Clinical Trial Recruitment from a Public Health Perspective
Amisha Kumar, MPH Candidate; Elaine Yu, MD; Vanita R. Aroda, MD
Massachusetts General Hospital (MGH), Harvard Medical School

Without clinical trials, there would be no medicine on the shelves of pharmacies. Clinical trials are an essential component to progressing the field of medicine to enhance treatment and build targeted therapies that overall prevent disease. We aim to further understand the intersection between Public Health and clinical trials in hopes of improving educational outreach in communities. To do so, we will be comparing the effects between a study centric and patient centric approach on clinical trial engagement.

Specifically, we will be working in collaboration Type 1 Diabetes (T1D) Bone Health Connection (PI: E. Yu, MD; Co-I: V.Aroda, MD). Previous studies have shown an increased risk for bone fractures in adult patients with T1D. Bone Health Connection is an observational, cohort study that aims to identify factors that contribute to this increased risk in hopes of developing future treatments to strengthen bone health in patients with T1D.

To convey the purpose of T1D to physician and patient populations, we will be creating versions of materials (ad template, letter, phone script, Rally Website post) in both a study and patient centric manner and measure T1D Bone Health Connections’ clinical trial recruitment engagement. We hypothesize that the patient centric approach will result in greater engagement and participation in the study.

Clinical trials are an effective process to advancing medicine and improving care. However, previous studies show that there are several challenges in engaging patients in clinical trials. For instance, 11% of sites fail to enroll a single patient, 37% of sites do not meet their enrollment goals and 40% of adults surveyed do not understand what a clinical trial entails (2013 Journal of Clinical Oncology). Complex trial protocols that are less relevant to the patient are correlated with diminishing likelihood of patient participation.

In Figure 1, the steps towards clinical trial recruitment are illustrated. We aim to improve steps 2 and 3 as the materials are developed and the mission for T1D Bone Health Connection is shared with possible participants and physicians.

In the T1D Bone Health Connection study, the MGH research team strives to: (1) compare 3D bone density, structure and strength of the hip and age-related changes in these outcomes in older adults with T1D to nondiabetic controls and (2) determine the influence of glycemic control, microvascular disease and advanced glycation end products (ACEs) accumulation on changes in femoral bone density, structure and strength in older adults with T1D.

The increased risk can be partially explained by lower bone mineral density (BMD) in patients with T1D or deficits in ACEs. To explore this further, the research team will work with participants to perform several measures indicated in Figure 2 over a 2-year study period. Certain measurements such as Continuous Glucose Monitoring (CGM) can be useful for the participant’s knowledge as well. This study will include 2 visits to MGH that will last 3-4 hours. Participants will be compensated by receiving up to $150. Our goals are to add a new perspective that will enhance the clinical trial recruitment process for T1D Bone Health Connection.

I would like to acknowledge mentorship and collaboration of Dr. Vanita R. Aroda and Dr. Elaine Yu, respectively, in providing the means to develop this study and create this poster.

Acknowledgements

References
3. Dr. Elaine Yu’s Protocol for Longitudinal bone health in adults with Type 1 Diabetes