

Core Messages: Women in Cardiovascular Clinical Trials

Patients

- **Clinical trials are research studies that explore whether a treatment approach or device is safe and effective for people. These studies also may show which medical approaches work best for certain illnesses or groups of people.**
 - Cardiovascular clinical trials are research studies designed specifically to determine whether a new product is safe to go to market for widespread use in patients with cardiovascular disease (CVD).
 - In addition, cardiovascular clinical trials can also be conducted after a product has been approved to collect information on long-term effectiveness, quality of life, and to better understand how the product is working.
 - Often these trials compare a new medical treatment to a standard one that is already available, or to no treatment. In all cases, enrolled patients receive the current gold standard of care, and in some cases, may even receive better care.

- **Historically, women have been underrepresented in cardiovascular clinical trials, making it difficult for researchers and clinicians to draw conclusions about the effects of new treatments on women.**
 - Clinical trials are often conducted with inadequate numbers of women.
 - Because of physiological differences between men and women, medical devices may affect each gender differently, including different side effects.
 - In addition, CVD can manifest itself differently in women than in men: Women often have subtler, less recognizable symptoms such as pain or discomfort in the stomach, jaw, neck or back, nausea and shortness of breath.
 - It is important that women participate in cardiovascular clinical trials to assess the benefits and risks of a new treatment given these physiological differences, and to demonstrate safety and effectiveness.

- **Significant challenges and barriers exist to recruiting women in to cardiovascular clinical trials.**
 - Women may present with CVD differently than men. Symptoms in women can include pain or discomfort in the stomach, jaw, neck or back, nausea and shortness of breath.
 - The result is that women may delay going to the doctor, discovering their heart disease at a later stage or when it's too late.
 - CVD in women may also be more difficult to diagnose, and health care providers may not recognize symptoms in women.

- Gender gaps in diagnosis of women with heart disease exist. Only 8% of primary care doctors, 13% of gynecologists and 17% of cardiologists were aware of heart disease as a greater cause of death in women than men.¹
 - The decision to participate in a clinical trial is often influenced by many factors, both behavioral and societal. On the behavioral side, women tend to be more risk averse than men in their decision-making processes, making them less likely to participate in a clinical trial.
 - On the societal side, women are often the primary caretakers for either children and/or elderly parents, and they may not feel that they have the time or ability to step away from these responsibilities to participate.
- **However, there are important benefits to women’s participation in cardiovascular clinical trials, and participation can help make a difference in a patient’s life, as well as the lives of future patients.**
- Volunteers in cardiovascular clinical trials participate in the development of medical therapies that may offer better treatments and even cures for life-threatening diseases affecting the heart and cardiovascular system.
 - By participating, women can play an active role in their health care, and often gain access to innovative new treatments before they are widely available.
 - Further, women can help to advance science and medical care by ensuring new treatments are safe and effective, and ultimately helping to make these treatments available to improve women’s health in the future.
 - Patients enrolled in a cardiovascular clinical trial receive the current gold standard of care, and in some cases, may even receive better care.
- **Physicians play an important role in referring and recruiting women to cardiovascular clinical trials, as many women are not aware that a cardiovascular clinical trial may be an option for them.**
- Women should feel empowered to ask their doctor about symptoms such as pain or discomfort in the stomach, jaw, neck or back, nausea and shortness of breath to rule out CVD.
 - If you have been diagnosed with CVD, ask your doctor about clinical trials being done for your disease. You can help yourself and other women by participating in trials.
 - Talking to your female friends and family members is important in raising awareness about CVD in women.

¹ Mosca L., et al. National Study of Physician Awareness and Adherence to Cardiovascular Disease Prevention Guidelines. *Circulation*. 2005 Feb 1; 111(4):499-510.