Summary of barriers to research participation for minority individuals with MS
October 17, 2017

Introduction

Although previously considered a “Caucasian disease,” multiple sclerosis (MS) is now understood to affect people of many races and ethnicities. In fact, in the United States, MS may be more common in African-Americans when compared to other racial groups, and may have more severe effects in both African-Americans and Hispanic-Americans.

Research holds the key to a better understanding of how to manage, treat, and someday possibly prevent and cure MS for all people. However, in many diseases, participation in research studies is lower among racial and ethnic minorities, reducing the applicability of research results to these groups. MS appears to be no different.

Many barriers may contribute to low research participation rates for minorities with MS. Some may be related to perceptions and attitudes towards research based on historical issues of research in minority communities; some may be due to lack of communication to minorities about available research opportunities; and yet others may be due to relative lack of research opportunities at clinics serving minority populations.

The MS Minority Research Engagement Partnership Network (MREPN) was formed to help address the imbalance in MS research participation by identifying the barriers to research participation by minorities, and by conducting outreach efforts intended to address these barriers. Funding for this network’s activities is provided by the Patient-Centered Outcomes Research Institute (PCORI) through a Eugene Washington Engagement Award. This report summarizes our initial findings about the existing barriers, drawing upon research conducted by others as well as our own survey of people with MS. We plan to update the report as we collectively learn more.

Background research: Factors influencing research participation

A large body of scientific literature exists on minority participation in research and the factors that influence willingness to participate. Investigations focusing on participation rates in actual studies vary in their findings, but recent systematic reviews have reported ongoing disparities in research studies such as clinical trials for several medical conditions, including MS.
For example, a recent review of phase III trials funded by the National Institute of Neurological Disorders and Stroke (NINDS) published between 1985 and 2008 identified 3 studies conducted in MS. African-Americans made up 6.6% of the participants in the first study (301 total participants), 9.1% in the second (22 total participants), and 0% in the third (59 total participants).\(^1\) For a more recent example, in the pivotal relapsing-remitting MS trials for Ocrevus, the latest MS drug to receive FDA approval, Black or African-American participants constituted 4% of the total population, and all other minority groups combined made up 5%. In the primary progressive MS trial for this drug, the percentages for African-Americans, American Indians/Alaskan Natives, and all other minority groups combined were 2%, 1%, and 3%, respectively.\(^2\)

Other studies have assessed perceptions and willingness to engage in research among people of different races and ethnicities in different healthcare contexts. A systematic review of qualitative and quantitative studies regarding barriers and facilitators of research participation in minority groups found several factors that were common across multiple groups. Barriers included mistrust, competing demands, and lack of access to information about clinical studies; and facilitators included cultural congruence, benefits of participation, and altruism, among others.\(^3\)

Recently, a study of research motivators and barriers was conducted by surveying people attending outpatient clinics at a single site.\(^4\) The strongest motivators in general were having the study explained well, and the potential for the research findings to benefit others. The strongest barrier overall was risk of unknown side effects. Statistically significant differences among racial/ethnic groups were found for certain factors, such as a desire to please the doctor and the doctor being of the same sex/gender or race/ethnicity as the respondent (motivators); and religious beliefs, risk of side effects, and access to transportation (barriers).

**Original research: Survey of people with MS**

The studies referred to above, as well as others, provide a great deal of information about barriers and facilitators to research participation in general, but we could not find any information specific to people with MS. To provide insights into how people with MS of different races and ethnicities view research participation, the MREPN conducted a targeted survey of this population. The survey was designed, developed, and tested collaboratively by MREPN members and hosted online. Network members and other

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\(^2\) FDA Drug Trials Snapshots for Ocrevus, April 18, 2017.
cooperating partners (e.g., MS advocacy organizations) disseminated invitations through email, web and social media posts, and flyers were distributed in clinics.

We received 2,611 responses, with approximately 7% of respondents identifying as Hispanic or Latino, and approximately 8% identifying as African-American, 7% as mixed race, and 1% as American Indian or Alaskan Native, Asian, or Native Hawaiian. A few of the results are highlighted below, and we plan to further disseminate these findings more formally through conference presentations, scientific journal articles, and a publicly accessible lay language report. The findings are also being used to inform the development of materials to help health care professionals and researchers engage racial and ethnic minorities and encourage participation in MS research.

*Note that the people who chose to respond to the survey may not be representative of the total MS population. In particular, respondents are limited to people with Internet access, and the mention of the survey topic in study notices may have attracted people with a particular interest in or opinions about research participation.

**How people learn about research:** For all races and ethnicities, people with MS are most likely to go to MS organizations followed by MS websites/blogs to search for information about research studies. The most trusted sources of research information included the person’s doctor or nurse followed by MS organizations. The fact that respondents would tend to seek information about research studies from sources other than their medical clinic indicates that people are not learning about research from their healthcare providers even though they would trust this information if given. Arming health professionals with information to share could further help expand exposure to research opportunities. In addition, the combination of high trustworthiness and being widely viewed as sources of MS research information make MS organizations particularly promising as disseminators of MS research opportunities.

**Concerns about research participation:** When asked about concerns regarding possible risks or issues having to do with research participation, the item that ranked the highest across all groups (>70% indicating it was a “strong concern”) was not being fully informed about the study. Receiving poor quality medical care, losing their health insurance, and having personal information released without their approval were also strong concerns for >50% of respondents in all groups.

African-American respondents were more likely to characterize each risk or issue as being a “strong concern” than Caucasian respondents. African-Americans were much more likely than Caucasians to have a strong concern about being used or taken advantage of by the research team (62% vs. 41%). With the exception of not being able to do what the study requires, Hispanics were also more likely than non-Hispanics to characterize each risk/issue as a strong concern. The sharpest difference between Hispanics and non-Hispanics had to do with risks to one’s job or legal status, with 44% and 30% of each group indicating this was a strong concern, respectively.

**Research activities:** When presented with a list of activities that might be included in a research study, such as taking surveys or having lab tests performed, respondents in all
groups indicated that most were acceptable, with a vast majority indicating they would consider or probably would consider participating in the activity. Receiving drug treatments was the least acceptable activity, with around 1/3 of participants in all groups saying they wouldn’t consider or probably wouldn’t consider doing this.

**Research study characteristics:** The survey also presented a list of characteristics that might apply to a given research study and asked respondents to indicate how well they would like or dislike each. Many characteristics were attractive across all groups, including the potential for the research to help people with MS, and being able to receive individual test results during the study and/or overall results after the study was completed. This implies that people who choose to participate in research want to be followed up with afterward to understand the impact of their participation for themselves and/or the broader MS community. This type of information sharing is not yet common practice in research, but shows promise for creating a positive experience for participants.

Several items were disliked equally strongly, such as potential health harms, written information about the study being confusing, and inconvenient study location. The percentage of people who disliked the unattractive items were quite similar (within a 10% range) in African-Americans compared with Caucasians and Hispanics compared with non-Hispanics. However, there were a few strong differences among responses to the attractive items. African-Americans and Hispanics had a greater positive response to research that would benefit people in their racial or ethnic group, and to studies that included people of different races and ethnic groups. African-Americans also responded more positively to being paid for study participation.

**Researcher- and clinician-related factors**

In addition to considering the attitudes and preferences of people with MS toward research participation, we must also consider barriers related to the involvement of healthcare professionals and researchers in minority research recruitment. Potential barriers may include, for example:

- Minority individuals with MS being less likely to receive healthcare at locations that engage in research
- Clinicians hesitating to refer their patients to a study out of fear of losing that patient to the study clinician
- Lack of translation of study materials into languages other than English, and lack of on-site translators to explain and answer questions about the study
- Clinicians and investigators being less likely to discuss research opportunities with minority patients, due to time constraints, language barriers, or perception that these patients will not want to or be able to participate

• Investigators being unaware of the value of recruiting a diverse study population, or being unfamiliar with resources and practices that would help them become more successful at recruiting minority participants

We are unaware of specific research evaluating these barriers in MS study recruitment, but we will be engaging with researchers and clinicians throughout the course of this project to learn more about the factors that may be most important to address in MS. We are also developing an informational toolkit to share with clinicians and researchers that draw upon resources developed by other initiatives (such as EMPACT for cancer research) to support recruitment of minority participants into research studies.

Conclusions

In our research and reflection to date, we have found that racial and ethnic minority groups are underrepresented in MS research, and that the factors that affect their participation appear to be similar to those that have been reported for other diseases. Our survey highlighted some factors that could facilitate the engagement of minorities in research, such as communicating the benefit of the research for their racial or ethnic group as well as the broader MS community.

While concerns about research participation and opinions about various study characteristics are largely similar across racial and ethnic groups, some differences do exist, which point to opportunities for outreach in the patient community. For example, outreach materials about the protections that exist to prevent exploitation of research participants could help African-Americans feel more comfortable about joining a study. Alleviating concerns about risks to employment or legal status may help increase Hispanic enrollment in specific studies. Recognizing and addressing these differences could help investigators become more successful at increasing minority participation in their studies.

We know less about MS clinician and researcher attitudes, perceptions and practices that affect minority enrollment in research. However, we recognize that this is a critical area to address. Minority individuals with MS do express willingness to participate in research, and would trust research study information provided by their clinicians, but they may not be receiving invitations to participate in research in equal proportions. Therefore, addressing patient-oriented factors is only part of the solution; researchers and clinicians must also be given tools and knowledge that enable them to contribute to closing the gap in research participation.