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Planning for Ancillary Care Provision: Lessons from the Developing World

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Ancillary care is the health care provided by researchers to research participants that “goes beyond the requirements of scientific validity, safety, keeping promises, or rectifying injuries” (Richardson & Belsky, 2004, p. 26). Questions about whether to provide ancillary care and what kinds of ancillary care researchers are obliged to provide have been of great interest to investigators conducting health research in low resource settings in the developing world, where concerns about exploitation and fairness are often highly salient. Ethical analysis has produced several frameworks meant to aid researchers in making these ancillary care determinations (Belsky & Richardson, 2004; Bright & Nelson, 2012; Brownsword, 2007; Dickert et al., 2007), while empirical studies have documented current practices of ancillary care provision (Krubiner, Syed, & Merritt, 2015; MacQueen, McLoughlin, Alleman, Burke, & Mack, 2008; Taylor, Merritt, & Mullany, 2011).

Although several authors have noted that investigators conducting health-related research in the developed world also may face decisions about ancillary care provision (Merritt, Taylor, & Mullany, 2010; Richardson, 2008), little has been published about ancillary care in these settings. With this paper we aim to begin a discussion about ancillary care in the United States. We first describe the expectations for care held by a group of research participants. We then draw upon the ethical and empirical literature on ancillary care in the developing world to explore what lessons it may have for investigators working with disadvantaged populations in the developed world.

The findings reported here arose as part of a study designed in response to the problem of the underrepresentation of lower income and minority populations in health research in the United States. National statistics reveal the stark health disparities that affect poor people and racial and ethnic minorities in the U.S. (Centers for Disease Control and Prevention, 2013). These populations are the least likely to benefit from the health improvements provided by research, in part because members of these communities are the least likely to

participate in such research (Bonevski et al., 2014; Ford et al., 2008; Gross, Julion, & Fogg, 2001). Despite decades of effort to remedy this underrepresentation, participation in health research by people from lower income minority communities has not increased significantly (Clay, Ellis, Amodeo, Fassler, & Griffin, 2003; Yancey, Ortega, & Kumanyika, 2006).

Community Advisors on Research Design and Strategies (CARDS) is a new approach to increasing research participation by members of underrepresented communities. CARDS is a group of lower income, ethnically and racially diverse people who have been trained in research basics and are available to provide feedback to investigators on their study designs and research materials. CARDS reviews can identify ways in which research procedures or materials are intimidating, offensive, misleading, or incomprehensible to members of the populations researchers wish to study. By incorporating CARDS advice, investigators can make their study designs and materials more appealing and more understandable, thus improving recruitment and retention of lower income minority populations.

As part of a recent mixed methods evaluation of the impact of CARDS review on the willingness of people from lower income and minority communities to volunteer for research, we had the opportunity to probe participants' assumptions about what it means to participate in health research. An unanticipated finding about participants' expectations of benefit led us to this exploration of ancillary care.

Methods

An investigator conducting an observational study of cognition and memory in older adults with congestive heart failure volunteered to allow her pre- and post-CARDS review research materials—a study flyer, a recruitment letter, and a consent form—to be used as an example. The study described in these materials required two research visits over the course of a year. At each visit, the materials explained, participants would undergo an MRI and a battery of paper and pencil memory tests. The research did not include an intervention component, and the study materials made no mention of providing treatment.

One hundred participants were recruited from attendees at food banks and other programs at two community centers in low income, racially and ethnically diverse neighborhoods of Madison, Wisconsin. Just over half the participants ($n = 55$) were shown the pre-CARDS review versions of the example study's research materials while the others ($n = 45$) were shown the materials after they had been revised according to the CARDS' recommendations. All participants were interviewed using the same tool, which included both fixed response close-ended (quantitative) items and open-ended (qualitative) questions that queried responses to the materials, likelihood of participating in the research described, and attitudes and behaviors related to research participation in general.

Responses to the quantitative items were entered into SPSS and analyzed using descriptive statistics. Interviewers noted participants' answers to the open-ended questions, capturing verbatim phrasing when possible. These qualitative data were analyzed using conventional content analysis (Hsieh & Shannon, 2005) in order to identify patterns in participants' attitudes toward and intended behaviors related to research participation.

Results

More than 60% of the participants had completed high school. 8% reported having completed an associate's degree and 10% a bachelor's degree, while 43% had some post-secondary training. 55% were currently employed (often in low wage positions in retail, childcare, or eldercare). 65% indicated they currently had health insurance, either Medicaid or private insurance. Because one component of the study was designed to explore participants' attitudes and behaviors toward demographic questions commonly used in health research, we did not collect additional demographic data related to gender, race/ethnicity, or income. However, our sample tracked the demographic composition of the neighborhoods from which we recruited: it was lower income and predominantly African American and was roughly evenly divided between men and women.

In speaking to participants about their hypothetical willingness to participate in the example study, we found it was extremely common for them to describe being motivated to participate in order to access health care. Specifically, participants assumed the tests mentioned in the study materials constituted “check ups,” or diagnostic tests, and that the results—particularly any abnormal findings—would be reported to them (or to their health care providers). Many, although not all, also expected they would receive treatment for any health problems discovered in the course of their participation. One man said, “Of course they would treat me. They have everything there that I would need.” Several people explained they would be likely to participate in the research because they were concerned about memory problems they were experiencing and would like to “get checked out.” Others noted they had been told at some point that they should have an MRI (for conditions unrelated to cognition or heart failure) and participating in this study would allow them to receive the test at no cost. There were no statistically significant associations between education, employment, or insurance status and participants' stated expectations about research participation as a means to access health care. However, when we explored our participants' perceptions of demographic questions about income, we found many participants understood these questions as a means test, a concept with which they were familiar from their interactions with social services agencies. Several people explained that once researchers knew how low their incomes were they would be given access to free health care.

We have considered the possibility participants' care expectations were by-products of low comprehension of written consent forms and other research materials, a phenomenon that has been widely reported in the literature (Montalvo & Larson, 2014). During the interviews we attempted to assess participants' recall and comprehension of the example consent forms used in our study (which did not address the issue of care provision) by asking people to tell us in their own words what they would have to do if they chose to volunteer for the study described. We found a range of comprehension levels, with some participants demonstrating significant gaps in both recall and understanding, but the expectation of care was common across participants.

The expected benefits of receiving test results and free health care were major contributors to our participants' willingness to take part in the example study. Indeed, once we became aware of their expectations and modified the interview to ask participants if they would still

volunteer for the example study if they (or their doctors) did not receive test results and no health care was offered, many people expressed incredulity that this could be possible and indicated that under these conditions they would decline to participate.

Discussion

The finding that potential research participants expect to receive improved access to health care as a result of their participation helps us to understand the practical problem of underrepresentation of lower income minority communities in health research that was our initial focus in this study. It seems plausible, for example, that people who agree to participate in research with the expectation that they will receive free health care are unlikely either to join or to remain in a study once they realize this is not the case. Just as important, we believe participants' unfounded assumptions raise a profound ethical issue.

The phenomenon of research subjects assuming they will receive direct personal benefit from their participation in research is known as therapeutic misconception (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987), defined as a state in which “individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit” (Henderson et al., 2007, p. 1736). Therapeutic misconception has been a particular concern for clinical trials, in which it is common for research subjects not to understand the concept of equipoise and be convinced the treatment being tested is superior to the standard treatment that would otherwise be available to them. As we have noted, however, the example study used in our research did not include an intervention component. Participants expected to benefit not from a specific treatment, but from the improved access to care they believed would follow from their association with the research. In the terminology set out in King's (2000) typology of research benefit, our participants assumed they would be gaining a collateral benefit of ancillary care.

In developed countries there is an assumption of “fair exchange” between researchers and their participants (Schroeder & Gefenas, 2012). That is, it is assumed that treatments developed through health research will be at least theoretically available to all sectors of society. While individuals may not benefit directly from their participation in health research, their communities will not lack access to these treatments. The research on health disparities in low income and minority communities in the US suggests, however, that this is not necessarily the case. While some portion of these disparities is attributable to other social determinants of health (Solar & Irwin, 2010), poor access to health care—even in the post-ACA United States—is also part of the picture. Among our participants, 65% of whom reported having health insurance, it was clear that structural barriers to care still existed: For individuals with private insurance, even covered services require some cost sharing. For those in the under-resourced public system, it can be difficult to find providers who accept Medicaid. No insurance compensates for the non-medical costs of health care, such as the loss of a day's wages (or risk of being fired) to keep an appointment or the transportation costs of traveling to a health care facility. Additionally, discussions with our participants suggested that their experiences of racism and other forms of discrimination in health care settings remain barriers to access.

Once our participants' expectations are viewed in this broader context, we would argue that we are faced with a problem of justice that is in many ways analogous to the situation in the developing world. Thus, the ethical and empirical work that has addressed ancillary care in those settings can provide direction for investigators working in low resource communities in the US.

As summarized in the guidelines produced by participants in the 2006 Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries (2008), whether or not researchers are obliged to provide ancillary care depends upon the severity of the health care needs likely to be identified among participants and whether such identification is integral or incidental to the research protocol, on the duration of the study and how extensive the interactions are between researchers and participants, on the capacity of the local health system to address these needs, on the resources available as part of the research infrastructure, and on the impact providing care would have on the research.

Taylor and colleagues (2011) found the type of research being conducted affects the types of needs identified, and thus the care responses of investigators. While a traditional clinical trial is likely to uncover needs only among individuals, health services or epidemiological research may uncover more systemic needs (Olson 2014). Merritt, Taylor, and Mullany (2010) delineated two types of needs: those that can be anticipated by investigators, for which plans can be made in advance; and those that arise ad hoc, which require that investigators respond on the spot. Clinic-based research is better able to address needs in an ad hoc manner, while community-based research tends to rely on prospective planning for ancillary care provision (Taylor, Merritt, & Mullany, 2011).

Ancillary care may consist of anything from “informational feedback” to “therapeutic assistance” (Brownsword, 2007, p. 689). The two main strategies for providing this range of care are for research teams to do it “in-house” (direct care), or for individuals in need of care to be referred by study investigators to other organizations (indirect care) (MacQueen et al., 2008). In the case of the former, advance planning for ancillary care provision includes staffing research teams with individuals who have the skills to provide such care. In the case of the latter, planning involves identifying organizations able to provide the types of care likely to be needed, connecting with these organizations, developing co-operative agreements for care provision (Krubiner, Syed, & Merritt, 2015) and putting in place systems for following up on referrals (MacQueen & May, 2008). A final strategy identified in the literature is for research teams to play a role in building the capacity of the local health system to respond to the population's needs (Krubiner, Syed, & Merritt, 2015).

In developed settings, as in the developing world, there are ethical risks involved in linking the provision of health care to research participation. The prevalence of therapeutic misconception is likely to increase (Molyneux, Mulupi, Mbaabu, & Marsh, 2012). Making the scarce commodity of health care available through research participation may become a form of coercion for individuals and communities that otherwise lack access to services (Schroeder & Gefenas, 2012). Imposing new obligations on researchers working in lower income minority communities may serve as a disincentive to engaging these communities

and thus become a barrier to conducting many types of health disparities research. Shifting the responsibility of providing care to the research enterprise may take some pressure off the health system, thus constraining the possibility of reforms that could lead to better health care access for all (King, 2000).

Best Practices

In deciding whether or not they bear responsibility for providing ancillary care, investigators in developed countries should reflect on the questions posed by the Georgetown guidelines or one of the other extant ethical frameworks. Once a decision has been made to provide care, researchers should use the recent empirical research to help them determine the nature and extent of the care that will be offered. Key questions include what kinds of needs are likely to be identified in the course of conducting the research, what the capacity will be within the research team to address these needs, and what external organizations exist that might be approached to become care-providing partners in the research. In identifying possible sources of care, researchers should think creatively about resources that might be available. For example, a university-based researcher might work with students in a service-learning course to identify sources of free or low cost health care in the community or enlist health professional students to provide basic screening or health education services. A hospital-based researcher might have personal or professional connections to clinicians able to provide some care on a volunteer basis. Investigators conducting community-engaged research should work closely with their community partners to better understand the care needs, resources, and priorities of the communities from which they will be recruiting. All researchers should use the ethics review process, and the resources of their IRBs, to clarify questions about how research participation may affect participant needs and how providing care may affect the research. Finally, fully addressing the issue of ancillary care will require changes to the research enterprise: funders will have to allow grant monies to be used for care provision and research institutions will have to invest in ancillary care infrastructure.

Research Agenda

Little is known about ancillary care practices in developed countries. Descriptive studies of these practices, using the methodologies applied to studies of research projects in developing countries, would allow for comparison of strategies (Merritt, Taylor, & Mullany, 2010). Pragmatic trials of different care provision models would promote the development of an evidence-based methodology for ancillary care provision. In addition, there is a need for environmental scans of local and national sources of free or low cost health care that might be made available to research participants.

Educational Implications

Research ethics education has tended to emphasize the analysis of risk. Equal attention should be given to the concept of benefit and to extant models of benefit sharing, such as the ancillary care practices discussed in this paper.

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