Producing Knowledge about Racial Differences: Tracing Scientists' Use of "Race" and "Ethnicity" from Grants to Articles

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Introduction

The research and publication practices by which scientists produce biomedical knowledge about race and ethnicity remain largely unexamined despite increasing interest in biological explanations for health disparities by race, as well as prominent critiques by social scientists highlighting the implications of conceptualizing race as a biological category.[1] Although a growing number of studies on lab and research practices are helping to map meanings of race and ethnicity on notions of difference and health,[2] we still have very little understanding of the earlier funding application stage or of the resulting publications. We know that knowledge production can involve a range of different processes, including consensus building, strategic and instrumental decision making, as well as conscious and subconscious cognitive filtering, through which we direct analytic attention only to those aspects of a problem or topic that are defined as "relevant" and "important."[3] These processes also involve the "translation"[4] of ideas such as race and ethnicity for different audiences (e.g., funders, other scientists, or the public), which occurs in broader contexts of cultural norms and institutional rules and practices. Increasingly, these norms, rules, and practices emphasize the importance of using an official classification system for race and ethnicity — not just in scientific investigations but also in state bureaucratic practices, illustrating an "alignment" of state policy and science.[5] As Steven Epstein argues, this alignment is clearly demonstrated in the ways the state's objectives on addressing inequalities in health are advanced through its financial support of scientific inquiry and the particular rules it attaches for governing such investigations. The premise that guides such efforts is the belief that what scientists propose to research translates into scientific knowledge, which is disseminated to other scientists and the public (taxpayers). Is this a fair assumption? Do scientists "deliver" on their proposals? The answers to these questions have important implications for better understanding how scientific knowledge is produced and if and how state policy can affect the knowledge production process.

Given the growing interest in race and ethnicity and health, we investigated knowledge production around the concepts of race and ethnicity in government-supported research. We specifically examined how scientists write about racial and ethnic categories in their research proposals, whether and how they analyze these variables, and the findings they ultimately present in their publications. For the purposes of this analysis, then, we conceptualized knowledge production simply as an input-output process that we captured at two points in time: grant proposal and published research. Our analysis builds most directly on the small but growing body of empirical studies that has recently begun to shed light on what researchers do and mean when they use racial and ethnic categories in their investigations. For example, David Williams[6] explains that the concepts race and ethnicity were widely used in the journal *Health Services Research* but were seldom defined. In a study of race and eth-

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nicity as variables in the journal *Nursing Research*, Denise Drevdahl et al.[7] found similar results. Although researchers often incorporated race and ethnicity in their investigations, they rarely defined what they meant in using such constructs. More recently, Pamela Sankar et al.[8] analyzed reports of genetics research and found that just 9.1% of articles from 2001 and 2004 explained the basis for using race or ethnicity terms, and no article actually defined these concepts.

Catherine Lee[9] previously examined the use of racial and ethnic categories in biomedicine more generally with similar results. This research demonstrates that while scientists often saw race or ethnicity as important for their research, they rarely defined or operationalized the concepts adequately. Moreover, when presenting findings of racial or ethnic difference, they generally did not provide explanations of the difference. Lee argues that this under-theorized and unspecified use of race or ethnicity and the biological conclusions drawn about health and difference have the potential to reify race and to limit our thinking about what these biomedical differences suggest about health disparities and inequalities in general.

Joan Fujimura and Ramya Rajagopalan[10] take a slightly different approach, highlighting the work of a small group of geneticists who have invented a statistical method and associated software specifically to *avoid* using categories of race in their genetic analysis. This method allowed the geneticists to operationalize the concept of "genetic ancestry" without resorting to notions of race and ethnicity. Despite their explicit challenge to institutional and cultural notions of racial and ethnic difference and similarity, this group of researchers concludes that some audiences continue to assume genetic ancestry is synonymous with race.[11] Finally, Andrew Smart et al.[12] examined science journals' attempts to standardize the classification of race and ethnicity and interviewed scientists regarding their use of the terms in research. Despite the urgings of some major science journal editors to use caution or to drop the terms of race and ethnicity altogether,[13] Smart et al. state that scientists adopted official Census terms, suggesting a crucial alignment of state bureaucracy and science.

Our study is also in conversation with a larger body of literature on the most productive way to conceptualize race and ethnicity in biomedical research, e.g., as sociopolitical "race," as genetic ancestry, or as an identity category. This includes debates about whether attempts to uncover genetic differences between demographic groups is the best way to understand and address health differences, or whether it is actually a distraction from well-established social causes of health disparities.[14] The issue of if and how race and ethnicity are used in biomedical research is particularly important to investigate now, given the rise in attention to health disparities as a political issue and the increasing emphasis on biomedical solutions for such matters.[15]

For this study, we examined how scientists funded by the National Cancer Institute (NCI) of the National Institutes of Health (NIH) constructed and used the concepts of race or ethnicity as analytical variables and what kinds of conclusions they drew about health and difference. We analyzed 72 grants (46 abstracts and 26 full grant proposals) funded by the NCI between 1990 and 1999. We also traced these grants to the subsequent articles in which the scientists reported on their findings in biomedical research journals. What is unique about our analysis is that we analyzed both the initial grant proposals and the published research, an approach which provided a more complete picture of the knowledge production process, as most of the existing research has looked at the research process at only one point in time. This also allowed us to capture changes over time in how biomedical researchers presented the meaning of racial and ethnic categories and the significance of racial or ethnic differences for their research.

The decade of the 1990s introduced many science policy changes and new funding opportunities related to race and ethnicity, beginning auspiciously with the start of the Human Genome Project. Other critical developments affecting biomedical research, especially on health disparities, were implemented throughout the decade. The NIH created the Office of Research on Minority Health in 1990. The year 1990 also marked the end of the decline in federally financed research and development (R&D) spending across all science and engineering fields that began in 1975. From 1990 through 2004, NIH's funding of academic R&D grew at an estimated annual rate of 6.4% per year (in 2000 dollars). The NIH's R&D budget doubled between 1998 and 2004, and its share of federal funding of academic R&D rose from 52% in 1990 to 63% in 2004.[16]

Perhaps the most significant policy change affecting biomedical research was the implementation of a new policy at the NIH regarding the inclusion of women and minorities in clinical research.[17] Following Congress's passage of the NIH Revitalization Act of 1993, the NIH issued an "inclusion mandate" in 1994, which had two critical goals: (1) to ensure that women and "members of minorities and their subpopulations" are included in all human subject research; and (2) for Phase III clinical trials, to ensure that women and minorities are included in sufficient numbers such that valid analyses of differences in

intervention effects can be accomplished. Furthermore, the NIH guidelines required that grants proposing Phase III clinical trials discuss any existing knowledge of the relevance of race and ethnicity for the proposed research question(s) and use that prior research explicitly to guide and target the proposed study.[18] Finally, the NIH instructed its grantees to use the racial and ethnic categories outlined in the Office of Management and Budget (OMB) Directive 15, which is the official schema used in most government record-keeping and data collection related to race and ethnicity.[19] The inclusion of women and minorities and the implementation of the official racial categories were and continue to be contentious. As Epstein chronicles,[20] scientists in particular objected to the intrusion of "affirmative action," "quotas," or "political correctness" into science. These criticisms notwithstanding, we do not yet have a clear picture of how race or ethnicity is proposed for study, how it is actually investigated, or how the Inclusion Mandate has influenced research practices. Epstein proposes that the pressure to enroll underrepresented groups resulting from the Inclusion Mandate has stimulated the development of what he calls "recruitmentology": a growing body of scientific research designed to investigate the efficacy of various means of enrolling people identified as difficult to recruit to participate in clinical studies.[21] In addition, there is now a small body of research on scientists' understanding of the Inclusion Mandate guidelines, including their assessment of the extent to which the policy has been successful in increasing the inclusion of underrepresented groups, as well some discussion of the ethical considerations that sometimes arise when using racial and ethnic categories in genetics research.[22] While these interview studies do not directly examine the knowledge production process, they may help explain some of what we find below. Our investigation is the first to compare pre- and post-mandate grants and articles, examining the effect of the 1994 law on the *content* of biomedical research on racial or ethnic differences. Although this study is unable to test the statistical significance of the impact of the Inclusion Mandate, and given our sample and study design our exploration of this issue is necessarily speculative, we highlight some potential effects of the policy change.

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Data and Methods

This study examined how race and/or ethnicity were defined, operationalized, and utilized in studies supported by research grants from the National Cancer Institute in the U.S. and the resulting publications, tracking the knowledge production process from conceptualization to reported findings. We focused on biomedical research funded by the NCI, which is the largest and oldest institute of the 27 institutes and centers that make up the NIH. For fiscal year 2012, the NCI awarded nearly 8,000 research project grants totaling over $415 million.[23] NCI is not an institute whose main mission is to address racial health disparities, and researchers funded by NCI have identified both racial and nonracial etiology for different types of cancer, the institute's disease focus. To locate grants that deal directly with race, we performed searches in 2004 and 2010, using the search engine CRISP (Computer Retrieval of Information on Scientific Projects, since replaced by the RePORT Expenditures and Results [RePORTER] query tool). We selected all new research projects (identified by the NIH as "investigator initiated, basic scientific support to principal investigator in his/her area of competency") awarded from 1990 through 1999 that had the following key terms in the grants: race (including racial and racism), ethnicity (including ethnic), minority, black, African American, white, Caucasian, Native American, Mexican American, Hispanic, Latino, or Asian. This generated over 200 grant abstracts. Given the length of time often required between grant award and first publication, we were able to generate a sample of grant-related publications by focusing on the decade of the 1990s, but not for more recent grants. We searched for published articles generated from the research grants first by using a unique database that links NIH

grant numbers to publication identification numbers (PMIDs) and then, once this information was made more readily available to the public, through RePORTER. We dropped grants unrelated to biomedical research — broadly defined to include any biological studies of pathways to disease, disease outcomes, and treatment — on humans (since mice are not classified racially or ethnically). Furthermore, we excluded grants that did not result in a published article since we are interested in the production of knowledge. Because the first published article from the supporting grant can often be a statement about the data collection process, we excluded grants that did not have at least two published articles[24] related to the stated objectives of the grant, which yielded a total of 72 grants. In addition to these 72 grant abstracts, we had access to full proposals for 26 of the grants, which were obtained through a Freedom of Information Act request. Because of limitations in time and funding, we randomly selected a subset of the 72 grants to include in the FOIA request.[25] We found no substantive difference in the grants to which we had full access compared to those cases in which we had access to abstracts alone. For example, similar proportions of the abstract-only cases and the full grant cases included discussions of pre-existing knowledge of racial/ethnic differences (35% of the abstract-only cases compared to 31% of the full grants) and/or included research objectives related to race/ethnicity (52% of the abstract-only cases and 61% of the full grants). Furthermore, the bulk of the information related to the use of race or ethnicity in the grants was available in the abstracts. The full grant proposals provided interesting and important discussions, however, which further illuminated the process by which these investigators proposed to investigate racial or ethnic differences, some of which we include in the results as illustrative narrative examples. Fifty-nine grants were R01s (research project), 10 were R03s (small research grants), two were R29s (first independent research support and transition award), and one was an R35 (outstanding investigator grant). Grants provided support for an average of 3.8 years and covered various cancers. Breast and prostate cancer studies received the largest number of grants; 16 grants were awarded for the study of breast cancer, and 13 were awarded for prostate cancer research. Thirty grants identified some component of genetic research as one of its foci.

All 72 grants resulted in at least two published articles related to the supporting grant's objectives. In the cases where there were three or more related publications, we chose the earliest two related articles using the publication date.[26] The articles were published between 1996 and 2010 in a wide range of biomedical and scientific journals. The most popular journal was *Cancer Epidemiology, Biomarkers & Prevention*, which published 24 of the articles in the sample. *The American Journal of Epidemiology* was the site of 17 publications, and *Cancer Research* included nine. The remaining articles were published in 52 different journals. The grant abstracts and articles (and full grants when available) were coded by four coders for information on definition and use of race or ethnicity, presentation of racial or ethnic demographic and results data, discussion of racial or ethnic differences, and use of prior knowledge of racial or ethnic differences. A test of inter-rater reliability showed 0.92 congruence. As we noted above, the Inclusion Mandate requires that grants proposing Phase III clinical trials discuss any existing knowledge of the relevance of race and ethnicity for the proposed research question(s) and use that prior research explicitly to guide and target the proposed study. Although none of the grants in our sample were new applications for clinical trials (of any stage), we coded all grants for their references to prior knowledge to assess the extent to which grant writers proposing research relating to racial and ethnic difference were engaged with the existing literature on race and ethnicity.

Results

Defining Race and Ethnicity

Our analysis of the NCI grant proposals confirmed the previous finding that even those scientists who specifically set out to study racial or ethnic differences rarely explained how or why race or ethnicity is important. First, we review the goals of the 72 grants. In our sample, 40 out of 72 or 56% of the grants explicitly stated that the investigation of racial or ethnic difference was one of the study's goals (perhaps not surprising given the selection criteria of the study — a mention of race or ethnicity), yet only 13 grants, or 18%, explained, hypothesized, or theorized the nature of the racial or ethnic difference. More to the point, of those grants which specifically set out to study race (N=40), only 12, or 30%, offered any theory or explanation of the *importance* of race or ethnicity. This finding is even more apparent when looking at the sample of 144 articles resulting from our set of grants: 131 of the 144 total articles (91%) mentioned race (again, not unexpected given the selection criteria for the related grants), yet only 41 or 28% cited prior knowledge of racial or ethnic differences, and only 44 or 31% defined or operationalized race or ethnicity in any way. However, nearly twice that many articles, 91 or 63%, included analyses with race or ethnicity as a variable or stratified their analyses by race.

Table 1
Information about NCI Grants, 1990-1999 (n=72)

	n (%)
Research objectives include investigation of race/ethnicity	40 (56%)
Grant discusses prior knowledge of racial/ethnic differences in genetics, morbidity, or mortality	24 (33%)
Grant includes hypothesis/theory about a racial difference	13 (18%)

Decreased Discussion of Race from Grants to Articles

The main benefit of our study design is that it allowed us to track the knowledge production process over time, capturing how scientists wrote about race and ethnicity both before and after they actually carried out their research. Our analysis showed a marked decrease in discussion of race and ethnicity in the articles compared with the grants.

In our sample, as stated above, 40 of 72 grant proposals included investigation of racial or ethnic differences as an objective. We might expect that articles resulting from this subset of grants would be more likely to discuss race or ethnicity in their resulting articles. Indeed, nearly all (38 or 95%) of these 40 researchers who included the investigation of racial or ethnic difference as an objective at the grant stage mentioned race in at least one of the sampled articles. However, 50 of the 80 articles produced from these grants (63%) did not present any discussion of prior knowledge of racial or ethnic differences. Similarly, of those 80 articles, 30 (38%) did not include any analyses with race or ethnicity as a variable or stratify their analysis by race. Further, of these 40 grants, 24, or 33%, cited racial or ethnic differences in morbidity or mortality, but only 18 of these researchers actually discussed such differences in at least one article. Using several different measures, then, we saw evidence of scientists retreating from their initial claims that the investigation of race or ethnicity was an important component of the study when writing about the completed research. Racial or ethnic variation may indeed remain an important research hypothesis, but a lack of findings or even lack of diverse clinical subjects may inhibit discussion.

As an illustration, consider Timothy Rebbeck's abstract[27] for his proposal to study genes associated with prostate cancer, in which he strongly asserted the impact of race and ethnicity on risk for cancer, remarking that "African American men have the highest prostate cancer rate in the world," and invoked racial and ethnic differences in each specific aim. He proposed to "systematically evaluate allelic and genotypic distributions at these candidate genes, and compare these distributions in four ethnic groups (Ghanaian, Senegalese, African American, and US Caucasian men)...evaluate the relationship of candidate genotypes with prostate cancer in African Americans...[and] evaluate differences in the genotype-prostate cancer relationship between African Americans and Caucasians." The grant described a research agenda that promised to identify why African American men have such high rates of prostate cancer, and suggested that the cause is gene variants related to West African heritage. In the first article published as a result of this research,[28] the authors reported the frequency of one of the genes discussed in the grant abstract in "Caucasian" "African-American" and "other" men, but they did not find differences in frequency of these genes. However, they did not discuss the data from Ghana and Senegal at all, and in more complex analyses, the "race" variable was used for control only, as the authors shifted their focus to categories of prognosis as predicted by a combination of genetic markers and tumor characteristics. Neither of these types of biological indicators were discussed in relation to race or ancestry. In the second article, Rebbeck et al.[29] assessed the impact of specific variants of certain genes on the risk of prostate cancer. Again data from the African continent is unmentioned, and "black," "white," and "other" race were discussed mainly

Table 2
Use of Race and Ethnicity in Sample of Articles Produced by Grants

	All articles (N=144) n (%)	Articles resulting from grants with race/ethnicity in aims (n=80) n (%)
Operationalize race/ethnicity	44 (31%)	34 (43%)
Prior knowledge racial/ethnic difference cited	41 (28%)	30 (38%)
Race/ethnicity used as analytical variable	91 (63%)	50 (63%)
Reported significant differences by race/ethnicity	21 (15%)	12 (15%)

as one of the factors on which cases and controls were matched. A second mention of race served only to assure the reader that no differences by race in the genetic markers existed. The authors did not include discussion of the elevated rate of prostate cancer for African American men, and subgroup analyses were completed with only the "white" cases and controls. Furthermore, the majority (about 85%) of the sample was identified as white — a curious condition for a grant purportedly focused on "the relationship of candidate genotypes with prostate cancer in African Americans," and which promised half of the case-controls used in the study would be African American.

One possible explanation for the decline in discussion could be that the authors simply did not find anything interesting regarding race or ethnicity. This is certainly one way to interpret the findings, particularly Rebbeck's studies. The authors might have chosen to not discuss racial variation in disease in the articles because their findings did not support the racial claims in the grant. What we want to stress here is that this is an indication of researchers' understanding that race or ethnicity is important to research and that, as a result, researchers may seek ways to incorporate them in their studies in ways that may not be warranted.

In another example of authors' seeming retreat from discussing race or ethnicity, researchers proposed a study of differences in androgen metabolism that may be linked to variation in genes coding for an androgen receptor and to cancer etiology. The wording suggested that understanding racial differences was one motivation for the research: "Since the frequency of the androgen receptor polymorphisms is substantially higher in the African American population, this mechanism could also explain the higher incidence of prostate cancer in African American men."[30] Despite the fact that examining racial differences was a central focus of the proposed research, so few of the men who enrolled in the study were African American that neither race nor ethnicity were variables in the main analyses in the first article[31] and only white men were included in the analyses for the second paper.[32] Although the Inclusion Mandate sought to ensure the inclusion of minority population subjects in all human subject research and of sufficient numbers of women and minority participants in all Phase III clinical trials to generate "valid analyses" of difference, the mandate never specified threshold numbers that could provide statistically significant results. The challenges William Henner et al.[33] faced in recruiting enough African American men for the study illustrates the difficulty of recruitmentology and of aligning scientific paradigms to socio-political ones.[34]

In addition to study designs that eventually failed to provide investigators the data to appropriately test the relationship between race and disease, it seems possible that part of what we captured was resistance to reporting confirmation of the null hypothesis. In other words, the authors may have simply left out a full discussion of racial or ethnic difference — even if it was a central motivation for the initial study — when their analysis did not yield statistically significant results.

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that 30 of the 80 articles (38%) resulting from grants that specifically proposed to study race did not include any analysis of race or ethnicity. We also know that the rate of statistically significant racial and ethnic differences overall was fairly low. Looking at all 144 articles in the sample, 91 or 63% of the articles included analyses with race or ethnicity as variables or stratified their analysis by race, but only 21 or 15% of all articles found statistically significant differences, and almost half of these cases (9 or 6%) were supported by grants that did not discuss the investigation of racial or ethnic differences as central to the proposed research. Also worth noting is that only one of the articles which found no statistically significant racial or ethnic difference cited prior knowledge of racial or ethnic differences in the abstract or introduction. Other than this one exception, the discussion of race and ethnicity was always limited to the results section of the paper. In other words, prior knowledge of racial and ethnic differences was simply not mentioned as part of the motivation for the study in articles where no significant differences were reported, even when it was an explicit objective of the research beginning from the grant proposal.

Emphasizing the Importance of Racial and Ethnic Differences

On the other hand, some investigators seemed to overemphasize the significance of race or ethnicity in their research. For example, one study proposed to identify genotypes relating to the metabolism of meat and heterocyclic amines (found in grilled meat).[35] In this case, the authors of the article emphasized that their sample was recruited from a "multi-ethnic cohort" with "five targeted ethnicities," but they provided no scientific rationale for the relevance of race or ethnicity for their research. Furthermore, the genotypes they discuss do not specifically correlate with racial or ethnic groups.[36]

An even more extreme example of overemphasizing the importance of race or ethnicity can be seen in studies in which racial or ethnic variation was not found, yet the authors continued to suggest in the articles that such differences exist. For instance, in the grant application for a study of prostate cancer,[37] the authors continually stressed the importance of race despite "compelling evidence for unidentified environmental causes" of prostate cancer. As they explained, "Research on men who migrate from areas of low prostate cancer mortality to areas of high prostate cancer mortality provides compelling evidence for unidentified environmental causes of prostate cancer. [...] These studies imply that immigrants are exposed, after their emigration, to environmental or lifestyle factors that place them at higher risk for prostate cancer." However, immediately following this statement they returned the focus to race: "we must identify risk factors for prostate cancer [...] in order to explain racial differences in prostate cancer incidence."[38] In addition, in an article resulting from this grant, the authors argued that the racial variations that they expected did not materialize in their data, not because such differences are not present, but because their study lacked statistical power. They wrote, "Our study did not have the power to detect small but meaningful differences between subgroups of our population. [Biomarkers] did not differ significantly by disease status or by race. Our study had 90% power to find a relatively large (0.35) difference between correlations, but smaller differences in correlation between racial groups or between cases and controls were much less likely to be detected."[39] These authors thus emphasized that even small differences by race, had they been detected, would have been meaningful. While in some cases this may be true, this study did not detect any small differences, yet by including this claim they nonetheless emphasized the importance of racial difference. Further, in their grant application the authors clearly recognized the level of recruitment of African American participants required to power their study. They proposed to recruit 100 cases and 100 controls, 40% of them African American. The article was based on 89 cases and 38 controls, 29 African American and 98 white, which they argued was underpowered to detect all meaningful racial differences. Although the researchers argued that their study site drew a diverse pool of patients with a relatively high number of African Americans, they did not meet their proposed sample goal. The fact that they did not achieve the proposed levels of recruitment once again highlights the challenge of recruiting sufficient numbers of minority subjects. Clearly, the investigators understood the statistical requirements necessary to generate statistically meaningful results. The Inclusion Mandate, however, does not require researchers to have minority subjects in numbers sufficient to meet this requirement, as previously explained. Thus, perhaps it is not surprising that the lower threshold for research (inclusion of minority subjects necessary for "valid analyses") does not always compel investigators to recruit subjects in numbers sufficient to generate findings that are statistically significant.

Although such an emphasis on race or ethnicity might have seemed unwarranted at times, it is also possible that the rote inclusion of racial or ethnic variables could generate interesting or unexpected findings. One way to examine this question is to look at grants *not* primarily focused on race that ultimately found statistically significant differences by race or ethnicity. In our sample, as we previously mentioned,

almost as many of the articles reporting statistically significant differences resulted from research that did not propose to investigate racial or ethnic differences (N=9) as research that did set out to do so (N=12). One example is a grant that proposed to link birth and cancer registry data to examine the possible role of prenatal exposures and/or experiences during pregnancy as adults in risk for breast cancer.[40] Both articles we examined that were produced as a result of this grant found significant racial differences though the grant did not include these differences as a motivation for the study in the grant. For example, in an article that discussed breast cancer in young women and the possible influences of various prenatal exposures, the researchers found "an increased risk for breast cancer, and particularly for advanced-stage breast cancer, among young African-American women."[41] The authors noted that this is a finding that supports similar results from other studies, which is interesting given that race and ethnicity were not discussed at all in either the grant or the abstract or introduction of the article. The authors suggested that intrauterine exposures, for example relating to maternal diet and circulating hormone levels during pregnancy, could be important factors. They theorized that a higher consumption of dietary fat among African American women may be responsible. The decision to focus on maternal diet as the only explicitly elaborated explanation for this observed difference was quite interesting, particularly since the evidence cited to support the idea that their mothers' diets were high in fat compared to white counterparts were from the 1990s, while the relevant fetal experiences were about 30 years earlier and potentially occurred in a completely different food environment. However, the authors ultimately asserted that "[t]he Black-White differences in breast cancer incidence and mortality remain largely unexplained, although socioeconomic, adult lifestyle, and genetic factors may all play a role."[42]

Examining the Impact of the Inclusion Mandate

One implicit question underlying this series of examples has to do with the possible impact of the Inclusion Mandate, which began in fiscal year 1995. While we were not able to test the statistical significance of the effects or demonstrate causality, we did look explicitly at this question. Of the grants in our sample, 50 are from the pre-inclusion mandate era (1990-1995). Of these, 26 or 52% mentioned the investigation of racial or ethnic differences as a specific objective. Of the 22 grants awarded between 1996 and 1999, 14 or 64% specifically set out to investigate racial or ethnic differences. Although this evidence suggests an increase in the investigation of racial and ethnic differences, the proportion of grants citing racial or ethnic differences in morbidity or mortality as a justification for this research did not change; prior to the Inclusion Mandate 16 or 32% noted such differences, while after the mandate was in place 8 or 36% did so. The proportion of grants which explained or theorized the reason for the racial or ethnic difference under investigation also did not vary between the time periods. Prior to 1996 such explanations were present in 9 or 18% of the grants, whereas between 1996 and 1999 it was also 18% (N=4). However, there was a very slight decrease in the proportion of grants specifically proposing to investigate race or ethnicity that actually explained or theorized the significance of race. Prior to the Inclu-

Table 3

Race and Ethnicity in Grants and Resulting Articles Pre- and Post- Inclusion Mandate

	Funded pre-mandate: FY 1990-FY 1995 n (%)	Funded post-mandate: FY 1996-FY 1999 n (%)
Total Grants	**50 (100)**	**22 (100)**
Research objectives include investigation of race/ethnicity	26 (52%)	14 (64%)
Grant cites prior racial/ethnic difference in morbidity/mortality	16 (32%)	8 (36%)
Grant includes hypothesis/theory about racial difference	9 (18%)	4 (18%)
Total Articles	**100 (100%)**	**44 (100%)**
Article defines or operationalizes race/ethnicity	24 (24%)	20 (45%)
Article cites prior knowledge of racial/ethnic difference	27 (27%)	11 (25%)
Article includes race/ethnicity as analytic variable	64 (64%)	27 (61%)
Article reports significant differences by race/ethnicity	15 (15%)	6 (14%)

sion Mandate, 8 out of 26 or 31% of this subset of grants provided such a theory or explanation, whereas after the mandate went into effect, the percentage decreased to 29% (4 out of 14 grants).

When comparing the articles resulting from pre-inclusion mandate grants with those resulting from grants awarded after the mandate went into effect, the mandate appeared not to have had an effect on reporting statistically significant differences related to race or ethnicity. Of the 100 sample articles resulting from pre-mandate grants, 15 (15%) reported significant racial or ethnic differences. Similarly, 6 (14%) of the 44 articles produced by post-mandate grants reported significant racial or ethnic differences. Furthermore, no substantial change was observed in articles that included analyses with race or ethnicity as a variable or stratified analyses by race/ethnicity; prior to the mandate, 64 (64%) of the resulting articles included these analyses, compared to 27 (61%) of the articles resulting from post-mandate grants. However, substantially more of the post-mandate articles defined or operationalized race and/or ethnicity. Before the Inclusion Mandate only 24 (24%) articles defined the racial or ethnic categories that they used. However, after the mandate 20, or 45%, of the articles operationalized the terms used. This increase in specificity may reflect a shift among investigators toward being more thoughtful and explicit in their use of racial or ethnic categories, although both the passage of the Mandate and these effects could also be tied to shifting views about the importance of defining racial or ethnic concepts in science.[43]

Discussion

Our objective in this study was to learn about the knowledge production process in biomedical research on racial and ethnic differences. In our sample, the investigators rarely explained or theorized race or ethnicity, which confirms the findings of prior research. While 40 or 56% of the grants explicitly stated that the investigation of racial or ethnic difference was one of the study's goals, only 13, or 18%, explained, hypothesized, or theorized the racial or ethnic difference. This disparity was even more pronounced when looking at the articles: 131 of the 144 total articles (91%) mentioned race, but only 44 or 31% defined or operationalized race or ethnicity in any way.

The fact that almost half of the articles reporting statistically significant racial or ethnic differences in our sample resulted from grants that did *not* propose to specifically study race or ethnicity further underscores these questions about the impact of routinely including racial or ethnic variables in statistical models, even when the investigators may not think they are particularly important. What we actually saw qualitatively, however, were authors who seemed to over-emphasize the significance of race or ethnicity in their research, suggesting, among other things, that the increasing institutional and cultural discourses around the biomedical importance of racial and ethnic differences are being taken quite seriously by some investigators.

As Lee[44] argues, this tendency to leave racial and ethnic categories undefined may reflect an *a priori* assumption by scientists that these categories are self-explanatory. Yet many social scientists insist that racial categories are far from self-evident.[45] Racial classification is not rooted in binary, discrete categories.[46] In reality, racial or ethnic classification in biomedical research is based on prototype theory, which is "fuzzier" than we usually realize or than the OMB categories can capture. We typically have a "broad picture" in our minds about what we think we are classifying. Yet, different social groups have different prototypes in mind. So while ethnicity defined as birthplace may make sense in a study of subjects in one setting, this may not be appropriate elsewhere especially since the meaning of race or ethnicity is not only fluid but also spatially variable.[47] Further, particularly in the current cultural climate of growing faith in biomedicine and genomics, leaving it to the reader to determine the meaning of racial and ethnic terms may inadvertently contribute to the circulation of biologically reductionist notions of race and ethnicity.[48]

In addition to examining biomedical scientists' definitions of race and ethnicity, comparing grant proposals to published articles allowed us to track

the knowledge production process over time, capturing how scientists wrote about race and ethnicity both before and after they actually conducted their research. In turn, this enabled us to examine the extent to which scientists "delivered" on their research proposals. Our analysis demonstrates a decrease in discussions of race and/or ethnicity in the articles compared with the grants. Of the 80 articles resulting from grants that mention racial or ethnic differences as a focus, 50 or 63% failed to mention any prior knowledge of racial/ethnic difference. Furthermore, 30 or 38% of these articles did not include any analysis with race or ethnicity as a variable or stratify their analysis by race.

It is possible that some of this decline is attributable to the endpoint we chose for our study, which was the second publication relating to the research proposed in the grant. Given this artificially defined stopping point for the knowledge production process, it is possible that the racial difference objectives have not truly been abandoned by the researchers; in some cases they may have waited to report their findings about race and ethnicity in a later publication. However, in designing our sampling strategy, we reviewed the abstracts of all available publications for each grant. In many cases, the majority of the articles were not related to the main research questions presented in the grant. The number of related articles ranged from 2 to 185 with an average of 15. Based on our review of the abstracts, by including the first and second related articles, we are reasonably confident that we are not overlooking significant analyses of race or ethnicity in later articles. Furthermore, given that a decline occurred across so many of the grants/article combinations in the sample, we believe this is a valid and interesting finding. Whether it reflects resistance to reporting confirmation of the null hypothesis (i.e., no effect of race or ethnicity) or some other cause, such as changing journal guidelines regarding the use of race or ethnicity (such as those cited by Smart et al.[49]), requires further research.

One additional possibility is that the decline indicates that the rates of inclusion of racial and ethnic differences in the grant proposals are artificially elevated, reflecting broader institutional pressures and cultural norms regarding the importance of including women and minorities in biomedical research studies. If this is the case, we may be seeing evidence of perfunctory adherence to the requirements of the NIH Inclusion Mandate, for instance, rather than a genuine interest in studying racial and ethnic differences. One of the biggest concerns about the Inclusion Mandate was that investigators whose primary research interests lie elsewhere would include race and/or ethnicity in their studies in a rote manner, simply because they are required to do so to receive funding from the NIH, and therefore might do so in a careless manner that presumes racial and ethnic categories are self-evident. These uses of racial and ethnic categories or data may be part of the general phenomenon of ritualistically including race or ethnicity, further demonstrating the alignment between state-sanctioned, bureaucratic categories and science.[50] In such cases, the investigator may not provide an explanation of what is actually captured by their racial or ethnic categories, or why they may be important for their specific research questions, leaving the reader to interpret what these categories mean in light of taken-for-granted cultural forms and frames that tend to support a biologically reductionist understanding. The fact that almost half of the articles reporting statistically significant racial or ethnic differences in our sample resulted from grants that did *not* propose to specifically study race or ethnicity further underscores these questions about the impact of routinely including racial or ethnic variables in statistical models, even when the investigators may not think they are particularly important. What we actually saw qualitatively, however, were authors who seemed to over-emphasize the significance of race or ethnicity in their research, suggesting, among other things, that the increasing institutional and cultural discourses around the biomedical importance of racial and ethnic differences are being taken quite seriously by some investigators.

Interestingly, even if the Inclusion Mandate did indeed have the effect of routinizing racial inquiry, this may simultaneously heighten and reduce the perceived significance of race and ethnicity. Social categories as omnipresent as race and ethnicity can come to feel like part of the natural landscape, rather than something socially significant. They take on the character of obviousness and inevitability, and as a result the social forces sustaining their salience tend to drop out of view.[51] Combating this assumption requires that we continually emphasize the social features of race and ethnicity in our research, explaining both what race and ethnicity mean and why they matter — both biologically and socially — for the research at hand. Further, when in this cultural context scientists are required to investigate race and ethnicity biologically, this increase in attention to the biological aspects of race and ethnicity risks further reifying these constructions while perhaps concomitantly de-emphasizing other dimensions of health. Some critics have therefore expressed concerns that the NIH's Inclusion Mandate may contribute to the naturalization of notions

of racial difference, particularly as it relates to heredity, genetics, and disease, providing a scientific rationale for racially targeted medical care and distracting attention from research that tries to probe the complex ways in which political, economic, social, and biological factors, especially inequality and racism, cause health disparities.[52]

While our study does not allow us to test the statistical significance of the impact of the Inclusion Mandate, we did find some evidence of a slight increase in the investigation of race and ethnicity after the mandate went into effect. Prior to 1996, 26 or 52% the grants cited the investigation of race or ethnicity as a specific focus of the research, whereas between 1996 and 1999 it was 14 or 64%. At the same time, there was a very slight decrease in the proportion of those grants that actually explained or theorized the significance of race. Prior to the Inclusion Mandate, 8 out of 26 or 31% of the grants specifically proposing to investigate race or ethnicity provided such a theory or explanation, whereas after the mandate went into effect, the percentage decreased to 29% (4 out of 14 grants). This finding demonstrates that — even looking only at those proposals where the investigation of racial and ethnic differences was a stated focus — not only is the proportion of grants that explain or theorize racial or ethnic differences problematically small, but the Inclusion Mandate also may have done little to alter this tendency or to improve the situation. The proportion of investigators who provided such explanations remained about the same or even decreased slightly after the mandate went into effect, even as the overall proportion of grants looking at race and ethnicity increased. However, at the publication stage, more authors provided information about how they defined and operationalized their racial and ethnic categories. Prior to the mandate, 18 of 52 articles (35%) supported by race-focused grants defined the racial or ethnic categories that they used, whereas post-mandate it was 16 of 28 articles (57%). This finding suggests that the Inclusion Mandate may have had some positive, if subtle, effects. Unfortunately, we are unable to conclude whether this effect is the result of the Mandate or of concomitant processes, including journal publication requirements on the reporting of race and ethnicity.[53]

The goal of this investigation was to examine the knowledge production process in biomedical research on racial and ethnic differences. In order to gain a more complete picture of the research process, we included both grant proposals and the resulting published research. This study design captures changes over time in how biomedical researchers presented the meaning of racial and ethnic categories and the significance of racial or ethnic differences for their research. Among other things, this provided some insight into the question of whether scientists "delivered" on their research proposals. Tracking these uses over the research process from grants to publications further permitted us to examine how scientists "translate" their ideas about health and notions of difference to varying audiences: first to an audience of funders and then later to other scientists and the public. In many cases, a focus on racial and ethnic differences at the grant proposal stage dropped out at the dissemination stage. In addition, our study is the first to provide any analysis of the possible effect of the 1994 Inclusion Mandate on the content of biomedical research on racial or ethnic differences. Our findings here are mixed. For example, there was a slight *increase* in the proportion of grants specifically proposing to investigate race or ethnicity, but among these grants there was little change in frequency in definition and operationalization of the variables used to capture race and ethnicity. The resulting articles, however, provided more information about how they conceptualized and measured racial and ethnic differences. Prior to the mandate, only 35% of the articles supported by this subset of grants defined the racial or ethnic categories that they used, whereas post-mandate authors did so in 57% of the articles.

Despite our study's unique contributions, our findings are limited by constraints in our data and study design. For example, as mentioned above, we do not know the particular institutional context in which decision-making processes at the grant review or journal submission stages dictated the parameters of reporting and use of race (besides the known conditions specified and discussed). More broadly, because we did not capture the entire knowledge production process, we are limited in our analysis to what we could observe at two points in time; we can only speculate about everything that occurs between those two points, including journal review and publication processes. One result of this limitation is that we are not able to determine with confidence whether the observed patterns are actually caused by the Inclusion Mandate, or whether these are both better explained as confounded or temporal effects, for example. Finally, our data refer to research proposals funded in the 1990s and their resulting articles. Research grants awarded since then and their related articles may be different.

Nevertheless, we had the unique opportunity — in one sense — to *follow* the knowledge production of race from study proposal to published findings. Our finding that race or ethnicity reporting declined from

grant to articles may suggest that the various rules and regulations requiring the use and reporting of race and ethnicity are encouraging an emphasis on race or ethnicity that is not ultimately revealed by the science itself. Whether this is a good or bad outcome is open to debate. One clear concern that arises and is underscored by the qualitative analysis we presented is that there may be a tendency to both undertheorize race and ethnicity and overemphasize their importance. Given the long, troubled history of scientific racism, it is crucial that biomedical researchers carefully consider the theoretical significance of race or ethnicity for understanding health differences and to remain cautious against the potential for biological reductionism.

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