Canadian HIV Vaccine Initiative Achievements Report



PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH



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TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.

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Table of contents

Executive summary	1
Introduction	4
Background	4
Conclusion	9
CHVI-funded research projects and activities	9
Sample of publications and conference presentations generated by chvi projects	.10

Executive summary

The CHVI, which concludes in March 2017, has been a unique collaboration between the Government of Canada (GoC) (the Public Health Agency of Canada (PHAC); Health Canada (HC); the Canadian Institutes of Health Research (CIHR); Innovation, Science and Economic Development (ISED).; the National Research Council (NRC); and Global Affairs Canada (GAC).) and the Bill & Melinda Gates Foundation (BMGF) to further strengthen global efforts to accelerate the development of a safe, effective, affordable and globally accessible HIV vaccine. An investment of \$139M (GoC - \$111M from existing resources; BMGF - \$28M.^a) was made to support CHVI activities since 2007, a small investment considering that, in 2009, the total costs of HIV in Canada (loss of quality of life, health care costs, and productivity loss) was estimated at just over \$4 billion.^b.

In general, HIV incidence both in Canada and around the world appears to be declining; however, HIV still affects a significant number of people, particularly in Africa, prompting continued work and research to find ways to prevent and/or eradicate HIV. Through its activities, CHVI has contributed to that body of work. It has been a key element in Canada's commitment to, and strategy for, a comprehensive, long-term approach to addressing HIV/AIDS domestically and internationally, and aligns with current GoC priorities.

There are many steps on the road to an HIV vaccine from basic lab research, to developing a candidate vaccine, to testing it in regulated clinical trials, to finally getting it approved for use and getting it manufactured. Each step in the process can take several years. For example, a vaccine for the Human Papillomavirus took approximately 20 years from initiation to approval for use. CHVI contributed to global efforts to develop an effective HIV vaccine through activities in five main areas: Advancing the Basic Science of HIV Vaccines; Translating Basic Science; Addressing Enabling Conditions; Preventing Mother-to-Child Transmission of HIV; and Supporting Coordinated Efforts (see Appendix I for more details).

Overall, CHVI activities served to advance global research and development (R&D) on HIV vaccine research and other HIV-related research, and to increase the visibility of Canadian HIV vaccine research, both domestically and internationally:

Collaborations among HIV vaccine researchers in Canada and low- and middle-income countries (LMICs) were supported and strengthened, with the aim of creating international teams which would contribute to HIV vaccine discovery and social research, and training the next generation of HIV vaccine researchers. More than 50 grants, that emphasized a multidisciplinary approach and tapped into the unique strengths and knowledge of researchers in both Canada and LMICs, were awarded. The results of the research that was conducted through CHVI investments added to the body of knowledge for HIV vaccine and HIV-related subjects through publications in peer-reviewed journals and conference presentations (see Appendix III). While some projects are still in early stages, they are expected to lead to larger research trials and to inform practices for future HIV vaccine trials.

^{*} Formerly Industry Canada and the Department of Foreign Affairs, Trade and Development respectively.

^a BMGF's actual grant total was \$35.9M, with increased funding primarily targeting the area of "translating basic science into clinical trials".

^b The Economic Cost of HIV/AIDS in Canada, Canadian Aids Society, 2011.

- Knowledge sharing amongst researchers improved, generating numerous publications, presentations and seminars; resulting in new diagnostic approaches and tools for HIV vaccine research, and communities with greater awareness of vaccine preparedness, and engagement for trials and vaccine development. The research collaborations and knowledge sharing activities also resulted in better-trained scientists in LMICs, and allowed involved trainees, junior researchers and students to complete advanced degrees.
- Through 29 projects, the number and *capacity* of 23 Canadian small- and medium-sized enterprises (SMEs) conducting R&D on HIV vaccine development and other technologies related to the prevention, treatment, and diagnosis of HIV increased. This funding allowed some firms to further advance their technology toward *commercialization*.
- A focus on the policy and regulatory environment to better prepare Canadian communities and LMICs for future vaccine clinical trials was highly successful: in Africa, CHVI efforts contributed to the doubling of the number of member countries of the African Vaccine Regulatory Forum capable of conducting vaccine clinical trials using internationally-accepted ethics, regulatory approvals and oversight.
- Progress on prevention of HIV/AIDS was made in strengthening the capacity of countries with a high prevalence of HIV/AIDS to prevent mother-to-child transmission of HIV (PMTCT) resulting in improved delivery and uptake of PMTCT services.

The achievements of the CHVI extended beyond its stated objectives. For example, it created a more cohesive and synergistic HIV vaccine research community through expanded and improved information sharing and knowledge transfer, and by enabling partnerships to form amongst government, academia and industry. The skills gained by LMICs through CHVI capacity-building activities have benefited other vaccine-related research. For example, increased capacity to conduct clinical trials writ large and to meet internationally-accepted ethics and regulatory approvals and oversight has led to successful vaccines now in use in the African region (e.g., conjugate meningitis A, rotavirus, human papillomavirus). Some research findings from CHVI projects have leveraged additional research grants to pursue related lines of research. For example, a finding from a project researching immune responses in HIV exposed uninfected infants in Africa led to a grant to study microbiota in infants' guts. The collaboration with the BMGF facilitated subsequent collaborations on other shared priorities, such as Ebola and Hepatitis C. CHVI also made it possible for CIHR and the BMGF to directly collaborate on research to improve understanding on the mucosal immune response to HIV. In fact, involvement in CHVI has enabled CIHR to leverage its investments in HIV research threefold.

The development of any vaccine is a long, complex process that can take years to complete. It has been more challenging compared to other vaccines, and despite the many developments in the HIV vaccine field, a vaccine remains elusive. CHVI has made a strong contribution to the overall field of HIV vaccine research, and its effects will endure beyond its completion in 2017. The numerous publications and presentations generated from the more than 100 projects have advanced and disseminated knowledge in the areas of HIV vaccine research and other HIV-related research. Additional publications may be generated in the final year of the CHVI. It enabled private sector companies to conduct HIV vaccine and other HIV technologies-related research and move their technology towards commercialization. Researchers in both Canada and LMICs will be able to use their work with CHVI to leverage future funding; this has already been happening. For example, the 9 capacity-building projects carried out in Africa all

succeeded in obtaining additional grants. Researchers and communities in LMICs are better equipped to conduct their own research and in turn contribute to research globally, a notable accomplishment. Collaborations and relationships that have been established will continue or lead to new ones; again, this has already borne out. Useful mechanisms for collaboration, knowledge sharing, networking and mentoring, such as the Alliance of researchers and webinars provide a valuable platform from which to continue these activities. And, in absence of an effective vaccine, the activities undertaken to increase the quality, access and uptake of PMTCT services will in turn reduce the incidence of mother-to-child transmission of HIV.

As a final note, the GoC's science and technology (S&T) system is evolving into a science and innovation ecosystem with an emphasis on networks of collaborative, multidisciplinary partnerships in order to draw upon the scientific expertise required, wherever it resides, to address national priorities. The concept of the CHVI is an excellent representation of such an ecosystem through its coordinated and collaborative undertaking, by various means, that brought together actors from different disciplines and settings to spur HIV vaccine development. And it did so in a cost-effective manner by utilizing existing funding mechanisms and by leveraging additional funding from other sources.

The way forward

As with S&T in general, the HIV research landscape is shifting. HIV vaccine trials are becoming more complex and costly to run because of the need to incorporate new HIV prevention technologies such as Pre-exposure prophylaxis and microbicides into study designs. There is also increasing attention and funding being put to HIV cure research. In recent years, there's been a shift in research funding for clinical trials (decrease) and for basic research (increase). In response to this changing landscape, there is a movement towards considering a more integrated and comprehensive approach to HIV prevention research. In 2014, the first Research for Prevention (HIV R4P) conference was held, bringing together researchers from around the world working in all areas of HIV prevention research. The broader focus on HIV prevention could help researchers gain a greater understanding of HIV immunology and to find solutions for cross-cutting issues.

The GoC remains committed to addressing HIV/AIDS in Canada and contributing to global efforts. Canada will continue to support HIV vaccine-related research under existing programs such as the Federal Initiative to Address HIV/AIDS in Canada. Canada will build on the achievements of the CHVI and will continue to work on comprehensive approaches to addressing HIV/AIDS prevention and treatment including vaccine research.

Introduction

HIV continues to be a major global public health issue. According to the World Health Organization (WHO), approximately 36.9 million people were living with HIV at the end of 2014, with Sub-Saharan Africa being the most affected region (25.8 million). Women and children make up 54% (17.4 million and 2.6 million respectively) of the total number of people living with HIV worldwide. In Sub-Saharan Africa, mother-to-child transmission of HIV remains an issue. Between 15% and 45% of children born to HIV-positive women can become infected with the virus during pregnancy, delivery, or breastfeeding. Interventions to prevent mother-to-child transmission of HIV can reduce the risk of transmission to less than 5%^c. In 2014, 2 million people became newly infected with HIV globally, with sub-Saharan Africa accounting for almost 70% of the global total^d. In Canada, an estimated 75,500 people were living with HIV at the end of 2014, with 2,570 people newly infected in that year.^e.

The development of an HIV vaccine is a challenge due to the nature of HIV, the lack of a natural protective response to it, and the inability to accurately predict the human immune response to HIV. Social and institutional barriers—such as difficulty recruiting volunteers to participate in HIV vaccine clinical trials, and insufficient capacity among African regulatory authorities to review and monitor clinical trials taking place in Africa—present additional challenges for HIV vaccine development. Still, a safe and effective preventative HIV vaccine is considered to be the best hope, as well as the most efficient and cost-effective means of controlling or eradicating HIV. This provided an impetus for the Government of Canada (GoC) and the Bill and Melinda Gates Foundation (BMGF) to partner on the Canadian HIV Vaccine Initiative (CHVI).

Background

The CHVI is a collaboration between the GoC (the Public Health Agency of Canada (PHAC); Health Canada (HC); the Canadian Institutes of Health Research (CIHR); Innovation, Science and Economic Development (ISED).^{*}; the National Research Council (NRC); and Global Affairs Canada (GAC).^{*}) and the Bill & Melinda Gates Foundation (BMGF) to further strengthen global efforts to accelerate the development of a safe, effective, affordable and globally accessible HIV vaccine. An investment of \$139M (GoC - \$111M from existing resources; BMGF - \$28M^f) was made to support CHVI activities.

In 2010, as a result of a significant increase in private sector HIV vaccine pilot scale manufacturing facilities in North America and Europe (a major plank when CHVI was initiated), funding originally earmarked for a manufacturing facility was reallocated to the key areas and governance structures identified in a renewed CHVI. CHVI concludes in March 2017.

^c <u>http://www.who.int/hiv/topics/mtct/en/</u>

^d HIV/AIDS Fact Sheet No. 360, World Health Organization, November 2015

^e Summary: Estimates of HIV Incidence, Prevalence and Proportion Undiagnosed in Canada, 2014, Public Health Agency of Canada, November 2015

⁺ Formerly Industry Canada and the Department of Foreign Affairs, Trade and Development respectively.

[†] BMGF's actual grant total was \$35.9M, with increased funding primarily targeting the area of "translating basic science into clinical trials".

The CHVI has been a key element in Canada's commitment to, and strategy for, a comprehensive, long-term approach to addressing HIV/AIDS domestically and internationally.*, and aligns with current GoC priorities. It served to mobilize Canadian HIV vaccine expertise to address gaps identified in the Scientific Strategic Plan (SSP), which was developed by more than 120 experts from 15 countries, WHO and UNAIDS and other international collaborators, under the auspices of the Global HIV Vaccine Enterprise (the Enterprise) established by the BMGF and the United States National Institutes of Health.

The Enterprise was established in 2004 with the aim to accelerate the development of preventive HIV vaccines by implementing the SSP, increasing and mobilizing significant new funding, and enhancing collaboration among HIV vaccine researchers. Canadian expertise aligned well with the objectives of the Enterprise, and the CHVI was seen as a significant Canadian contribution to global HIV vaccine efforts and to strengthening the capacity to undertake HIV vaccine research and development in in low- and middle-income countries (LMICs).

PHAC provided the lead on the CHVI and through the CHVI Secretariat, ensured the horizontal coordination across partner departments/agencies and with the BMGF. CHVI Ministers and the BMGF were provided with strategic advice and direction, and recommendations on projects to be funded through the CHVI by an Advisory Board, made up of three external experts, three representatives of the BMGF, and the Director of the CHVI Alliance Coordinating Office (ACO), all leaders in their respective fields. The ACO, housed within the International Center for Infectious Diseases, provided administrative support to the Advisory Board, and created and promoted a network of HIV researchers (the Alliance).

To address its mandate, the CHVI sought to:

- Advance the basic science of HIV vaccine discovery and social research in Canada, and in LMICs;
- Support the translation of basic science discoveries into clinical research, with a focus on accelerating clinical trials in humans;
- Address enabling conditions to facilitate regulatory approval and community preparedness;
- Prevent Mother-to-Child Transmission of HIV (PMTCT) by enhancing the accessibility, quality, and uptake of services in LMICs; and
- Support coordinated efforts to enable horizontal collaboration within CHVI and with domestic and international stakeholders.

The following highlights the key achievements associated with each of the areas:

Advancing the Basic Science of HIV Vaccines (ABS) (\$30M)

(CIHR - \$15M; GAC - \$12M; BMGF - \$3M)

<u>Objective</u>: to strengthen the capacity of, and promote greater involvement and collaboration amongst, researchers in Canada and in LMICs working in HIV vaccine discovery and social research.

Through over 60 vaccine-related research projects involving investigators from Canada, Africa, India, the U.S., New Zealand, and Switzerland, the CHVI made a strong contribution to HIV

^{*} The Government of Canada's domestic approach to addressing HIV/AIDS is framed by the Federal Initiative to Address HIV/AIDS in Canada and CHVI; its global contribution is led by Global Affairs Canada.

vaccine discovery and social research, and preparing the next generation of HIV vaccine researchers both in Canada and in LMICs. These projects made progress in advancing novel ideas, tools, approaches, and best practices, which will feed into future research to help develop an HIV vaccine. Research findings were made available to the HIV vaccine community through publications and conference presentations for use by other researchers, thus contributing to the global effort to find an HIV vaccine. Appendix II provides an indication of the breadth of research supported through the CHVI, while Appendix III provides a list of some of the publications and conference presentations they generated.

One of the key achievements of these projects was the relationships and synergies strengthened and developed both among team members and with other research teams working in HIV vaccine research. The multidisciplinary nature of the teams and collaboration with international researchers facilitated the exchange of ideas and knowledge, thus advancing research faster than what would have been possible for researchers working on their own. Bringing team members together from across the HIV research field provided opportunities to bring new "out of the box" ideas to HIV vaccine research that may lead to potential discoveries and has laid the groundwork for future research collaborations. The team grants, in particular, which linked researchers from Canada and LMICs, yielded positive and potentially lasting results, including future collaborations amongst team members, the potential to pursue new research paths, and the formation of new collaborations.

CHVI projects strengthened the field of HIV vaccine researchers, both in Canada and LMICs, by helping trainees and junior researchers increase their capacity to conduct HIV vaccine research, allowing them to pursue higher education and advancing their careers. Senior researchers became mentors and leaders in the area of HIV vaccine research.

Perhaps most importantly, the CHVI projects strengthened the capacity of LMICs to conduct their own HIV vaccine research, and to apply their new-found knowledge and skills to other health issues affecting their countries.

Translating Basic Science into Clinical Trials in Humans (TBSCT) (\$60M) (GAC - \$16M; BMGF - \$26M; ISED - \$13M; PHAC - \$5M)

<u>Objective</u>: to assist researchers, in the public and private sectors, in moving promising HIV vaccine candidates from preclinical research into clinical trials in humans.

Under this area, Canadian small- and medium-sized enterprises (SMEs) were provided funding to develop an HIV vaccine and other technologies related to the prevention, diagnosis, and treatment of HIV. To date, 29 projects were funded (see Appendix II). While systemic barriers for SMEs persist in the pursuit of an HIV vaccine (e.g., lack of financing, lack of vaccine candidates), research and development (R&D) activity in HIV-related technologies increased as a result of funding. For some firms, the available funding was a catalyst to enter the field of HIV vaccine research. Project funding also increased SMEs' capacity to conduct HIV vaccine and other HIV technologies-related R&D, and enabled them to move their technology further towards commercialization, led to new research findings, and the development of new technologies. For example, a whole-virus method developed by one firm that could potentially prohibit both the initial acute infection and the establishment of a latent reservoir of HIV virus in cells, was subsequently used in a Phase I clinical trial on a vaccine candidate.

Through the CHVI, the capacity of researchers in LMICs to conduct HIV prevention trials were strengthened and physical infrastructure was upgraded through 9 research projects (involving researchers from 23 countries and conducted at 30 sites), 5 complementary grants, and 10 pilot awards to young researchers. These projects generated more than 70 peer-reviewed publications and more than 50 conference presentations. Researchers and students received training in good clinical laboratory practice, qualitative and quantitative research skills, research management, and ethics. Researchers' new skills translated into new opportunities. For example, based on the strengths they acquired through their involvement in the CHVI, the Senegal team was selected to perform part of phase 2 trials of an Ebola vaccine, funded by the Canadian Partnership on Ebola Vaccine.

Collaborations amongst the nine research teams were increased and greater synergies and complementarities were achieved across the research teams, with other CHVI research teams, and with other global efforts to build capacity for HIV prevention trials. These efforts resulted in additional funding in excess of \$14M and new collaborations with other organizations such as CIHR, McGill University and the European & Developing Countries Clinical Trials Partnership.

Addressing Enabling Conditions (AEC) (\$19.4M)

(BMGF - \$6.9M; PHAC - \$5.5M; HC - \$5M; GAC - \$2M)

<u>Objective</u>: to better prepare LMICs and Canada for future HIV vaccine clinical trials by focusing on policy and regulatory issues related to vaccine clinical trials.

Regulatory capacity to conduct HIV vaccine clinical trials was strengthened in both LMICs and Canada through knowledge exchange, training and mentoring. Conferences, workshops, and satellite sessions were used to bring together National Regulatory Authorities (NRA) in LMICs to share knowledge about systems, tools, approaches, current challenges, and lessons learned; to network with regional and international regulators; and to learn about specific subjects such as biologics and quality review, and building relationships between ethics boards and regulatory authorities. A mentorship program was developed to address specific regional needs and challenges. For example, NRAs in Malawi and Nigeria were trained in various processes and procedures to better equip them to deal with the policy and regulatory processes related to clinical trials.

Through support to the World Health Organization's (WHO) African Vaccine Regulatory Forum (AVAREF), a network of NRAs and national Ethics Committees in 19 African countries, the GoC played a role in strengthening countries' regulatory capacity for vaccines to provide reviews, approvals, and oversight of vaccine trials. The provision of advice, and technical and regulatory expertise aided in the development of guidelines, norms and standards for vaccine regulation, and a platform for online collaboration and information exchange. These efforts have resulted in increased capacity of these countries to conduct vaccine clinical trials with internationally accepted ethics, regulatory approvals and oversight. While these improvements have largely benefited the conduct of clinical trials for vaccines in general, it is expected that the skills learned and knowledge gained will be transferable to HIV vaccine clinical trials.

Finally, the capacity and knowledge of Canadian and LMIC organizations and communities were strengthened, through the development of toolkits, training tools, workshops and outreach activities, so that they would be able to support potential future vaccine trials and new prevention technologies.

Preventing Mother-to-Child Transmission of HIV (PMTCT) (\$30M) (GAC)

<u>Objective</u>: to increase the quality, access and uptake of PMTCT services, and to help reduce the spread of HIV in the absence of a safe and effective vaccine.

While separate from CHVI's other vaccine-related activities, activities to improve the quality, access and uptake of PMTCT services provided an important interim measure to address the PMTCT gap in the absence of an HIV vaccine. Grants were provided to WHO and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) to enhance access, quality and uptake of services to PMTCT of HIV by determining innovative and effective implementation strategies and programmatic solutions to overcome existing barriers and bottlenecks, and to enhance PMTCT service delivery. The WHO project (six projects, two each in Malawi, Nigeria, and Zimbabwe) resulted in strengthened collaborations between researchers, health workers and community leaders, and significantly increased the capacity of health care workers. Since this project began, over 2,600 health care workers were trained in areas such as good clinical practices, service delivery, implementing national protocols, data collection and management, and research techniques; and almost 5,000 mother-infant pairs have been enrolled over the six projects (47%-188% of target enrolment). One project in Malawi was able to leverage additional funding from a number of sources for a sub-study monitoring the effects on infants exposed to antiretroviral drugs given to HIV-infected mothers during breastfeeding.

The EGPAF project resulted in an increase in antenatal care before 20 weeks, facility deliveries, and male partner HIV testing. The project also strengthened collaboration among researchers and health care workers, engaged community leaders to share knowledge at the community level and to promote the uptake and adherence to interventions related to PMTCT.

Supporting Coordinated Efforts (SCA) (\$7.5M) (PHAC)

<u>Objective</u>: to strengthen the coordination of Canadian HIV vaccine-related activities with other global efforts.

Together, the CHVI Secretariat and the ACO strengthened the coordination of Canadian HIV vaccine-related activities with other global efforts. An Alliance network (now consisting of 300+ members) of leading researchers from the public and private sectors, and from the international community, government agencies, international HIV/AIDS organizations, and national community organizations was created.

Through this network and other activities, opportunities were created for information and knowledge dissemination and exchange, research collaboration, networking, mentoring, and learning for both domestic and international HIV vaccine researchers. For example, the ACO regularly provided training webinars and workshops to new and early career researchers. It published a monthly e-bulletin that showcased researchers, and provided information on upcoming events and conferences, funding opportunities, and new HIV vaccine research. It also promoted the CHVI to external audiences through its website, social media, and international conferences. The overall results have been a greater number of collaborations among HIV researchers and other disciplines, improved communication between and amongst researchers, more new and early career investigators entering the field of HIV vaccine research, and increased visibility of Canadian HIV vaccine research to multidisciplinary audiences.

Projects supported by the Bill & Melinda Gates Foundation (BMGF)

HIV is one of the leading priorities of the BMGF. Its goal is to support efforts to reduce the global incidence of HIV significantly and sustainably, and to help people infected with HIV lead long, healthy, and productive lives. Efforts are focused on the poorest hyper-endemic countries of Sub-Saharan Africa. The BMGF's largest investment is in vaccine research and development, one of six areas in which it invests to advance the development and delivery of new HIV prevention methods while improving the efficiency and effectiveness of existing prevention and treatment efforts. The BMGF provides funding to move novel product concepts toward human clinical trials through to investments in late-stage clinical trials.

Under the auspices of the CHVI, the BMGF supported projects in the areas of Advancing Basic Science, Translating Basic Science into Clinical Trials in Humans, and Addressing Enabling Conditions. For example, BMGF funding supported projects aimed at: gaining a better basic understanding of HIV-mucosa interactions and immune responses; enhancing biostatistical, computational biology, and mathematical modeling research for assessing correlates of vaccine efficacy in randomized clinical trials; seeking new biomarkers that reliably identify recently HIV infected individuals; developing an immunology laboratory in Cape Town, South Africa; and advancing promising HIV vaccine candidates to licensure through investments in late-stage clinical trials, such as the Pox-Protein Public Private Partnership.

Conclusion

Overall, the CHVI was successful in achieving its expected outcomes, and it did so by leveraging additional funding and using pre-existing funding mechanisms to ensure the optimization of resource use. Since the launch of CHVI in 2007, the HIV vaccine environment has evolved. Advances in HIV/AIDS research has led to a change in the research focus and priorities of major funders and players, with activities falling under three main areas of interest: HIV vaccine R&D and advancing a comprehensive approach to prevention, investigating early treatment and achieving functional cure, and exploring cross-cutting research themes (e.g., mucosal immunology). The completion of the CHVI and the changing HIV vaccine environment mark an opportunity for Canada to refocus its priorities and scope of activities. The objectives set out for the CHVI remain relevant: Canada will continue its commitment to work in partnership with its domestic and international partners, and to support HIV vaccine-related research. It is believed that Canada's strengths in HIV vaccine and vaccine-related R&D, and the foundation laid through CHVI, Canada's contribution to the field, both domestically and globally, can be met by the existing Federal Initiative to Address HIV/AIDS in Canada.

CHVI-funded research projects and activities

To obtain a PDF copy of CHVI- funded research projects and activities, or for any comments or inquiries, please contact <u>ccdic-clmti@phac-aspc.gc.ca</u>.

Sample of publications and conference presentations generated by CHVI projects

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