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Extensive Study in Canada to Assess COVID-19 Vaccine Immune Responses and Effectiveness among People Living With HIV

NEWS RELEASE EMBARGO

MONTREAL, June 16, 2021 - People living with HIV are less likely to mount an adequate immune response, which may put them at higher risk for both serious COVID-19 illness and reduced response to COVID-19 vaccination. The Government of Canada, through its COVID-19 Immunity Task Force (CITF) and Vaccine Surveillance Reference Group (VSRG), is investing approximately \$1.75 million in a study that will assess the immune responses, safety, and effectiveness of COVID-19 vaccination for this vulnerable population that has been understudied with respect to COVID-19. The study is further supported by the Canadian Institutes of Health Research (CIHR), the CIHR Canadian HIV Trials Network (CTN) and Stop the Spread Ottawa, bringing the total funding to more than \$2.6 million.

Conducted by the CTN and a large team of co-investigators and collaborators from across Canada, the study, called COVAXHIV, is the most extensive study in Canada to date to evaluate the immunogenicity, safety and effectiveness of COVID-19 vaccination in a diverse population of people living with HIV.

"There have been very limited data from clinical trials for this at-risk community," says Dr. Aslam Anis, Principal Investigator, National Director of the CTN and Director of the University of British Columbia's School of Population and Public Health. "The results of this study will provide critical and timely evidence to inform immunization guidelines and public health strategies for all of the approximately 67,000 Canadians living with HIV."

A small number of people living with HIV who are in stable health and without other medical conditions have been included in previous clinical trials for COVID-19 vaccines, but the information is not generalizable to specific key vulnerable populations that have not been studied yet.

"Our COVAXHIV study focuses on older patients, those who have suppressed levels of white blood cells that fight infection (CD4 T-cells), and people with multiple medical conditions," explains CTN Co-Principal Investigator Dr. Cecilia Costiniuk, Associate Professor at McGill University's Faculty of Medicine and Health Sciences and Scientist at the Research Institute of the McGill University Health Centre (RI-MUHC).

Dr. Costiniuk and Co-Investigator Dr. Curtis Cooper, Associate Professor at the University of Ottawa's Division of Infectious Diseases and Scientist with The Ottawa Hospital, will recruit 400 people living with HIV from clinics in Montreal, Ottawa, Toronto, and Vancouver to determine COVID-19 immune responses. The first part of the study will evaluate how well antibodies react to fight off SARS-CoV-2, the virus that causes COVID-19, up to a year after vaccination. That data will be compared with the immune reactions from a control group of 100 people who do not have HIV.

The second part of the study will look at vaccine effectiveness in people living with HIV compared to people who do not have HIV through a population-based analysis of provincial public health records in Ontario and British Columbia. This part will be led by CTN Investigators Dr. Ann Burchell, Associate Professor at the University of Toronto and Research Director at St. Michael's Hospital's Department of Family and Community Medicine, Unity Health Toronto, and Dr. Hasina Samji, Assistant Professor at Simon Fraser University and Senior Scientist at the BC Centre for Disease Control and is supported in part by the Ontario HIV Treatment Network.

"We will follow more than 35,000 people living with HIV in both provinces to note COVID-19 vaccine uptake and rates of SARS-CoV-2 infection and hospitalization, which will allow us to study vaccine effectiveness in this population," explains Dr. Burchell. "We will also be looking at social determinants of health such as sex, age, geography and socioeconomic status to see what effects they have, if any, on the effectiveness of COVID-19 vaccines."

"We know that most existing vaccines require higher or additional doses to provide optimal protection for people living with HIV," says Dr. Catherine Hankins, member of the VSRG and a renowned HIV expert. "It is crucial to determine if this is also true with COVID-19 vaccines, especially for those within this population who are at higher risk for SARS-CoV-2 infection or for developing severe COVID-19 disease. With a vaccine rollout as massive as the current one underway, it is crucial to study the efficacy and safety of the vaccines in diverse priority populations such as people living with HIV. That is what the VSRG aims to do."

"COVID-19 has had significant health and social impacts on all people in Canada, but the negative impacts have been greater for vulnerable populations, including those living with and affected by HIV," says Canada's Chief Public Health Officer, Dr. Theresa Tam. "This study will help inform Canada's COVID-19 vaccine rollout, supporting the development of more effective immunization and public health strategies for vulnerable and diverse Canadians living with HIV."

Participants who have already received their first vaccine dose or have already had COVID-19 are eligible for the study. To participate or for more information about the immunogenicity study, please visit: https://www.hivnet.ubc.ca/study/ctn-328-covid-19-vaccine-in-hiv/.

About the CIHR Canadian HIV Trials Network (CTN)

The <u>CTN</u> is a Canada-wide partnership of researchers, people living with HIV and their caregivers, governments, health advocates, and the pharmaceutical and biotechnology industry. Together we have pioneered three decades of practice-changing clinical studies (including vaccine trials) in preventing, treating and managing HIV, hepatitis C (HCV), and other sexually transmitted and blood-borne infections (STBBIs). The CTN is represented by community and advocacy groups that voice the priorities of Canadians living with HIV. The CTN National Centre is housed within the Centre for Health Evaluation and Outcome Sciences, which shares a joint affiliation with the Providence Health Care Research Institute and the University of British Columbia Faculty of Medicine.

About the Vaccine Surveillance Reference Group

The Vaccine Surveillance Reference Group (VSRG) supports the monitoring of the safety and effectiveness of COVID-19 vaccines in Canada. It is a consortium of Canadian organizations —the Public Health Agency of Canada (PHAC), the Canadian Research Immunization Network (CIRN), the National Advisory Committee on Immunization (NACI), and the COVID-19 Immunity Task Force (CITF)— working collaboratively to pool expertise on vaccine surveillance. The VSRG reports to PHAC and is supported by the CITF Secretariat. It is co-chaired by the leaders of NACI and CIRN. Among its responsibilities, the VSRG, through the CITF Executive Committee, makes recommendations to PHAC on funding research teams that can address important aspects of the immune response, safety, and effectiveness of COVID-19 vaccines with public health relevance and with attention to all priority groups. For more information visit: https://www.covid19immunitytaskforce.ca/vaccine-surveillance-reference-group-vsrg/

About the COVID-19 Immunity Task Force

The Government of Canada established the COVID-19 Immunity Task Force in late April 2020. The Task Force is overseen by a Leadership Group of volunteers that includes leading Canadian scientists and experts from universities and healthcare facilities across Canada who are focused on understanding the nature of immunity arising from the novel coronavirus that causes COVID-19. To that end, the CITF is supporting numerous studies to determine the extent of SARS-CoV-2 infection in Canada (in the general population as well as in specific communities and priority populations), understand the nature of immunity following infection, develop improved antibody testing methods, and help monitor the effectiveness and safety of vaccines as they are rolled out across Canada. The Task Force and its Secretariat work closely with a range of partners, including governments, public health agencies, institutions, health organizations, research teams, other task forces, and engages communities and stakeholders. Most recently, the Task Force has been asked to support vaccine surveillance, effectiveness and safety as part of its overall objective to generate data and ideas that inform interventions aimed at slowing—and ultimately stopping—the spread of SARS-CoV-2 in Canada. For more information visit: https://www.covid19immunitytaskforce.ca

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