GUEST EDITORIAL

ESTABLISHING A COMMUNITY NETWORK FOR RECRUITMENT OF AFRICAN AMERICANS INTO A CLINICAL TRIAL
The African-American Antiplatelet Stroke Prevention Study (AAASPS) Experience

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African Americans experience survival disadvantage in almost every major category of mortality.[1,2] Health-care trends suggest a general lack of access to medical care and use of preventive and palliative diagnostic and treatment services.[3-5] This may explain in large part the disproportionate mortality statistics. African Americans also are underrepresented in clinical trials, which play a major role in the development of safe and effective diagnostic tools and treatments that reduce the societal burden of disease. Given these trends, the National Institutes of Health (NIH) has mandated inclusion of minorities and women in research proposals.[6-10] The challenge, however, remains to overcome major barriers to African-American participation in clinical trials and the health-care system.

We are conducting a double-blind, randomized, controlled clinical trial for secondary stroke prevention in the African-American community. The program was developed in response to the epidemic stroke rates among African-Americans.[2] The program is sponsored by the NIH and is called the African-American Antiplatelet Stroke Prevention Study (AAASPS). We detail the steps taken to establish a community network to assist with patient recruitment.

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WHY ESTABLISH A COMMUNITY NETWORK?

Each racial or ethnic community serves as a major focus for intellectual activities, political initiatives, economic programs, inspiration, and overall direction. Communities are led and directed by individuals of trust who are active in the target area. The leaders may possess considerable power or influence with regard to community acceptance of health-care initiatives. In the African-American community, church leaders, physicians, key politicians and civic leaders, the local press and news media, and spokesperson celebrities may be of considerable assistance in persuading the community and publicizing the benefits of such health-care programs. A frequent criticism lodged by minority communities relates to a lack of community representation in the planning phase of such initiatives. The exclusion of community leaders in the planning phase may lead to rejection and failure of the health initiative once it is launched.

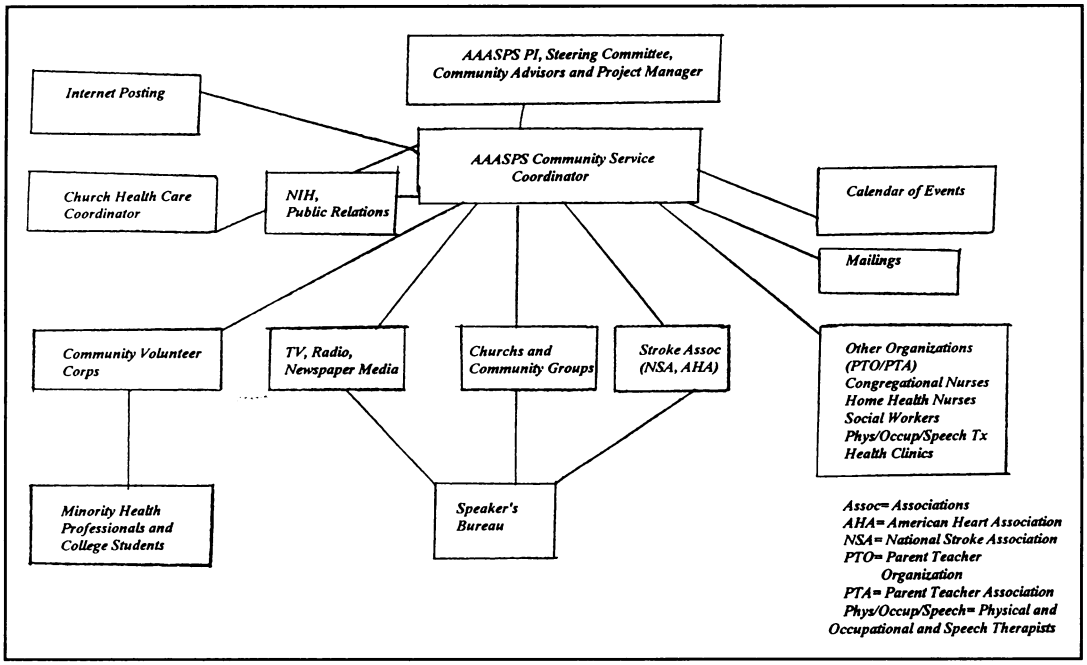

Figure. AAASPS community awareness model: organizational scheme.

THE AAASPS CHICAGO EXPERIENCE

Preclinical Trial Planning Phase

The AAASPS leadership established the need for community support as a major component of the research program proposal. Community support from major African-American church organizations, the Cook County Physicians Organization (the Chicagoland branch of the National Medical Association), Operation PUSH, and key federal and state political officials was deemed mandatory before the research program proposal was submitted to the NIH for peer review. Thus, support from the community was obtained well in advance of program start-up. This gave community organizations an opportunity to review key aspects of the program and have input in crafting the initiative. Furthermore, direct involvement by community members was established through employment in key project positions. Finally, questions about assurance of safety and ethical conduct, key issues for African Americans given the legacy of past medical abuses in the antebellum South and the infamous Tuskegee Syphilis Study,[12-14] were addressed and answered satisfactorily.

Establishment of a Community Advisory Panel

African-American community members were sought to serve on an advisory panel that meets with the study team on a regular basis to advise them on ways to interact and network with the community. The advisors include three physicians, two stroke victims who had excellent recovery, a health-care consultant, and a past state legislative representative. The advisors have been involved in all phases of preclinical trial planning as well as the actual conduct of the study.

Establishment of a Community Service Coordinator

The task of developing and organizing a community network among approximately 1.03 million African Americans in the Chicagoland area was substantial. After several brainstorming sessions by key staff members and invited guests, a community service coordinator (CSC) position was established. The CSC serves in a full-time capacity to develop a community program awareness network. In our case, the CSC is African American and has past experience networking with churches and community groups.

Components of the Community Network

Study team members, community advisors, and other key guests met to identify major components of a community network and to develop an organizational awareness scheme for the program (Figure). The major components of the community awareness network include churches, key organizations, nurses, health-care professionals, community volunteers, the news media and cable access channels, Internet, a newsletter, national stroke associations, and a local African-American events calendar. A speaker's bureau has been established to promote the study and stroke

prevention throughout the network. Furthermore, two pastors who are highly trusted and visible in the community have been recruited to serve as spokespersons for the program.

The Community Network in Action

The charge of the community network is to raise community awareness about the study and to educate persons about stroke prevention. Under the direction of the Principal Investigator and Project Manager, the CSC has responsibility for organizing and directing the awareness effort. Church and community organizations, volunteers, health-care professionals, and the news media are kept updated on the activities of AAASPS through a quarterly newsletter. Furthermore, the CSC schedules appointments to meet with church and community groups to create awareness about the study. These efforts lead to participation in church and community health fairs, Sunday speaking appearances at churches, and radio interviews. The National Stroke Association has supplied customized educational materials about stroke prevention for African Americans that are used at these events.

A calendar of community activities that targets events attended or viewed by African-American audiences also has been established. The calendar was developed with the assistance of the city's Office of Chicagoland Community Affairs and various African-American organizations. As a result, major African-American community events have been targeted for AAASPS participation.

The news media represents an important source to help heighten program awareness. A news conference was organized that occurred in conjunction with an inaugural reception to announce the study and to thank community leaders for their assistance. This media event led to 427 telephone inquiries about the AAASPS program and many requests from patients and family members to screen potential program candidates for study enrollment. Other media efforts include public service radio spots, a cable television show, an Internet posting, attempts to reach African-American audiences via nationally syndicated television and magazines, and a billboard campaign.

The Community Network's Focus to Assist in Recruitment of Reluctant or Undecided Patients

Recruitment of patients for clinical trials may be a challenging task. The prevailing question in the potential enrollee's mind may be "What's in it for me?" The research team must be able to present a safe program and honestly answer the question of "What is in it" for the enrollees. African Americans have been underrepresented in clinical trials and may be unfamiliar and frightened by the prospect of participation in a study.[7-11] These factors as well as other barriers, such as suboptimal communication by a program team, economic factors, and mistrust of the medical system, may lead to high study refusal rates and lack of recruitment.[11]

Given these challenges, AAASPS staff and advisors have developed strategies to deal with these potential barriers to recruitment. The program offers many benefits that are discussed with potential enrollees. Study safety questions are addressed by assuring potential enrollees that the study drugs are FDA-approved and routinely used by medical doctors for stroke prevention. Furthermore, comprehensive study visits and laboratory monitoring are being carried out to ensure safety. Volunteers from the community network are enlisted to serve as recruitment counselors for those potential enrollees who might be reluctant or frightened, or who are undecided about participation. The counselors are trained by AAASPS staff, and an unpressured, patient approach is emphasized.

SUMMARY

A major aspect of a clinical trial is the ability to successfully recruit patients. There is a paucity of information concerning the nuances of recruiting study patients, especially those from minority communities. As minorities generally have been underrepresented in the health-care system, they may be less likely to participate in clinical trials or other studies.[11,15] Thus, a strategy is needed to overcome this potential shortfall.

One of our solutions has been the development of a community network to help disseminate information about our program. We believe that a key aspect has been the involvement of community members during pre-trial planning, community awareness programs, and our Community Advisory Panel. We also believe that it may be a major error to bring a health-care initiative unannounced into a targeted community without extensive pre-program planning in cooperation with that community.

As our community awareness scheme suggests (Figure), there are many possible avenues to heighten awareness about a health-care program. While the church remains an important institution for religious and cultural activities in the African-American community, we have found that the news, television, and radio media also can be a powerful source for spreading awareness.[16] Thus, we recommend creating awareness

about an initiative through a "grassroots" approach of church and community organizations, along with a global approach through news, television, and radio media. As part of the awareness promotion campaign, it must be emphasized that the study is safe and provides benefits to enrollees.

The success of health programs is largely dependent on community acceptance, which must be established in the pre-program planning stages of the initiative. This concept of obtaining community approval and acceptance prior to program initiation is not a new one, nor does it exclusively apply to the African-American community. Community leaders and members need to have a vested interest in such a program and a sense of empowerment. Through this type of communication, patient enrollment and community satisfaction can be substantial. Such success can serve as a springboard for other targeted health-care studies or programs in high-risk communities.

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further investigations are warranted of this herb's potential in AIDS, cancer, and infections.

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