Tip Sheet: Clinical Trials and Diabetes

**Topic:** Hispanic representation in clinical trials and the burden of diabetes

**What is the problem?**
Currently over 29 million adults in the United States are living with diabetes; and about 1 in 4 of these people are unaware they have the disease (CDC, 2015a). Diabetes is a group of diseases that results in too much sugar in the blood, which over time can cause serious health problems, such as heart disease, vision loss and nerve damage.

About 40% of US adults are expected to develop type 2 diabetes over their lifetimes; for Latino/Hispanic adults, it is predicted that over 50% will develop type 2 diabetes (CDC, 2016). Addressing this particular disease burden on the Latino/Hispanic community will require a variety of efforts, including increasing Latino/Hispanic representation in clinical trials.

To effectively address the issue of diabetes in the Latino/Hispanic community, information from clinical trials will be needed to shed light on how different Latino/Hispanic groups (i.e., US born vs. foreign born; Mexican vs. South American) respond to different treatments, particularly for diabetes. Moving forward, it is critical that researchers and health professionals learn more effective and culturally competent methods to outreach to the Latino/Hispanic communities. This can help motivate the community to participate in activities focused on supporting their health, including clinical trials.

**Who’s at risk?**
Results from the first national study on Latino/Hispanics’ health risks were published in the Spring of 2015. Until that time, there were many gaps in information regarding risk factors and death rates for health issues that are common among the Latino/Hispanic population. This knowledge is important for identifying disparities in health issues across populations and understanding which health issues affecting Latinos/Hispanics need critical attention.

Similarly, there has been a lack of Latino/Hispanic representation in clinical trials, which has made it difficult to develop new treatments and therapies for the health issues disproportionately affecting Latinos/Hispanics. According to the National Institutes of Health (NIH), among clinical trials funded by NIH, Latinos/Hispanics make up only 7.6% of participants (and 16% of the U.S. population), compared to African Americans, who make up 15% of clinical trial participants (and 13% of the U.S. population) (McGill, 2013).

Overall, Latinos/Hispanics experience major differences in health risks, compared to Caucasian adults. Latinos/Hispanics are 50% more likely to die from diabetes than Caucasians. This community is also
significantly affected by diabetes, as 23% more of adults in this population are obese and 24% more have poorly controlled high blood pressure, compared to their Caucasian counterparts (CDC, 2015b).

**Can it be prevented?**
Outreaching to Latinos/Hispanics in the U.S. about clinical trials, and healthcare in general can be somewhat challenging. There are a unique set of issues that research teams need to keep in mind, including language barriers, concerns about immigration status, and a different cultural view on the benefits of medical care (McGill, 2013).

With this in mind, it may be helpful to use patient navigators (individuals from the community who can be trained to outreach to other community members) during a clinical trial. The Latino/Hispanic community may respond better to individuals who understand their culture and perspectives, and are members of the community. Partnering with community hospitals located within a largely Latino/Hispanic area can also be helpful in accommodating those who have transportation issues or are more comfortable staying in their local area (McGill, 2013).

Religion and family can also play a role in motivating families to participate in clinical trials. Some of these families prioritize their faith and religion, rather than scientific data, and may want to consult other family members before making healthcare decisions. Accommodating for these beliefs and preferences will help establish a positive relationship between the Latino/Hispanic community and the research team, which is essential for successfully outreaching to this community.

**Bottom line**
- Representation of Latinos/Hispanics, both U.S. and foreign born, in clinical trials will lead to better treatments for Hispanics in the future.
- There are a unique set of issues that research teams need to keep in mind, including language barriers, concerns about immigration status, and a different cultural view on the benefits of medical care.
- Latinos/Hispanics are the largest racial/ethnic group in the US (nearly 57 million), yet only 7.6% of clinical trial participants are Hispanic or Latino (McGill, 2013).

**Case example**
Lorena stopped by the healthy snacks program table stationed in front of the local middle school to look at the recipe list they were giving out to parents. A student researcher approached her and began explaining a new clinical trial focused on understanding which healthy diets lower diabetes risk among overweight kids. Knowing that her daughter has struggled with weight issues for some time, Lorena decided that this could be something helpful. She has been cooking low fat meals (i.e., lean meats, whole-grain products, vegetables) to help her daughter lose weight, but has not seen any major results. The research team put Lorena’s daughter on a low glycemic diet (low glycemic foods include: avocados, celery, beans and whole wheat pasta), and compared her changes with kids on a low fat diet. After nearly a year of being a part of the clinical trial, her daughter’s blood pressure and body fat (BMI) went down. Lorena realized that if it weren’t for the clinical trial, she would not have known that a low glycemic diet was better for her daughter than a low fat diet. (Mirza et al., 2013)

**References**

