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For immediate release

Canadian-led research shows integration of clinical and social sciences necessary to advance HIV vaccine clinical trials

With more than 40 HIV vaccine trials in various stages of progress around the world, researchers and industry experts are optimistic that a successful vaccine will be developed. Testing candidate vaccines ultimately involves human clinical trials, but recruiting trial volunteers can be difficult and planning needs to happen well in advance.

Canadian researcher Peter A. Newman, based at the University of Toronto, is collaborating with research teams in India and South Africa to determine to what extent potential volunteers understand clinical trials before they agree to participate. His work emphasizes strategies to optimize ethical approaches to conducting research with marginalized populations.

Newman's research focuses on recognizing and understanding the social, cultural, and language barriers to obtaining informed consent of trial participants. His team is using that understanding to develop and test more effective ways of explaining key HIV vaccine trial concepts as part of the informed consent process.

"We don't want trials to be built on misunderstanding because participants are then much more wary and may pull out of a trial. It's important that participants understand no one is trying to hurt them," says Newman, the principal investigator of a project on Social and Behavioural Research on HIV Vaccines, which is funded in part by a large-team grant through the Canadian HIV Vaccine Initiative (CHVI).

"Dr. Newman's work is setting the stage for vaccine uptake in the long term because it addresses the social and behavioural factors that are relevant to potential participants in future vaccine clinical trials," says Greg Hammond, Director of the CHVI Research and Development Alliance Coordinating Office (ACO). "The integration of social and clinical science is vital to advancing HIV vaccines."

Newman's current research is examining clinical trial comprehension levels of men who have sex with men (MSM) and sex worker communities in Mumbai and Chennai, India. Preliminary results show there is "widespread misunderstanding and lack of acceptance" of placebo and random assignment. Those misconceptions can cause clinical trial participants to become suspicious that the trials are somehow "cheating" them or, on the other hand, may result in the false belief that products tested in clinical trials will offer protection from HIV infection.

Researchers aim to use simple, sixth-grade language when explaining a clinical trial to potential volunteers, but Newman says investigators must also consider the cultural context and the potential for

perceived mistrust. “What is the way local communities understand and communicate about what a vaccine does? How are you engaging with trial participants beginning with their existing conceptions of HIV, vaccines and clinical trials? We can avert a lot of misunderstanding by asking such questions,” he says.

Engaging key local community leaders and educators early on is important because they are best suited to inform potential trial participants and enable decision-making that is truly informed. “It will pave the way to more effective communication and more solid clinical trials,” he says.

Newman’s work will be the subject of an upcoming webinar on the CHVI Research and Development Alliance Virtual Community (Alliance VC) – a web-based communication tool for the HIV vaccine research and development community. For more information about the Alliance VC, visit alliance-aco.ca.

The CHVI is a five-year collaborative initiative between the Government of Canada and the Bill & Melinda Gates Foundation, and represents a significant Canadian contribution to global efforts to develop a safe, effective, affordable and globally accessible HIV vaccine. The ACO was established by the Government of Canada and the Bill & Melinda Gates Foundation in 2011 at the International Centre for Infectious Diseases (ICID), a not-for-profit, non-governmental organization based in Winnipeg, Manitoba. The ACO is funded by the Public Health Agency of Canada.

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