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media release

# Participants of cardiac clinic trials do not represent real world patients, study finds

*Study calls for broader enrollment in clinical trials to improve generalizability of studies in patients with heart disease*

TORONTO, ON, August 27, 2014 — A new analysis of clinical trial participation in the largest ongoing observational study of U.S. heart attack patients has found participants are not representative of the larger patient base, according to a study led by Women's College Hospital cardiologist Dr. Jay Udell. The study authors call into question the general applicability of the findings to the wider population, and suggest the use of broader enrollment criteria and existing patient registries to increase trial participation.

"We know that clinical trials can be tremendously expensive and a huge burden on our healthcare system," said Dr. Udell. "Our study shows participants often reflect a small portion of the typical patients we see in offices and hospitals, and we are missing a large number of potentially eligible patients who are right at our fingertips."

The study, published in the *Journal of the American Medical Association,* reviewed data collected from the American College of Cardiology's National Cardiovascular Data Registry of heart attack patients treated at 466 hospitals across the U.S from July 1, 2008 to March 31, 2011. The researchers found:

- Less than three per cent of patients (4,008 patients) were enrolled in the clinical trial during hospitalization.
- An estimated 66 per cent were eligible to participate but did not.
- Trial participants were:
    - Younger
    - More frequently male
    - Had less previous heart disease and shorter hospital stays
    - Had faster access to diagnostic testing, and
    - More frequently received recommended medical therapy within the first 24 hours of hospitalization, prescribed exercise and diet counseling, and referral to a cardiac rehab centre.
- Trial participants had the best health outcomes
- Those who were eligible to participate in the trial but did not had a nearly two times greater risk of dying compared to trial participants

While the findings are significant, the authors caution that trial participants are likely chosen because of anticipated health and compliance; added links between clinical trial participation and optimal health require further research. However, the authors emphasize the results provide valuable information that may help scientists find ways to improve clinical trial enrolment.

“Cardiac trial participants represent a low-risk population with more favourable care and outcomes compared with the typical heart attack patients we see in routine practice,” noted Dr. Udell. “What this tells us loud and clear is that we have an opportunity to do better -- there is a huge cadre of patients that we should be studying by better leveraging data from our national and provincial patient registries while continuing to maintain our highest standard of data privacy and safety.”

Clinical trials, a gold standard for testing new therapies and treatments for disease, are costly and often have poor enrollment.

“Rather than reinventing the wheel and continuing to perform each costly clinical trial starting from scratch, we should be using these registries to boost participation in clinical trials, so that we can minimize study co-ordination, data monitoring and clinical followup – all of which pose significant financial barriers to launching a clinical trial,” said Dr. Udell. “With minimal investment, we can transform our current electronic health records and healthcare service databases to serve this dual purpose, and provide an infrastructure with economies of scale to support multiple clinical trials at a fraction of the cost of one traditional study.”

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