TrialSite News

SURVEY

African American Clinical Research Disparity

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An extensive body of literature and references points to the fact that health disparities continue to exist in the United States. Across multiple therapeutic and disease categories, African Americans fare worse than others—particularly white or Caucasian Americans. For example, according to American Cancer Society's "Cancer Facts & Figures for African Americans 2016-2018"[1] African Americans experience significantly higher death rates from major diseases including:

Death Rates	African American	White
Heart Disease	216.8	171.2
Cancer	199.2	170.2
Cerebrovascular Disease	50.7	35.5
Diabetes	39.8	18.5

*Rates are per 100,000 and age adjusted to the 2000 US standard population.
Source: National Center for Health Statistics, Centers for Disease Control and Prevention as provided by the SEER program in the SEER*Stat database.

Moreover, it is common knowledge that a range of other health disparities remain unaddressed from Alzheimer's Disease to cardiovascular conditions. TrialSite News has covered news centered on health disparities, particularly among minority communities in the United States. A profound mistrust amongst certain groups and the health sector exists in general and specifically for African Americans, challenges and concerns exist.

Core underlying themes include mistrust driven by historical precedent, socioeconomic barriers and perceptions of unequal treatment in interacting with healthcare institutions.

TrialSite News is committed to the mission of improving healthcare for all in our society. With our specific focus on clinical research transparency, we are supporting a series of surveys and outreach activities into select communities including the African American and Hispanic/Latino communities. Our goal is to engage directly with individuals in communities experiencing inequality to elicit direct feedback, commentary and perspective. We can then document, analyze and publish for all to read and consider for future policy and program formation, as well as strategic and tactical consideration when it comes to matters such as clinical research education and outreach.

Survey

Our survey centered on an African American population in the Beaumont Texas area. Approximately 100 African Americans were surveyed from late August 2018 to mid-September 2018. Our survey created by TrialSite News team in collaboration with a network of trusted advisors from healthcare as well as community organizing. The survey outreach was led by a consultant to TrialSite News, Richard Ellis, an African American, native Texas, Vietnam Veteran who has over years been involved in community outreach including periods where he worked as a substance abuse and guidance counselor. The population sample included the following attributes:

- 100% African American
- 65% Male
- 35% Female
- Primarily Beaumont/Houston metropolitan areas
- Predominantly moderate income with representative jobs/positions including law enforcement, oil & gas facilities, education, military and transportation sectors for employment
- Age group predominantly 80% 50 and above with about 30% retired of the total
- Approximately 10% with 4-year university degrees/50% some college and 40% high school educated only

The TrialSite News Clinical Research Disparity survey fared better than expected. We not only found individuals willing to answer questions but once they felt comfortable, were willing to provide perspective and even consideration for how health systems, research sites and even biopharmaceutical companies can engage with African American communities for better results.

Survey Findings

Our key findings based on this sample population include the following:

- ✓ **83%** were not directly aware of what a clinical trial is upon first being approach and surveyed
- ✓ Once clarified, **90%** of the **83%** had a general understanding of clinical trials, their purpose, etc.
- ✓ Although a few were clearly not interested in learning more, **85%** would be open to learning more about clinical research—especially if the topic is of relevance to a current adverse healthcare situation (e.g. there is someone in the family with a specific cancer)
- ✓ **100%** of the sample population could directly relate to healthcare crisis with family member or someone close to them struggling with adverse healthcare condition
- ✓ Overwhelming majority of the sample population had health access coverage in form of Medicare, Medicaid, VA or private insurance
- ✓ Over **80%** expressed concerns involving trust and perception of inequality with health care system (providers and payers as well as pharmaceutical industry)

- ✓ Mistrust and perceptions of lack of fairness have historical precedent (some had heard of Tuskegee experiments however more imminent were stories of mistreatment at the hands of health systems & providers (example family member sent home from hospital and died from infection—perception that hospital did not want to keep them)
- ✓ **30%** of those that engaged more deeply on the clinical trials topic exhibited or expressed mistrust about government and commercial clinical trial sponsors—that black people could be taken advantaged of; experimented on and essentially expressed that there was not a sufficient informed consent process in place. This same group pointed that healthcare professionals don't communicate in a way that conveys trust
- ✓ Well over **50%** had somewhat negative attitude toward pharmaceutical companies with the number one grievance involving the price of drugs and treatments.
- ✓ There was an overwhelming sense of economic insecurity in the context of health care generally and drug prices in particular
- ✓ The sample population learns about healthcare related topics primarily through their interactions with a physician, word of mouth through friends and family and local church network although at least **30%** will actively search for health-related terms (when topic is relevant) via Google search; not as many (10% or under) are actively engaged with specialized health websites such as WebMD
- ✓ At least **50%** of the sample were using Facebook to communicate with family, friends and those in their networks. They participate in groups (often African American-centric) and frequently these groups are "closed" and open by invitation only

SURVEY DISCUSSION

The TrialSite News Clinical Research Disparities Survey produced to some extent expected results. Although not in the technical sense a random sampling, we nonetheless generated qualitatively interesting data for purposes of better understanding clinical research disparities. Among this population sampling we extrapolate broader trends and considerations. However, we are designing a much larger online survey via Facebook to continue to validate our understanding. Facebook is a powerful way to tap into and connect with broader groups if digital trust is established. Healthcare disparities do exist, and socioeconomic and historical ethnic and racial inequality must be factored in and understood in any healthcare engagement program.

African Americans, especially those over 50, are facing significant healthcare struggles either individually or within family or social network. There is a general sense that health systems are cumbersome and costly; healthcare and economic burden represents a pervasive theme.

Although this initial survey covered a population that was overwhelming working to middle-class with access to healthcare coverage, nonetheless, pervasive economic anxieties are exacerbated by healthcare topic. Generally, clinical trials are not a well-known topic among the sampled African American population and mention of the pharmaceutical industry triggers the specter of cost—overwhelmingly the sampled population feels they pay far too much for their drug prescriptions (even though most all are covered by insurance).

But this sample population, primarily over 50 and already a part of a demographic group with disproportionately higher health concerns and death rates, is facing imminent healthcare troubles.

Potentially devastating costs await the next crisis. Nearly everyone in the population sample either was struggling with a healthcare issue or had a family member or a friend stressed with health worries. Moreover, once the sample populations' felt safe to open, it was clear to the TrialSite team not only a sincere openness to dialogue about healthcare issues, but also a willingness to engage in an open and dynamic manner. Additionally, based on discourse with the sample population as well as our team's experience with social networks such as Facebook, we believe that there is a tremendous opportunity for digital engagement via Facebook groups for not only future surveys but also digital engagement programs. What is clear to us, but needs more validation, is that the existing healthcare sector's African American outreach produces mix results at best (pharma outreach results even more tenuous).

What's Next

But what can work? For greater African American clinical research participation, localized social networks must be identified, engaged and sustained. Trust, empathy and engagement must be fostered in an organic and authentic manner. Healthcare sector participants (payer, provider and biopharma) must become vested into the local community--engaged ongoing--in a sustained and material way. There are examples of community engagement across the United States, from payer

to provider initiatives that TrialSite News staff believe represent models to consider for further investment. Additionally, for medicines and clinical trial participation, government and commercial sponsors will need to expand the perception of what clinical subjects represent; not one time or episodic touchpoints based on a specific clinical program need, but an ongoing community investment that results in empowered and enlightened healthcare consumers.

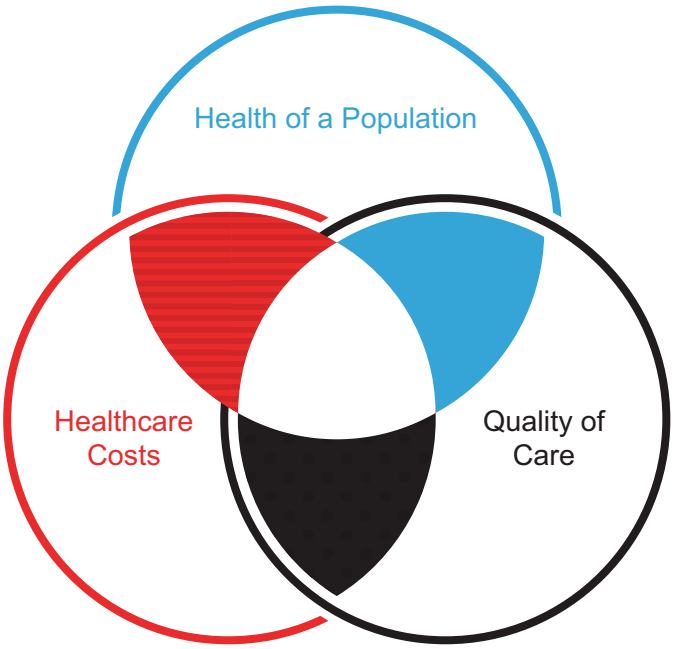
At any given time, government, academic or commercial sponsors may be involved with many community engagement campaigns involving clinical research education and community engagement. There have undoubtedly been many different programs and initiatives to bridge health divide gaps. However, based on our survey feedback (and our knowledge of the overall market and specific statistics) we believe that the campaigns may not go deep enough nor long enough to sustain lasting results.

We believe that purpose-driven combinations of local health systems, academic medical centers, biopharma sponsors as well as representatives from communities can result in tremendous improvements in clinical research education, awareness and participation. Based on our experience it will take forward thinking organizations to take the lead. This could be in the form of a biopharmaceutical company that maintains a diversity program initiative. Conversely it could be a local healthcare system or academic medical center. As TrialSite News, staff have been involved with “whole person care” and “community care coordination” models in various parts of the United States, we hypothesize that emerging models can be infused directly to clinical research with considerably positive results.

Community Clinical Navigator Program

TrialSite News staff are involved with several Medicaid and/or Title V System of Care community care coordination and at-risk population patient navigation initiatives around the United States. With the Triple Aim goal in mind including:

- Improved patient experience and quality of care
- Improved targeted at-risk population quality of care
- Lower overall healthcare costs.



THE TRIPLE AIM

Additionally, we have prior experience with patient recruitment initiatives in the clinical trials industry. After considerable literature reviews, interviews, and examinations of our own experiences, we know that the community care coordination/patient navigator model directly applies to disparities in clinical research. Depending on therapeutic area, targeted population, geography and local culture a dynamic, engaging and locational and culturally-tailored care coordination patient navigator model can be designed and executed with the specific goal of clinical research awareness, capacity building and engagement which will lead toward rapid improvement in African American clinical research participation.

Local health systems (often with Medicare and/or Medicaid funded options) represent tremendous opportunity in each region nationwide. With overlapping payers (Medicare, Medicaid, Commercial Insurance, etc.) there have been community care coordination pilots across the United States—especially targeting at-risk populations such as those receiving Medicaid benefits.

Community Clinical Navigators

TrialSite News proposes a Community Clinical Navigator Program framework that can start in one geographic location and community and thereafter can be leveraged and scaled across many more. It can be paid for out of a combination of public and private sector funds. In some cases a government or commercial sponsor may seek to help fund local research sites targeted at-risk populations such as certain African American demographic segments. In fact, forward thinking commercial sponsors seeking competitive advantage may act sooner rather than later, capitalizing on the concept of community and human capital; that our communities and people represent our markets.

Community Clinical Navigation Programs not only heighten clinical research and trial awareness in at-risk and harder-to-reach communities, but will also enhance patient participation in critical research (not just emphasis on participation in Phase I safety trials but steadfast engagement in Phase II and III efficacy trials that can directly save lives --or make quality of life much higher).

Examples include therapeutic areas such as Alzheimer's disease where sponsors are on the record that they cannot elicit enough participation in the African American community. For any commercial sponsor that not only backs such a program, but invests sufficiently to ensure it scales across different therapy areas and regions, they will see the potential for considerable return on investment that their competitors will not realize. The program and supporting core role (Community Clinical Navigator) may be replicated across health systems and their corresponding communities as well as across social networks both physical and online.

The Community Clinical Navigator role can be attached to a health system; local provider (such as a federally qualified health center); payer or managed care organization (MCO); prominent community-based organization or even biopharmaceutical company. The role can be outsourced to a community-based organization or even commercial company that maintains the right focus and understands the significant implications of getting this type of thing right. Once in place, the Community Clinical Navigators must possess and maintain certain attributes and skills including:

- Originate from the community or be able to establish trust with specific community of interest and engagement
- Emotionally intelligent and empathetic to others' situations and scenarios
- Understand the socioeconomic demographic forces, elements and layers that represent health inequality and comprehend the grave consequences for ongoing healthcare apathy
- Possess the ability to interact and engage in several settings from health care provider environment to homes to local churches and community centers
- Deep understanding of clinical research and how various programs can map to and align with individual-specific profiles
- Believe in the healthcare and clinical trial navigation mission
- Committed to long-term programmatic participation

The job function of a Community Clinical Navigator includes the following:

- Works with their organization and funder to establish strategy and tactical elements for program execution
- Conducts outreach to communities most affected by health/social and clinical research inequities to inform them about the Community Clinical Navigation Program as well as other community services, activities and resources
- Provides care coordination, case management and system navigation to program participants and their families, including but not limited to assisting participants to learn to use not only heal care system but also access and understand clinical research assets, activities in the community
- Provide coaching and social support to participants and families, using active listening skills, motivational interviewing and other techniques

Advocates for participants' access to regional (county, city, community), health system and clinical research resources

Facilitates relations between the community, health and social services as well as clinical research assets by conveying community cultural norms, strengths and needs to funder agency staff and communicating funder agency policies and programs to participants, families and community residents

Receives and screens referrals from other professionals involved in a regional program (e.g. social workers, eligibility workers and medical case workers) to assist participants and or other marginalized individuals and communities in a variety of ways (could be access to food, housing, mental health services, substance abuse counseling, etc.).

Conducts individual and community assessments using both qualitative and quantitative methods

Provides culturally appropriate health education and health information to participants, families and community groups.

Builds individual and community capacity using popular/people's education

Travels within assigned region or service planning area to offer program services and activities to participants in their home, churches, community organizations, local health systems, etc.

Conclusion

TrialSite News concludes that there are several care coordination/patient navigation programs across the United States that possibly may be leveraged for clinical research initiatives—especially where relevant for African American population. A systematic study should be taken

up to look more closely at this subject. Additionally, a broader online survey of African American perceptions of clinical research will be undertaken by TrialSite News. We invite feedback from anyone interested in engaging on this important subject.

Finally, we provide a listing of examples of community care coordination programs, pilots or research endeavors that can influence, inform, impact, and integrate a potential Community Clinical Navigator Program. These types of initiatives and programs can be incorporated by clinical research sponsors into programs that interface, integrate and engage with African American communities for achieving long lasting results of greater healthcare quality, healthier populations and overall higher quality of life.

Example Programs/Studies

California Whole Person Care Pilots
http://www.dhcs.ca.gov/services/Pages/WholePersonCarePilots.aspx

Los Angeles County Department of Health Services Whole Person Care
http://dhs.lacounty.gov/wps/portal/dhs/wpc/

Implementation and Maintenance of Patient Navigation Programs
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5294695/

Care Coordination Models
http://healthtransformation.ohio.gov/Portals/0/OHT%20Web-Archive%20docs%202011/IHICareCoordinationModelWhitePaper20111%20(2).pdf?ver=2012-06-13-112934-977

The Role of Patient Navigators in Eliminating Health Disparities
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4121958/

Evaluation of Diabetes Care Coordination & African American Women
https://www.mdedge.com/jcomjournal/article/146525/diabetes/evaluation-diabetes-care-coordination-program-african-american

Diabetes Management with Care Coordinator (African Americans, Hispanics)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5441206/

Perceptions of Care Coordination in Population Sample of Diverse Patients
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2997113/

Merging Care Coordination and Clinical Research Models
https://www.wilmingtonhealth.com/service/clinical-research

Integrated Model for Patient Care/Clinical Research
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3716847/

Eccovia Solutions ClientTrack for Community Care Coordination Data Tracking
https://eccoviasolutions.com/

Funders Support Social Determinants of Health Projects
https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1515

Lessons from the Camden Coalition of Healthcare Providers
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6070124/

Endnotes

1 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/cancer-facts-and-figures-for-african-americans-2016-2018.pdf