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The Legacy of the U. S. Public Health Service Study of Untreated Syphilis in African American Men at Tuskegee on the Affordable Care Act and Health Care Reform Fifteen Years after President Clinton's Apology

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INTRODUCTION

The Legacy of the U. S. Public Health Service Study of Untreated Syphilis in African American Men at Tuskegee on the Affordable Care Act and Health Care Reform Fifteen Years after President Clinton's Apology

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This special issue addresses the legacy of the U.S. Public Health Service Syphilis Study on health reform, particularly the Affordable Care Act. This article offers readers a guide to the themes that emerge in this issue. These themes include individual consent interrelated to consequences in populations issues, need for better government oversight in research and health care, and the need for overhauling our bioethics training to develop a population-level, culturally driven approach to research bioethics. We hope the guidance offered in this issue will help shape a new framework to bioethics that can be integrated into the foundation of health care reform.

Keywords: Tuskegee, research bioethics, survivors

This year, 2012, represents 80 years since the U.S. Public Health Service (USPHS) Study (now Centers for Disease Control and Prevention) of untreated syphilis in African American men. It is also 40 years since the study was stopped thanks to a reporter, and it is also the 15-year anniversary of President Clinton's public apology at the White House to the remaining survivors, acknowledging the wrongdoing of this study by the federal government to these men and their family. Although the study was stopped 40 years ago, the egregiousness of the study is often remembered as well as cited as the cause of the low level of participation by African Americans in biomedical research. Some have taken the position that 40 years is a long time and that we

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need to move on and put what happened at Tuskegee in perspective given the changes mandated by the Belmont Report and the checks and balances that are in place through Institutional Review Boards (IRBs). Yet for many reasons that I hope this special issue underscores, there are many reasons to not forget and put behind what began 80 years ago as a study with the initial goal to understand and develop a treatment for syphilis. During the 40-year study, a treatment was developed but denied to the African American participants so that the outcome could become studying the clinical process through to death.

Bioethicists and historians such as Susan Reverby today talk about Tuskegee as a metaphor (Brandt, 1978; Caplan & Annas, 1999; Corbie-Smith, 1999a, 1999b; Fairchild & Bayer, 1999; Reverby, 2010) for racism, experimentation, deception by the federal government, paternalism, and in general a disvaluing of the lives of African Americans. Reverby, one of the authors in this special issue, reminds us, "If we only look at what happened in that study as the past, or learn from it in narrow ways, we are in danger of re-creating the thinking that made it possible in the first place" (Reverby, 2010). We conceived of this special issue within that very warning and coupled with the promise of President Clinton's Apology in which he committed the federal government to making sure that such a study as the Syphilis Study at Tuskegee should never happen again.

This special issue of *Ethics & Behavior* speaks to researchers, policymakers, medical school educators, and public health educators. It will contribute to our understanding of the powerful role that a population-based, community-oriented research bioethics can play in advancing health care reform and transforming and eliminating racial and ethnic health disparities in health research and public health services. Articles from former Surgeon General Jocelyn Elders, President of Morehouse School of Medicine John Maupin, and Director of the Tuskegee National Center for Bioethics in Research and Health Care Rueben Warren express hope that the lessons of the egregious USPHS Syphilis Study will drive true health care reform (Elders, 2012; Maupin & Warren, 2012; Warren, Williams, & Wilson, 2012). Dr. Elders expresses so passionately in her commentary her hope that the Patient Protection Affordable Care Act will provide equal and accessible health care regardless of skin color, economic status, or sexual orientation but cautions that we must learn from the past in order not to make the same mistakes (Elders, 2012). Similarly former Surgeon General David Satcher (2012) in his commentary encourages us to remain vigilant to ensure that we do not lose ground. His words are particularly poignant as he was at the Presidential Apology and, as the "people's doctor," actively worked to ensure that the apology would take place. Many articles in this issue cite Dr. Satcher's work as evidence of the widening disparity gap in the health of African Americans, which he urges must be addressed.

One of the most pervasive themes throughout all of the articles is how far we must still go in educating ourselves and instituting a different approach to bioethics training in order to ensure benefit of research and medical care for racial/ethnic minorities (Mays, 2001). The articles are rich in their ability to teach us about the history as well as the current perspectives and dilemmas faced by racial/ethnic minorities. Each article tells a story. Some help us to better understand why some racial/ethnic minority populations hesitate to participate in research studies, or as Lee (2012) argues, that cultural rules governing relationships and status can make it difficult if not impossible for some to say no to requests to participate in research. It is hoped that after reading these articles, those responsible for implementing health care reform will take away the lesson that if you build it they, often the most vulnerable, may not come despite their need. If the foundation of health care reform does not include training to addresses the metaphors of the

USPHS Syphilis Study that have left some fearful of accessing care, then disparities will still remain with little hope of their elimination.

As 2012 represents the 15-year anniversary of President Clinton's Apology to the remaining survivors of the Tuskegee Study of Untreated Syphilis in the Negro Male, these articles examine whether as we attempt to move forward in health care reform we have sufficiently met the promises of President Clinton to those survivors—that this would never happen again. The co-editors of this special issue we are driven by questions posed by President Clinton's promises in his apology. Have we produced a research workforce sufficiently trained in the lessons learned from events at Tuskegee so that this will never happen again? Has the federal government met the president's goal of increasing the number of racial and ethnic minority biomedical researchers as one of the strategies to prevent what happened at Tuskegee from happening again? Has the legacy of what happened at Tuskegee for 40 years served as a reminder to the federal government of its required stewardship of bioethics in its research enterprise such that it will never again value the collection of data in the name of science over the protection of the lives of some of its most vulnerable in society, namely, poor, uneducated racial and ethnic minorities?

Sadly, we must say that there has been a failure to achieve some of the promises made by President Clinton in his 1997 Apology. The year 2010 saw Secretary of State Hillary Clinton, Secretary of Health and Human Service Kathleen Sebelius, and President Obama apologizing to Guatemalan president Alvaro Colom for newly emerging documentation of a study similar to the USPHS Tuskegee syphilis experiment in African American men that occurred between 1946 and 1948 by the USPHS, National Institute of Health (NIH), and Pan American Health Sanitary Bureau in Guatemalans (McNeil, 2010; Presidential Commission for the Study of Bioethical Issues, 2011; Stein, 2010). The NIH appointed a panel designed to explore why so few African American PIs receive NIH funding. This occurred after a publication in *Science* that included the former acting director of NIH. Results indicated that regardless of the type of grant mechanism, African Americans were the least likely to be Principal Investigators compared to Whites and other racial/ethnic minority groups (Ginther et al., 2011). Is any of this relevant to health care reform and the Affordable Care Act? I hope that the articles in this issue will help readers to understand that although much has been invested in changing the accessibility and affordability of health care services and making sure that research participants are protected, we still have a long way to go. However, what the articles in this special issue offer is guidance in search of leadership on how to better achieve the goals of the Affordable Care Act. The articles, when taken as a set, call for developing research bioethics training that is population-based, culturally driven, and achieves optimal health.

This special issue starts with a set of articles driven by the goals of helping to educate all of us about both the history of research and medical care abuses in the past and also policy choices we make today in our research and clinical care enterprises that for some racial/ethnic groups are similar to the Syphilis Study. The introduction of the Mays, Coles, and Cochran (2012) article, reviews studies conducted post-2000 in which data are cited showing that African Americans are still concerned and believe that their health care providers are more likely to treat them like guinea pigs, give them experimental medications and withhold information about their health care (Brown & Topcu, 2003; Corbie-Smith, Thomas, & St. George, 2002; Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999; Green et al., 2000; Katz et al., 2008; Scharff et al., 2010). These concerns are not unfounded as illustrated in the *Unequal Treatment* report (Smedley, Stith, & Nelson, 2003). The stunning study by Shulman in which African American and White

patients played by actors were given the same set of symptoms of a cardiovascular disease event but African Americans consistently were given less intensive treatment than Whites supported the fears expressed by African Americans. The Institute of Medicine *Unequal Treatment* report (Smedley et al., 2003) burst onto the scene gathering several instances of differences in health care services for African Americans (Ayanian, Udvarhelyi, Gatsonis, Pashos, & Epstein, 1993; Ayanian, Weissman, Chasen-Taber, & Epstein, 1999; Barker-Cummings, McClellan, Soucie, & Krisher, 1995; Canto et al., 2000; Escarce, Epstein, Colby, & Schwartz, 1993; Gaylin et al., 1993; Hannan et al., 1999; Johnson, Lee, Cook, Rouan, & Goldman, 1993; Kasiske, London, & Ellison, 1998; Peterson et al., 1997; Ramsey, Goff, Wear, Labarthe, & Nicharnan, 1997; Todd, Deaton, D'ardarno, & Goe, 2000; Todd, Samaroo, & Hoffman, 1993). So before we are too quick to dismiss their concerns as cultural paranoia or to blame the legacy of the USPHS Syphilis Study, data supports that such concerns are wise and to act differently within the community of African Americans is considered foolish. If we do not address these concerns—whether real or perceived—despite access through provisions in the Affordable Care Act African Americans may be reluctant to pursue the opportunities in the Affordable Care Act designed to reduce poor health outcomes targeted to their needs.

The Hodge (2012) article reminds us about horrendous medical experimentation in the past with Native Americans. We learn President Obama issued an Apology to Native American Indians for atrocities that they experienced at the hands of the federal government. Yet few know of this apology as it is buried and was not carried out at the White House. It has lacked the healing that Clinton's Apology brought about for some in the African American community.

The dilemma that Latinos who are classified as undocumented face in being participants in biomedical research is well presented in the Cacari-Stone and Avila (2012) article. Although this group's classification allow them to participate in NIH research, it does not provide them with the benefit of the population-level evidence based findings because they will be excluded at the federal level from the benefits of the Affordable Care Act. Cacari-Stone and Avila have done a stellar job in this article with helping us to better understand how policies that allow inclusion and exclusions create inequities and develop for some racial/ethnic groups a sense of being treated differently, unfairly, and inequitably. As with the Hodge article, the authors provide a wealth of examples to help us to understand the abuses and experiences of Latinos as research participants.

A second theme of the articles is the notion of the need for a reexamination of the individual as they are interrelated to the community- or population-level of informed consent and protection. Lee (2012) uses the Millennium case to illustrate the influence of hierarchy and status in a village in China. A Harvard post-doc sent back to a small village was able to gain an unusually high participation rate because he was male and a representative of a prestigious American institution. She raises a question for IRBs as well as researchers to think about how social relations within racial/ethnic minority communities can override true individual consent based on gender and social status norms. This article challenges our customary thinking that the quality of the consent process improves if patients and the person obtaining consent are members of the same racial/ethnic/cultural group.

We have devoted so little research to empirically assessing racial/ethnic population dynamics in research. Instead we are guided by a number of assumptions about intra- and interpersonal relationships that may influence or enhance the consent process. I published an article on ethical training to enhance research participation and indicated that for African American heterosexual men, gay men, and men who have sex with men participating in an HIV study of their sexual

and drug behavior, when allowed to choose the gender, race, and sexual orientation status of their interviewers, the majority of the men chose a heterosexual White female (Mays, 2001). The reason is that she was the least likely to know anyone they knew, and hence the likelihood was high that what they shared would not get back into their networks. It was also the case that the quality of the data was enhanced as they felt little in the way of social desirability to either exaggerate or obscure their risk-taking behaviors. Of interest, in this same study they were also given the same opportunity to choose who after the interview and HIV testing would give them their HIV results, and they again chose the White female interviewer but in subsequent follow-ups, if they were HIV positive, wanted to talk with an African American male interviewer, especially if he too was positive. The Lee (2012) article helps us to understand how our assumptions of the value of race matching to enhance the ethical consent process may not be working as we imagine.

The theme of the implications of seeking individual consent when it is intertwined with population or in this instance tribal consent is also raised in the Hodge (2012) article. Any researcher conducting research in American Indian tribal groups must understand how sovereignty changes the consent process, the ownership of the research data, and the IRB review process. As indicated by Hodge, a legacy of the USPHS Syphilis Study at Tuskegee is that tribal groups developed their own IRBs in which studies are reviewed in the context of tribal governance procedures. Permission is granted for research that is beneficial to tribes. Tribes within the context of the review, in addition to assessing whether the research is conducted in a manner that benefit outweighs harm, can determine if the research is of value to the tribe and answer questions that are of value and priority for the tribe's welfare.

In Mays (2012), population versus individual and/or subgroup factors are discussed within the context of ethnic/racial classification in the design of the research. Research that continues to classify all Blacks together despite their racial/ethnic diversity is not helpful to developing efficacious physical and mental health care and treatment. The article provides evidence that taking within-group diversity into account in areas of race/ethnicity classification, nativity, and socioeconomic status makes a difference in study results (Mays, 2012). If health reform is to be successful, taking population and subgroup characteristics into account is necessary.

A third theme in this issue is the need for better government oversight to protect vulnerable populations in the area of research and medical care. Most of the injustices cited by the authors in this issue were either due to a lack of oversight of internal government research or promotion of government policies that conveyed a bias toward racial/ethnic minorities groups; this bias was carried over into research, care, and treatment. Both Maupin and Warren (2012) and Warren et al. (2012) discuss how the very foundation of our bioethics training and ways of training the next generation of health providers needs overhauling. The precedent-setting Flexner and Frenk et al. (2010) reports discuss how changes in medical education can benefit the health care system. What Maupin and Warren and Warren et al. suggest in bioethics training for healthcare providers is as transformative for medical education as the Flexner Report.

Another theme important to the co-editors is the legacy of the USPHS Syphilis Study on the study participants and their families. I am of the firm belief that if we discuss the USPHS Syphilis Study without remembering it occurred in African American men, we make it easier for it to happen again. We make it more about science, less about the inhumanity of that science. In the commentaries and essays section we start with a powerful reminder of the legacy of the USPHS Tuskegee Study of Untreated Syphilis in the Negro Male by hearing from the daughter of one of the participants (Head, 2012). Ms. Head's article, entitled "One Voice," is a powerful

voice for researchers to hear. It bears witness to the negative inter-generational consequences in study participants' families. We learn of the stigma that the families experience from their relative being a participant in the USPHS Syphilis Study.

The driving force for completing this special issue was my attendance at one of the Tuskegee University National Center for Bioethics in Research and Health Care annual meetings. I was privileged to sit at a table with several of the family members. It was a humbling and powerful experience as I listened to their stories; heard feelings that came from promises unfulfilled; heard questions and concerns about potential hidden health problems that might emerge in later generations; and heard the uniqueness of their experience, which they shared with one another. Their stories are a part of the legacy, but researchers, particularly those who are not minorities, quit listening to their voices in favor of their own experiences of woe and inadequacy in collecting data, which they assert the legacy of Tuskegee. There are several articles in this special issue that challenge the belief that the low participation rate of African Americans in research is a legacy of Tuskegee. Rather, low participation stems from the lack of trust victims of bias, discrimination, and other acts of inhumanity have in our federal government's commitment to protecting research participants and the civil rights of those who receive health care. The "One Voice" commentary helps us to understand this.

Ms. Head also helps us to realize that our responsibilities may last beyond the time that participants are in our studies if there are long-term consequences. Reverend Dr. Wimberly (2012) in his article cautiously proposes to employ narrative story-telling among the survivor families to promote healing. The pain the families are experiencing represents a hidden adverse event; much is still needed to address the USPHS Syphilis Study in the families of the African American study participants. President Clinton's commitment to the survivors and their families has not yet been achieved. I hope that these articles can inform the way forward to complete President Clinton's promises in time to serve as a foundation in health care reform.

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