Is It Ethical to Assign Medically Underserved African Americans to a Usual-Care Control Group in Community-Based Intervention Research?

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The purpose of this commentary is to foster discourse regarding the need to conduct research that is scientifically rigorous while according patients the benefits and protections that they are due as human subjects. These two laudable goals can conflict with one another, leaving researchers, institutional review boards, grant application review groups, and funding agencies with the responsibility of striking an appropriate balance. For the past 14 years, our research (1) has focused on evaluating community-based interventions designed to help urban African Americans in metro Detroit live well with type 2 diabetes. Even if previous research on similar interventions has been promising, it is not possible to know a priori if a particular intervention, with these patients in this setting, will be shown to be effective. Therefore, the ideal design (from a scientific perspective) for many of these studies would be a randomized controlled trial using a usual-care control group. However, we have ethical concerns about assigning the African-American patients recruited in metro Detroit to a true usual-care control group.

Types of control groups used in diabetes-related randomized controlled trials

Best-known care control groups. A well-known type of control group involves comparing a new medication or procedure with the best medical care known (also known as current standard of care). The Diabetes Control and Complications Trial provides a good example of this type of control group (2). To test the glucose hypothesis, patients were randomized to either an intensive treatment intervention group or a "best-known care" (at the time of the study) control group. This type of control group differs from a usual-care control group in two very important respects. First, usual care in diabetes, particularly for medically underserved populations, is likely to be suboptimal when compared with best-known care (3). Second, in the Diabetes Control and Complications Trial, the diabetes care received by patients in the control group was precisely defined and under the control of the investigators. Neither of the above features apply to usual-care control groups recruited for community-based studies involving African-American patients in Detroit. These patients are receiving diabetes care in a wide variety of settings from a number of providers working in different health systems. Best-known diabetes care and usual diabetes care are very different types of control groups.

Enhanced usual-care (our term). In this type of design, patients receive several enhancements to the care they would have received had they not joined the trial. The Diabetes Prevention Program (4) offers a relevant example of this design. The control group in the Diabetes Prevention Program received educational materials about healthy eating, healthy weight, physical activity, smoking, and alcohol intake. Also, they received periodic counseling sessions and free care for hypertension, lipid abnormalities, and psychological diseases. Patients benefit directly from their participation in an enhanced usual-care control group.

Value-added control group (our term). In this type of control group, patients are not receiving best-known medical care or enhanced usual care. However, they are receiving diabetes-related materials and services that they value in helping them live well with their illness. The Look AHEAD (Action for Health in Diabetes) trial (5), which is now underway, is a good example of a diabetes-related value-added control group. The control group in this study is referred to as the "Diabetes Education and Support" arm. Patients in this group receive an initial diabetes education session and can participate in education and support groups throughout the study. As with the enhanced usual-care control group, study patients assigned to the value-added control group receive a direct benefit from their participation.

Usual-care control groups in diabetes-related randomized controlled trials. To learn more about the use of usual-care control groups in diabetes studies, a search of literature published between 1950 and 2005 was conducted, identifying 88 studies. Of that number, 16 articles described diabetes clinical trials in which patients were randomized to true usual-care control groups (6–21). All of these studies shared some important features. They were all conducted in extant health care systems with which the investigators had some affiliation. This meant that a certain amount of consistency of care existed as a result of system-wide features such as standards of care. It also meant that the investigators had some knowledge of what constituted usual diabetes care. None of these studies recruited medically underserved patients from the community who were receiving care from multiple sources (with which the investi-

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Abbreviations: IOM, Institute of Medicine; NIH, National Institutes of Health.

gators had no affiliation whatsoever) and randomized half of them to usual care.

Equipoise. Equipoise refers to an investigator's genuine uncertainty about which arm or group is more likely to benefit from a clinical trial (22). The University of Michigan Medical School Institutional Review Board works to ensure equipoise in its clinical trials. In three meta-analyses (23–25) of randomized controlled trials conducted to evaluate a wide variety of diabetic patient education programs, the studies have consistently shown the positive impacts from participation in these programs. In other words, these meta-analyses have established that something (i.e., a patient education program) is almost always better than nothing (i.e., usual care with no intervention).

As we describe our studies to potential subjects, can we tell them that we are certain that benefits of participation will be superior to not participating at all? No, we cannot. Can we say to potential subjects that it is reasonable to hope that they will receive a direct benefit from participation in the intervention group? Because of the evidence, we can answer "yes." Can we say that it is reasonable to hope for a direct benefit from participation in a usual-care control group? We would have to answer "no." The National Institutes of Health (NIH) would not fund these studies if one could answer the questions they address with complete certainty. And yet, the NIH does not approve funding for R18 studies without convincing evidence from earlier studies that the proposed interventions have a high probability of succeeding. In fact, much of the advice given to patients with diabetes every day is not based on certainty but instead on the probability of certain outcomes.

Usual diabetes care. Although there are readily available guidelines that describe optimal diabetes care, it is difficult to define or generalize about usual diabetes care with any precision except to say that multiple studies indicate that for the most part, it fails to meet published guidelines (26). If most diabetes care is less than optimal, how can one decide that the diabetes care being received by a particular population of patients is likely to be substandard enough to raise ethical concerns about assigning them to a usual-care control group? One can weigh the body of evidence in a given situation and make a judgment based on that evidence. Some of the evidence related to the health care received by African Americans living in Detroit will be examined below.

Health and health care for African Americans in Detroit

African Americans and diabetes. African Americans are twice as likely to have diabetes as their Caucasian counterparts (27). Compared with Caucasian Americans, African Americans suffer greater diabetes-related complications with a higher incidence of kidney failure, eye disease, and amputations (28–30).

Racial disparities and health care. After an exhaustive study, the Institute of Medicine (IOM) concluded that African Americans as a group receive poorer health care than Caucasian Americans. "Racial and ethnic minorities tend to receive a lower quality of healthcare than non-minorities, even when access-related factors, such as patients' insurance status and income, are controlled" (31). The IOM also concluded that a "large body of published research reveals that racial and ethnic minorities experience a lower quality of health services and are less likely to receive even routine medical procedures" (31). One study comparing Caucasian and African Americans with diabetes found that African-American patients were less likely to have their A1C measured, lipids tested, and eyes examined. Also, African Americans had fewer physician visits and more visits to the emergency department. In this study, the investigators controlled for sex, education, and age (32). The literature in the related area of cardiovascular disease is substantial and consistently reveals similar disparities in the health care of African Americans (33).

Health insurance for African Americans living in Detroit. After completing another exhaustive study (34) on the impact of lacking health insurance, the IOM concluded that "adults without coverage do not get the care they need and are more likely to suffer poor health and premature death than are insured adults" (35). Even when controlling for social, demographic, health status, and health behavior, uninsured adults still have a 25% greater risk of premature death (36). The percentage of uninsured African Americans in the U.S. is 73% greater than the percentage of uninsured Caucasian Americans (21.6 vs. 12.5%) (37). In Michigan, 22.5% of patients are either uninsured or Medicaid eligible; however, in Detroit, the figure (52.5%) is more than double the state average (38). Lack of health insurance is also related to income levels. Those living below 200% of the federally established poverty level account for 66% of the uninsured nationally (39). Fifty-nine percent of Detroit residents have incomes below 200% of the federal poverty level compared with 26% for the state overall (38). Much of the health care provided to the poor comes from federally funded neighborhood health clinics (38). Detroit has nine "federally qualified clinics." Chicago has 57, and Minneapolis-St Paul, with less than half as many people living in poverty, has 26 such clinics. In 2002, those nine federally funded clinics saw only 35,000 of Detroit's 180,000 uninsured residents (40).

In our 5-year community-based retinopathy screening clinics study (41) in metro Detroit, 43.5% of the African-American patients ($n = 817$) reported having no health insurance, 59.4% had never been referred to an ophthalmologist, and only 22.4% reported having an eye exam during the past year. Finally, 32.3% of those patients were found to have serious undetected and untreated eye disease. These data illustrate the type of patients who joined this study in search of help.

People in need. The least quantifiable element of this equation is perhaps the most compelling. Most people join our studies because they want and need help in caring for their diabetes. When we began addressing the challenge of improving care for urban African Americans 14 years ago, we had to overcome their mistrust of government research and large research universities (42). We had to earn their trust because it did not come with our credentials or institutional affiliations (43). We made two fundamental promises to the patients living in the communities in which we conduct our research. First, we promised not to study a problem and then leave. We assured community leaders that we were making a long-term commitment to help patients in our studies and the communities in which they lived (1).

For example, in 1999, when the NIH funding ended for the 5-year eye screening study mentioned above (41), we were able to obtain a small amount of funding from the Michigan Department of Community Health to continue to offer free retinopathy screening clinics in metro Detroit. The state funding ended in 2002.

Since then, we have solicited volunteer ophthalmologists who provide us with vouchers for free eye exams. We give those vouchers to patients who call our toll-free number (which has been in operation since we began the original study in 1995) seeking a diabetes eye exam. This is not just a moral issue. Keeping our promises is one of the main reasons that we receive continued access to and support from a variety of leaders and organizations in Detroit.

Our second promise was to design studies so that all patients had the potential to benefit directly from their participation. In recent years, minority communities have been unwilling to support studies in which some patients have little or no chance of receiving a direct benefit from their participation. When the University of Michigan and a coalition of community agencies in Detroit applied for a Centers for Disease Control and Prevention–funded (REACH [Racial and Ethnic Approaches to Community Health]) grant, the community advisory board made it clear that they would not support or cooperate with the study if it contained a randomized controlled trial with a usual-care control group.

Summary

In our studies, we are conducting community-based research with a vulnerable population of patients at substantially higher risk for diabetes and its complications. They are also at increased risk of receiving inadequate diabetes care because of a combination of factors, including race, income, health insurance status, and lack of access to care. Furthermore, the community with which they identify has been exploited by research institutions in the past (i.e., Tuskegee Experiment), producing a legacy of mistrust of the medical establishment and the research that it conducts (42).

It has taken our research team years to earn the trust of this community. African-American patients join our studies with the explicit hope of receiving help in living with and caring for their diabetes. Given the weight of the evidence discussed above, can we in good conscience assign 50% of these patients to a true usual-care (which is very likely to be significantly substandard) control group that offers them no direct benefit? For our research team the answer is "no," which leaves us with the challenge of trying to design intervention studies that are scientifically rigorous and ethically sound. We have yet to find a middle ground that will satisfy all of our stakeholders.

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