LAUNCHING THE AMBASSADORS

In Fall 2010, it was my good fortune to be invited to a conversation by the late Presiding Elder Reverend Timothy Howard and Tesheia Johnson, deputy director and chief operating officer of the Yale Center for Clinical Investigation (YCCI), to a meeting with other AME Zion pastors and community leaders from Junta to discuss the need for diversity in clinical research. As a pastor, I must admit that I was unaware of how underrepresented minorities are in these studies, and how this disparity affects positive health outcomes in our communities. Why the under-representation in clinical research? The answer was staring me in the face and I did not recognize it. I passed it every day on my way to work. The abandoned houses I saw were telltale signs that things are not right. The over-crowded emergency rooms; the parking lot at Home Depot filled with men seeking work to feed the empty bellies of those at home who often went to bed hungry. The answer is poverty. An obvious conclusion, because access to health care can be expensive, especially if your income is limited or if you have no income.

The concept of noblesse oblige translates as ‘nobility obligates,’ and denotes that having rank or power extends beyond mere entitlements. It implies that those persons or institutions of privilege have an obligation and responsibility to meet social needs. It was clear that the medical community engaged in clinical research, which we typically hear as “clinical trials,” had until now fallen short of its mission. I would be remiss not to mention that the role of the minority communities has been intentionally small for some obvious and not-so-obvious reasons.
LAUNCHING THE AMBASSADORS

Medical malfeasance, and such shameful, ugly scars left in history as that of Henrietta Lacks or the Tuskegee study, and hundreds of other stories recorded in *Medical Apartheid*, which explores the dark history of medical experimentation on Black Americans from colonial times to the present, raises the question of why African Americans should ever trust the medical community. The idea of participating in clinical trials carries with it the stigma of being a guinea pig. In our meeting at Yale, we examined the why and the why not. It became clear to pastors from the AME Zion Church that we need to change the trajectory. As leaders within our community, we recognized the need to reach out and address the disparities that adversely affect our community. We spent many months in dialogue, discussion, and eventually in training to formulate a mission and arrive at a goal.

By the winter of 2010, a true partnership began between the community and the Yale School of Medicine: the Yale Cultural Ambassadors program. As partners, we would assist in the development of protocols for specific trials as well as in translational services for informed consent. We would also assist in development of and recruitment for trials that would specifically affect the minority community. As Ambassadors who completed an enormous amount of training and engaged in bilateral collaboration with YCCI, we have already demonstrated that we can make a significant difference in clinical research. Much of this success can be attributed to the trust that the black community places in its clergy, and the work in getting the message to the people who most need to hear it.

I look forward to sharing our stories of success with you in this newsletter and in future issues.

Reverend Dr. Leroy O. Perry

“Our mission became clear: we would become ambassadors for recruitment and empowerment for an underserved community to change the trajectory of the disenfranchised.”

Reverend Dr. Leroy O. Perry
The Cultural Ambassadors program is a crucial development for the New Haven area—for both the wider community and Yale. Minority populations suffer from more diseases, worse health outcomes, and lower life expectancies than their white counterparts. And while African Americans represent 12% of the U.S. population, they make up only 5% of the participants in clinical trials. Clearly, more work was needed to both recruit minorities for clinical research and to treat their ailments. Over the past several years, the Cultural Ambassadors have ensured that minority participation in clinical trials for which they have been directly engaged has ranged between 22 and 89%, with just one study at only 12%. Additionally, with the support of the Ambassadors, the Yale School of Medicine achieved last year an all-time high with 30% of the total accrual to clinical trials coming from historically underrepresented minority populations.

Part of the success of the Cultural Ambassadors program, and a major reason it won the Elm-Ivy Award, is the trust the Ambassadors have helped foster between community members and researchers. In fact, this program has been such a success that it has been expanded to Duke University (next page).
Changing the narratives of Tuskegee and Henrietta Lacks also means changing the protocols of clinical research. Linda Coleman, director of Yale’s Human Research Protection Program, outlined federal regulatory efforts toward optimizing human participation in research, including policies that seek to ensure that women and minorities are adequately represented in research protocols. The summit closed with Eric J. Velazquez, MD, professor of medicine and chief of cardiovascular medicine at Yale, who discussed how pragmatic principles in clinical trials can potentially increase the enrollment of typically underrepresented populations by citing a case study in which he is examining how to recruit minority populations to a study exploring the use of loop diuretics in the treatment of heart failure. He is working toward 40% African American enrollment in the study, and will collaborate with Yale’s Cultural Ambassadors to critique and improve the study protocol. “[[There has] never been a more exciting time do to this kind of work,” said Velazquez.

“The partnership will cultivate YCCI’s successful Cultural Ambassadors program, which partners with members of minority communities to provide feedback on clinical trial communications and protocols in order to make them more culturally competent,” said Tesheia Johnson, MBA, MHS, of pediatrics (emergency medicine) and chief medical information officer for the Yale School of Medicine and Yale New Haven Health, described the partnership will cultivate YCCI’s successful Cultural Ambassadors program, which partners with members of minority communities to provide feedback on clinical trial communications and protocols in order to make them more culturally competent. Jovonni Spinner, MPH, senior public health advisor for what became a milestone book, The Immortal Life of Henrietta Lacks. That story inspired Victoria Baptiste, Lacks’ great-granddaughter, to become a registered nurse. Baptiste seeks to “advocate for my patients, and make sure they give consent and understand their treatments.” Both women in their remarks underlined the importance of consent in reestablishing trust among minorities in medical research. “I believe that had she been asked and informed about the process, she would have been willing to donate her tissue sample to science,” said Shirley Lacks.

The summit also highlighted a new partnership between the U.S. Food and Drug Administration (FDA) and YCCI that seeks to correct this historic distrust by encouraging minorities to participate in medical research and pursue careers in the health professions. “This partnership with the FDA began with Henrietta Lacks,” said Rear Admiral (RADM) Denise Hinton, MS, chief scientist at the FDA. The partnership is focused on raising awareness about the need for minority populations to participate in clinical trials; patient-centered approaches to care and research; and the role technology plays in achieving these goals. To that point, Allen Hisao, MD, associate professor of pediatrics (emergency medicine) and of emergency medicine, and chief medical information officer for the Yale School of Medicine and Yale New Haven Health, described how electronic health records can be used to engage minority populations in clinical trials in a culturally competent fashion.
I was fortunate to become an AME Zion Cultural Ambassador in the summer of 2018. One of my first learnings was that many diseases affect the minority community at an alarmingly greater rate. These include diabetes, high blood pressure, and such various forms of cancer as stomach, lung and prostate. Uncovering new treatments requires people – volunteers. And while there is a general shortage of volunteers, recruiting minority volunteers presents an even greater challenge. Stated simply, effective clinical trials require the participation of a diverse representation of the population—particularly minorities. This fact forces us to overcome mistrust, which can lead to misconceptions—Will I be a guinea pig? What side effects might there be? How much time will be involved? What will I get out of it? Understandably, there is a concern of family members who summoned up a smile of encouragement at every visit. Even though George was a late candidate to be admitted to this study, 5 months ago he happily reported that the cancer was in remission. In the weeks following, he underwent a successful bone marrow transplant. I see George more frequently now that he is back in the office. His hair has grown back, his complexion is once again rosy, and more importantly he is cancer-free. There is a smile on his face that tells me personally his private story.

The faith community would consider this a modern-day miracle, while the Yale School of Medicine would view this outcome of clinical research as bringing us one step closer to finding a cure that would save the lives of many. They are both right. More of these stories should be shared. I often wonder why that is not the case. Perhaps, it is the stigma that goes with the sickness and you are not ready to reveal that diagnosis to a stranger. Or perhaps one needs some private time to reflect on what it means to be a survivor.

George told me that while at Smilow, his visits to the children’s ward opened his eyes to the evils of cancer, and somehow the importance of his own personal fight with cancer diminished as he told stories, played games, and interacted with the children.

Upon his release George sponsored a trip to the movies for the children at Smilow Cancer Hospital. George’s kind reminder me of a book by Henri Nouwen titled The Wounded Healer, which speaks of a man who sat by the gate binding the wounds of others while also treating his own wounds. George told me that the children so enjoyed just getting out on the bus and seeing people on the street that it brought him laughter and joy. I plan to revisit this idea of doing something for the children at the cancer center at our next Cultural Ambassadors meeting at YCCI. Helping somebody is the true mission of what we are about as Cultural Ambassadors at YCCI. Stay tuned for more to come.

Reverend Dr. Leroy O. Perry

Ray Anderson, member
St. Stephens AME Zion Church, Branford, CT

Barbara Foster, 78, received a flyer about an Alzheimer’s disease prevention study, and remembered all too well caring for her mother, aunt, and uncle and the challenges they faced when they had dementia. “I don’t want it to be like that for me and I want to know if it’s going to happen,” she said. Dorothy Hughes, 82, heard about the same study, and because she was experiencing minor memory issues, decided to find out whether she could participate. Both women ultimately enrolled in the study, which is the first effort in history to try to prevent Alzheimer’s symptoms before they appear.

Barbara and Dorothy enrolled in the Anti-Amyloid in Asymptomatic Alzheimer’s (AA) study. This is the first effort in history to try to prevent Alzheimer’s symptoms before they appear.

Dorothy had never participated in a research study before, but she hopes that the results will help doctors learn more about how Alzheimer’s affects the brain and how it progresses. “I feel like I am getting information and can prepare myself, or even prevent or slow down Alzheimer’s,” said Barbara. She believes people should participate in clinical research not just to possibly help themselves but also for the potential benefits to others. To read more stories like this, visit YaleStudies.org and find out how you can be a Help Us Discover Hero too.
Yale has hundreds of clinical studies under way for a wide variety of conditions. None of them would be possible without volunteers who were willing to take part in clinical studies. Volunteers like you are the only way for medical breakthroughs to reach the public. Please consider participating in a clinical study and helping Yale continue its tradition of advancing medical knowledge.

Diabetes and Obesity Research Studies

We need your help.
You can play an important role in research by volunteering for free and confidential Research Studies.

If you are between the ages of 18 to 84, and have type 1 or type 2 diabetes, obesity, or struggle with your weight, you may be eligible to participate in a variety of research studies. Compensation up to $150.
Healthy volunteers are always needed.
To learn more or see if you are eligible to participate, please contact (203) 737-4777 or email diabetes.research@yale.edu.

Mood Disorders Study

Do you suffer from Bipolar Disorder or PTSD?
If you are between the ages of 18 to 65 years old and suffer from major depression, bipolar disorders, or PTSD, you may be eligible to participate in a free and confidential study that will help us better understand the neurological causes of mood disorders. The study will entail a screening session that includes a physical and blood work, and a PET scan and MRI. Compensation up to $300.
Healthy volunteers are always needed.
To learn more or see if you are eligible to participate, please call (203) 737-6401 or email at mooddisorders@yale.edu.

GENEX – Lung Disease Study

Do you have asthma?
If you are 18 years of age or older and have asthma or COPD, you can help us learn more about lung diseases. This will entail a single, 2 to 3 hour study visit that may involve a medical history review, lung function testing, spirometry, blood draw, and blood work. Compensation of $60 for completed visit. Healthy volunteers are always needed.
To learn more or see if you are eligible to participate, please call (203) 500-3180 or email asthma@yale.edu.

Binge Eating and Exercise Program

Interested in a free program for binge eating and weight loss?
If you are concerned about binge eating and weight and want to take part in an exercise program, and are 18 to 65 years old, you may be eligible to participate in a free and confidential study that will provide behavioral therapy. Compensation up to $50.
Healthy volunteers are always needed.
To learn more or see if you are eligible to participate, please call (203) 500-3180 or email BingeEating@yale.edu.

Sarciodosis or Granuloma Annulare Study

Have you been diagnosed with Sarciodosis or Granuloma Annulare?
If you are 18 years of age or older and have been diagnosed with cutaneous sarciodosis or granuloma annulare (GA), you may be eligible to participate in a free and confidential study that may help the clearance of skin lesions and improve the way we feel. Compensation up to $50.
To learn more or see if you are eligible to participate, please contact Yvette Strong at (203) 737-4500 or email yvette.strong@yale.edu.

Lupus Studies

Do you have active Lupus?
If you are 18 years of age or older, you may be eligible to participate in a treatment study. There are very few treatment options available to patients with Lupus. Dr. Kompouras at Yale University is currently conducting several clinical research studies that examine investigational new treatments for Lupus symptoms. Compensation is offered, but varies by study.
To learn more about our clinical trials program and see if you are eligible, please contact Allison Ready, Study Coordinator at (203) 737-6031 or email allison.ready@yale.edu.

Cardiovascular and Lupus Research

Healthy volunteers needed.
If you are a healthy adult with no history of cardiovascular disease and do not take cardiovascular medication, you may be eligible to participate in studies that further cardiovascular and lupus research. All that is required is a blood draw and urine sample. Participants will receive a $20 gift card. Parking is free.
To learn more or see if you are eligible to participate, call 877-978-8343 or visit helpusdiscover@yale.edu.

Aging Brain Study

Learn more about how the brain changes as you get older.
If you are healthy and are between the ages of 18 to 35 or 65 and older, you may be eligible to participate in a free and confidential study that looks at the effects of normal aging on the brain. The study involves screening for diabetes, an assessment of body composition, and an MRI scan of your brain. Compensation up to $300.
To learn more or see if you are eligible to participate, please contact (203) 737-4777 or email diabetes.research@yale.edu. Or visit bit.ly/YaleDiabetes.

Stress Reduction Study for Partners with Early Dementia

Does your partner have early stage dementia?
If you are married or in a committed relationship, are at least 60 years old, and you live with a partner who has early stage dementia, you may be eligible to participate in a study geared towards lowering daily stress and supporting you in your relationship. Participation involves three short home visits. During the visits, we will teach you a stress reduction technique and ask you and your partner to complete a brief survey. Compensation up to $200 per couple.
To learn more or see if you are eligible to participate, please contact Joan Monin (203) 775-2590 or email her at joan.monin@yale.edu.

Primary Biliary Cholangitis Study

Stop Smoking Study
Do you want to quit smoking?
If you are 18 to 60 years old and would like to quit smoking, you may be eligible to participate in a free and confidential study that will look at how treatment can affect a person’s ability to regulate cravings for cigarettes. Participants will be compensated $20 per hour, up to $280.
To learn more or see if you are eligible to participate, please call (855) 931-8145.

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Yale Moms Study

Healthy Women Needed for a Research Study at Yale New Haven Children's Hospital.
We are recruiting women between the ages of 18-45 who had a baby within the past 12 months to play an important role in research by volunteering for this study.
Your participation in this research study involves drawing blood in order to better understand how some pregnancy complications can effect long-term health. The research will involve two 40-60 minute visits and blood pressure monitoring.
Compensation of up to $50 for participation and you will also receive a personal evaluation of your blood sugar, blood pressure, and cholesterol and learn skills on how to get (and/or stay) healthy after having a baby.
To learn more or see if you are eligible to participate, contact Lauren at (203) 500-3180 or email yalehealthmoms@yale.edu.

Binge Eating and Exercise Program

Learn more about how the brain changes as you get older.
If you are healthy and are between the ages of 18 to 35 or 65 and older, you may be eligible to participate in a free and confidential study that looks at the effects of normal aging on the brain. The study involves screening for diabetes, an assessment of body composition, and an MRI scan of your brain. Compensation up to $300.
To learn more or see if you are eligible to participate, please contact (203) 737-4777 or email diabetes.research@yale.edu. Or visit bit.ly/YaleDiabetes.

Gastroenterology Research

Primary biliary cholangitis with moderate to severe fatigue, and on stable therapy for at least 6 months, you may be eligible to participate in a free and confidential study. This will entail completing an 8-week mindfulness-based intervention program (2.5 hours one weekly, and one weekend day retreat) in a group setting at the Yale Stress Center, as well as blood tests, symptom questionnaires, and wearing an activity monitor as needed.
To learn more or see if you are eligible to participate, contact Laura Cusack at (203) 777-6835 or email autoimmunelver@yale.edu.

To find out more about trials at Yale, visit our website, www.yalestudies.org. Or call 1-877-y-studies for more information.
MINORITIES HAVE HIGHER RATES OF CERTAIN DISEASES.

It is an unfortunate fact that minorities suffer disproportionately from such diseases as cancer, diabetes, cardiovascular disease, and HIV. The fastest and safest way to determine whether new treatments work for these and other diseases is through clinical research. Yet it’s often difficult to find volunteers—especially minorities—willing to participate in clinical trials. There is a shortage of participants in clinical research—and minority participation is even lower than that of the general population.

IT’S IMPORTANT TO INCLUDE ALL TYPES OF PEOPLE IN CLINICAL STUDIES.

Human beings are very much alike. Only 0.01% of our genes varies from one person to the next. But even with these tiny differences, there are still people with different appearances and different health conditions. Illnesses affect each of us differently—as individuals, as families, as racial and ethnic groups, and as communities. Because of these differences, it’s important to study different groups of people in order to understand which treatments work best for them. The best way to know that a particular medicine is right for someone is to test it in similar people.

Many diseases affect African Americans more often than people from other groups. For example:

- African Americans are more likely to have stomach cancer than other groups. Men have higher rates of lung and prostate cancer. Breast cancer is more common in African American women under 45, and they are more likely than other women to die from this disease.
- African Americans are twice as likely as non-Hispanic white adults to be diagnosed with diabetes. They are also more likely to have kidney disease, to be hospitalized, and to die from diabetes.
- African Americans have higher rates of high blood pressure. Men are more likely to die from heart disease. Women are more likely to be obese.
- African American infants are almost four times as likely to die from causes related to low birth weight compared to non-Hispanic white infants.
- African Americans are more likely than white adults to have a stroke. Men are 60% more likely to die from it. Survivors are more likely to become disabled and have difficulty with daily activities.

Courtesy of US Department of Health and Human Services Office of Minority Health.

WHY SHOULD I PARTICIPATE IN CLINICAL RESEARCH?

Reverend Dr. Leroy O. Perry, St. Stephens AME Zion Church, Branford; Reverend Elvin Clayton, Walters Memorial AME Zion Church, Bridgeport; Reverend Kelcy Steele, Varick Memorial Church, New Haven.