WINTER
2021

NBNA NEWS

SPECIAL EDITION ON CLINICAL TRIALS

THE NBNA NEWS IS THE OFFICIAL PUBLICATION OF THE NATIONAL BLACK NURSES ASSOCIATION

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NBNA NEWS

The NBNA News is printed quarterly; please contact the National Office for publication dates.
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Looking Ahead – The Power of Nurses

Welcome to 2021 and the extension of the *International Year of the Nurse and Midwife!* We begin this new year continuing our efforts in the fight against the COVID-19 pandemic. Throughout 2020, NBNA chapter members exemplified the best of what nursing represents. The resilience, endurance, expertise, and caring behaviors of nurses were on full display in our communities, health care facilities, and in the broadcast media. In our continuing efforts to provide direct care for those affected by the coronavirus, we must remain vigilant in our communication of health care information. We serve as role models and must continue to promote frequent hand washing, social distancing, and the importance of wearing a face covering. Now that we have vaccines in the fight against COVID-19, we must educate our communities, and provide the basic facts about the vaccines. We must encourage our population to seek out information, and make informed decisions for themselves and their families. Our voices are critical in the quest to protect the public from this deadly virus. In many of our historically underserved minority communities, we are a trusted resource and the major source of information.

For 5 decades NBNA has advocated for equal access to educational opportunities, to culturally sensitive health care, and for improving the health status of all people, particularly populations of color. During this ongoing health crisis, we must continue to take the lead in educating the public and in working for the optimal health of all citizens. NBNA and its local chapter members are a constant presence in the communities and are trusted to be respectful of local values, beliefs, and customs. Let us continue to honor the faith that is placed in us. We must continue to exercise our considerable power to make a positive impact where we live, work, and play. The significant influence and diverse power of nurses were definitely on full display at the nationwide COVID-19 Memorial Service the night before the presidential inauguration when a superhero nurse from Michigan sang *Amazing Grace* in memory and honor of the lives lost to COVID-19. I smiled and cried as I listened to her powerful display of caring and respect.

Recognition of the contributions of NBNA and its members is the legacy of 2020 and the introduction to 2021. The general population has a front row seat in understanding and appreciating the value of nursing. I challenge each of us to continue to engage our collective power as we advocate for our citizens. We have a tremendous challenge and a great opportunity to positively impact the health and well-being of those often underserved groups. Participate in political conversations; join the Nurses on Boards Coalition; be an advocate in your work place; speak out about environmental risks in our neighborhoods; and yes, be a staunch supporter of accurate, culturally sensitive health education. NBNA's aim, for nearly 50 years, is to make a difference in the quality of life in our communities.

Plan to join us in Dallas in August 2021 for the NBNA 49th Annual Institute & Conference. Help us celebrate 50 years of *Innovative Community Service, Practice, Education, and Research in Nursing.*

.Jennifer J. Coleman, PhD, RN, CNE, COI
Co-Editor

NBNA Presidential Moments

In this issue of *NBNA News*, we continue our look at the NBNA past presidents.

9th NBNA President – Bettye Davis-Lewis, EdD, RN, FAAN (2003-2007)

Dr. Bettye Davis-Lewis earned her bachelor's in nursing from Prairie View A&M University in Texas. She received a master's and doctorate of education from Texas Southern University, Houston, Texas. Among her many leadership activities, she is a Senior Fellow of the American Leadership Forum, Fellow in the International Society on Hypertension in Blacks, executive board member of the National Coalition of Ethnic Minority Nurse Associations, and the Advisory Council of the Office of Minority Health, U.S. Department of Health and Human Services. Dr. Davis-Lewis is founder and owner of Diversified Health Care Systems, a home health agency and consulting firm.

Dr. Davis-Lewis has been listed in *Ebony* Magazine 100 Most Influential Black Americans, Who's Who in American Nursing, Who's Who in America and Distinguished African Americans. She serves on numerous boards and has presented papers nationally and internationally. In 2008, Dr. Davis-Lewis was honored as a distinguished alumnus by Prairie View A&M University.

As the ninth president of NBNA, Dr. Davis-Lewis began the *Institute of Excellence* to honor African American nurses for their work in the areas of clinical skills, research, academia and policy. The NBNA choir performed for the first time at Dr. Davis-Lewis' President's Gala in 2006 during the NBNA Annual Institute and Conference.

10th NBNA President – Debra A. Toney, PhD, RN, FAAN (2007-2011)

Dr. Debra Toney focused on collaborative leadership and member input during her service as NBNA's 10th president. Visibility of the organization increased as executive committee members discussed health care issues on CNN, the National Action Network, and with legislators on Capitol Hill. Several national initiatives, including the *Obesity Initiative,* provided the opportunity for NBNA local chapters to receive assistance and stay engaged. In 2012, Dr. Toney was a Torchbearer in the London Olympic Games Torch Relay.

During Dr. Toney's tenure, the NBNA *Founders Leadership Institute* and the NBNA *Summer Youth Institute* were born. An Electoral Commission was created, and electronic voting was initiated. National and international partnerships continued as members conducted disaster relief missions to Haiti, provided testimony at the Institute of Medicine, worked with the U.S. Health and Human Services Office, and were regularly featured on radio and television.

Dr. Toney is director of quality management at Nevada Health Centers, Inc., a federally qualified health center. Previously she was president and CEO of TLC Healthcare Services, a home health care agency and served as the inaugural chair of the Nevada State Office of Minority Health. Dr. Toney is a BSN graduate of Oklahoma University School of Nursing, received a master's in health services administration from the University of St. Francis in Joliet, IL, and earned a doctor of philosophy in human services with a specialization in health administration from Capella University in Minneapolis. She is a graduate of the Robert Wood Johnson Executive Nurse Fellows program and was inducted as a Fellow in the American Academy of Nursing. Dr. Toney is founder of the Southern Nevada Black Nurses Association and received the 2017 NBNA Lifetime Achievement Award. She is the current president of the National Coalition of Ethnic Minority Nurse Associations.

11th NBNA President – Reverend Dr. Deidre Walton, JD, MSN, RN-PHN (2011-2015)

In addition to her degrees in nursing, Reverend Dr. Deidre Walton also earned a juris doctor. She is a graduate of the US Army Command and General Staff College and holds the rank of US Army Lieutenant Colonel (retired). She is an Elder in the African Methodist Episcopal church. A sampling of her expertise includes resolution of issues regarding healthcare finance, quality patient care, culturally competent care, and safety for patients and employees.

A few of Reverend Dr. Walton's leadership activities are participation on the White House Conference on Aging, guest chair for the Nursing on Boards Coalition, member of the steering committee with AARP's Center for Championing Nursing in America, Table Leader for the United Health Foundation Diverse Scholar Forum, panelist for the Veterans Braintrust at the Congressional Black Caucus Annual Legislative Conference, and the ICN 25th Quadrennial

NBNA Presidential Moments (cont.)

Congress 2013 in Melbourne, Australia. In 2018 Reverend Dr. Walton was awarded the Distinguished Nurse of the Year by the Arizona chapter of the March of Dimes.

Prior to assuming the presidency of NBNA, Reverend Dr. Walton served as board member at large, treasurer, secretary, first vice president, member of the board of directors, and on numerous NBNA national committees. During her presidential tenure, NBNA focused on membership growth and retention, health policy initiatives, and on expanding efforts in relation to diversity and elimination of health disparities. Thus, the NBNA *Diversity Institute* was launched in 2012 and remains an integral component of the NBNA Annual Institute and Conference. NBNA members also attended its first White House Briefing during the annual NBNA Black Nurses Day on Capitol Hill.

Population Health: Clinical Trials Overview

Martha A. Dawson, DNP, RN, FACHE
President, National Black Nurses Association

During the COVID-19 pandemic, the public and many professionals have heard much about clinical trials. However, the majority of Americans are still unsure and skeptical of medical research and health care innovation. Prior to the COVID pandemic, the National Black Nurses Association (NBNA), Inc was working with the National Institutes of Health (NIH). NIH is a part of our government Health and Human Services Administration (HHS). NBNA worked with the NIH All of Us Research Program educating and recruiting individuals for possible participation in research studies. The All of Us Research Program started under President Barack Obama's administration with a goal to recruit at least one million research participants from diverse background to further develop "precision medicine."

NIH is just one of many U.S. research and health care improvement agencies that NBNA partnered with prior to and during the COVID pandemic. The Agency for Healthcare Research and Quality (AHRQ) is another HHS agency that NBNA is connecting with to ensure quality care. AHRQ is a bridge between research and quality patient care. AHRQ's goal is make health care safer, accessible, equitable, affordable and of higher quality. The Centers for Disease Control and Prevention (CDC) is the third agency of HHS that is involved in research and protection of the US public. CDC's primary role is to protect US citizens from threats of harmful diseases, providing for health security of our nation. The NIH, AHRQ, and CDC are all involved in supporting research within their agency and between their agencies and other health partners such as universities and other public and private entities.

Government agencies and researchers protect the public by studying prevention of diseases and disorders; developing interventions and treatments; and monitoring results, adverse events, and outcome data. Research agencies and researchers accomplish their work through the clinical trial (CT) process. Most Americans have not participated in research and do not have a baseline nor working knowledge about what is entailed in CT. In the US vaccine development follows steps outlined by the CDC. There are six stages to clinical trial steps or stages. The first is the Exploratory Stage (1) with basic research conducted by scientists and researchers under controlled laboratory conditions. This stage consists of laboratory and animal studies. The next is the Pre-clinical Stage (2) where scientists use animals to test the overall safety and immune responses and identify amount (dose) of vaccines; this phase may also include researchers from the private sectors such as Pfizer, Johnson & Johnson, AstraZeneca, and others. The Clinical Development Stage (3) consists of testing the vaccine with humans. Stage 3 consists of at least three Clinical Trials Phases I where the first uses a small group of humans, again testing the safety and now the immune responses in humans. In Clinical Trials Phase II the number of people in the clinical trial target participants that mirror characteristics of the population that the drug is intended for treatments. The scientists use what is called randomization, meaning some participants will receive the vaccine/drug being developed and some will not receive the medication; this study population will receive a “placebo.” In Clinical Trials Phase III the vaccine is tested in yet a larger population with more rigor to examine if it works as intended to produce antibodies, prevent the targeted infection, and what dose is required to achieve the desired responses and outcomes. Clinical Trials Phase IV starts after regulatory review, approval, and release. Phase IV is ongoing monitoring and data collection that occurs after medication/vaccine has gained approval for use in the general population. This is phase that we are currently in with COVID-19 vaccinations. The CDC, academic medical centers, and other scientists are collecting tracking and collecting data on safety and expected and unexpected events with the COVID vaccine. These monitoring activities are the Quality Control Stage for the larger population of participants.

In Phases II, III, and IV of the Development Stages, it is so important to recruit and include participants from diverse ethnic and racial backgrounds and different gender, age, and pre-existing conditions. Each person and potential user/taker of a vaccine or medication are unique individuals. Therefore, the more diversity we have in clinical trials, the better researchers can test for safety, efficacy, and identification of populations that may not respond as expected. The National Black Nurses Association (NBNA) has had members, colleagues, and friends participating in clinical trials. NBNA also includes nurses who are researchers, clinical trial coordinators, and translational scientists. As your national president, I am in conversation with NIH, AHRQ, CDC, and universities regarding increasing the number of Black and Brown nurses and others to develop more career opportunities in the research disciplines. We are also restructuring our research committee and grant committee bringing them together as a single entity to refocus our work on inquiry and funding.

During the COVID pandemic, NBNA nurses and leaders have demonstrated our value in educating and vaccinating people. In addition to being trusted voices, we have proven resilient in service, practice, advocacy, research, and leadership. I am both grateful and thankful for all that our nurses are doing to get this country and the world to a safe place. Again, I also want to thank the many corporate partners, community and faith-based groups, and those in political seats for working with NBNA members at the national, regional, and local levels. It is our collective efforts that are making the world safer.

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Building Trust in the Medical System Can Help Ensure Clinical Trials Represent *All of Us*

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Clinical trials are at the heart of all medical advances, and they need volunteer participants from all backgrounds to succeed. Everyone should have a role to play in clinical research because if a community is not included in the research, it's possible for them to be left out of the breakthroughs that stem from it. But, due to past injustice and current mistreatment at the hands of the medical system, communities of color are vastly underrepresented in clinical studies.

African Americans make up about 13.4% of the U.S. population, but account for only 6.7% of NIH clinical trial participants nationwide. The Latinx community represents 18.5% of the U.S. population, yet make up only 3.1% of clinical trial participants. In order to overcome this underrepresentation, we first have to understand that it is a product of distrust—distrust that traces back to historical abuses.

Racist studies like the Tuskegee Study in Alabama or the Contraceptive Trials in Puerto Rico have sown seeds of distrust in minority groups across the United States for generations. Add to that the current disparities in health care for communities of color, particularly when it comes to COVID-19, and it is no surprise that many communities do not feel safe in the hands of medical researchers.

While none of us can wave a magic wand to erase the past, in order to regain trust, our job is to be authentic and honest about the transgressions of the past. The first step is understanding and acknowledging the fear and mistrust these abuses instilled in many communities. We have to reveal the trauma, deal with it, heal it and then press forward.

But beyond acknowledging the past, we have to take actions to redress it. We have to reach people where they are, prove to them that we can do better, and never, ever make the same mistakes again. That's what the *All of Us* Research Program is all about.

The *All of Us* Research Program is helping to build one of the most diverse health databases in history by inviting one million people across the U.S. to join and provide their health information. A key part of the *All of Us* strategy is working closely with community partner organizations, like the National Black Nurses Association, to serve as trusted intermediaries that can build trust and help educate people about the importance of research.

There are also some important differences with *All of Us* compared to other research programs that help foster trust. Participants in the program are viewed as true partners—not subjects—with ongoing opportunities to help shape the research with their input. Participants also have access to information and data about themselves, and will actually benefit from the research by getting detailed genetic information once the program has analyzed it.

The program wants to involve participants in our program in a meaningful way and do whatever they can to protect their privacy and security. Concerns about who gets to see this very sensitive health information can be another barrier to trust, which is why data privacy is paramount to everything the program does.

All of Us means all of us, not just a select few. The program is committed to helping all of those who have concerns to understand that the only way to eliminate health disparities is to have diverse participation from everyone in research and clinical trials.

It's not easy to address the past wrongdoings that have led to mistrust, but it is worth it— and we have seen some great success so far. As of this month, over 80% of participants in the *All of Us* Research Program come from historically underrepresented communities, and more than 50% come from racial/ethnic minorities.

By reaching people where they are, being open about their concerns, and working directly with community partners, we can build trust, chip away at the unacceptable health disparities that continue to plague us, and create research that represents *All of Us*. Join us: www.joinallofus.org/together

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Dr. Sheldon D. Fields is 1st Vice President & Founder of the Greater New York City Black Nurses Association.

Dr. Mary L. Kelly is President of the New Orleans Black Nurses Association.

Dr. Julius Johnson is President of the Greater New York City Black Nurses Association.

Trilby Barnes-Green, is an NBNA Board Member and Treasurer of the New Orleans Black Nurses Association.

Sasha DuBois is the NBNA Secretary and the President of the New England Regional Black Nurses Association.

Dr. Gaea Daniel is a Member of Atlanta Black Nurses Association.

Laurie C. Reid is Past President of the Atlanta Black Nurses Association.

Seara McGarity is President of the Atlanta Black Nurses Association.

Dr. Evelyn Collier-Dixon is the NBNA Treasurer and Past President of the Chicago Chapter National Black Nurses Association.

Eligibility Criteria: Help or Hindrance to Improving Diversity in Early (Phase I-II) Oncology Clinical Trial Patient Participation?

Fedricker D. Barber, PhD, ANP-BC, AOCNP

Over the last two decades significant progress has been made in the treatment of cancer partly due to the success of clinical trials involving targeted and immunotherapy agents (Malik & Lu, 2019). However, minority enrollment in these trials continues to be low even though African Americans and Hispanics account for approximately 15% and 13% of patients with cancer in the United States (US) respectively (Duma et al., 2018). In fact, Duma et al., (2018) reported a decrease in African American (6% versus 9.2%) and Hispanic (2.6% versus 3.1%) enrollment in clinical trials compared with historical data from 1996 to 2002. Similarity, another study reported that only 2.9% of African Americans participated in pharmaceutical company-sponsored trials and only 9.0% in Southwest Oncology Group (SWOG) trials compared to 12% of the US cancer population (Unger et al., 2020). The absence of diversity in targeted and immunotherapy early phase clinical trials may lead to outcome disparities because the interpretation of trial results might not reflect the true tolerability and potential efficacy of an investigation agent in the racial/ethnic minority population (Nazha et al., 2019).

Early (Phase I-II) clinical trials

The main objectives of phase I clinical trials are to determine the maximum tolerated dose (MTD), the recommended phase II dose, and the dose-limiting toxicity (DLT) of an investigational drug or multi-drug combination (Agarwal et al., 2019; Cook et al., 2015). Whereas, the main objective of phase II clinical trials is to continue to evaluate the safety of the MTD of the investigational agent as well as the efficacy (Nie et al., 2016). Yet, many minorities do not enroll in early phase clinical trials secondary to well documented barriers such as: mistrust of researchers and medical institutions, low level of awareness and knowledge of clinical trials, structural barriers (costs, transportation, child care), access to a clinical trial site, and a fear of exploitation (Nazha et al., 2019). Another potential barrier to minority enrollment in early phase clinical trials is the eligibility criteria (Nazha et al., 2019).

Dr. Fedricker D. Barber is a manager of advanced practice providers, Department of Investigational Cancer Therapeutics (A Phase I Program) at the University of Texas MD Anderson Cancer Center. She is well known for her expertise in oncology, advanced practice nursing, and early phase clinical trials. Her last paper was published in the Clinical Journal of Oncology Nursing on "Clinical Trial Sub-investigator: An Emerging Role for Oncology Nurse Practitioners." October 2020.

Eligibility Criteria

Generally, the key to a successful early phase trial is identifying appropriate patients to participate in the trials (Huang et al., 2018). The task of identifying appropriate patients is usually accomplished by establishing eligibility criteria, which ensures that trial participants are as homogenous as possible regarding cancer diagnosis, previous cancer treatment, and overall general health (Kim et al., 2017; Malik & Lu, 2019). Another role of eligibility criteria is to minimize the likelihood of patients experiencing serious adverse events from an investigational agent that has limited safety data (Malik & Lu, 2019). However, if the eligibility criteria are too strict, it may limit the access and availability of early phase trials to patients. For example, the eligibility criteria may require specific biomarkers/molecular alterations, have a maximum number and type of prior cancer treatments, restrict certain co-morbidities (i.e.., cardiovascular disease, chronic renal disease, or HIV infection), and may limit patients with a prior or concurrent history of another primary cancer (Kim et al., 2017). Unfortunately, co-morbidities such as HIV infection, chronic renal disease, and cardiovascular disease disproportionately impacts minority patients, thus potentially limiting minority access to early phase clinical trials (Chang et al., 2016; Nazha et al., 2019).

Recommendations

To improve diversity in clinical trial enrollment and the generalizability of clinical trial results, the American Society of Clinical Oncology and Friends of Cancer Research recommends broadening eligibility criteria for clinical trials (Kim et al., 2017). Their recommendation is that patients with co-morbid diseases be included in clinical trials unless there is a specific rationale for exclusion (Kim et al., 2017). For example, if there is a risk of minority patients developing organ dysfunction or a potential investigational agent-disease reaction, then, these patients should be excluded from participation in a clinical trial secondary to concerns for patient safety.

Conclusion

Minority enrollment in early phase oncology clinical trials continues to be low even though African Americans and Hispanics have a higher incident of cancer. Targeted and immunotherapy agents are rapidly becoming the mainstay of cancer treatment, yet there is limited information regarding the impact of these emerging agents on minority patients secondary to low minority participation in these pivotal trials. Therefore, it is vital that the eligibility criteria for clinical trials is broaden so as to improve the diversity and generalizability of clinical trial results across the patient population that is likely to receive the drug in clinical practice.

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Vaccine Hesitancy in the Black Community

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> *From the beginning of slavery, White physicians played a crucial role in the abuse and mistreatment of Black bodies.*
>
> *Black people experienced medical neglect and abuse; slaves were not considered legally human.*
>
> *Slave owners provided healthcare to Black people when they decided to give it.*

Despite overwhelming evidence that vaccines are safe and effective, there has been a rise in vaccine hesitancy and refusal leading to increases in communicable diseases in communities of color, specifically in the Black community. Some Black people may be hesitant due to historical mistrust of the medical community such as the "Tuskegee Study of Untreated Syphilis in the Negro Male."

Resistance to vaccination has been present in the United States since the 1850s when smallpox mandates were a violation of liberty. In 1879, in response to states' attempts to enforce vaccination when smallpox again became epidemic, America's Anti-Vaccination Society was formed.

Additionally, there is mistrust of the government, as evidenced by executive leadership at the beginning of the pandemic, with one of our leadership espousing different sentiments on how to handle risk mitigation. It continues by a statement with some wanting to ignore risk mitigation strategies by NIH's Dr. Anthony Fauci.

The success of vaccination programs is:

1. Contingent upon robust scientific safety data. Vaccination for COVID-19 is a significant concern for non-medical people because they question its safety as they received Food and Drug Administration approval quickly.
2. High rates of the public believing that the vaccine is the best avenue of prevention
3. And enough vaccine to cover who needs it.

Myths regarding COV19-19 vaccination.

- We cannot trust COVID-19 vaccines because they rushed to make them. Pfizer's and Moderna's COVID-19 do have new technology, but at the center of the vaccines is something called messenger RNA or mRNA that researchers have been working on for three decades as a vaccine strategy. The Johnson and Johnson single-dose vaccine is different from the Pfizer and Moderna vaccine as it uses a viral vector called Ad26.
- The vaccine will cause COVID-19? Not true, vaccines prime the immune system to recognize and fight off disease without causing an infection.
- We do not know what vaccines are: the drug companies publish their ingredients just like on a food label. There are no microchips or any form of a tracking device (social media)
- The current vaccines alter the body's DNA. No, the vaccines use mRNA to instruct our cells to make a piece of the SARs-CoV-2 spike protein to spark an immune system response. Once the mRNA does that, our cells destroy it.
- I already had COVID-19, I will not benefit from the vaccine: We do not know how long natural immunity to COVID-19 lasts, so it is still appropriate to get the vaccine to ensure protection.
- Since COVID-19's survival rate is high, I do not need a vaccine: No, it is true that people do recover from COVID-19, but some people develop severe complications and die.
- Once I get the vaccine, I will not have to wear a mask or worry about social distancing: According to Dr. Fauci it is too early to pull back. They recommend for us to consider masks, washing hands, and physical distancing. It takes a week to 10 days after the first vaccine for the body to develop antibodies.

- Now that we have vaccines, the pandemic will be over soon: To receive herd immunity, which is the point at which the disease is no longer likely to spread, about 70% of the population will need to be vaccinated or infected.

- The vaccine will cause infertility: Because the COVID-19 does not contain live viruses, they are thought not to cause an increased risk of infertility. Also, there is no evidence that the vaccine is a risk to a breastfeeding baby.

What can we do:

Nurses can get involved in policy-level interventions. While policy and community-level interventions may not directly address vaccine hesitancy, it sets the stage for interventions.

Interpersonal-Level Interventions: addressing the interactions between healthcare professionals and patients or parents. The strength of recommendations is consistently associated with higher vaccination rates.

Individual-Level Interventions: target members of the healthcare team to provide individual-level education interventions that can empower the health care team to promote vaccination and optimize efforts to address hesitancy among patients.

Healthcare Providers: to ensure readiness, such as information on readiness to offered strong recommendations to their patients, HCPs must have adequate training on the COVID-19 vaccines.

Organization-Level Interventions: using implementation science to increase vaccination rates by supporting the work of HCPs or removing barriers to vaccination for patients.

Patients: developing and offering patient education materials in combination with other evidence-based strategies to improve vaccination rates (social media, television, radio).

Deborah Wafer is a Nurse Practitioner and Physician's Assistant where she works at Gilead Science Inc. as a HIV Prevention Medical Scientist. In this role she provides education to healthcare providers on PEP, PrEP and other prevention modalities. She has also worked on the Gilead HIV and HCV Community Marketing teams. She is an accomplished marketing professional with demonstrated experience in developing innovative programming and tools designed to engage healthcare providers, staff and communities.

Bethsheba Johnson is a board certified gerontological (ger-on-to-log-i-call) nurse practitioner (GNP-BC) and certified as an American Academy of HIV Medicine Expert (AAHIVE). She received her Bachelor of Science in Nursing (BSN) from Chicago State, and pre-doctoral fellowship in immunology from Rush University in Chicago, IL. She completed her Doctor of Nursing Practice (DNP) from the University of Texas Health Sciences Center Cizik School of Nursing as an Executive Leader.

Ms. Johnson is currently employed by Gilead Sciences, Incorporated as a Senior Director, HIV Prevention Medical Scientist (HPMS). The HPMSs role is to educate the community on HIV prevention. Bethsheba covers the state of Texas except Dallas/Fort Worth educating on treatment as prevention (TaSP), pre-exposure prophylaxis (PrEP), and post-exposure prophylaxis (PEP) for HIV infection.

I’m Speaking: A Village Supporting Clinical Research to Improve Sickle Cell Outcomes

Tranaka Fuqua, MBA, CCRP®, BSN, RN

Clinical Trials

Sickle cell disease (SCD) affects approximately 100,000 persons in the US; 1 out of every 365 African American births results in a SCD diagnosis. Individuals living with SCD are medically and socially complex while faced with significant health disparities and implicit bias in health care systems due to cultural and economic barriers. Patients facing these hardships are a “medical mirror,” with the reflection of racial injustice staring back at us. Dr. King once stated, “Our lives begin to end the day we become silent about things that matter.” As medical leaders around the US issue statements denouncing racial injustice and calling for us to “dismantle racism at every level,” we must ensure that these pledges translate into durable improvements for patients with SCD.

Over the last 30 years, children with SCD have seen drastic improvements in their survival and quality of life through the adoption of a standardized approach to treatment, disease modification, and preventive care. Adults with SCD, on the other hand, have often found it difficult to access these types of services and have thus ended up experiencing higher amounts of disease-related complications. In order to meet the needs of all individuals with SCD in our community regardless of age, the Comprehensive Sickle Cell Disease Program developed a lifespan approach that allows for strong transition support from pediatric to adult care, with a focus on prevention of complications, disease modification, and development of a robust clinical research offering with key pharmaceutical companies to achieve and maintain optimal health outcomes for persons with SCD.

Our Comprehensive SCD team is a passionate group, embodying this mission by offering the multidisciplinary, team-based approach necessary to achieve optimal care and wellness for the SCD community, which includes clinical trials. Each member of the team is a steadfast advocate who believes in the power of supporting bidirectional relationships between patients, caregivers, and their medical team. We work diligently to enhance local and national partnerships to foster positive changes that reach beyond hospital walls.

Our team is continuously seeking opportunities to enhance practice, build community awareness, foster mutual respect, reinforce inclusion, and share knowledge through collaboration with patients and their families, community members, and different health care organizations. Our team continually partners with several organizations willing to serve. Key community stakeholders include the SC Upstate SCD Advisory Board, the L.D. Barksdale Sickle Cell Disease Foundation, Sickle Cell Lights of Hope, the Greenville NAACP, Long Branch Baptist Church, The Blood Connection, and the Greenville Black Caucus of Elected Officials.

Tranaka Fuqua is a passionate Clinical Research Nurse/Coordinator who has worked with the adult oncology population at PRISMA Health since 2014 as a caregiver, clinician, and published researcher. My involvement with the Comprehensive Sickle Cell Disease Program has been rewarding as our clinical research team’s focus includes purveying feasible treatment options for our patients and ensuring accurate reporting of relevant data to advance the application of viable evidenced-based practice strategies to aid in maximizing positive outcomes for the adult and pediatric sickle cell population.

Clinical Trial Diversity - Developing Better Medicines for All

Sandy Amaro

Judy Sewards

The Importance of Diverse Representation in Clinical Trials

Race, ethnicity, culture, age, and gender are all factors that can impact patient outcomes, and different segments of the population can be disproportionately impacted by certain diseases. Because medicines and vaccines can work differently in different populations, diverse representation in clinical trials helps us better identify and research these differences in clinical outcomes. The more diverse our clinical trial participants are, the more we can learn about the safety and efficacy of a potential medicine or vaccine for individuals who have characteristics like those of the participants.

Ensuring diversity in clinical trials is also a matter of equity and reducing disparities in healthcare. All individuals, regardless of background, should have the opportunity to participate and contribute to clinical research which could benefit them and their community. Yet, historically, many racial and ethnic groups have not been fully represented in clinical trials. For example, Black Americans account for roughly 13% of the U.S. population[1] but represented only 8% of clinical trial participants for the 53 newly approved drugs and biologics in 2020,[2] according to the FDA's Center for Drug Evaluation and Research.

Driving Progress, Together

There are barriers to clinical trial participation, some higher for communities of color. They include language barriers, distrust of medical researchers and the healthcare system, low levels of awareness and limited access to clinical trials. Many in the Black community still remember, or have heard of, the syphilis study conducted with Black men in Tuskegee, Alabama. The study ended 50 years ago, but the sentiments of betrayal and exploitation felt by many remains to this day. Overcoming these barriers won't happen overnight, but we know the work that must be done.

We have seen progress over the past months by regulators and the industry at large. For example, in November 2020, the FDA issued its final Guidance, *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs,* with the aim of providing recommendations for how clinical trial sponsors can increase enrollment of underrepresented populations in their clinical trials.[3] In addition, last year the Pharmaceutical Research and Manufacturers of America launched the first ever industry-wide principles on clinical trial diversity which will take effect in April 2021.[4]

Pfizer is fully committed to equity in clinical research, and we saw firsthand the importance of racial and ethnic representation in trials as we developed an investigational COVID-19 vaccine. In turn, we have committed to design our clinical trials so that enrollment can reflect the racial and ethnic diversity of the countries where we conduct clinical trials and the epidemiology of the diseases we intend to treat or prevent.[5]

Some examples of how we are working to fulfill this commitment include: choosing investigative sites in communities that represent a diverse pool of potential participants and make it easier for people living in the community to participate; doing more to engage diverse clinical trial investigators and site staff; and working closely with our medical, government and patient advocacy partners, including the National Black Nurses Association, who are trusted voices and advisors for patients. Also, a critical component of improving access to clinical trials is making it easier for people to find clinical trial information. To help address this need, we recently launched Pfizerclinicaltrials.com which serves as a single destination for education and information on Pfizer clinical trials, learning more about how clinical trials work, and how to participate.

The Critical Role of Healthcare Providers

Participation in clinical trials is an important and personal choice. However, a key issue that remains is that most people simply don't know that participation in a trial is an option. Today, there are 19 thousand clinical trials that are actively recruiting participants in the United States[6] yet according to a 2017 Center for Information & Study on Clinical Research (CISCRP) survey only 14% of those who have never participated in a clinical trial are very confident they could find a clinical study that is right for them.[7]

An individual's personal healthcare provider plays an important role in educating patients about clinical trials as an option that they may want to consider, and according to CISCRP, "discussions with my physician or specialist" is the preferred way to learn about clinical research.[8]

To hear more on the importance of clinical trial diversity from the NBNA's President Dr. Martha Dawson and Pfizer's Chief Development Officer, Dr Rod MacKenzie, click here: Ask A Pfizer Expert: Why Is Diversity In Clinical Trials Important? - YouTube. And if you would like to learn more about specific clinical trials, you can visit: www.Clinicaltrials.gov.

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Sandra Amaro has 17 years experience in the pharmaceutical industry, specifically within Clinical Trials Operations and Supply Chain Management. In her current role at Pfizer, Sandra is the Head of Clinical Trial Diversity, leading a team that is responsible for raising awareness and education on the importance of equity and inclusion in clinical trials.

Judy Sewards serves as Vice President, Head of Clinical Trial Experience for Pfizer. In this role, she leads cross functional teams who create and activate new communications and services to increase awareness and access to clinical trials and build trusted relationships and experiences with investigator sites and clinical trial volunteers. Judy has held a variety of leadership roles across marketing, innovation and strategy at Pfizer and has a background in brand advertising and consulting.

Bioethics and the Physicians Pathway to Trials Diversity (PPTD):

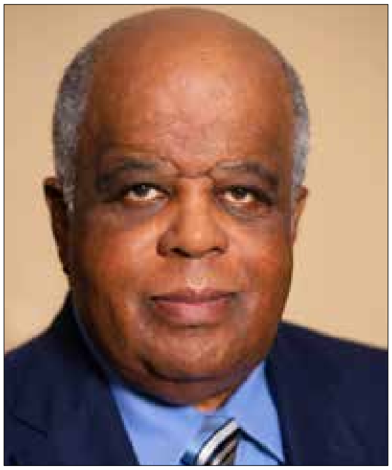
Advancing a Formal Network of Diverse Physicians and Community Influencers ("The PPTD Network") for Rapidly Engaging Racially and Ethnically Underrepresented Populations for Participation in Clinical Trials

Randall C. Morgan, Jr., MD, MBA

The W. Montague Cobb/NMA Health Institute (Cobb Institute) is advancing an intervention to address consistently low clinical trial participation by underrepresented minorities (URMs), especially given the need for equitable vaccine development observed under the current Coronavirus 19 (COVID-19) pandemic. The percentage represented by Black Americans was less than 5% of total participation and only marginally higher for Hispanics at 8%. Adequate diversity in clinical trials has been an unmet target for over 40 years, and the Cobb Institute has created a Formal Network of Physicians and Community Influencers also known as "The PPTD Network" to increase access and participation of URMs to non-URM levels in clinical trials.

The 1979 *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,* prompted by ethical violations during the Tuskegee Syphilis Study (1932–1972), empowered institutional review boards (IRBs) to protect the rights of participants in clinical trials and assure ethical practices for research. Since then, an additional stated goal has been increased enrollment of URMs in clinical trials. Success has been elusive and most clinical trials lack a level of diversity that would be demographically representative.

The growing success of our PPTD Network intervention is based on the latest research on effective URM trials recruitment and retention and builds upon our expansive network of physicians and community partners nationally. We expect that intensively engaging physicians around clinical trials and incorporating online technologies through our website will enhance trial diversity as well as measurably improve URM perspectives on clinical trials and biomedical research participation.



Randall C. Morgan, Jr., MD, MBA is the Executive Director of the W. Montague Cobb/NMA Health Institute; 95th President of the National Medical Association; and, Practicing Orthopedic Surgeon, Sarasota, FL

A trusted voice for the development of solutions for racial and ethnic health disparities, the Cobb Institute has made stronger calls to action with the emergence of a COVID-19 public health crisis that could negatively affect our communities for the next 3 to 5 years. Currently Black/African American and Latino/Hispanic populations account for nearly half of the deaths nationwide related to COVID-19, and even that number may be underestimated due to lower testing levels and underreported infections for URMs. Therefore, we look to swiftly implement comprehensive solutions for vaccine and clinical trial participation that work well for our target populations.

Building trust and partnership represent guiding strategies. Given structural racism and the history of segregation of housing, hospitals and medical centers, clinical trial sites are not distributed evenly, nor does the racial-ethnic identity of study investigators often reflect the demographics of the populations most impacted. While the incorporation of telemedicine and telephone appointments are counteracting transportation and location barriers, additional new and enlightened approaches are also demanded. As an example, evidence shows that diligently mitigating distrust will also depend to a great degree race concordance among URM patients and clinical trial investigators or their referring physicians. This has led us to partner with the National Medical Association (NMA), the National Black Nurses Association (NBNA) and the historically-Black medical schools in collaboration with communities.

Toward lasting improved trials diversity and studies in general that is lasting, this pilot consortium of health professionals and community partners is:

1. Studying the present enrollment centers and statistics for URM populations.
2. Driving a measurable increase in health provider recall and explanation of vaccine knowledge for current vaccines and vaccine trials. This includes hosting a curriculum that presents multiple opportunities for education and practice around clinical trial recruitment, referral, navigation and retention.
3. Connecting primary care physicians to opportunities to facilitate their becoming independent investigators and researchers or joining research teams.
4. Harnessing the social capital of the URM healthcare provider community and partners to help deepen the connections for problem-solving overarching challenges in the clinical trial and biomedical research environments.
5. Developing the digital strategy to immediately encourage and enroll vaccine Phase III Trials candidates. This includes educating health providers on available technology platforms that facilitate referral to vaccine trial sites so that patient engagement and outreach can be directly supported.

Studies show uneven epidemiologic burden from COVID and among communities with fewer resources for recovery – alongside inequitable levels of participation in current vaccine trials. Therefore, PPTD intervention is urgently equipping our physician network with knowledge about the vaccine development process. Our success is the extent to which physicians become comfortable offering informed vaccine trial referrals to their patient populations and commit to investing alongside local partners in diversifying clinical trials.

Consensus among our community of physicians is that now is a momentous opportunity to improve the current and future health status of African Americans and other underrepresented minority groups by achieving health equity. As a component of addressing structural determinants of health, we must achieve a diversity in the clinical trials that equals or exceeds the diversity in the general population so that the benefits of science and medicine are equitable and broadly applicable.

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Finding Solutions: Eli Lilly and Company's Commitment to Diversity in Clinical Trials

Stacey Bledsoe, RN, MSN

In 2015, my family begin a journey that many had traveled before us, when my father was diagnosed with lung cancer. I prayed for a miracle – as any loving child would do. But I also asked his oncologist about the possibility of my father participating in a clinical trial. To my dismay, the good doctor informed me that she had very little information about trials. It was evident right then, that she had given very little thought to this potentially life-saving effort, as part of my father's treatment plan. As a nurse, in my heart, I believed this was not okay. At the time, I had been working at Eli Lilly & Company for 12 years and I knew I had to do more, so I made it my mission to elevate the topic of diversity in clinical trials with my Lilly leadership. After conducting research on how other pharmaceutical companies were addressing the issue, and representing Lilly on external committees and workstreams, my desire and passion to truly impact Lilly's role to increase diversity in our trials was re-ignited and I am honored to be a part of this work and mission.

Underrepresentation of minority groups, particularly amongst African Americans, has historically been a challenge in clinical trials conducted by pharmaceutical companies. Some in society distrust medical research, and skepticism is common amongst African Americans, in part generated by the notorious Tuskegee Syphilis Study that ran into the 1970s. Physician investigators typically are the intermediaries between study sponsors and patient volunteers, but access to and trust in these investigators is uneven. Additionally, access barriers driven by differences in culture, socioeconomic challenges, and lack of identification with those doing clinical studies appear accentuated amongst minority group populations, and particularly amongst African Americans. This challenge has come to further prominence recently given both the differential impact of COVID-19 on communities of color and current events highlighting social injustice impacting the communities of color. Amongst broad efforts to promote social justice, stakeholders are prioritizing fairness and access to clinical trials.

Lilly understands that achieving diverse representation in our clinical trials will require clear, measurable goals.

Stacey Bledsoe is the Advisor for Global Medical Engagement and Outreach at Eli Lilly and Company. Her professional experience includes a Master's of Science degree in Nursing Administration. Stacey has over 18 years in the pharmaceutical industry across multiple disciplines including Research & Development, Global Health Outcomes, Medical and Six Sigma.

We've developed the following to guide our work:

- Create a Robust Clinical Trial Strategy and Reach Diverse Populations
- Intentionally Select a Diverse Range of Trial Sites and Investigators
- Increase Diverse Representation through Partnerships and Collaboration.

Lilly is committed to addressing the underrepresentation of minorities in our clinical trials. Among the 12,000 U.S. patients Lilly has enrolled in our trials from 2016 to 2020, minorities made up nearly 40% of the U.S. population, and in some diseases an even greater proportion, they constitute less than 20% of participants in the key clinical trials that lead to the approval of new medicines [1]. Lilly is able to recruit more minority patients to diabetes clinical trials, but this is because diabetes is more common in minority populations. And in oncology, our numbers are even lower. We are committed to addressing these gaps. Lilly believes there's more that we and our peers can do, and we're committed to working to make sure all people are represented.

Addressing racial disparities in clinical trial representation is an important part of Lilly's Racial Justice Initiative. This initiative is driven by Lilly and the Lilly Foundation's desire to create a more diverse and inclusive culture within our company and within our communities. We have joined the national discourse on race, inequity, and our economic future by increasing our participation and amplifying our voice in our communities. As a result, we are taking substantive actions to partner, influence and invest in lasting change to make life better for our people, patients and communities.

My family's story did not end as we had hoped because my father lost his battle with cancer. However, I am proud to be helping Lilly to win the fight for others.

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Clinical Trials and Nutrition Research to Address Health Disparities

Mary Beth Arensberg, PhD, RDN, LDN, FAND
Lacresha Johnson, MS, RDN, LDN

Recognition of the disparities in managing health and disease across various population segments is driving change in policy, practice, and public health research. Indeed, the FDA recently launched several initiatives to help address/eliminate health disparities in clinical trials, research, and treatment of chronic disease. (Arajo et al, 2020)

Diet is a key contributor to disparities in many chronic diseases/conditions. For example, cardiovascular disease (CVD) is the leading cause of death and disability in the US. African Americans have the highest rates of death due to CVD. In 2018, African American were 30 percent more likely to die from CVD compared to their white counterparts. (Office of Minority Health, 2021)

Suboptimal diet quality is responsible for a greater percentage of CVD-related morbidity/mortality than *any other* modifiable risk factor and there are stark racial/ethnic and socioeconomic disparities in US diet quality. (Kris-Etherton et al, 2020)

At the same time, these disparities in diet quality may contribute to poorer health outcomes in acute medical conditions too. Belanger et al underscored this in their recent *New England Journal of Medicine* commentary, stating "Though the factors underlying racial and ethnic disparities in Covid-19 in the United States are multifaceted and complex, long-standing disparities in nutrition and obesity play a crucial role in the health inequities unfolding during the pandemic."

> *As we move to address health disparities in clinical trials, likewise there should be a call for increased clinical trials to investigate the intersection between race/ethnicity and diet/nutrition.*

Last year, the National Institutes of Health (NIH) released its new strategic plan to accelerate nutrition research over the next 10 years. One of its goals is to develop targeted and effective diet interventions in a diverse population. Specifically, NIH has organized its plan around 4 strategic goals:

1. Spur Discovery and Innovation through Foundational Research: What do we eat and how does it affect us?
2. Investigate the Role of Dietary Patterns and Behaviors for Optimal Health: What and when should we eat?
3. Define the Role of Nutrition Across the Lifespan: How does what we eat promote health across our lifespan?
4. Reduce the Burden of Disease in Clinical Settings: How can we improve the use of food as medicine?

The strategic plan also has 5 cross-cutting areas: minority health and health disparities, health of women, rigor and reproducibility, data science/systems/artificial intelligence, and training the nutrition scientific workforce. NIH comments that as the plan is put into action, they will continue to seek input from the nutrition community and other groups. (NIH, 2020) **NBNA members can advocate for the importance of adequate minority enrollment in NIH clinical trials targeting nutrition.**

Malnutrition is impacted by health disparities and is a specific condition where NBNA members can advocate for increased research and enrollment of minority populations. In one recent study, 1 in 4 older adults living in an urban community prone to health disparities was classified as "high" nutrition risk. Decreased oral intake, weight loss, and compromised functioning were the most common nutrition risk factors and Black respondents constituted the greatest proportion of those with high nutrition risk scores. (Sheean et al, 2019)

One way to help bring greater attention and action to the issue of malnutrition is through adoption of a malnutrition-specific quality measure by the Centers for Medicare & Medicaid Services (CMS). NBNA's 2020 Malnutrition Resolution recommended CMS adopt malnutrition quality measures in its inpatient rule. (NBNA, 2020) There is an opportunity for this to happen as a *Global Malnutrition Composite Score* measure was included in the CMS 2020 Measures Under Consideration List (Academy of Nutrition and Dietetics, 2021), and the measure was recently favorably voted on by both Measures Application Partnership and the National Quality Forum committees.

> *Adoption of the "Global Malnutrition Composite Score" measure could provide a benchmark for future clinical trials and nutrition-focused quality improvement research.*

It can take time for clinical trial results to become integrated into evidence-based practice. Yet steps can be taken now to address malnutrition. These include screening and intervening for malnutrition, particularly among older adults who are among those at greatest risk. NBNA is a member of the Defeat Malnutrition Today Coalition (defeatmalnutrition.today). The Coalition's resources and information can help reduce the nutrition disparities that lead to malnutrition and can help improve health outcomes.

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Dr. Arensberg is the Director of Health Policy and Programs for the Abbott Nutrition Division of Abbott where she works to research, develop, and partner on programs/policies that help improve the nutrition of vulnerable populations and communities.

Lacresha is a Health Policy Consultant for Abbott Nutrition Division of Abbott. She is passionate about healthy aging, food justice, and health equity with an emphasis on utilizing nutrition as the vehicle to improving chronic health conditions and cancer prevention.

Why Nurses Play a Crucial Role in Improving Clinical Trial Diversity

Rear Admiral Richardae Araojo, PharmD, MS
Jovonni Spinner, MPH, CHES

African Americans make up 13% of the United States population, yet only about 5% participate in industry sponsored clinical trials. To get new and better treatment options, clinical trials are needed to provide evidence on the safety and effectiveness of medical products that treat and manage diseases and conditions like diabetes, heart disease, and prostate cancer that disproportionately impact African Americans. Under-representation of African Americans in clinical trials is problematic because sometimes African Americans may respond differently to medical products. Adequate representation in clinical trials is critical to reducing health disparities and improving health equity.

The Food and Drug Administration's (FDA) Office of Minority Health and Health Equity (OMHHE) works collaboratively with a wide range of stakeholders, including nurses to improve health equity. In 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA), specifically section 907, emphasized the need for increased racial and ethnic minority participation in clinical trials. In response to FDASIA, OMHHE created the Diversity in Clinical Trials Initiative to raise awareness around racial and ethnic minority participation in clinical trials. The Initiative aims to raise awareness around the importance of minority representation in clinical trials to ensure medical products are safe and effective for everyone. This initiative includes an ongoing multi-media campaign consisting of digital and print health education materials, social media outreach, webpage, webinars/lectures, videos, and stakeholder engagement. All of which are culturally tailored, written at low literacy levels, and feature diverse spokespersons to ensure the materials are relatable and easy to understand.

Many barriers exist as to why African Americans do not participate in clinical trials. Simply not asking the patient if they would consider participating in a clinical trial is often the most cited barrier. This is where patient and provider communications become imperative. Materials from the *Initiative* are designed to help stimulate dialogue and to educate consumers on the risks and benefits of participating in a clinical trial. To date, millions have been exposed to our resources and we have worked with stakeholder groups like the National Black Nurses Association to help disseminate these resources to diverse communities.

As a nurse on the frontline, you can play a pivotal role in advancing clinical trial diversity. Here are 3 ways you can help engage, educate, and recruit patients into clinical trials:

1. **Talk to your patients about clinical trials:** We have a cadre of health education materials that you can display in your office, clinic, or hospital. Also, you can send out announcements via your newsletter or social media.
2. **Stay Up to Date:** Visit our website (www.fda.gov/healthequity), sign up for our newsletter, or follow us on Twitter (@FDAHealthEquity) to get the latest information on clinical trials. Our website offers a one-stop shop with brochures, fact sheets, videos, and other educational materials available free of charge that can be used to start a conversation with your patient.
3. **Make Your Voice Heard:** FDA needs to hear from you! Communicate your issues and ideas to FDA at public meetings, respond to dockets or apply to be an advisory committee member.

This initiative has been successful in mobilizing stakeholders to advance the shared priority of increasing minority participation in clinical trials. New resources are continually added to advance the Initiative's goals; several are in the pipeline slated to be released later this year. All materials can be found on our website at www.fda.gov/healthequity.

Increasing minority participation will take a multifaceted, all-hands-on-deck approach to ensure that both patients and providers are educated and help move the needle forward. We are committed to reducing health disparities and closing the health equity gap. Progress has been made, but much more needs to be done. With your help, we have a fighting chance to do that.

Richardae Araojo serves as the associate commissioner for minority health and director of the Office of Minority Health and Health Equity at the U.S. Food and Drug Administration (FDA). In this role, she provides leadership, oversight, and direction on minority health, health disparity, and health equity matters for the agency. RADM Araojo received her doctor of pharmacy degree from Virginia Commonwealth University, completed a pharmacy practice residency at University of Maryland, and earned a master's degree in pharmacy regulation and policy from the University of Florida.

Jovonni Spinner is an award-winning public health strategist and thought leader with a deep passion for improving health equity across the lifespan through research, communication, multi-sector partnerships, and leadership coaching. She is a senior public health advisor at the FDA's Office of Minority Health and Health Equity, overseeing the strategic direction of the outreach and communications team and leading the *Diversity in Clinical Trials Initiative.* She is an alum of Virginia Commonwealth University and Emory University and is pursuing her doctorate from Morgan State University.

Challenges in Outcomes Research in Total Hip and Knee Replacement

Chloe Dlott, BS
Mary I. O'Connor, MD

High-quality healthcare is dependent on continued research focused on outcomes of particular interventions and practices. This research strives to ensure that patients receive optimal care regardless of age, gender, race, or socioeconomic status. The results of outcomes research studies can be used to drive quality improvement initiatives at specific institutions and then monitor the impact that these initiatives have on patient care. Successful initiatives and practices can then be implemented nationally to advance care. Total hip arthroplasty (THA) and total knee arthroplasty (TKA) significantly improve quality of life for patients and are areas of focus for improved outcomes given their high demand as elective procedures [1,2]. Outcomes research is especially important in the coming years as THA and TKA are already common orthopedic procedures that will only increase in frequency as the population of the United States ages [3].

However, disparities in both utilization and outcomes for Black patients undergoing THA and TKA persist and prevent Black patients from receiving the standard of care treatment for osteoarthritis [4]. While the implementation of the Affordable Care Act (ACA) has led to increased utilization amongst minority patients, many barriers remain for patients including strict eligibility criteria that disproportionately excludes minorities [5–7]. Outcome disparities in THA and TKA for Black patients include longer length of stay, increased readmission rates, increased complication rates, and decreased rates of discharge home [4,8]. All outcomes that can reduce patient satisfaction in these procedures and increase both individual and hospital costs.

Outcomes research studies for THA and TKA overall have a limited number of Black patients. Black patients often make up less than 10% of the patient populations included in outcomes research while the United States population is approximately 13% Black [4,8,9]. This in part speaks to underutilization of these procedures by minority patients but also further highlights potential disparities. Perhaps disparities in outcomes would be more pronounced or manifest in unexpected ways if the demographics of the study more closely mirrored the demographics of the overall population.

Potential reasons for the underrepresentation of Black patients in outcomes research include disparities in access to surgeries, disparities in utilization of surgeries, and other factors such as physician bias in offering surgery to minority patients. The ACA has begun to improve access to THA and TKA surgeries for patients, yet more must be done at the institutional level to improve access for minority patients. Additionally, recruitment efforts to increase access may in turn lead to increased utilization. Provider level biases must be addressed to ensure that all patients are offered treatment for severe osteoarthritis. Standardized protocols for patients can help reduce bias and improve delivery of high-quality healthcare for all patients.

Researchers must deliberately include more Black patients in their studies. This may not be possible without first combating the barriers that lead to reduced access and utilization for Black patients. More outcomes research and quality improvement studies can be specifically focused on Black patients so that interventions may be targeted for patients that are already receiving suboptimal care. Action at every level is necessary to improve THA and TKA care for Black patients and outcomes research is only one step to achieving more equitable healthcare for all.

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The Role of a Clinical Research Nurse Practitioner

Alyssa Macchiaroli, AGPCNP-BC, RN, AOCNP

When friends or acquaintances asked what I do at cocktail party, or now-a-days Zoom-call, the most straightforward answer that does the trick is "I care for patients participating in clinical trials to treat their cancer; these patients are often one of the first 50 people in the world to try a new experimental drug". It is a flashy statement and gets to the point, but truly most people, even those in the medical field, have never heard of a clinical research nurse practitioner (NP).

Cancer is the second leading cause of death in the United States according to the Centers for Disease Control and Prevention as of January 2021. This statistic exemplifies the need for scientific development to improve the lives of all Americans and why in 2016 Congress passed what is commonly known as the Cancer Moonshot authorizing $1.8 billion over seven years to fund cancer research. Yet, as of 2019 a systematic review and meta-analysis by Unger et al found that only 8.1% of adults with cancer enrolled in a trial. The role of a clinical research NP is essential and critical, expanding cancer research through enrolling more patients and providing access to trials at institutions nationally.

The clinical research NP functions as a trial investigator providing patients more access to appointments and availability when physicians may be busy establishing care with new patients or fulfilling other responsibilities. This encompasses serving as an expert resource for an ever-changing portfolio of clinical trial protocols with specific rules detailing who can enroll, required schedules of assessments, specifications of drug administration, and which concurrent medications and foods are allowed. Extra time and consideration are needed to find appropriate patients for enrollment and then to navigate them through the consent and screening process. Typically patients are newly diagnosed or have learned that their cancer progressed, making it a time of heightened emotions, uncertainty, and urgency to begin treatment. Patient visits are often longer than a typical visit and require follow up phone calls to answer questions and allow for thorough assessment of their baseline condition.

Once patients enroll in a trial, NPs are able to independently see patients frequently, sometimes multiple times per week, to ensure safety while assessing and managing adverse events (AE). NPs have the expertise to parse out whether an AE is attributable to a study drug versus another disease process in a complicated oncology patient. Depending on how study medication is tolerated the dose may need to be held or decreased, or interventions may need to be prescribed, the rules for how to do this are outlined in the protocol and must be strictly followed. Documentation is meticulous as all de-identified data is entered into a database, which is analyzed to determine the study drug safety information, leading to further development of the drug, and ultimately possible Food and Drug Administration (FDA) approval. Scheduled teleconferences with the study sponsor and other participating research sites around the world usually occur every few weeks to discuss the status of study patients sometimes to make decisions to dose-escalate study drugs based on tolerability of those who are already on trial. Clinical trial patients require more hands on care and behind the scenes work than a typical oncology patient, which is why the clinical research team consisting of NPs in addition to physicians, registered nurses and coordinators must be part of a well-established framework to support the entire process. Communication and collaboration between study team itself as well as with the sponsor of the trial is essential.

Caring for a clinical trial patient is complex, as is the role of a clinical research NP. Drugs takes years to develop, many

Alyssa Macchiaroli graduated from the University of Arizona and went on to become a nurse practitioner at Columbia University in the City of New York. She currently works in the Phase I program at University of Texas Southwestern. She is passionate about cancer drug discovery and development while caring for clinical trial patients. She loves spending time with her husband and new quarantine puppy, Reggie, at home in Dallas, TX.

of which do not reach FDA approval, but those that do are miracles for patients enrolled in a trial. Being on the front lines to see a patient have a dramatic response in their tumor or stabilization of their metastatic cancer allowing them to see another birthday, milestone such as a child's wedding, birth of a grandchild, or hopefully a cocktail party instead of a Zoom-call in the future, it is one of the most incredible feelings. Which, in my opinion, makes being a clinical research NP one of the most rewarding career paths. Clinical research NPs are in the unique position to expand access to trials for patients and further oncology research, which will lead to an impact felt for generations to come, as patients who benefit will be able to live with a cancer diagnosis longer in the future.

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Identifying the Financial Burden on Cancer Patient's Enrolling into Phase I Clinical Trials

Sandra Musekiwa-Adjei, MSN, RN, FNP-C
Isabel Cepeda, MSN, RN, AGNP-C

Introduction

Health care costs in the United States continue to rise at a staggering rate, with cancer being one of the most expensive chronic diseases that is ultimately associated with early mortality (Chino et al, 2019). This is usually caused by medical costs that seemingly are shifted to the patient through their insurance and copayments. In this article, we will address the financial burdens that our phase I clinical patients face daily, as well as, the potential solutions to aid patients' out of pocket medical expenses while enrolled in a clinical trial.

Background on Phase I Clinical Trials

In the phase I clinical trial, the focus is on innovative cancer treatments that will lead to new frontiers in standard of care options for oncology patients. This first phase of the development of a new drug involves determining the safety of the drug, dose level or any toxicities the patient may develop. In general, our patients are the first humans to receive these treatments that have been previously studied in labs and have shown supporting research data to be safe and effective in animal subjects. Enrollment into a clinical trial may be difficult, as there may be participation criteria that must be met, along with financial clearance. Oftentimes, patients are not able to participate due to a financial issue or insurance not approving coverage. It is worth noting that at any point during enrollment or treatment in a phase I clinical trial a patient may withdraw from participation.

Obstacles

There are a multitude of obstacles that oncology patients face including but not limited to; emotional distress, cancer treatment side effects, family counseling, transitioning to hospice care, and most difficult of all, financial burdens. Financial hardships are also commonly referred to as financial toxicity and this is a major roadblock in cancer care. The National Institutes of Health (NIH) describes financial toxicities more appropriately as, "problems a cancer patient has related to cost of treatment." Along with the health insurance disparities, there are also out of pocket costs such as lodging, transportation, child care, lost wages, and general upkeep. According to Rotter et al. (2019), despite having health insurance coverage no patient is ever immune from the individual financial burden of cancer.

It is noted by Chino et.al (2019), that "stark disparities in trial enrollment exist along age, ethnic and sociodemographic lines; populations at highest risk of financial toxicity are exactly those less likely to participate in clinical trials." Financial toxicity can affect clinical trials and it is important to note possible interventions to help maintain scientific integrity of studies. As this can lead to populations being under-represented in clinical trials and data not being comprehensive.

Often patients are unaware of the gravity of the commitment related to enrolling in a clinical trial such as, frequency of visits that can only be performed at our specific location, the time allotted for treatment and monitoring. Treatment visits can vary from once a month to multiple times weekly, which can be taxing both physically and financially.

Interventions

To alleviate the financial burden for patients, some protocols offer travel and lodging reimbursement. Most experimental medications are covered by the sponsor, which is an added benefit to local patients. Open discussions are held with the patient regarding the nature of clinical trials, travel and time prior to enrolling to ensure transparency. Social workers can assist patients with finding housing at a lower cost and transportation options. Phase 1 clinical trials are typically done at multiple facilities, and where possible, we refer patients to a site closer to home to reduce travel cost.

Financial incentives could make a difference in participation of clinical trials for those that experience financial toxicity and wish to enroll. However, there have been some ethical concerns as it can be perceived as pressuring those in a lower socioeconomic state to participate.

Conclusion

Financial toxicity is a burden to patients and their caregivers, contributing to a series of psychosocial issues along with a progressive disease ending in mortality. Despite the interventions available to aid patients in enrolling into clinical trials, there will always be ethical concerns when attempting to provide incentives for enrollment. Payment for participation in a clinical trial remains to be the top ethical concern, with many concerned that financial incentive should not be perceived as a type of economic pressure to participate in a trial (Chino et al, 2019). Overall, it is important that healthcare providers discuss the financial burdens associated with treatments and assist patients where possible.

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Isabel Cepeda is a nurse practitioner at the University of Texas M.D. Anderson Cancer Center. She graduated from the University of Texas Medical Branch as an undergraduate and graduate and has dedicated all her years of service to M.D. A.C.C. She currently works at the Department of Investigational Cancer Therapeutics, caring for patients who are requiring new frontiers for their cancer treatments.

Integrating Truth and Trust in Clinical Trials for the Pursuit of Health Equity

James H. Powell, MD

Most African Americans and others with knowledge of American history recognize that during over 200 years of slavery and its "Jim Crow" aftermath, Americans of African descent have never enjoyed health equity. In consideration of this history, it is important that every physician and nurse provider of healthcare (providers) to patients of African descent acknowledge a greater role beyond delivery of medical care that helps to address deficits in knowledge that provides guidance for that medical care if health equity is to be achieved.

An important contributor to health equity is the acquisition of clinical trials data to inform the safe and effective use of medical interventions. For African Americans, this inevitably requires an understanding of centuries of exploitation in experiments with no rights under the law to resist. The most often quoted example of African American abuse in research is the "US Public Health Service's Study of Syphilis in the Negro Male at Tuskegee, Alabama (1)." In this experiment, 399 men with syphilis were untreated for their disease for 40 years. This "study" is cited by researchers and patients as a major reason for medical mistrust and underrepresentation of African Americans in clinical trials. Though it included "only" 399 men and concluded nearly 50 years ago, it has led to African American avoidance of medical care for fear of inappropriate experimentation (2) as well as avoidance of participation in appropriate research. These circumstances in our community can ostensibly be implicated in the death of millions who because of fear did not receive timely or appropriate treatment or was unnecessarily harmed by the treatment they received due to the lack of relevant data.

The "Tuskegee experiment" and other documented research abuses led to issuance of The Belmont Report in 1979 (3) which codified the fundamental legal-ethical underpinning of human research in America. Principles of Autonomy and Respect for Persons, Beneficence, and Justice stated therein provide for patient protections such as written informed consent, written research protocols, institutional review boards, financial interest disclosures and other policies that seek to remove the circumstances associated with past abuses.

Dr. James H. Powell is a graduate of Weill Cornell Medical College. After 24 years in the biopharmaceutical industry with Procter & Gamble Pharmaceuticals he retired as Senior Medical Director. He has served as Principal Investigator for the National Medical Association's Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials) and is co-Founder and Chief Medical Officer, knowRX, Inc. (jpowellmd@knowrx.mobi)

While many African Americans with knowledge of past abuses may harbor some research mistrust, relatively few are adequately informed about policies and procedures derived from these experiences that protect patients in modern clinical research. The unfortunate fact is that mistrust reverberates in communities to include providers who represent the resource most trusted by patients for providing them information on clinical trials (4). Thus, lack of awareness of research protections among providers can create potential barriers to clinical trial participation by the multitude of patients who trust them.

Under few circumstances is this more burdensome than in the conduct of clinical drug trials. FDA Drug Snapshots (5) reveals that nearly 80 percent of drugs approved annually for U.S. marketing indicate insufficient data to determine safety and effectiveness in non-White patients even for diseases that disproportionately impact them. Some patients may see this as avoiding the role of "guinea pig." However, they may fail to recognize the potential consequences poor participation such as ineffective treatment and unnecessary adverse events both of which can lead to morbidity, mortality, and a perpetuation of health disparities.

Not every healthcare provider can or should assume the role of clinical researcher, but all members of the healthcare delivery team who enjoy the trust of patients can serve a great need by accepting the role of advisers to their patients about clinical trials value, protections, and participation. The challenge then becomes making available the resources to equip providers with easily accessible, unbiased information that perpetuates the trust relationship and creates a path to health equity rather than a barrier to it.

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Expanding Clinical Research Opportunities for People Living with Kidney Disease

Kurt Mussina

Incidence rates of chronic kidney disease continue to rise on a global basis, and with disproportionate affects on people of color. While gene sequencing and analysis have driven the development of advanced therapeutics for a broad range of diseases such as cancer and cardiovascular disease, kidney disease remains under-represented in genomic research. To close this gap, Frenova, the contract clinical research division of Fresenius Medical Care, has launched an initiative to build the world's largest kidney disease-focused genomic registry.

Frenova's new genomic registry will contain genetic sequencing data from chronic kidney disease patients in the United States and eventually worldwide, which will be used by researchers to improve the understanding of kidney disease. Frenova developed the registry after researchers identified the lack of a large-scale, renal-focused registry of genomic and clinical data as a major impediment to kidney disease research.

The registry will be a sustainable and comprehensive tool for kidney-focused research and will bring patients, their families, patient advocacy groups, nurses, physicians and researchers together in the common cause of improving the lives of people living with kidney disease.

Designed in collaboration with providers and the research community, Frenova's genomic registry initiative is a research program inviting a large number of people to help build a diverse health database. Participants enable this research by consenting to share their genetic information (such as the sequence of their DNA) and health information in their medical records. This health database will include participants from diverse backgrounds and will help researchers better understand the causes and potential treatments for kidney disease and associated diseases.

Rapidly advancing technologies for gene sequencing and analysis over the last decade have created unprecedented opportunities to explore human disease. Nephrology has been under-represented in clinical research, even as significant progress in gene sequencing and analysis has led to advances in precision medicine and individualized care in oncology, cardiology and other medical areas.

Kurt Mussina is a passionate advocate for expanding clinical research in the fight against chronic diseases. A chemist and global healthcare executive with a 30-year career spanning research, development, and approval for drugs and medical devices, he serves as President of Frenova Renal Research—a contract clinical development services company dedicated exclusively to medicines and medical products in kidney-related research—a world-class network of more than 550 principal investigators across 360 research sites. He began his career as an analytical chemist and R&D scientist for leading pharmaceutical companies, and holds his bachelor's degree in chemistry from Montclair State University and his master of business administration from the Fuqua School of Business at Duke University.

"The new Frenova registry will close this gap by generating data that adds a clinical and genetic backbone to help support and fuel scientific innovation," said Franklin W. Maddux, MD, Global Chief Medical Officer of Fresenius Medical Care. "The evidence for genetic drivers in kidney diseases is substantial, but much larger data sets are needed to untangle the complex interactions that lead to kidney injury. By combining clinical and genetic sequencing data from ethnically and pathologically diverse participants, this genomic and phenotypic research resource will help scientists better understand how genetic variations in patients can lead to more precise diagnoses and therapies that help improve outcomes by individualizing care."

The program has been launched in pilot phases at a number of Fresenius Kidney Care clinics in the United States and will soon be open to the general public in the United States with the launch of the initiative's public website, www.WhatsYourReason.com. The registry will ultimately be available for participation on a global basis.

Making clinical research opportunities a standard offering to patients is an important area of opportunity in kidney disease care. Through our work at Frenova, and in collaboration with patients, nurses, physicians and researchers, efforts like these are important to fuel innovation and progress in the fight against kidney disease.

Nurses Play an Important Role in Clinical Trials

Rose Blackburne, MD, MBA

Rhonda Henry

As pharmaceutical and medical device companies advance their programs to bring new treatments to patients, various partners are engaged to play key roles in all aspects of the development process, from initial drug discovery to its ultimate launch. A contract research organization (CRO) is hired by a life science company or a governmental institution, foundation or university to manage clinical trials and perform other tasks to help bring a drug or device to the market. In addition to CROs and life science companies, there is an entire ecosystem of health care professionals, patients and caregivers who play an important part in the drug development process.

Pharmaceutical companies and CROs have long embraced nurses as key members of the clinical research workstream. Historically, the CRO workforce consisted primarily of nurses because of their clinical training, as well as their innate ability to consider patients holistically. Because of their knowledge of patients in hospital and outpatient settings, nurses excel in clinical operations and project management functions where their business, finance and people management skills compliment their clinical and nursing backgrounds. Nurses also are well suited for drug safety roles that are responsible for monitoring the adverse effects of drugs in patients and report those effects for review and drug modification.

Nurses often serve as the face of a clinical trial by performing the initial outreach and telephone screening of patients for a study. That often affords them the opportunity to build a rapport with patients and their families, enabling them to become a trusted source and a strong advocate for patients.

Site study coordinators usually have a nursing background and have many accountabilities at clinical research sites, including the preparation and procurement of supplies and equipment; recruiting and training of other research staff; implementation of the study protocol; and the collection of data. Nurses also are key to explaining the research protocol, study procedures and study assessments to patients and their family members during the informed consent process. Nurses in the research setting can leverage their clinical expertise to educate patients about their disease, administer medications, train patients on the use of electronic diaries and instruct them on how to submit patient-reported outcomes information. Whether working in the hospital, doctor's office, nursing home or home health care setting, nurses play a crucial role in promoting the health and well-being of their community.

Aligning trials with the intended population

Science has shown that drug metabolism varies by race, ethnicity, age and gender, which highlights the importance of ensuring clinical trial participants mirror the population that will benefit from a proposed drug. And, in order to ensure a drug is safe and effective for patients, the data collected in trials must be clinically relevant to the intended population.

CROs have undertaken several steps to expand and enhance access to trials among as broad and diverse a population as possible. Increased awareness of clinical trials as possible care and treatment options is crucial to public acceptance and understanding. Some of the industry solutions to reach more individuals with clinical trials involve the use of digital-based options in the trial process, making it easier for patients and their caregivers to participate in trials because of the flexibility it affords them. Deploying home health care, clinical trial educators and nursing networks are resources that can be used to bring clinical trials to the patient's home when site visits become burdensome and pose a barrier to participation because of work demands, transportation needs and child care logistics. In addition, patient engagement methodology including relevant messaging that speaks to the varied perceptions of, and historical experience with, clinical research in underserved/undertreated populations is important in encouraging minority populations to participate in clinical trials.

It is also critically important as we seek to enroll minority populations in clinical trials to employ clinical research personnel, including nurses, who reflect the diversity of the communities to which we seek to bring more access to trials. There is robust scientific, regulatory and business rationale to ensure that clinical trial participants are representative of the population that is most affected by the disease or condition being studied and most likely to benefit from the drug or device being studied. Nurses have a significant role in fostering greater diversity and inclusion of all populations in clinical trials, thereby ensuring that safety and efficacy data is relevant to the ultimate recipients of the approved drug.

The goal of pharmaceutical clinical research ultimately is to deliver life-changing therapies that improve health. Nurses play an important role in that mission because of the connection they have with the patients and volunteers who are so crucial to the success of clinical trials. We will continue to rely on the significant experience, expertise and knowledge nurses offer in support of the drug development process.

Rhonda Henry: From nurse to clinical research executive

Rhonda Henry, vice president of patient solutions at PPD, became a nurse to help people, which she expected would lead to a career working in hospitals or doctor's offices.

"What I never imagined was that my experience and training would take me out of the hospital and into drug development," she explains. "As a result, I've had the opportunity to help improve the lives of others for nearly 30 years through clinical research."

Starting as a clinical research associate in 1991, Rhonda has applied her nursing knowledge to train physicians and their staff on the conduct of clinical research. She has reviewed countless patient records, ensuring important safety and efficacy data is being captured appropriately. Throughout her career, Rhonda has worked diligently to expand access to clinical trials as care options for all individuals by training and mentoring research-naïve physician practices into clinically research-enabled sites. In her current role, she supports patients and caregivers by making participation in clinical trials less burdensome by advocating for more patient-centric trial designs and offering home health care and/or transportation to study visits.

"Now, more than ever, as we face a global pandemic, it's important to ensure clinical trial participants accurately reflect the population that will benefit from a proposed drug," she says. "Based on my experience—both in nursing and in clinical research—I know there is still much to be done to improve the health of others in our community. Promoting greater support for clinical research and more inclusive clinical trial enrollment brings us one step closer."

Dr. Rose Blackburn is Vice President, Global Head of General Medicine PPD/Evidera Provides pharmaceutical/medical device product development expertise across numerous therapeutic areas including women's health, urology, nephrology and dermatology. Industry representative to FDA Patient Engagement Advisory Committee (PEAC) since 2016.Board-certified physician; MD degree from Morehouse School of Medicine; MBA from University of Virginia Darden Graduate School of Business.

Rhonda Henry is Vice President, Patient Solutions. Responsible for developing customized patient centric strategies to engage, recruit, and retain patients throughout clinical trials, as well as enhancing the patient experience. Works with key stakeholders internally and externally to bring the voice of the patient into drug development. Has a bachelor's degree in nursing from the University of North Carolina Wilmington.

Howard University: Leading the Way to Inclusion of Diverse Groups in COVID-19 Vaccine Trials

Florencia Gonzalez, MPH

Howard University participated as a study site for a Phase 3 COVID-19 clinical trial to evaluate the safety and effectiveness of a new coronavirus vaccine developed by Novavax. Please see press release.

Howard University's involvement as a clinical study site was strongly motivated by concerns about Black, Latino, and other vulnerable population especially at risk of contracting COVID-19 and dying at disproportionately higher rates. Likewise, these groups, to-date, have not been well represented in vaccine trials.

"Black and Latino communities already have an unequal burden of chronic health conditions like cancer, heart disease, and hypertension. Oftentimes, individuals have more than one of these health problems. If the vaccine trials include significant numbers of people with these diverse medical histories, we can have greater confidence that vaccines will be safe for people with a wide range of health conditions," said Dr. Siham Mahgoub, Medical Director of the Center of Infectious Diseases Management and Research and principal investigator for the Novavax trial at Howard University.

From late December 2020 to early February 2021, 150 participants were recruited at Howard University. The study participants were of diverse ethnic and racial backgrounds (29% African-American, 43% White, 21% Hispanic, 5% Asian, 1% mixed race). Overall, 115 sites throughout the United States and in Mexico took part in the trial and close to 30,000 participants were enrolled and are being followed for a two-year period.

Novavax and its sites are currently preparing for a blinded crossover of vaccination for its study participants. In the blinded crossover, those participants who have received 2 doses of either active vaccine or placebo, will be provided 2 doses of the opposite treatment, which effectively will ensure that all participants in the trial have received active vaccine. Novavax plans to initiate the first vaccinations of the blinded crossover toward the end of April 2021.

Florencia Gonzalez specializes on leading efforts to establish community-academic partnerships for inclusion of underrepresented groups in health research. She also supports investigators in the implementation of community & patient engaged best practices. She has prior experience managing clinical trials and overseeing disparity health research within community settings.

Planning, recruitment efforts, implementation of the Novavax vaccine study at Howard University has been, in great part, supported by the Georgetown Howard Universities Center for Clinical and Translational Science (GHUCCTS). GHUCCTS is a multi-institutional consortium of medical research institutions forged from a desire to promote clinical research and translational science. The members of the GHUCCTS consortium include Georgetown University (GU), Howard University (HU), MedStar Health Research Institute (MHRI), Oak Ridge National Laboratory (ORNL), and the Washington Veteran's Affairs Medical Center (VAMC).

Additionally, to ensure active community involvement and representation of racially and ethnically diverse participation in the study, the Howard University clinical trial team formed a diverse community advisory board (CAB) who asked pertinent questions about the research and offered invaluable guidance about appropriate ways to partner with the community. The research team is particularly grateful to the study CAB members for their time and contribution to the development and implementation of the study at Howard University.

Improving Clinical Research Through Technology Advancements

Maduka Nnadozie, MD

As society maneuvers into the Fourth Industrial Revolution categorized by automation and technology, it is important to highlight its impact on the healthcare sector. Advances in healthcare over the last decade exploded in the face of the 2020 pandemic. We are in a unique position to observe the intersection between COVID-19 and breakthroughs in technology. This has substantially changed the way clinical researchers are able to collect data, analyze it, and produce results. There is a great utility in implementing forms of technology for reasons such as the following: cost efficiency, patient management, data collecting, as well as ensuring unbiased and ethical results. Essentially, the time spent on collecting and computing data will be simplified by use of Artificial Intelligence and wearable devices.

Artificial Intelligence has made way for groundbreaking changes in the clinical research realm and has made data collection and processing more efficient and accurate. As the researchers transition from processing such information manually to more automated techniques, there will likely be an increase in accuracy. Moreover, researchers will potentially process far greater amounts of data in less time than ever before. The time saved processing data also makes it a positive economic factor as it brings forth a reduction in overall costs.

A newer approach to data collection and patient monitoring utilizes wearable devices and remote sensors to monitor patient health and patient activity. Additionally, these devices have demonstrated the ability to produce reliable, real-time data. This form of technology is known as IoT, the Internet of Things. IoT are essentially Internet-connected devices that can analyze, collect, and transmit data over the Internet without being prompted by a human. This can benefit both the patient and the researchers in ways for example reducing the number of in-office interactions. Moreover, it facilitates the idea of a more patient-centered approach to clinical trials via remote yet continuous patient monitoring. Decreased patient burden increases retention. Without too much emphasis solely on retention, researchers also need to highlight the importance of screening and enrollment.

The screening of patients and their enrollment into clinical trials are critical aspects to name. According to a study conducted by a company called Softweb Solutions, 48% of trial sites do not meet their enrollment goals. One obstacle is that potential patients do not know where to find these research opportunities. Luckily, coupled with the amplifying effects of social media, there are online platforms that can enable patients to find clinical trials that are suitable for them. There are multiple companies that are currently developing clinical trial matching apps that will simplify enrollment. This helps to reduce the burden of recruitment that is usually the responsibility of the researchers. Hopefully, diversity and inclusion in clinical trials will also gain from such platforms.

All in all, the overall quality of research is greatly improved by the groundbreaking advancements in technology. The ability to collect accurate data can be simplified and streamlined with the use of artificial intelligence. The use of IoT reduces patient burden and responsibility in the trials, thereby increasing protocol compliance and improving patient experience. Online platforms and apps are making research participation more widely available to people who once may not have had access to information about clinical trials. People are now more aware of opportunities to volunteer thus allowing sample groups to be more reflective of the population. In conclusion, there is much to look forward to with hope and anticipation as researchers work with technology to solve the challenges that are here and yet to come.

Dr. Maduka Nnadozie is a clinical research coordinator in Laurel, Maryland. He was born and raised in Baltimore, Maryland and attended college at Bowie State University. He studied medicine at American University of Antigua, and graduated with an M.D. in 2020. Since graduating, he has aided in urgent patient care and coordinated clinical research trials with emphasis on COVID-19 related studies. His hobbies include traveling, reading, and exercising.

Better Cancer Care for All Starts with More Inclusive Clinical Trials

Leah Szumita, MS, RN, CCRN, ACNS-BC

Leah Szumita is director of the Clinical Trial Support Center at The Leukemia & Lymphoma Society. You can find more information about this free, national, telephone-based service at https://www.lls.org/support/information-specialists/clinical-trial-support-center-ctsc or by calling 800-955-4572.

Clinical trials are vital to improving cancer treatment, but only about 5-8% of cancer patients participate in them.[1] Participation rates are even lower among underrepresented groups, including those without insurance or with low income; Black, Indigenous, and people of color; patients from rural areas; young adults and the elderly.[2,3]

To get the full benefit of cancer research, we need to increase participation among individuals who represent the diversity of the U.S. population. Well-designed clinical trials give us crucial information on how people of different ages, races and ethnicities respond to medical treatments so that everyone can benefit equitably from new therapies when they become available.

But clinical trials are not just about improving care for future patients. Clinical trials give people who are newly diagnosed access to the most state-of-the-art therapies and care and can also be a lifeline when no standard of care is available or when conventional treatments have failed. This is particularly important for those underrepresented in clinical trials, because these same people also tend to have higher cancer mortality rates compared to the general population.[4]

Clinical Trials too Often Halted Due to Low Enrollment

Up to one quarter of U.S. clinical trials do not finish because they cannot enroll enough patients.[5] Among the reasons cancer patients do not seek out clinical trials are low awareness, self-efficacy, fear, distrust of the medical system, costs and logistical challenges.[6-12] Another major barrier is that oncologists often do not discuss the possibility of trial participation with patients who appear to be eligible.[1] All of these barriers are more pronounced for patients in underrepresented groups.

Innovative Science Is Improving Cancer Care, Increasing Complexity of Clinical Trials

I lead a team of eight Nurse Navigators at the Leukemia & Lymphoma Society (LLS) Clinical Trial Support Center. LLS is the largest nonprofit funder of cutting-edge research to advance blood cancer cures, a leading source of free education and support for blood cancer patients and families, and an advocate for policies that accelerate development of new cancer treatments and break down barriers to care. LLS has invested more than $1.3 billion in research since its founding in 1949 and care for individuals with blood cancer has come a long way since then.

Survival rates for some blood cancers have doubled, tripled and even quadrupled in recent decades. New innovations like genomics, precision medicine and immunotherapy — which sounded like science fiction not long ago — are now saving and extending more lives every day. These advances, and new ones in the research pipeline, would not be possible without clinical trials, which means it is critical for every cancer patient to have access to information to make an informed decision about whether a trial is right for them.

LLS Engages and Empowers Patients to Explore Clinical Trials as a Treatment Option

Finding a clinical trial can be overwhelming. The LLS Clinical Trial Support Center is a free, national, telephone-based service that offers patients personal assistance through the entire clinical trial process. Our nurses stay informed about ongoing clinical trials and perform national, comprehensive searches for each patient based on his or her characteristics and personal preferences. Our primary goal is to educate, support and empower patients and their caregivers to be active participants in their treatment decisions.

For trials to work for everyone, they must represent everyone, that's why we work to minimize enrollment barriers. Just how challenging is it to enroll in a clinical trial? On average, our highly trained nurses have 25-30 interactions with patients, caregivers, health care teams and clinical trial sites to help enroll just one patient and ensure that each has the resources he or she needs.

Influential Voices: The Power of Nurses

Frontline health care workers remain at the top of the list of trusted professionals.[14] And for the 19th year in a row, nurses lead the way with 89% of Americans rating our honesty and ethical standards as "high" or "very high."

This puts us in a unique position as influencers. I urge every nurse to embrace their leadership role. Let's elevate our voices to help patients—all patients—get the most out of medical research starting with equal access to clinical trials.

This means not just elevating our voices at the bedside, but also among our colleagues and communities to encourage everyone—particularly underserved individuals—to feel empowered to learn about clinical trials and explore trials that might be right for them.

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The Role of Clinical Trial Diversity in Advancing Health Equity

DeChane Dorsey, JD

> *How do we get more minority patients to enroll in clinical trials?*
>
> *Why are minority patients hesitant to get the COVID -19 vaccine?*
>
> *Has this treatment been adequately tested on patients of color?*

DeChane Dorsey, Esq. is the Executive Director of AdvaMed Accel, the division within AdvaMed dedicated to the needs of smaller medical technology manufacturers. DeChane is also team lead on AdvaMed's heath equity workstream, spearheading the creation and execution of AdvaMed's Principles on Health Equity. She holds a Bachelor of Arts in Political Science from Syracuse University and a Juris Doctor from Georgetown University Law Center.

In the wake of the COVID-19 pandemic, these commonplace questions highlight the need to address health disparities in general and especially within communities of color. Significant attention has shifted to the problem of inadequate racial diversity in clinical research and the ramifications of developing technologies and procedures through clinical trials that do not encompass a range of races and ethnicities.

Many of the issues underlying the deficit of participants of color in clinical trials are tied to historical and ongoing shortcomings in the health care experience of these patients. Historical breaches of ethics and trust, combined with social determinants of health, bias, accessibility and affordability concerns, have long contributed to the disparate treatment of patients of color. These issues have deeply affected how patients of color: view the health care system, are viewed and treated by providers, and are engaged in the processes for developing lifesaving technologies and therapies.

While patients of color – especially Black people – are statistically more likely to suffer from a wide range of chronic and infectious diseases, including cardiovascular disease, stroke, diabetes, kidney disease, cancer, and chronic lower respiratory disease (some of the leading causes of death and disability in the United States), they are far less likely than white patients to be included in the research that unlocks the mysteries of these illnesses and leads to cures and effective treatments.

The absence of populations of color in medical technology research perpetuates issues of distrust, limits access, and reduces exposure to the benefits of these technologies. Research shows that patients of color are less likely than white patients to access medical technologies or undergo procedures utilizing them, despite evidence demonstrating that medical devices and diagnostic tests are critical in the prevention, detection, and treatment of many acute and chronic conditions.

The Advanced Medical Technology Association (AdvaMed), the world's largest medical technology trade association, and its member companies have an important role to play in solving these problems and improving patient outcomes by advancing health equity. Our work started with the development of our Principles on Health Equity to address key areas in which the medical device industry can engage and impact change. We are working collectively, and with intentionality, to increase education and awareness of the societal benefits of ensuring access to medical devices by patients of color.

We are also focusing on promoting research equity in the medtech industry. AdvaMed is committed to improving how medical devices and technologies are designed, researched, tested and used in different populations. We understand the need for greater diversity and inclusivity in the processes through which medical technologies are developed and for more diverse researchers and investigators to apply a culturally appropriate lens to these processes.

The next phase of our health equity work involves collaborating with non-industry stakeholders to identify tools and approaches to address the lack of diversity in clinical trials. We will host a series of clinical trials workshops in partnership with Meharry Medical College to begin addressing this long-persisting problem. While we know we cannot resolve this complicated issue within such a short window, we are optimistic that by working collectively and creating a forum for this important dialogue our industry can help advance the case for more equitable medical technology research and development.

As the myriad issues in health equity continue to gain attention, it is our hope that we, along with other stakeholders, can help address these concerns that have persisted for far too long.

Learn more about AdvaMed's health equity work at: https://www.advamed.org/issues/principles/health-equity-initiative.

Collaborating with Trusted Community Leaders to Build Diversity, Equity and Inclusion in Clinical Research

Ramona Burress, PharmD

> *Who must be included in clinical research?*
> ***Everyone.***

While certain aspects of health are advancing, some people continue to be left behind, and this disparity is especially apparent in the clinical trials process. Pharmacogenetic research has uncovered significant differences among different groups in the metabolism, effectiveness, and side-effect profiles of many clinically important drugs. Yet, clinical trials for these therapies don't always represent the demographics of the people who will use them.

Since 2019, the Janssen Pharmaceutical Companies of Johnson & Johnson have been working to change these dynamics, and to ensure our clinical research efforts across our organization mirror the populations that will benefit from our medicines. Our vision is a world where clinical trials are representative of the patient populations we serve, and we know that this vision can be achieved with transparency, commitment, and accountability.

Investing in reaching and recruiting underrepresented participants will only advance progress in medicine by ensuring the relevance of clinical trials to the real world. By developing and adopting inclusive clinical trial design, execution and analysis across all our therapeutic areas, we aim to ensure data and insights from underserved and underrepresented populations inform the development of safe and effective therapies and treatments.

Ramona Burress is the Associate Director, Diversity & Inclusion in Clinical Trials at Janssen. In this role, she is committed to leading activities necessary to increase participation of underrepresented and underserved populations in clinical research through partnerships with community organizations. Along with her team, she aims to create more inclusive and equitable clinical trials in order to advance health equity, close gaps in care, and create a better future for patients.

Our Approach to Promoting Diversity, Equity and Inclusion in Clinical Trials

We are scaling our approach to deliver impact across Janssen's entire portfolio to advance health equity, close gaps in care, and create a better future for our patients. To achieve this vision, we have created a formula for success:

In 2021, we will continue to:

- **Educate investigators and increase diversity of trial personnel**
  We are increasing the focus on the importance of

Strategy + Operational Excellence + Community Engagement = Success

diversity, equity and inclusion within our clinical trials with our external partners and study sites, and working together to develop the strategies and resources needed to execute. This includes equipping healthcare personnel with educational resources and preparing them for conversations about the importance of diversity and inclusion in clinical trials. Identifying and engaging study sites with personnel who reflect underrepresented populations is also crucial.

- **Remove logistical barriers**
  Meeting people quite literally where they are is critical to driving clinical trial participation of underrepresented populations. We can help to mitigate challenges—such as travel and time off work—by expanding the network of sites and investigators we work with to include those serving underrepresented communities, and when needed, contributing our expertise and resources to support their growth, so more people have local access.

- **Establish trust through community partnerships**
  Understandably, many Black and Brown communities struggle to trust clinical research due to past incidents, such as the Tuskegee Syphilis Study, and current systemic inequities in healthcare. Engaging with trusted community figures and institutions—churches, civic groups, professional associations, and non-profit organizations—to increase transparency and disseminate accurate information about today's clinical trial process—and protections in place for participants—is pivotal in earning trust.

Johnson & Johnson's ongoing collaboration with the National Black Nurses Association is a key example of two organizations combining our resources and reach to achieve our shared goal of ensuring access to the highest quality of healthcare for persons of color. Since 2016, Johnson & Johnson has worked with NBNA on a variety of initiatives, including COVID-19 vaccine education, scholarships for nursing students, and nurse resiliency training and recognition efforts. We are proud of our continued work together and look forward to expanding our collaboration to include pursuing equity in clinical research.

Learn More: Research Includes Me

We encourage you to learn more about the clinical trial process, and the importance of ensuring that all people are represented. Janssen's Research Includes Me program was created to raise awareness about clinical trials and encourage people from all communities to participate. More information can be found on ResearchIncludesMe.com.

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Research
includes me
Diversity, Equity + Inclusion in Clinical Trials

Good Nutrition Now More Important Than Ever for Older Americans!

Mary Beth Arensberg, PhD, RDN, LDN, FAND

The COVID-19 pandemic has revealed the increased need for preventative medicine and care. Data demonstrates that individuals with underlying medical conditions have a more severe illness from COVID-19, meaning that individuals may require hospitalization, ventilation, or have greater risk of death. Older adults are at the highest risk of having severe illness from COVID-19.

One factor that is not often considered in the fight against COVID-19 is nutrition. A focus on good nutrition may help decrease the effects of COVID-19 on the older adult population and other vulnerable groups and also help promote vaccine effectiveness. Here are several recommendations for nurses:

1. **Reinforce the importance of good nutrition.** Eating a well-balanced diet is always important for good health. There are many resources that offer tips on basic food planning and shopping, even during the COVID-19 crisis. A few great resources for older adults are:
    - ChooseMyPlate: Start Simple with MyPlate--Food Planning During the Coronavirus Pandemic
    - Abbott Nutrition Health Institute: Good Nutrition Helps Support Your Immune Health
2. **Screen for malnutrition and food insecurity.** Malnutrition screening on admission helps identify undernourished patients and can help get nutrition interventions started quickly. A factor effecting malnutrition is food insecurity. Food insecurity was an issue before the COVID-19 pandemic and has been on the rise with the increase of unemployment. Performing two simple screenings can help identify if someone is malnourished and if food insecurity is one of the contributing factors.
    - Malnutrition Screening Tool (MST)
    - Food Insecurity screening
3. **Promote community-based resources.** With many older adults continuing to stay home; how can they get access to the food they need?
    - Community older adult nutrition programs are an invaluable resource. During the pandemic, federal legislation has successfully increased both the funding and flexibility for older adult nutrition programs, which includes Meals on Wheels.
    - DMT member organization Meals on Wheels America has a network of over 5,000 programs and is offered in nearly every community in America. Their site includes a look up by zip code feature to help identify local programs and also provides information on keeping seniors safe amid COVID-19.
    - The United States Department of Agriculture (USDA)'s Local Food Directories page helps locate local farmers markets, on-farm markets, community supported agriculture resources, and food hubs.
    - The USDA Commodity Supplemental Food Program helps supplement the diet of lower-income older adults with nutritious foods.
4. Help link food insecure older adults to support. Many older adults and their families have limited resources, which will be stretched even further during this crisis. What support is available?

Dr. Arensberg is the Director of Health Policy and Programs for the Abbott Nutrition Division of Abbott where she works to research, develop, and partner on programs/policies that help improve the nutrition of vulnerable populations and communities.

- The Supplemental Nutrition Assistance Program (SNAP) provides nutrition benefits to supplement the food budget of those who quality. To apply for benefits or get more information about SNAP, contact the state SNAP office.
- Federal legislation increased SNAP funding and states are working to make it easier for all Americans to get SNAP benefits, including not requiring face-to-face interviews, and temporarily raising SNAP benefits to the maximum amount.
- DMT's members and partners have also offered COVID-19 specific guidance to help people to better understand community nutrition programs and how sign up for them.
- The National Council on Aging (NCOA) posted a blog on where to get food help now.
- The National Association of Nutrition and Aging Services Programs (NANASP) has posted a page to keep members up to date on the COVID-19 crisis.
- The Administration for Community Living (ACL) has created a resource page specifically for older adults and program providers.
- The Congressional Research Service (CRS) has released an insight report on COVID-19 and nutrition programs authorized under the Older Americans Act (OAA) and administered by the ACL.

5. **Urge family and neighbors to check in on the older adults in their life.** This can help vulnerable older adults have an adequate supply of food. Suggest family/neighbors offer to bring groceries or drop off homemade or restaurant takeout meals. They may also wish to bring them oral nutrition supplements, which are easy to store, require no preparation, and can provide much-needed protein and vitamins and minerals.
6. **Support a** #BeANutritionNeighbor Campaign.
    - In late 2020, Massachusetts employed a grassroots "surround sound" activation--the #BeANutritionNeighbor Campaign. The Campaign recognized malnutrition among older adults as a serious problem in the state, especially during the COVID-19 pandemic, and encouraged people to stay connected in a socially distant way with the older adults in their life.
    - This Campaign could launch as a pilot in other states with updated graphics and links to state-specific programs and resources. If you are interested in starting a #BeANutritionNeighbor campaign in your state, please email us, and check out the Massachusetts toolkit here!

Good nutrition for our nation's seniors is now more important than ever and presents an opportunity for NBNA members to help reinforce the importance of a healthy diet, connect older adults and their families/caregivers to community-based nutrition services, and perform screenings for malnutrition.

Nursing School Graduation During a Pandemic

Melanie Wren, MHA, BSN, RN

Being a December graduate in the midst of the coronavirus pandemic has really changed nursing school for me in a major way. I remember being on Spring Break 2020 when I received the email from Samford University that we would not return the following week due to this deadly virus. Initially, I was excited because I really enjoy remote learning. That was when I knew my senior year of nursing school wouldn't be like any other year I've experienced. My pediatric and critical care exams were online, and we had more clinical paperwork and assignments to make up for the hours we would've been in the hospital setting. However, as the weeks proceeded along, reality began to set in, and I realized that this virus was steadily trending up. Needless to say, my in-person spring semester was officially changed to remote learning.

I was grateful when the fall semester started, and our classes were hybrid. This meant that at my professor's discretion, some weeks would be online, and other weeks would be in-person instruction. I was elated to discover that we would be allowed to complete our preceptorship experience in the hospital setting. I really looked forward to having this clinical experience, and I received the opportunity to be where I wanted to be: the neonatal intensive care unit. The hospital implemented temperature checks upon entry, as well as when I arrived on my clinical unit. It was different being in a mask for 12 hours a day, but I managed because I wanted to stay protected as well as keep my patients safe.

As I matriculated through the semester, it was disheartening to receive the email that the COVID-19 numbers had trended up tremendously and, as a result, our in-person pinning ceremony and graduation activities were canceled and had to be moved to a virtual platform instead. For many of my peers, they had waited 4 years to see this day where they could walk across the stage and receive their degree. Unfortunately, this was not the case.

This virus has taught us so much about cherishing what matters, setting priorities, and appreciating the people God has placed into our lives. My hope is that a nursing student will see a glimpse of my journey and aspire to press through nursing school knowing that if I made it during a pandemic, certainly they can too.

Melanie Wren is a registered nurse at the University of Alabama at Birmingham Hospital. In addition to a bachelor's in nursing, she holds associate and bachelor's degrees in Biology Pre-Health. She also holds a master's degree in Healthcare Administration. She is currently the Assistant Secretary for the Birmingham Black Nurses Association. Her goals are to serve in underprivileged communities, and to implement changes to what our healthcare needs today to be effective and efficient for the community.

Birmingham Black Nurses Association: Still in the Community

Deborah Thedford-Zimmerman, MSN, RN, WOCN

COVID-19, an ongoing and fearful pandemic, has not deterred the Birmingham Black Nurses Association (BBNA); chapter members are not standing still, nor have we thrown in the towel. While these past 11 months have been a challenge, BBNA is standing the test of time. We have charged on to be available for the community in need at this time. We have continued to participate in community events. We have not let COVID-19 stop us. We frequently and routinely wash our hands for 20 seconds; we are wearing masks, and have always worn our masks; and we keep a 6 feet distance in everything we do. When there is no opportunity for soap and water, we use hand sanitizer. So, we adhere to the guidelines provided by the Centers for Disease Control and Prevention. Let me just tell you about a few of our recent community initiatives.

BBNA received a $3,000 grant from the National Black Nurses Association, Inc. (NBNA) called the Just In Time COVID Assistance Program for Older Adults. This grant was awarded to provide resources to African American adults aged 55 years and older who are surviving the COVID-19 pandemic and are in need of primary care services. After receiving the grant funds, BBNA immediately began planning an event to serve older adults. We decided to join forces with an established non-profit organization and provide funds to purchase meat and protein to donate to the needy. Most food banks in our area do not have access to meat; produce, staples, and canned goods are offered. BBNA began the search for a vendor to purchase the meat at a reasonable rate, began locating partners in the community that provided a food pantry to older adults, and started to schedule a food drive give away. We located two non-profit organizations that were willing to provide food drives to give away a total of 285 boxes of food to families in need. Both of the non-profit organizations were churches that were geographically located on opposite sides of the Birmingham community. Each church's parishioners are predominately African Americans of low income. We held food drives on two separate Saturdays, starting early in the morning. We posted informational flyers; we advertised on Facebook, Twitter and Instagram; the churches also advertised the events. At each of the food drives, cars were lined up around the corner when we arrived.

Deborah Thedford-Zimmerman is the immediate past president of the Birmingham Black Nurses Association. She is co-chair of BBNA Membership Committee, NBNA Membership Committee, and chair of the NBNA Chapter Development Subcommittee. She is a retired wound ostomy continence nurse.

In addition to food boxes, BBNA members provided health literature on heart disease, diabetes, kidney disease, and tips for healthy cooking. This was a joyous occasion for the churches, BBNA, and the community.

"Reach One Teach One", is the name of the community educational program on COVID-19 that BBNA provided on Facebook Live. We partnered with the Jefferson County Department of Health to provide four different topics per week for 4 weeks on COVID-19 for a total of 16 broadcasts. During October and November BBNA members offered information on (a) Health Care Workers Perspectives on COVID-19, (b) Talking to Children about COVID-19 and Pediatric Specific Prevention Topics, (c) Essential Items for a COVID-19 Survival Plan and Kit, and (d) What is COVID-19 and How Can I Protect Myself and Others? Over 1,000 viewers attended many of the broadcasts and were located in Alabama, California, Georgia, and Mississippi. Sessions were also viewed and shared with others.

In January, BBNA partnered with Summit Media for air time to present a weekly Saturday morning radio show on health topics of our choice. In January, we presented information on the coronavirus and the vaccines. February is heart health month; colorectal cancer screening and awareness are the topics for March; and April will focus on Alzheimer's disease and pediatric injury prevention. We also negotiated for space for 30-second health vignettes to be broadcast at varied times during each month.

BBNA will continue to serve our community. We are presently negotiating to help in the delivery of the COVID-19 vaccine to residents of Jefferson County, Alabama. Whether we are needed to direct traffic, perform clerical duties, observe for untoward effects of the vaccine, or other duties, we are ready to serve.

Human Papillomavirus (HPV) and the Importance of the HPV Vaccine

Theresa Rodgers, BSN

Human papillomavirus, or HPV, is the most common sexually transmitted infection affecting both males and females. Unlike other sexually transmitted infections, most signs and symptoms of HPV are nonexistent. Within the United States, the CDC states there are nearly 80 million people currently infected with HPV and nearly 14 million people, including teenagers, that become infected with HPV each year.

Of the more than 40 types of HPV, some types may cause genital warts and a small number may lead to cervical, vulvae, vaginal and anal cancers in women or anal and penile cancers in men. Various types may also transmit infection to the mouth and throat and have been associated with an increased risk for cardiovascular disease.

It is estimated that approximately 12,000 new cases of HPV-associated cervical cancer are diagnosed in the United States each year. More Black and Hispanic women get HPV-associated cervical cancer than women of other races or ethnicities. HPV is thought to be responsible for about 91% of HPV-associated cervical cancers.

The good news is that HPV infections, genital warts, and cervical precancers have dropped significantly since the HPV vaccine has been in use in the United States. Infections with HPV types that cause most HPV cancers and genital warts have dropped 86 percent among teen girls. Among young adult women, infections with HPV types that cause most HPV cancers and genital warts have dropped 71 percent. Among vaccinated women, the percentage of cervical precancers caused by the HPV types most often linked to cervical cancer have dropped by 40 percent.

HPV vaccination is recommended at age 9–14 years requiring a 2-dose series at 0 and 6–12 months. The minimum interval is 5 months. If given too soon, an additional dose is required. If the initial vaccine is given at age 15 years or older; a 3-dose series is needed: at 0, 1–2 months, and 6 months. A repeat dose is needed if administered too soon.

HPV vaccination continues to lag far behind other vaccines recommended for adolescents. Girls continue to be vaccinated at a higher rate than boys, but boys made a bigger improvement in 2018. About 53.7% of girls were up to date on HPV vaccine, up from 53.1% the year before. Among boys, 48.7% were fully vaccinated compared to 44.3% in 2017. The CDC found teens were more likely to get at least one dose of HPV vaccine if a health care provider recommends it. Providers should give strong recommendations that emphasize the importance of HPV vaccination in preventing cancer as they address parental concerns regarding the vaccine.

HPV subtypes 16, 18, 31, 56 39 and 66 were the most frequently detected among White women. For African American women, though, the HPV subtypes 33, 35, 58 and 68 were most frequently detected. Gardasil targets subtypes, Types 6, 11, 16, and 18. Gardasil 9, HPV 9-valent vaccine prevents diseases caused only by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. Gardasil 9 is the widely used vaccination and is now approved for individuals to age 45.

If you are a provider, please encourage HPV vaccination. If you are a parent or grandparent, please ensure that your loved one is vaccinated.

Theresa Rodgers earned a BSN from Tuskegee University (formerly Tuskegee Institute). She is a certified pediatric nurse practitioner and certified asthma educator at Children's of Alabama. She is the nurse faculty for the Pediatric Pulmonary Center, a Maternal-Child Health program that provides leadership opportunities for graduate students. Dr. Rodgers is a founding member of the Birmingham Black Nurses Association, Inc.

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The Problem of Obesity in America: A Common, Serious and Costly Health Problem

Helen Horton, BSN, RN

Obesity is a serious medical condition that occurs when a person's weight is higher than what is considered healthy for someone of their height. It is a complex disease that can cause complications such as high blood pressure, heart disease, diabetes, high cholesterol, cancer, and sleep disorders (CDC 2019). Resulting from a combination of inherited, environmental, and/or physical factors, obesity is increasingly common in the United States(CDC 2019).

Did you know...

- In 2017–2018, the age adjusted prevalence of obesity in adults was 42.4%, and there were no significant differences between men and women among all adults or by age group (Research America 2019).
- The age-adjusted prevalence of severe obesity in adults was 9.2% and was higher in women than in men (Research America 2019).
- Obesity-related conditions include heart disease, stroke, type 2 diabetes, and certain types of cancer that are some of the leading causes of preventable, premature death (CDC 2019).

Obesity affects some groups more than others:

- Among adults, the prevalence of both obesity and severe obesity was highest in non-Hispanic Black adults (Research America 2019).
- Non-Hispanic Black adults (49.6%) had the highest age-adjusted prevalence of obesity, followed by Hispanic adults (44.8%), non-Hispanic White adults (42.2%) and non-Hispanic Asian adults (17.4%) (CDC 2019).

More than financial - Obesity is a costly disease:

- The estimated annual medical cost of obesity in the United States was $147 billion in 2008; the medical cost for people who have obesity was $1,429 higher than those of normal weight (CDC 2019).
- If the incidence of obesity continues to climb, combined health care costs associated with treating obesity-related diseases could rise by $48 billion to $66 billion per year by 2030; the loss in productivity could total between $390 billion and $580 billion per year (Endocrineweb February 2019).

Helen Horton is a retired Clinical Educator with 48 years of nursing experience. She is a member of Central Carolina Black Nurses Council, Inc. (CCBNC) and currently spends her time volunteering in community events with CCBNC and other community partners. Her primary goal is to do her part in eliminating health disparities in underserved communities through advocacy, education, and health promotion.

Why Are We Packing On the Pounds?

Changes in our society and eating habits have contributed to the increase in obesity. Here are just a few examples:

WE EAT DIFFERENTLY.

- We consume too much sugar.
- It often costs more to eat healthy.
- Some people—especially those in lower-income, minority, and rural areas—may not have ready access to stores that sell healthy, affordable foods.
- Portion sizes, especially of less-healthful foods and beverages, have gotten bigger.

WE DO NOT GET ENOUGH PHYSICAL ACTIVITY.

- We rely on our cars, even for short trips.

- Most chores are now mechanized—gas or electricity powers the machines we use.
- Technology has made us sedentary.
- **We have become a nation of "couch potatoes"**, spending too much time watching TV or in front of computers or other electronic devices.
- Not only do these passive pursuits detract from time that could be spent on physical activity; we eat meals and have snacks around the TV and computers.

DISEASE AND HEREDITY PLAY A ROLE.

- Scientists believe that a combination of certain genes and behavior may be needed to trigger obesity. A person's genetic makeup may make him or her susceptible to obesity, but other factors are required to complete the picture.
- Certain disorders can cause a person to gain weight.

MEDICATIONS

- Some drugs (antidepressants, steroids, and diabetes medications) can cause weight gain.

An individual's behavior, socioeconomic status, culture, and environmental factors also contribute to overweight and obesity. In addition, hormones in the brain, the gastrointestinal tract, and fat cells themselves influence metabolism, eating habits, and, ultimately, weight gain (Endocrineweb, August 2018).

According to the Mayo Clinic **obesity** is a complex disease. It is not just a cosmetic concern. It is a medical problem that increases you risk of other diseases and health problems (Mayo Clinic 2020). Obesity is costly, reduces the quality of life, and increases the risk for many serious chronic diseases and premature death (CDC 2019).

We all were aware of the statistics; obesity continues to be a significant public health problem in the United States. These numbers are alarming and a call for action imperative. As nurses, our mission is to reduce and/or eliminate health care disparities. We must also recognize the fact that we, as nurses must serve as role models for those that we are attempting to teach and affect change. We must educate patients/families on the importance of nutrition, physical activity and obesity related illnesses. We must identify health goals and develop plans to achieve (CDC2019).

In conclusion, research has shown that obesity in the United States is at epidemic levels. While there is no single or simple solution to the obesity epidemic; it is a complex problem and there must be a multifaceted approach to create an environment that supports a healthy lifestyle.

NBNA Membership Recruitment

Marcia Lowe, PhD, RN
Sabrina Newton, LPN

Everyone who recruits a new member is a champion. The theme this year is, "Each One, Reach One, Teach One, Help One". The membership committee of the National Black Nurses Association, Inc. (NBNA) has taken on the challenge to develop strategies that will enable chapters and individuals to recruit members. This year the NBNA Board of Directors voted to continue the reduced rate for membership without any pairing of members. This is great news and an excellent tool for you to use for recruitment of new and existing members.

NBNA is celebrating 50 years of nursing distinction this year. What can we do as members of NBNA to continue the legacy? Where are the "Under 40" nurses, and how can we attract them to become members of NBNA? What member benefits are appealing to potential members when selecting a professional organization to join? These are all valid questions that need more inquiry. What can your chapter, or you as a member, do to recruit? Many chapters have developed innovative strategies to meet the goal of increasing membership.

NBNA board member and licensed practical nurse (LPN) representative, Sabrina Newton from the Greater New York City Black Nurses Association, takes recruiting for NBNA to the heart. Sabrina is very passionate about NBNA and tries to spread the word to every nurse she encounters. Sabrina states, "I engage with potential members on Facebook, Instagram, and LinkedIn. I have saved some information on my clipboard for easy editing as needed". Here are some samples of Sabrina's encounters with potential members.

- Good morning Oye, thanks for accepting my connection request. I hope all is well with you. I love to connect with other nurses here. Are you familiar with the National Black Nurses Association?
- I reply to their interest with: It's great to see your response. I happen to be a Lifetime member and try to tell everyone about it.
- NBNA was started in 1971 by 12 innovative nurses with a plan to improve the healthcare of Blacks where health inequities still exist today.
- NBNA holds a 5-day conference every summer, offering up to 23 CEU credits, a health fair, employment/school fair, networking, and scholarship opportunities for nurses and nursing students.
- There are 108 chapters spread across 34 states. Then I refer them to the appropriate chapter.

We must invest our time and talents to ensure that NBNA remains a viable professional organization. The NBNA Membership Committee invites you to share innovative strategies that have been successful for your chapter in the area of membership recruitment. May we count on you to recruit this year?

Dr. Marcia Lowe is a member of the National Black Nurses Association where she is currently serving as 2nd vice president and membership chair. She is a past president of the Birmingham Black Nurses Association. Dr. Lowe is a nurse educator in staff development at the Veterans Administration Medical Center in Birmingham, Alabama, and has mentored many nursing students and novice nurses. Dr. Lowe believes nursing is not just a profession, but a passion.

Sabrina Newton is a lifetime member, currently serving on the NBNA Board of Directors as the LPN Representative. She is also the First Vice President of the Greater New York City Black Nurses Association. She has been an LPN for 22 years and is employed as a nurse case manager in a pediatric clinic for youth in foster care.

Greetings NBNA Student MEMBERS!

Briana Charles, NBNA Student Representative

My name is Briana Charles; this year I have the pleasure of serving on the NBNA Board of Directors as the Student Representative. First let me say congratulations to you for making it through a semester of nursing school during a pandemic! Give yourselves a pat on the back because you deserve it! As a student I believe that I speak for most when I say that it has surely been a challenging journey thus far. Nevertheless, as nursing students, we are passionate, resilient, and highly equipped to conquer any obstacles we may face. I am currently a junior nursing major at Howard University's College of Nursing and Allied Health Sciences. I am active in student government leadership, serving as the student council president for the 2020-2021 school year, the founder and president for Howard University's first Nursing Club, and a member of Alpha Chapter, Delta Sigma Theta Sorority, Inc.

I strive to channel my leadership abilities into my role in the NBNA to assist in bridging the gap between nursing students and the greater nursing professional community. I represent the student nurse population by ensuring that our voices are heard in the decision-making processes that affect our experience as members of this organization.

I am so honored and humbled to serve you in this position. I look forward to building relationships with you, whether it be virtual or in-person soon. Please feel free to contact me via email brianacharles01@gmail.com or via LinkedIn with any questions, concerns, or simply to connect! I wish you the best for the remainder of the academic year and have a happy holiday season!

P.S. - Remember to wear your masks, practice social distancing, and wash your hands. Be safe!

Sincerely,

Briana Charles, Student Representative NBNA

Briana Charles is a third year nursing student attending Howard University College of Nursing and Allied Health Sciences and later plans to pursue her doctor of nursing practice in women's health. She currently serves NBNA as the Student Representative on the Board of Directors. Briana's passions lie in public service and health care, working closely with various nonprofit organizations striving for the greater good of her surrounding communities and beyond.

Thank You NBNA and Soles 4 Souls

Deborah Thedford-Zimmerman, RN, MSN, CWOCN

Where do I begin? How do I start? The gift of shoes was such a wonderful gesture, to show love and appreciation to those who are always giving to others. I will begin by saying thank you Soles4Souls and the National Black Nurses Association for thinking of the front-line nurses during the COVID-19 pandemic. While nurses have always been on the frontline, the current health crisis has really tested us.

NBNA sent a notice to all of the members of the Birmingham Black Nurses Association (BBNA) stating that Soles4Souls was giving each nurse a pair of Reebok shoes to wear to work as a token of appreciation. We would receive a token of appreciation for the hard work and long hours dealing with combative patients and families and consoling those dying of COVID-19. The only thing required of us was to send our name, shoe size, and gender to Mrs. Estella Lazenby.

Of the 163 members in BBNA (at that time) about 145 nurses responded with the required information. The shoes were shipped to my home via UPS since I am retired and at home most of the time. When the shoes arrived, it was an overwhelming experience. Thirteen large boxes of shoes with about 13 to 14 pairs of shoes in each box were brought into my den. In addition to the shoes, there were 300 pairs of Bombas socks. This was an unexpected bonus! Bombas socks are the most comfortable socks in the history of feet. The fabric, extra-long staple cotton, keeps you warm in the winter and cool in the summer, and the moisture-wicky properties ensure that the socks are dry and comfortable year-round. They have a seamless toe with no annoying bumps and a soft little pillow for your ankles, that prevents any uncomfortable rubbing between you and your shoes. So, when I say that the nurses were excited to receive the shoes and socks, this is an understatement. A list of shoe sizes with each nurse's name was sent with the shoes, and each nurse received two to three pairs of socks.

BBNA nurses were notified that the shoes had arrived and would be available via drive by to ensure social distancing. The Reebok shoes are leather with a textile upper and are designed for walking. The shoes have memory tech foam that provides fast-feel comfort and cushioning. The cushion moves air from heel to forefoot and back as the wearer moves. Shoe sizes ranged from size 5.5 to 15EE.

Deborah Thedford-Zimmerman is the immediate past president of the Birmingham Black Nurses Association. She is co-chair of BBNA Membership Committee, NBNA Membership Committee, and chair of the NBNA Chapter Development Subcommittee. She is a retired wound ostomy continence nurse.

The plan was to have the shoes outside on tables near the curb, and members would drive by and receive their shoes. Well, it didn't happen as planned. Everyone was so excited to see one another. Some exited their cars to speak with other members; others stayed in their cars and communicated. Each member maintained safe distancing, and all members wore masks. Keeping social distance and wearing masks, this turned out to be a very sociable event. Seeing one another was so refreshing for some; getting out of the house to see another person was joyful to others, and just having someone else to talk to was exciting. One nurse brought her 2-year-old son who ran around the yard playing.

Some of the remarks and comments about the shoes included, "Just in time for clinicals. I start clinicals next week", said Lonnitria Keenan, Samford nursing student. One nurse said "Reebok are the only shoes I wear; I just threw away a worn pair. I just told my husband I needed to purchase another pair". Another nurse stated she was so thankful, and others commented how well the shoes look on their feet.

BBNA is grateful to Sole4Souls and the NBNA for putting a smile on our faces and joy in our feet.

Misinformation and Disinformation

Ardra Bey, JD

> *A lie gets halfway around the world before the truth has a chance to get its pants on.*
>
> WINSTON CHURCHILL*

In the contest of ideas, misinformation and disinformation have significant advantages over the truth. Misinformation is not moored to limiting factors such as evidence, integrity, and responsibility. For those reasons, misinformation and disinformation often spread widely before the truth can even be known. Many consumers of these lies become spreaders of these lies. To avoid the spread of falsehoods, a savvy reader must inoculate themselves. Fortunately, spotting lies is fairly simple.

Ardra Bey currently serves as a judge for the Municipal Court of Atlanta, Georgia. She presides over criminal, traffic, and civil cases in the Atlanta metro area. Prior to taking the bench, Judge Bey was a trial attorney whose practice spanned multiple states and included both federal and state cases.

Misinformation vs Disinformation

There are two basic kinds of deliberate falsehoods a reader will encounter online: misinformation and disinformation. The two types are similar but have significant distinctions. Misinformation is any kind of false information that is spread regardless of intent. For example, a person might read an article they believe to be true and share it online for others to read. If the article contains falsehoods, that is misinformation. Disinformation, on the other hand, is a falsehood that is spread with the deliberate intent to deceive. This term comes from the work of intelligence agencies. Propaganda is a common type of disinformation. In many cases, lies begin as disinformation; but once they have infected their first hosts, they spread as misinformation. For example, a malicious actor might create a website designed to mimic actual news sites. The propagandist will populate the website with lies about current events; democratic elections, product releases, and pending legal cases are common targets for propagandists. Once that initial article gains a foothold, well-meaning readers can spread it without knowing they are contributing to a plague of lies.

Peer Review

In professional settings—scientific research is a common example—claims are subjected to peer review. This process involves a researcher producing their findings as well as their methodology. Other professionals, their peers, will then scrutinize the work and attempt to recreate it. If several of their peers reach the same conclusion, the conclusion is considered to be more trustworthy. A discerning reader can do the same thing. If you read an article or see a video online that makes a claim, you should attempt to corroborate that conclusion.

News outlets are often chasing down the same stories at the same time. So, if one source produces a piece of news, it should be echoed in other outlets. When you do this follow-up research, watch out for sites that reuse the exact same verbiage. Obviously, reputable media outlets do not plagiarize each other. However, disinformation content farms often copy-and-paste entire articles onto various websites under different names. If you see entire sentences or paragraphs repeated on different outlets, that is a sign you've encountered disinformation.

The Truth Is Not Emotional

Typically, a reputable media outlet seeks to inform their readers. They do not seek to evoke emotional responses from their readers. If you find yourself responding emotionally to a news story, you should ask yourself if the writer of the article is attempting to elicit that reaction. Oftentimes, propagandists attempt to elicit anger in their readers. Angry or outraged readers are more likely to share the article and spread the lie.

Adjectives Are Not Heavy Lifters

A dispassionate writer avoids adjectives and adverbs that categorize a piece of information. A disinformation writer will likely use them liberally. For example, a dispassionate writer might write "The pitcher threw five strikeouts in three innings." A propaganda writer might write, "The brilliant pitcher struck out five laughable batters in three innings." In this example, the root of the information is the same; but the propagandist has inserted their opinion through the use of adjectives. Adverbs, words that modify verbs, work similarly.

Nobody Has Been Eviscerated

Propagandists understand the power of a headline. Oftentimes, readers will see a headline that evokes a strong emotion and then share the article without reading on. For this reason, disinformation headlines are oftentimes overwritten. They evoke violent imagery that suggests a triumphant victory for the reader's "side" of a debate. For example, a headline might read something like "[Favorite Politician] Eviscerates [Opposing Politician]." Another headline might read "[New Product] Absolutely Destroys [Opponent's Product]."

This tactic is similar to the tactic of using adjectives and adverbs. It is rare that anyone is eviscerated; be skeptical.

The Internet is the Public Square

Finally, a savvy reader should imagine the writer of an article telling them these things in person. Far too often, online articles create a distance that lowers one's credulity. The screen serves as a barrier that sanitizes obvious nonsense. So, when you read an article online, imagine the writer of the article next to you in line at the grocery store and telling you this in person.

Using all-caps is essentially the equivalent of yelling. So, a typical disinformation article might read "You Can Make A Million Dollars In One Month With This AMAZING Trick." Imagine someone next to you at the department of motor vehicles shouting that you can make a million dollars in one month. Would you believe them?

There Is a Fight For Your Attention

Clicks and views are the coin of the realm online. Propagandists might be seeking to enrage you, fool you, or just capture your attention. No matter what they are doing, they need you to click. They will say anything needed to make that happen. If you have some healthy skepticism, you can protect yourself against the spread of lies.

* In an ironic twist, the quote at the beginning of this article has been attributed to Mark Twain, Edgar Allan Poe, Winston Churchill, and others. There is no evidence that any of those men actually said this. This is misinformation.

Nurse Leaders Who Have Taken or Administered the Shot

Dr. LaDonna Christian

Dr. Marcia Lowe, NBNA Second Vice President

CJ Marbley, New Orleans Black Nurses Association got vaccinated – May 2021
Watch his video here

Elizabeth George, Member, New England Regional Black Nurses Association

Dr. Marie Etienne, President, Black Nurses Association, Miami

Nurse Leaders Who Have Taken or Administered the Shot

Dr. Dawndra Jones, President, Pittsburgh Black Nurses in Action

Trilby Barnes-Green, NBNA Board Member

Army Nurse giving the shot
Photo by Reese Brown, DoD Public Affairs

Dr. Angela Amar, Dean, UNLV School of Nursing

Nurse Leaders Who Have Taken or Administered the Shot


Dr. F. Diane Barber, Fort Bend County Black Nurses Association


Patricia Lane, President-Elect, American Association of Neuroscience Nurses


Dr. Debra A. Toney, President, National Coalition of Ethnic Minority Nurse Associations; NBNA Past President


Gloria Qualles


Sheila Caldwell, BSN, RN, CSN-NJ


Mia Glover, Black Nurses Association of Greater St. Louis

Nurse Leaders Who Have Taken or Administered the Shot

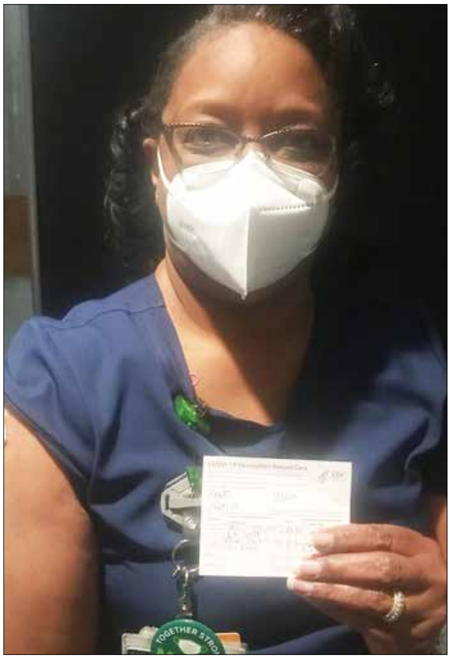
Trilby Barnes-Green giving a vaccination to Dr. Keith Ferdinand.

B. Midge Julun-Jacobs RN, president South East Texas BNA

Pat Curry, President-elect, Birmingham Black Nurses Association

Sasha DuBois, NBNA Secretary and President, New England Regional Black Nurses Association

Nurse Leaders Who Have Taken or Administered the Shot



Alean Nash, President, Birmingham Black Nurses Association

Lauren Banks, President, Little Rock Black Nurses Association of Arkansas

Bethsheba Johnson, DNP, APRN, CNS, GNP-BC, AAHIVE

Devyn Denton gives immunizations

Dr. Sheldon Fields, NBNA First Vice President, was featured in "Today's Nurse You Should Know". Dr. Fields' career started in a health professionals high school and led to roles in research, leadership, health policy, consulting, and education. He is currently Associate Dean for Equity and Inclusion & Research Professor at Penn State University. Check out his video and the full article.

https://vimeo.com/536525774

https://lnkd.in/ed42Ufa

Dr. Sheldon Fields, NBNA First Vice President has been selected to receive the 2021 *"Lillian Sholtis Brunner Alumni Award for Innovation"* from the University of Pennsylvania School of Nursing.

The ceremony will take place virtually on May 14, 2021 4 - 5:30 PM EST.

Dr. Sheldon Fields was a panelist for a session entitled, *"*Advancing Health Equity by Eliminating Systemic Racism in Clinical Research*"*, hosted during the annual National Minority Quality Forum on April 26, 2021.

Dr. Linda Thompson, Dean, University of Massachusetts, Boston has been named President of Westfield State University in Massachusetts.

Honors

Dr. Martha A. Dawson, NBNA President, was one of several NBNA members to receive the University of Alabama at Birmingham School of Nursing 70 Visionary Leader Award. The Visionary Leader distinction recognizes outstanding UAB School of Nursing graduates for exemplary service in education and research, exemplary leadership, innovation, and far-reaching impact on nursing and health care on state, national, and international levels. Recipients were nominated by fellow graduates, colleagues, and peers in their respective fields for their outstanding achievements and leadership. We thank Dr. Millicent Gorham, NBNA Executive Director, for writing many of the letters of support for our members.

Dr. Dawson was honored by the National Black Nurses Association as one 50 Notable Nurses.

Presentations

Dawson, M. A. (2021, March 23). *Making It Plain: A COVID-19 Town Hall for Minority Health Professionals*. Webinar presentation for the Black Coalition Against COVID. Youtube.com/BlackDoctorOrg

Dawson, M. A. (2021, March 18). *A Vaccine Confidence Model: Chat about the COVID-19 Vaccine*. Webinar presentation for Gear Up Alabama at the University of Alabama at Birmingham, Birmingham, AL.

Dawson, M. A. (2021, March 5). *Breaking Barriers to Advance Equity for Women of Color in Healthcare, Research and Leadership*. Panel Presentation. Webinar presentation Women History Month. Agency for Healthcare Research and Quality.

Dawson, M. A., Harris, L., Smith, T. & Richardson, R. (2021, February 25). Diversity, Equity and Inclusivity in Nursing and Health Care. Webinar presentation at the University of Alabama School of Nursing, Birmingham, AL

Dawson, M. A. (2021, February 22). *The Voice of the Nurse: Health Policy, Advocacy, and the Black Nurse*. Webinar presentation United Healthcare Group.

Dawson, M. A. (2021, February 15). Navigating your career. Webinar presentation to the University of Michigan School of Nursing. https://www.youtube.com/watch?v=JQzSCFO_Osw

Publication

ANA Nursing News (2021, March). Nurse-led national commission examines racism in nursing https://www.myamericannurse.com/wp-content/uploads/2021/02/Frontline-MARCH-2021.pdf

Media/Press

National Urban League and the Black Coalition Against COVID-19 Team Up with HBCU Medical Professionals https://lasentinel.net/national-urban-league-and-the-black-coalition-against-covid-19-team-up-with-hbcu-medical-professionals.html

NBNA RE:SET and RETHINK – Taking Care of Frontline Nurses TMZ https://tmz.app.box.com/s/7lj3m8nthlfkp2z5skk1zsd93t9m21m2

Mental Health and COVID: RE:SET and RETHINK Think Birmingham Black Nurses Association WTMM 13 News (20+) Watch | Facebook

Dr. Julius Johnson, President, Greater New York City Black Nurses Association and GNYCBNA hosted a webinar with the Black Greek Letters Consortium on the NIH All of Us Research Program. https://www.youtube.com/watch?v=tZttlY-K1vo

Birmingham Black Nurses Association

The University of Alabama at Birmingham School of Nursing honored 70 alumni in celebration of its 70th anniversary with the Visionary Leader distinction. Recipients were recognized for exemplary service in education, research, leadership, innovation, and far-reaching impact on nursing and health care on state, national, and international levels. The Birmingham Black Nurses Association is proud that six of its members were presented the Visionary Leader Award in April:

Jennifer J. Coleman, PhD, RN, CNE, COI, Professor, Moffett & Sanders School of Nursing, Samford University, Co-Editor in Chief of NBNA News

Martha A. Dawson, DNP, RN, FACHE — Associate Professor, UAB School of Nursing, ***NBNA President***

Deborah F. Grimes, BSN, RN, JD, MSHQS — Chief Diversity Officer, Ochsner Health System, New Orleans, Louisiana

Lindsey M. Harris, DNP, CRNP, FNP-BC — Inpatient Nurse Practitioner, UAB Hospital, president of the Alabama State Nurses Association

Carthenia W. Jefferson, Esq., JD, BSN, RN — Senior Attorney, Jefferson Law Firm LLC

Loretta T. Lee, PhD, CRNP, FNP-BC — Associate Professor, UAB School of Nursing

BBNA member, **LaBrenda Marshall** received an academic scholarship from the Alabama State Nurses Association. LaBrenda is a doctoral student in the Moffett & Sanders School of Nursing, Samford University.

Olympia Oliver received her Doctor of Nursing Practice degree in December from the Moffett & Sanders School of Nursing, Samford University.

Dr. Marcia Lowe, NBNA Membership Chair, participated in the NBNA Virtual Career Day panel on April 3, 2021.

Fall 2020

On October 3, 2020 at its weekly council meeting, the Birmingham City Council with Mayor Randall Woodfin, presented a proclamation to BBNA member Dr. Lindsey Harris. Dr. Harris is the newly elected president of the Alabama State Nurses Association, the first African American president in the organization's 107-year history of existence.

BBNA member Tarsha Wynn-Scott, MSN, RN has been inducted into the National Coalition of 100 Black Women LLC-Birmingham Metropolitan Chapter. The mission of the organization is to uplift, advocate, and educate Black women and girls on leadership development and gender equality in the areas of health, education, and economic empowerment. Ms. Wynn-Scott's master's in nursing focuses on leadership and management.

On November 12, **Dr. Lindsey Harris**, former BBNA president, was honored by Samford University as the 2020 Outstanding Young Alumnus of the Year. Dr. Harris received her baccalaureate degree in nursing from the Moffett and Sanders School of Nursing at Samford University in 2006. At Samford she was a student athlete as a member of the women's varsity basketball team. In 2012 she received the Living Legacy Award from the school of nursing at Samford. She is a nurse practitioner at the University of Alabama at Birmingham Hospital. Dr. Harris is currently president of the Alabama State Nurses Association.

The University of Alabama at Birmingham (UAB Medicine) honored Dr. Lindsey Harris with an in-person and virtual celebration in recognition of her presidency of the Alabama State Nurses Association. BBNA president, **Deborah Thedford-Zimmerman**, was a special guest and an invited speaker.

Dr. Lindsey Harris

Deborah Thedford-Zimmerman

Tarsha Wynn-Scott

Greater New York Black Nurses Association

Dr. Julius Johnson, President, Greater New York City Black Nurses Association leads discussion on the NBNA NIH All Of Us Research Program with members of Zeta Phi Beta Sorority, Inc.

Birmingham Black Nurses Association

On September 13, BBNA members received a donation of hand poured luxury candles. Devereaux Candle Company donated 100 candles to the chapter in appreciation of the chapter's work in the community.

BBNA held an Under 40 Mentorship Panel on October 11th for nursing students, new graduate nurses, and nurses interested in advancing their careers. Panelists from varied areas of nursing provided, tips, thoughts, and suggestions on career advancement and strategies on socialization into the nursing profession.

BBNA's annual Scholarship and Awards Program was held on October 18, 2020. Five nursing students received awards during the virtual event. Key note speaker was NBNA President Dr. Martha Dawson.

On October 25, BBNA collaborated with the Birmingham City Council president for *Jazz in the Gardens* held at the Birmingham Botanical Gardens. BBNA chapter members provided temperature checks and COVID-19 health screenings for all participants at the free event held to support breast cancer awareness.

BBNA held a 4-week series of community educational presentations titled *COVID-19 Reach One Teach One* during October and November. Four topics that were presented each week included (a) Healthcare Workers Perspectives on COVID-19, (b) What is COVID-19? How can I protect myself and others, (c) Talking to children about COVID-19 and pediatric specific prevention, and (d) Essential items for COVID-19 survival plan and kit. Question and answer sessions were held during each presentation. BBNA chapter members collaborated with the Jefferson County Department of Health to present the live educational sessions. The 4-week series of presentations were recorded and are now available on Facebook pages of BBNA and the Jefferson County Department of Health.

As part of the *COVID-19 Reach One Teach One* community education initiative, BBNA provided free face masks to children at four Birmingham area child care centers.

BBNA members received donations of Reebok shoes from the collaboration of NBNA and Soles4Souls, a nonprofit charitable organization. BBNA members are appreciative for the gift of shoes to assist with the long hours and work shifts caring for the community's patients. BBNA president, Deborah Thedford-Zimmerman coordinated distribution to chapter members.

BBNA members with Reebok shoe donations

- Alean Nash
- Tedra Smith
- Taylor Washington
- Myra Holifield
- Cynthia Hill
- Linda Butler
- Nursing student-Jenine Henley
- Nursing student-Ardenia Norris

On November 12, Dr. Lindsey Harris was honored by the University of Alabama at Birmingham Department of Medicine and the School of Nursing with a congratulatory celebration. Dr. Harris is president of the Alabama State Nurses Association, the first African American president in the organization's 107-year history. She is a nurse practitioner in glycemic management at UAB Hospital.

Dr. Marcia Lowe, second vice-president of NBNA, was a guest panelist at the virtual presentation of the Association of Black Cardiologist's Spirit of the Heart Community Forum and Wellness Symposium on Saturday, November 14, 2020. Dr. Lowe was a panelist on the topic of Coronavirus (COVID 19) and Cardiovascular health.

Dr. Lindsey Harris received the Young Alumnus of the Year Award at Samford University's homecoming activities in November 2020. Dr. Harris received her bachelor of science in nursing from the Moffett & Sanders School of Nursing at Samford.

Miracle Reese

Miracle Reese, infection preventionist at the Birmingham VA Medical Center, received recognition for successfully implementing Dedicated Environmental Management Services (EMS) Training Specialist. The standardized program includes strategies to reduce the risk of hospital acquired infection, to improve patient satisfaction, and to increase employee morale. The Veterans Health Administration Diffusion of Excellence Team presented Ms. Reese with a certificate of recognition and acknowledgement of exemplary work at Birmingham VA Healthcare System.

Birmingham Black Nurses Association (cont)

Dr. Tedra Smith

Dr. Tedra Smith is leading an initiative to ensure health and wellness for elementary school-age children. The venture involves a partnership with Woodlawn's i3 Academy in an underserved area of Birmingham. Dr. Smith and nursing students provide regular hearing and vision screenings, physical assessments, and health education services for the elementary students and families. Dr. Smith, a pediatric nurse practitioner, is associate professor and pediatric partnership director at UAB School of Nursing. She is co-chair of the Membership Committee of the Birmingham Black Nurses Association.

BBNA member, Dr. Tedra Smith and co-author Dr. April Weatherly, received the 2019 Donna Wong Writers' Award presented by *Pediatric Nursing* journal. The *Pediatric Nursing* Writers' Award competition was established in 2007 in honor of Donna Wong, long-time editorial board member of *Pediatric Nursing*. Drs. Smith and Weatherly received the award for their article "Effectiveness of Two Psychiatric Screening Tools for Adolescent Suicide Risk" published in the July/August 2019 issue of *Pediatric Nursing*.

BBNA held a free community flu clinic on November 21. Chapter members provided influenza vaccinations for adults and children in the Birmingham area.

BBNA's compassionate care project for 2020 was the Jefferson County Child Development Council. The nonprofit agency provides comprehensive developmental services, nutrition, and education for eligible families. BBNA provided a cash donation to sponsor Christmas toys and gifts for the children.

BBNA was awarded the NBNA Just in Time COVID Assistance Program for Older Adults. BBNA used the funds to sponsor two drive-through food giveaways in January at two churches. Food boxes and health education were provided to 400+ households. The chapter also provided financial assistance to several Birmingham residents who are over the age of 55.

In January 2021, BBNA began a weekly radio show that is broadcast each Saturday morning. January and February topics for the show included COVID-19 and heart health education. Chapter members also pre-recorded eight 30-second educational vignettes on the topics to be aired daily on three radio stations. Educational topics for March focus on colorectal cancer awareness and education.

BBNA is continuing its weekly radio show, *Your Best Life,* providing community education on varied health topics. BBNA is also collaborating with three Birmingham area health care facilities to provide COVID-19 vaccinations in underserved areas. BBNA nurses serve as vaccinators, monitors, and varied other tasks at the vaccine clinics.

BBNA's Community Outreach Committee provided relief supplies for the Bessemer, Alabama community after the devastating effects of recent inclement weather in the area.

BBNA's Annual Open House & Membership Drive included an educational session on Alzheimer's disease and the latest research on dementia presented by Lisa Holman, Director of Programs for the Alabama Chapter of the Alzheimer's Association.

Drs. Martha Dawson, Lindsey Harris, and Tedra Smith participated in a panel discussion on diversity, equity, and inclusion in nursing and health care in recognition of Black History Month. The program was sponsored by the University of Alabama at Birmingham School of Nursing.

On March 13, 2021, BBNA presented its spring workshop on cancer awareness and education. The virtual event included education on varied types of cancers.

BBNA, in collaboration with all Alabama chapters of NBNA, held a virtual education session on COVID-19 on March 29, 2021. NBNA President, Dr. Martha Dawson, was the speaker in the program titled *Update on COVID-19 and Vaccine Confidence in Communities of Color; Immunization & Vaccines in Alabama. The program was sponsored by Pfizer Pharmaceutical Corporation.*

Birmingham Black Nurses Association (cont)

Community Outreach-Carolyn Coleman, Dena Richard

Vaccine clinic-BBNA

Chapter Presidents

ALABAMA

Birmingham BNA (11)	Alean Nash	Birmingham, AL
Montgomery BNA (125)	Katherine Means	Montgomery, AL
Northern Alabama BNA (180)	Frederick Richardson	Harvest, AL
Tuskegee/East Alabama NBNA (177)	Dr. Cordelia Nnedu	Tuskegee Institute, AL
West Alabama Chapter of the NBNA (184)	Dr. Johnny Tice	Tuscaloosa, AL

ARIZONA

BNA Greater Phoenix Area (77)	LaTanya Mathis	Phoenix, AZ

ARKANSAS

Little Rock BNA of Arkansas (126)	Lauren Banks	Little Rock, AR

CALIFORNIA

Bay Area BNA (02)	Norma Faris-Taylor	Oakland, CA
Capitol City BNA (162)	Carter Todd	Sacramento, CA
Central Valley BNA (150)	Ozena Floyd	Fresno, CA
Council of Black Nurses, Los Angeles (01)	Barbara Collier	Los Angeles, CA
Greater Inland Empire BNA (188)	Nia M. Martin	Corona, CA
San Diego BNA (03)	Samantha Gambles Farr	San Diego, CA

COLORADO

Eastern Colorado Council of BN (Denver) (127)	Robin Bruce	Denver, CO

CONNECTICUT

Northern Connecticut BNA (84)	Marlene D. Harris	Hartford, CT
Southern Connecticut BNA (36)	Andrea Murrell	West Haven, CT

DISTRICT OF COLUMBIA

BNA of Greater Washington, DC Area (04)	Dr. Pier Broadnax	Washington, DC

FLORIDA

Big Bend BNA (Tallahassee) (86)	Katrina Rivers	Tallahassee, FL
BNA, Tampa Bay (106)	Rosa Cambridge	Tampa, FL
Central Florida BNA (35)	Eloise Abrahams	Orlando, FL
First Coast BNA (Jacksonville) (103)	Dr. Carol Jenkins-Neil	Jacksonville, FL
Greater Fort Lauderdale Broward Chapter of the NBNA (145)	Catrice Ackerman	Fort Lauderdale, FL
Greater Gainesville BNA (85)	Voncea Brusha	Gainesville, FL
Miami Chapter - BNA (07)	Dr. Marie Etienne	Miami, FL
Palm Beach County BNA (114)	Rochun McCray	West Palm Beach, FL
St. Petersburg BNA (28)	Bonita Clark	St. Petersburg, FL
Treasure Coast Council of BN (161)	Ruth Davis	Port Saint Lucie, FL
Volusia Flagler Putnam Chapter of the NBNA (187)	Dr. Alma Dixon	Palm Coast, FL

GEORGIA

Atlanta BNA (08)	Seara McGarity	College Park, GA
Columbus Metro BNA (51)	Gwendolyn McIntosh	Columbus, GA
Concerned National BN of Central Savannah River Area (123)	Romona Johnson	Martinez, GA

Middle Georgia BNA (153)	Dr. Debra Mann	Dublin, GA
Okefenokee BNA (148)	Connie Bussey	Waycross, GA
Savannah BNA (64)	Pam Cummings	Savannah, GA

HAWAII

Honolulu BNA (80)	Linda Mitchell	Aiea, HI

ILLINOIS

Alliance of BNA of Illinois (178)	Beatrice Mbaocha	Chicago, IL
BNA of Central Illinois (143)	Dr. Elaine Hardy	Bloomington, IL
Chicago Chapter NBNA (09)	Ethel L. Walton	Chicago, IL
Greater Illinois BNA (147)	Patricia Roberts	Bolingbrook IL
Illinois South Suburban NBNA (168)	Dr. Carol Alexander	Matteson, IL
North Shore BNA (172)	Linda Spriggs	Gurnee, IL

INDIANA

BNA of Indianapolis (46)	Katherine Bates	Indianapolis, IN
Lake County Indiana BNA (169)	Michelle Moore	Merrillville, IN
Northwest Indiana BNA (110)	Mona Steele	Gary, IN

KANSAS

Wichita BNA (104)	Linda Wright	Wichita, KS

KENTUCKY

KYANNA BNA, Louisville (33)	Cynetha Bethel-Jaiteh	Louisville, KY
Lexington Chapter of the NBNA (134)	Dr. Lovoria Williams	Lexington, KY

LOUISIANA

Acadiana BNA (131)	Iris Malone	Lafayette, LA
Bayou Region BNA (140)	Salina James	Thibodaux, LA
New Orleans BNA (52)	Dr. Mary Kelly	New Orleans, LA
Shreveport BNA (22)	Bertresea Evans	Shreveport, LA
Southeastern Louisiana BNA (174)	Rachel Weary	Abita Springs, LA

MARYLAND

BNA of Baltimore (05)	Dr. Vaple Robinson	Baltimore, MD
BN of Southern Maryland (137)	Kim Cartwright	Clinton, MD
Greater Bowie Maryland NBNA (166)	Dr. Jacqueline Newsome-Williams	Chevy Chase, MD

MASSACHUSETTS

New England Regional BNA (45)	Sasha DuBois	Roxbury, MA
Western Massachusetts BNA (40)	Anne Mistivar-Payen	Springfield, MA

MICHIGAN

Detroit BNA (13)	Nettie Riddick	Detroit MI
Grand Rapids BNA (93)	Aundrea Robinson	Grand Rapids, MI
Greater Flint BNA (70)	Juanita Wells	Flint, MI
Kalamazoo-Muskegon BNA (96)	Dr. Birthale Archie	Kentwood, MI
Lansing Area BNA (149)	Meseret Hailu	Lansing, MI
Southwest Michigan BNA (175)	Deborah Spates	Berrien Springs, MI

Chapter Presidents

MINNESOTA

Minnesota BNA (111)	Sara Wiggins	St. Paul, MN

MISSOURI

BNA of Greater St. Louis (144)	Dr. Leonora Muhammad	St. Louis, MO
Greater Kansas City BNA (74)	Iris Culbert	Kansas City, MO
Mid-Missouri BNA (171)	Felicia Anunoby	Jefferson City, MO

NEBRASKA

Omaha BNA (73)	Shanda Ross	Omaha, NE

NEVADA

Southern Nevada BNA (81)	Lauren Edgar	Las Vegas, NV

NEW JERSEY

Concerned BN of Central New Jersey (61)	Terri Ivory	Neptune, NJ
Concerned Black Nurses of Newark (24)	Banita Herndon	Newark, NJ
Mid State BNA of New Jersey (90)	Tracy Smith-Tinson	Somerset, NJ
Middlesex Regional BNA (136)	Marchelle Boyd	New Brunswick, NJ
New Jersey Integrated BNA (157)	Thomas Hill	Lyons, NJ

NEW YORK

Greater New York City BNA (167)	Dr. Julius Johnson	Brooklyn, NY
New York BNA (14)	Dr. Rose Ellington-Murray	New York, NY
Rochester BNA (182)	Dr. Yvette Conyers	Rochester, NY
Suffolk County BNA (183)	Jacqueline Winston	Ridge, NY

NORTH CAROLINA

Central Carolina BN Council (53)	Bertha Williams	Durham, NC
Piedmont BNA - Charlotte (181)	Tammy Woods	Charlotte, NC

OHIO

Akron BNA (16)	Deandreia Mayes-Bell	Akron, OH
BNA of Greater Cincinnati (18)	Dr. Regina Hutchins	Cincinnati, OH
Central Ohio BNA (185)	LaToya Gibson	Columbus, OH
Cleveland Council BNA (17)	Dr. LaTonya Martin	Cleveland, OH
Columbus BNA (82)	Janice Smith	Columbus, OH
Youngstown Warren BNA (67)	Carol Smith	Youngstown, OH

OKLAHOMA

Eastern Oklahoma BNA (129)	Wendy Williams	Tulsa, OK
Oklahoma City BNA (173)	Irene Phillips	Jones, OK

OREGON

Alliance of BNA of Oregon (186)	Danaya Hall	Portland, OR

PENNSYLVANIA

Pittsburgh BN in Action (31)	Dr. Dawndra Jones	Pittsburgh, PA
Southeastern Pennsylvania Area BNA (56)	Monica Harmon	Philadelphia, PA

SOUTH CAROLINA

Midlands of South Carolina BNA (179)	Lisa Davis	Columbia, SC
Tri-County BNA of Charleston (27)	Vivian Frasier-Gathers	Charleston, SC

TENNESSEE

Memphis-Riverbluff BNA (49)	Betty Miller	Memphis, TN
Nashville BNA (113)	Shawanda Clay	Nashville, TN

TEXAS

BNA of Austin (151)	Janet Van Brakle	Austin, TX
BNA of Greater Houston (19)	Cynthia Brown	Houston, TX
Central Texas BNA (163)	Mack Parker	Temple, TX
Fort Bend County BNA (107)	Marilyn Johnson	Pearland, TX
Galveston County Gulf Coast BNA (91)	Leon McGrew	Galveston, TX
Greater East Texas BNA (34)	Melody Hopkins	Tyler, TX
Metroplex BNA (Dallas) (102)	Dr. Becky Small	Dallas, TX
Southeast Texas BNA (109)	Bernadine Julun-Jacobs	Port Arthur, TX

VIRGINIA

BNA of Charlottesville (29)	David Simmons, Jr.	Charlottesville, VA
Central Virginia Chapter of the NBNA (130)	Dr. Tamara Broadnax	North Chesterfield, VA
NBNA: Northern Virginia Chapter (115)	Joan Pierre	Woodbridge, VA

WISCONSIN

Milwaukee BNA (21)	Karina Brown	Milwaukee, WI
Racine-Kenosha BNA (50)	Joyce Wadlington	Racine, WI

Direct Member (55)*
*Only if there Is no Chapter in your area.