understanding of appropriate ethical and scientific standards for evaluating community health intervention research in the 21st century.

NEW ETHICAL CONSIDERATIONS IN CONDUCTING COMMUNITY HEALTH INTERVENTION RESEARCH

Since the promulgation of the Nuremberg Code, voluntary, informed consent has been recognized as a fundamental norm of health research.* Based on the principle of respect for autonomy, individuals have the right to decide if they want to participate after being informed about all relevant aspects of the research. In clinical trials, one important way that respect for autonomy is demonstrated is by obtaining written informed consent.

In clinical research, the process of gaining informed consent is straightforward. The purpose of the research, methods, and risks and benefits (if any) are explained and the individual decides whether she or he wants to participate. But how is this procedure supposed to be extended to a community? If community members have a right to autonomy and it is ethically unwarranted for researchers to conduct health research without their approval, then the major ethical challenge is to specify how respect for community autonomy should be secured. We see three progressively more inclusive possibilities.

In past practice, Institutional Review Boards (IRBs) have generally ignored the issue of respect for community autonomy. IRB approval has been considered sufficient to authorize community health intervention research, based on judgments about whether the risks are sufficiently minimal that individual informed consent can be waived. When an experimental intervention has been deemed to pose minimal risks, IRBs have waived the consent requirement and permitted community intervention trials to proceed.

Although IRB review of community health intervention research may be adequate in certain circumstances, it restricts the scope of investigations to relatively innocuous interventions (e.g., mass media campaigns), and hence is not sufficient in many cases. Consider the following: the effect of police roadblocks to test for impaired drivers, with the goal

* The analysis presented here is based on the ethical framework of principlism. The reader is referred to Beauchamp and Childress,[5] Emanuel et al.,[6] and Kass[7] for definitions of key principles of respect for autonomy and justice discussed in this report.

of identifying effective strategies to reduce traffic fatalities. At the individual level, is it fair to assume that the average social drinker would consider participating in the roadblock experiment in one's interest? At the community level, do community members have a right to question why their community was selected, whether they want to participate or not, or whether alternative strategies should be considered? Would an IRB be justified in designating such research as minimal risk?

To test more powerful community interventions, IRB approval alone cannot suffice. There must be a process that serves the same ethical function as individual informed consent, where the community as a whole can decide whether they want to participate. The dual needs for avoiding exploitation and affirming the community's right to self-determination lead into questions of representation: Who can legitimately speak on behalf of community interests? Drawing on the model of oversight in community health centers, one common procedure for addressing these concerns is to establish a Community Advisory Board (CAB).

Stipulating an ethical standard requiring oversight by a CAB is an important first step, but it is not enough. Further issues include the composition of CABs and the scope of their responsibilities: Who and how many should sit on these boards? How should they be selected? What should they be authorized to decide? Significantly, beyond CABs, CBPR proponents recommend other procedures to establish community approval of the research, including interviews with stakeholders and key informants, focus groups, community surveys, community forums, and partnerships with community associations.[8]

STRUCTURAL IMPEDIMENTS CONFRONTING COMMUNITY INTERVENTION RESEARCH

Like the rise of evidence-based medicine, public health interventions face mounting pressures to demonstrate that programs are effective in decreasing morbidity and mortality rates and reducing health disparities. Over time, certain scientific standards for assessing the quality of research evidence have become well established; the gold standard for conducting health research is the RCT.[9,10] Like the challenges in identifying appropriate ethical requirements when one shifts from the individual to the community level, it also is complicated to specify appropriate scientific standards for assessing community interventions. For public health interventions, the most rigorous research design requires randomly assigning communities to the different study conditions, in what are called *group-randomized trials*.[11] Conducting such research, however, is frequently not feasible, due to various structural impediments.

The most significant complicating factor is that public health interventions often involve policy changes, and randomly assigning communities to comparison conditions is generally not possible for pragmatic political reasons. For example, it is reasonable to hypothesize that limiting the amount of added sugar in food products will reduce obesity rates, but politically it is not feasible to randomly assign counties or states to treatment and comparison conditions to test this hypothesis. The feasibility of using RCTs becomes even more tenuous if unintended adverse effects are conjectured. Needle exchange programs, for instance, have been embroiled in arguments about whether their establishment condones drug use.[12] Because of such moral and political compunctions, many public health interventions cannot be investigated in RCTs.

Another major problem is that, in contrast with well-controlled laboratory studies, communities are open and dynamic systems, with a virtually unlimited number of factors influencing health behaviors. To produce an effect at the community level, public health interventions thus often require tests of the cumulative impact of multiple interventions simultaneously, to achieve a critical mass with detectable effects. To improve the quality of community interventions, Flay[13] has recommended testing interventions in phases, from pilot tests, to efficacy trials, and so on. But, because of the many influences operating at the community level, single discrete interventions have generally been found to yield a null or minimal effect. To reduce alcohol-involved traffic fatalities, Holder,[14,15] for example, implemented a study designed to assess the combined impact of (1) community mobilization through media advocacy, (2) responsible beverage service training programs, (3) stepped up police roadblock sobriety checks, (4) crackdowns on alcohol sales to minors, and (5) reductions in the number of alcohol retail outlets. Significantly, because it is frequently not possible to demonstrate the efficacy of individual components first, community health interventions face a much greater burden in providing convincing preliminary

evidence to demonstrate the plausibility of achieving positive results in a full-scale trial.

Furthermore, because of small sample sizes (i.e., number of communities), group-randomized trials are particularly susceptible to selection biases, differential histories, and contamination.[11] If the number of groups is less than 20, odds are that systematic differences between groups cannot be overcome by standard randomization procedures. In these situations, the recommended course is to use matched stratification procedures, but matching can be implemented only if the most significant variables influencing community dynamics are known in advance, and then, such comparable communities identified and recruited for participation. Likewise, with small numbers, it takes few external events that differentially affect the target communities (e.g., teens killed in a drunk driving accident) to undermine the validity of the results.

There are additional technical issues that we could present (e.g., questions of external validity[16,17]), but the point is that there are many intractable barriers to conducting RCTs of community interventions. A small number of group-randomized research designs have been conducted; the most well known is the COMMIT trial, in which 22 cities were randomly assigned to treatment and comparison conditions in an experiment designed to reduce smoking prevalence.[18,19] But such studies require a tremendous investment of public resources, and as Murray notes, "The disappointing results for several large trials have led some to question the value of group-randomized trials."[11,p.310] Based on their expense and intrinsic threats to their validity, it appears unlikely that major group-randomized community intervention trials will be undertaken in the foreseeable future.

Given the many factors that make group-randomized trials less feasible than clinical studies, one might then ask how the value of community health intervention research can be demonstrated and limited federal research resources allocated fairly. We return to this point in the final section.

THREE PURPOSES OF CBPR

In their 2003 text, Minkler and Wallerstein define CBPR as follows: "Although often and erroneously referred to as a research method, CBPR and other participatory approaches are not methods at all but *orientations to research.*"[20,p.4, emphasis in original] They state that fundamental characteristics of CBPR include that it (1) is cooperative, engaging community members and researchers in a joint process in which both contribute equally; (2) achieves a balance between research and action; (3) involves systems development and local community capacity building; and (4) is an empowering process through which participants can increase control over their lives.

In reviewing the literature,[3,20–24] three major purposes of CBPR stand out. CBPR is used to (1) demonstrate respect for community autonomy; (2) elicit ideas from community members for potential health interventions; and (3) strengthen the capacities of participants to gain control over the conditions that affect health. CBPR is thus a means to fulfill an ethical obligation, a method for identifying new interventions, and an intervention itself, a social process that is expected to change the participants positively as a result of their participation. These purposes are seen to operate simultaneously in a mutually reinforcing process. The multiple purposes, however, may foster potential confusions with regards to how CBPR initiatives should be evaluated. To ensure a fair process of evaluation, it is critically important to distinguish these three purposes and to identify appropriate criteria to evaluate the merits of each.

CBPR as Ethical Obligation

When proponents declare that CBPR is not a method but an orientation to research, it is fair to suggest that they mean the researchers' ethical orientation; that is, it is essential for researchers to demonstrate respect for community members. On this point, there should be no argument: all community health projects must fulfill this fundamental ethical obligation. We see CBPR as the most viable attempt to resolve the problem of respecting community autonomy in public health research today. However, problems may arise when the imperative to demonstrate respect is equated with blurring the respective roles of the different parties involved.

It bears repeating that the goal of health research is to discover new knowledge, with the aim of improving health. Federal agencies have a fiduciary responsibility to invest limited public resources to achieve this goal. Unfortunately, because federal grants are capped, there are direct trade-offs between the amount of money allocated to the intervention and the amount devoted to the research. In typical subcontracting arrangements, the percentage of funds going to the academic

and community partners, respectively, may be perceived to reflect the relative value and respect due each partner, and hence, can cause serious frictions in these partnerships when funding appears imbalanced. Thus, it is imperative for CBPR consortia to acknowledge these constraints and determine a fair process for decision making about budgetary issues, where simple democratic "majority rules" procedures may not be appropriate. Based on a shared responsibility to use taxpayer dollars prudently, it is essential for all parties involved to uphold the highest scientific standards possible in conducting the research.

CBPR as Research Method

To the extent that CBPR is understood as a method for eliciting or adapting ideas for promising health interventions, then, in principle, these suggestions should be subjected to testing in the most rigorous research design possible. One primary justification for using CBPR is that efforts to develop effective interventions or translate them into more diverse settings have not been consistently successful. If identifying more effective interventions is the goal, then CBPR consortia must strive to achieve agreement about how evidence of effectiveness can best be produced.

As a method for eliciting ideas for interventions, the different steps in the research process need to be recognized and distinct responsibilities of the respective partners acknowledged. Just as it would be inappropriate for researchers to insist on implementing an intervention that community members found objectionable, so community members need to respect the knowledge that researchers bring regarding research design, validated measures, and statistical analysis. Questions about which methods are best suited to the situation need to be kept distinct from questions about whose opinions deserve more respect. The major pitfall is to accept compromises that would permit less than the highest quality research feasible.

CBPR as Social Intervention

Finally, to the extent that CBPR is seen as a process for enhancing community capacities, then it should be evaluated as a social intervention in itself. CBPR advocates refer to the "added value" of CBPR and criteria are evolving for assessing the impact of participation. Many see the benefits in terms of community empowerment, and so look to measures of the capacities of community members to engage in research, develop effective interventions, push for policy changes, and so on.

It is not difficult to pose the question of added value as a hypothesis, and one can imagine a group-randomized trial to test it, at least in theory. One problem is that consensus about the hypothetical added value has not yet been achieved, with ideas ranging from eliciting new ideas; to improving recruitment and retention rates; to enhancing adaptation and implementation of interventions in diverse settings; to those who suggest that the process of participation itself may have an even greater impact than the intervention under investigation. The challenge of capturing this broad range of outcomes is further compounded by unresolved questions about the primary beneficiary of community participation: all community members, all targeted community members, advisory board members, or only those who most actively involved?

To assess the "CBPR effect," the ideal research design would be a group-randomized trial that compared communities randomized to the CBPR process to communities assigned to the comparison condition of a traditional researcher-driven investigation. Such an investigation, however, would be tremendously complicated and practically impossible.

RECOMMENDATIONS TO ACHIEVE A SOUND BALANCE BETWEEN SCIENTIFIC AND ETHICAL CONSIDERATIONS

In the preceding analysis, two underlying ethical issues emerged regarding perceived tensions between demands for scientific rigor and calls for community participation. First, CBPR proponents are concerned that the scientific community has paid insufficient attention to the ethical requirement of respect for community autonomy. Second, supporters are troubled that demands for scientific rigor have shortchanged the need for greater investment in community intervention research.

One problem that fosters continuing controversies is that these two issues often get fused, where calls for greater community participation are used almost interchangeably with calls for greater support for community health intervention research. In this line of thought, if community participation is more moral than traditional paternalistic approaches, then it deserves greater support in the National Institutes of Health

(NIH) funding priorities. Conversely, anyone who questions the priority of community research must not respect community members and their right to participate in making decisions that affect their lives. It is critically important, however, to keep these two issues distinct and evaluate each on its own merits.

Respecting Right to Community Autonomy

As shown herein, there is an urgent need to develop new ethical guidelines that specify standards for obtaining community endorsement of the goals and methods of public health research. Therefore, we recommend a major revision of IRB review procedures. To ensure that the goal and methods are acceptable to community members, we propose that IRBs require researchers to use a progressively more inclusive process proportionately geared to the potential risks and threat of exploitation. The more powerful the intervention and the greater the possibility of exploitation, the more extensive the level of community participation, both in outreach to the community and in their involvement in all phases of the research. Models for community participation are now being put into practice, notably in the work of the Navajo Nation IRB.[25] As these models attest, the consent process must establish widespread community support, where residents agree that the proposed intervention is relevant and the methods of evaluation appropriate. There is growing debate about the ancillary duties of researchers these days,[26] but in general, evolving model standards also include provision for community benefit and dissemination of the results to the community.

Fair Allocation of Federal Research Dollars

The second major ethical concern identified here entails allocating scarce public resources designated for health research fairly, a matter of distributive justice. The process for determining how federal research dollars should be allocated is a relatively neglected area of ethical analysis. The mission of the NIH is "to uncover new knowledge that will lead to better health for everyone." The key question is what kinds of knowledge are most likely to succeed in achieving better health for everyone.

In the 1997 report, *Setting Research Priorities at the National Institutes of Health*, NIH officials identified five criteria to guide distribution decisions: (1) public health needs, (2) scientific quality, (3) potential for scientific progress, (4) portfolio diversification, and (5) support for research infrastructure.[27] Clearly, different value judgments are involved in assigning different weights to the different criteria.[28,29] The issue that CBPR proponents raise is whether "scientific promise" has taken undue precedence over community responsiveness.

In light of these conflicting value judgments, we recommend that NIH establish fair procedures for resolving such disagreements. Daniels and Sabin[30] have developed a procedure, called "accountability for reasonableness," to assist in setting priorities in medical care settings—specifically, decisions to cover particular medical interventions in insurance policies—but their procedure is directly applicable to setting research priorities. They state that the decision-making process will be fair if the system has four features:

> One key feature is the provision of publicly accessible reasons, that is, a public rationale, for decisions. A second is that the rationale must constitute a reasonable construal of how to meet the needs of a population under acceptable resource constraints. A third key feature is that there must be mechanisms for considering challenges to decisions that are made and for revisiting those decisions in light of counter-arguments . . . [Fourth], there is voluntary or public regulation of the process to ensure that conditions 1-3 are met."[30,p.307]

Regarding the fourth point, NIH officials have acknowledged that their interactions with the public are "generally weak" and affirmed the need to more fully engage the public to redress concerns about the fairness of its distribution decisions.[27,p.7] Thus, it is critically important that community members and public health professionals vigorously advocate for the just distribution of public resources held in trust at NIH. NIH officials and review groups are charged with evaluating proposals based on their prospects for uncovering new knowledge that will lead to better health for everyone. Their deliberations, however, must be reasonable with respect to the cogency of the rationales put forward about the prospects that the research results will lead to improvements in population health. Because of the feasibility constraints enumerated, we recommend that reviewer guidelines unequivocally affirm that methods other than experimental research designs are acceptable in assessing the merits of CBPR proposals.

Given the many structural impediments, the most feasible study designs may only be quasi-experimental or even one-group designs. Proponents must not be daunted. To enhance public and professional appreciation of the validity of non-experimental epidemiologic research designs, the field has recently embarked on a major new policy initiative, the Project on Scientific Knowledge and Public Policy (SKAPP; see www.defendingscience.org).[31]† Although there can be little doubt that RCTs are best at controlling threats to internal validity,[32] in situations where RCTs are not feasible, it is essential to evaluate the merits of proposals using appropriate scientific criteria. Specifically, we recommend "weight-of-evidence" standards, like Hill's criteria, based on items such as biological plausibility, consistency in association, dose–response relationships,[33] and triangulation of multiple methods to strengthen confidence in the research results. The critical point is that review criteria must be reasonable, in the sense of providing adequate assurances that the research will produce the most robust results possible in a given context.

CONCLUSION

In conclusion, we want to reaffirm that calls for community participation should not be confused with sanctioning unwitting concessions or excuses for lowering scientific standards. A rapidly growing literature in bioethics has laid the foundations for establishing a new ethical requirement for community collaboration in health research.[34–36] Yet, properly understood, community collaboration is an ethical mandate, and hence, must be evaluated in terms of meeting moral standards, such as those outlined here, which are independent of questions of scientific standards and rigor in research.

That said, it is equally important to note that it will frequently be difficult and require a depth of judgment and discussion—in community partnerships and in study review panels—to determine whether a more rigorous research design, such as an RCT, in a given context is feasible or not. To work through these issues, trust is critical, and therefore, as CBPR advocates have long argued, it is critically important for funding agencies to allocate support for a startup "pilot" period of 2 or 3 years to allow the partners to develop confidence and respect for their mutual integrity. Although it will often not be possible to conduct an RCT, the collaborators have an obligation to seek the most generalizable knowledge possible to maximize the social value of the research.

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†The Project on Scientific Knowledge and Public Policy (see www.defendingscience.org) examines the nature of science and how it is used and misused in government decision-making and legal proceedings. Through empirical research, conversations among scholars, and publications, SKAPP aims to enhance understanding of how knowledge is generated and interpreted. SKAPP promotes transparent decision-making, based on the best available science, to protect public health.

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