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African Americans in Clinical Trials

Recession and acquisitions make recruiting America's second-largest minority even harder.

Recruitment of African Americans into clinical trials is going through another evolution. With global patient outreach far from peaking, the uncharted growth of outsourcing overseas for patient recruitment is beginning to raise genetic issues at home.¹ As American pharmaceutical and biotech companies rapidly expand to other parts of the world, recession and acquisitions compromise efforts to recruit hard-to-reach American minority patients for clinical trials.

African Americans make up the second largest minority group in the United States—increased by 13 percent between 2005 and 2006. More than 45 percent of America's population is non-white or classified non-Caucasian. In some states, African Americans can make up as much as 30 percent to 60 percent of the residents.² Yet, too many clinical study results, related to diseases critical to African Americans, show as few as 2 percent recruitment of African Americans, or vaguely stated as 9 percent “other” or “non Caucasian.”

Illnesses such as asthma, diabetes, hypertension, HIV-AIDS, and certain kinds of cancer affect African Americans more than other

people. Little is known about the ways African Americans respond to treatment for these and other conditions. Despite government regulations that require minorities to be included in federally funded research projects, African Americans remain underrepresented in these critical projects.³

Most clinical research sponsors are aware of this shortfall, and admit there is a problem. Yet many don't specify or request even 10 percent to 15 percent of African Americans in studies unless there is a special protocol, or unless it relates to HIV-AIDS, sickle cell anemia, and certain cancers. Setting minimum requirements with your team is the first step in the complex chain to reach African American participants.

With the 2010 US Census expected to assertively focus on hard-to-reach minorities and underserved populations,⁴ the results are predicted to reveal even higher numbers of minorities than in the past. If so, the omission of mandatory clinical recruitment policies regarding African Americans and minorities will be somewhat like playing Russian roulette with an entire population. Though efforts such as EDICT⁵ (Eliminating Disparities in Clinical Trials) has begun to recommend new policies, changing the present scenario requires due-diligence and creative partnerships, both within and outside of this clinical trial and cultural void.

In a recent health disparities symposium on cancer, Dr. David Satcher, MD, PhD, Director of the Satcher Health Leadership Institute, Morehouse School of Medicine in Atlanta, GA, spoke

C.E.D.R.I.C.T Quick Facts

C.E.D.R.I.C.T. (pronounced *ced'rick*) (*Coalition to Eliminate Disparities and to Research Inclusion in Clinical Trials*) is a national, three-year pilot field research study on how to increase clinical participation and retention through the education of African Americans in clinical and medical trials.

C.E.D.R.I.C.T., a National Physician and Family Referral (NPFR) Project, began in June 2009, collaborating with National Black Leadership Initiative on Cancer (NBLIC III), Morehouse School of Medicine, Center for Information and Study of Clinical Research Participation (CISCRP), National Medical Association (NMA) *Project IMPACT*, and National Human Genome Center at Howard University.

Through this field research study, a model for African Americans in Clinical Trials (AACT)—*pronounced ACT*—a coalition pilot will be developed in key cities. The intervention will serve as a community model for ongoing recruitment and retention of African American and minority participants.

C.E.D.R.I.C.T. will reach over 10 million African Americans and survey over 20,000 during the three-year period. The field research will both validate and define previous data about fears or apprehensions about participating in medical research. It will also bring to light new data, from ground-zero perspective, on ways to eliminate the health disparities of African Americans in clinical trials.

The potential impact: C.E.D.R.I.C.T. responds to the missing pieces of the puzzle that identifies barriers, as seen by African Americans themselves, and creates access to networks of coalitions to assist them in becoming more educated about clinical trials. With access to these coalitions, disease therapy education and clinical research recruitment becomes easier as it expands into target populations.

C.E.D.R.I.C.T. is not a scientific, academic or medical research. It is conducted by nonprofit companies with years of successful work in patient education, clinical trials outreach, and recruitment of African Americans; utilizing dozens of community-based and medical networks around the country.

Source: Patricia R. Sanders

Table 1. C.E.D.R.I.C.T. evolved to gather face-to-face data on African Americans nationally.

on “A Right to Care.” He outlined significant barriers to healthcare of African Americans in the United States that he calls the “UNs:” uninsured, underinsured, underserved, and underrepresented.⁵

Satcher stated that 40 million Americans are uninsured; 25 million underinsured. “Doctors tend to clump together where it’s comfortable and usually it’s not near the underserved,” he said.

“Over the past 10 years, black doctors (and nurses) are underrepresented in our healthcare system, and we are not making significant progress in that area.” When seeking healthcare or in clinical trials, it is important that a person see themselves represented in the healthcare system.

Minority education

Eliminating racial disparities in clinical trials begins and ends at the top, with education. Educating the doctors and medical providers is a start, but it’s not enough. It is critical to begin the educational process with sponsors of clinical trials. They should set the bar higher by

first requesting, and then requiring larger numbers of African Americans pre-screened for all trials for diseases critical to this population.

The problem with recruiting and retaining African Americans in clinical trials should be viewed as the “problem with us”—those responsible for clinical recruitment, rather than the “problem with them.” Finding solutions should be a multi-level, multi-tasking function of the sponsor; recruitment team; clinical research organization’s or patient research organization’s vendors; project managers; and local site investigators, all working in concert toward this goal.

With new drug discoveries in the pipeline, many offering hope for African Americans,⁶ recruiting them requires new strategies that provide ground-zero opportunities across the board, and with the highest ROI—one that will bridge cultural gaps.

For sponsors of trials, the corporate model at the community level offers opportunities to feed the need in black communities for disease education. Pair this with clinical trials and disease therapy education, and you can simultaneously shortcut community access to new prospects while opening new venues from which to recruit for clinical trials.

African American outreach strategies

The investment return for expanding minority outreach can dramatically increase if that expansion includes strategies for a closer, personal, and more trusted outreach to venues such as black churches and community health partnerships. This outreach could logically make the difference between 2 percent or 10 percent recruitment of minorities in that community.

If sponsors of trials want to build and sustain trust for future trials, they should tap into community health networks that already provide local health education about diseases. Look into trial outreach through black professional newsletters, flyer distribution to partnered church health initiatives, and community organizations. Use your site investigators as resources. This will make your trial more important to the community than other trials trying to recruit from a distance.

Sometimes, for example, your local site investigators are already involved with these organizations. A community-

involved site investigator means there is already an important trust factor present. Something as simple as a brief site investigator survey could produce a treasure of resources right under your nose.

Where site investigators are involved in the community, you'll usually have greater access to African American patients. Likewise, patient recruitment of this population could increase dramatically in key states⁷ if project management is focused upon identifying, training, and funding African American physician investigators already involved in the community.

A new ground-zero field research, called C.E.D.R.I.C.T., pronounced CED' rick, [Table 1] (Coalition to Eliminate Disparities and to Research Inclusion in Clinical Trials) has evolved to gather face-to-face data on African Americans nationally. The initial surveys observed three obstacles that must be tackled for better ground-zero patient recruitment. It also has observed three keys to addressing these obstacles. The obstacles from ground-zero standpoints are trust, interest, and opt-in opportunities. The keys are disease, patient, and community education.

Developing an outreach to recruit minorities for clinical trials, while at the same time creating trust often relies on media data that does not provide a true picture of potential African American clinical trials participants. So we take the standard shortcut when looking for minorities: Advertise in black media.

Advertising is a proven outreach strategy and it works on many fronts. However, the obstacle of trust cannot be overcome solely by talking to African Americans about a clinical trial between R&B songs. Trust involves an "in-your-face" approach to such an intimate undertaking as participating in a clinical trial. And for many minorities this is not an option.⁸

Elise D. Cook, MD, Chair, Minority and Medically Underserved Subcommittee, for SELECT trials⁹ was part of the team that developed focus groups to get input from men in target population(s). During the study, ways to enhance minority recruitment were explored and three one-day minority recruitment workshops were developed, along with community partnerships with NBLIC II and others [see sidebars]. They found that trust was built among participants where open and ongoing communications evolved, and continued with participants even after the trials ended.

Developing ethnic-focused communication tools

Tools for developing ethnic-focused, community-based project management could be as simple as creating a selection of educational trials flyers, posters, brochures, or pamphlets for distribution by your "community-involved" site investigators in their communities.

Familiar, face-to-face exchange and distribution of culturally-sensitive information, both in doctor's offices and

Focus Groups

- Input from men in the target population
- 78 men participated: 16 African American and 32 from the Veteran's Administration Hospitals system
- Recommendations regarding communications
 - Highlight personal incentives
 - Explain why the study supplements were chosen
 - Provide frequent study updates
 - Include family members, especially spouses
 - Special strategies for recruitment of minority, low literacy, low income, and medically underserved men

Minority Recruitment Workshops

- Three 1-day workshops
 - Round table discussions
 - Sharing strategies, develop mentoring relationships, and discuss problems
 - Panel discussions with local community leaders and SELECT Investigators
 - Shared recruitment ideas
 - Disseminated workshop proceedings to all SELECT staff at the semi-annual SWOG/SELECT Workshops

Partnership with NBLIC II

- Minority outreach initiative of the NCI
- Innovative outreach strategies partnering with the local SELECT sites
 - For Men Only retreats, Wellness on Wheels, and Taking it to the Top,
- Promotional items for events
 - T-shirts, squeeze water bottles, and caps with the SELECT logo

the community, presents huge recruitment opportunities toward establishing trust among African Americans for multiple diseases.

Support project management by providing what is known as an 800 ERN (Educational Referral Number) to buttress the unfamiliar pre-screening interview. The ERN allows participants to ask questions and allows for smoother transition into pre-screening. Utilizing an 800 ERN throughout the recruitment campaign could be a positive, escalating educational tool.

Appropriate city and site selection is critical. Unfortunately, it's often easier and quicker to stick with the famil-

iar sites. If you are looking to recruit African Americans, selecting a site in the suburbs, as opposed to one with a heavy concentration of African Americans, can present obstacles for participation. Finding sites that are within a comfortable distance from African American communities could be a matter of finding African American site doctors and then helping them to outreach for your trial.

Sponsors could increase their chances for successful minority recruitment by making mandatory a percentage of investigators who are both African American doctors as well as non-minority physicians in areas with large African American patient bases. *Applied Clinical Trials*' Editor-in-Chief Lisa Henderson, aptly noted in May 2008 that "trial availability in that community; physician participation in the trial; and finally, being able to meet the criteria," were elements in successful recruitment of African Americans in an oncology trial.¹⁰

Sparkling interest is an illusive obstacle that is best facilitated through site community partnerships. The question arises, "If 30% to 70% of (minority subjects) say they'd be willing to be in a clinical trial... why do so few actually enroll?"¹¹ Of the African Americans surveyed, over 40% stand firm on willingness to participate in clinical trials if someone asked them. However, 92% are firm about their willingness to participate if they had more information (education) *before* they are called to pre-screen. Clearly, this is an important key.

Creating an interest in clinical trials participation among African Americans requires face-to-face exchange for maximum effectiveness. It then becomes the question of how to develop ground-zero techniques that impact African Americans targeted for inclusion. The residual benefits of shifting a small percentage of the site project management resources to a community ethnic-focused campaign will translate to a greater ROI on current and future trials. As FDA guidelines become more inclusive, this shift will also avoid wasting time and money backtracking later in order to recoup minority participants for final drug approval.

With the new Health Insurance Portability and Accountability Act (HIPPA) regulations, outreaching to gain minority interest in clinical trials without perks and incentives requires building strong community partnerships. Often this is done directly at the project management and site investigator levels.

The most profitable investment

The third obstacle, creating opt-in opportunities, directly impacts patient recruitment vendors and site investigators. Influencing African Americans to opt-in to a database or referral list for trial participation can be site-based, event-based, web-based, or via sponsor's patient recruitment vendors.

Creating interest in clinical trial participation among African Americans requires face-to-face exchange.

When trial sponsors outsource to clinical and patient recruitment organizations, they are hoping these vendors are able to pull their trials across the invisible line of "minimum requirements" for African Americans and minorities. For some trials (and a few diseases), this happens. Taking responsibility for minority patient recruitment at the beginning helps sponsors and project management teams take control.

Clinical trial participant databases identified as exclusively African Americans are rare. However, one recent educational outreach that evolved from the 2009 C.E.D.R.I.C.T. field research is, "African American Health Matters." African American Health Matters is an opt-in mobile health text message program that sends health reminders and tips to over 25,000 subscribers about selected health matters. Fifty-eight percent of this audience is not on the Internet, but 84 percent have cell phones.

Text messages also offer toll-free numbers and websites to find disease educational materials, clinical trials reminders, and positive reinforcement messages designed to help participants maintain a positive mental attitude, an important element of good health.

Planned involvement

Sponsors and recruitment organizations should adhere to quality checks of their minority patients and physician databases. Vendors should keep updated information about targeted African American participants and doctors for referral to trials. Look at track records. Whether performance-based plus community advocacy or advertisement-based recruitment, the yardstick for a vendor's ability to recruit for multiple racial populations is database development of specialized audiences.

Sponsors should require "minimum goals" for recruiting African Americans in all US-based trials. The national average population of African Americans is around 12%, and over 100 cities have more than 30%. With these numbers, recruiters should consider requiring at least 10% participation for diseases with high mortality rates in this population. This requirement will present new recruitment opportunities and offer increased education for critical diseases such as diabetes, hypertension, cholesterol, asthma, arthritis, obesity, and tobacco use.

In C.E.D.R.I.C.T.'s initial field surveys, other diseases were found to be of interest: orthopedic, cardiovascular, prostate related, breast, lung and colon cancers, gastric,

menopausal, post menopausal, addiction, and depression trials. The point is to reach out initially with multiple diseases in multiple cities in order to identify your new patient populations. You'll then find the community hierarchy that offers access for future trials.

Disease, patient, and community education

The obstacles are not insurmountable to recruiting African Americans into clinical trials. However, the obstacles must be overcome to avoid playing Russian roulette with this population. How? By initiating proven market strategies that work on many levels. When a company is willing to give minority recruitment more than a cursory glance, there are keys that will help them move forward:

Key one. Start with disease education related to the trial. African American churches with health ministries score big points for trust and openness. For a trial targeted to grass-roots participation, a study flyer with trial and disease facts, and ERN numbers for pre-screening consultation is extremely valuable information at African American churches or local health fairs.

Key two. Follows up with more patient education about the clinical trial being conducted. This can be done with various clinical trials recruitment outreach tools such as trial information on black websites and community media that cater to African American audiences, phone surveys, web, or e-mail announcements and mobile messaging. Paid advertisements can support this effort, but should never be used as the primary recruitment mechanism. Also, recognize the many community levels for event ads and outreach.

Key three. Keep your community network open and active. Once you've established a community partnership within selected African American communities, follow through with each disease trial. Success depends not just on the clinical trial, but also upon your community relationship. From the relationship comes trust; from trust comes word-of-mouth, which equals interest. From the right selection of sites and site investigators comes a cost-efficient, focused outreach support that the sponsor or patient recruitment vendor can provide its sites.

Conclusion

In summary, recruiting African Americans into clinical trials is not rocket science. However, it takes focus, commitment, and a plan to develop your minority outreach around your existing site resources by:

- Outlining ways to include African Americans, look for strategies for inclusion and retention in your key cities by site project managers and patient recruitment organizations.
- Developing the networks you may already have in place in the communities with people who "talk their language," and with an outreach that focuses upon disease education and health support resources.

- Supporting ground-zero opportunities in your site communities with custom, IRB approved trial information and disease education materials. Most importantly, encourage site outreach programs and offer bonuses and incentives for qualifying African American doctors and for outreach to new participants.

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