Community-Driven Research on *H. pylori* Infection in the Inuvialuit Settlement Region

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Abstract

Despite limited systematic data on its presence in northern Canada, Helicobacter pylori infection has been an emerging health concern in northern Aboriginal communities, where people are becoming aware of its health risks. In many such communities, people worry about the link between H. pylori and stomach cancer, a cancer that occurs more frequently in this region than on average across Canada. Physicians in the north view this infection as a major challenge because it is found in many patients with common stomach complaints and standard treatment is often ineffective in this setting. Health authorities have identified the need for research aimed at developing H. pylori control strategies appropriate for the north. This research program seeks to generate knowledge about how health care decision makers can effectively manage H. pylori infection in a manner that addresses community concerns. To achieve these goals, the applicants formed the Canadian North Helicobacter pylori (CANHelp) Working Group, a collaborative team that links the University of Alberta with northern health officials and community organizations. While the research goals require data from multiple northern settings, the team conducted a pilot project as a starting point in Aklavik, NWT, where they found that 61% of participants had H. pylori infection, and among those infected, there was a high prevalence of precancerous stomach conditions. This research program, developed at the request of the Inuvialuit Regional Corporation, aims to: 1) Expand the research to additional communities in the Inuvialuit Settlement Region to obtain representative data required for developing regional public health strategies pertaining to H. pylori infection; 2) Identify cost-effective and culturally appropriate H. pylori management strategies for northern communities; 3) Create knowledge exchange strategies to help community members understand H. pylori health risks and currently available solutions.

Key Messages

- Health risks from *H. pylori* infection include chronic digestive problems, stomach ulcers and in rare instances, stomach cancer
- Chronic *H. pylori* infection induces chronic inflammation of the stomach lining, glandular atrophy and intestinal metaplasia, which are all associated with increased risk of stomach cancer
- Communities in the Inuvialuit Settlement Region (ISR) are concerned about health risks from *H. pylori* infection
- Community leaders seek research to understand the health risks and develop locally appropriate strategies for reducing these risks throughout the Inuvialuit Settlement Region
- The Canadian North Helicobacter pylori (CANHelp) Working Group formed to link University of Alberta investigators with northern community leaders and health care providers in the conduct of research aimed at addressing community concerns about health risks from *H. pylori* infection
- The Aklavik *H. pylori* Project, the initial project of the CANHelp Working Group, found that:
    1. Of 355 participants tested, 61% were *H. pylori*-positive
    2. Around 90% of *H. pylori*-positive participants had moderate to severe inflammation of the stomach lining
    3. Of treatments investigated in Aklavik, early results show that a 4-drug regimen is much better than the 3-drug regimen most commonly used in Canada to treat *H. pylori* infection (HP-Pac), but we need more data to be sure about this
    4. In addition, the treatments are burdensome and more research is needed to find out how to make the treatments more effective
    5. Follow-up *H. pylori* testing in Aklavik suggests that most people who were successfully treated remained *H. pylori*-free during the next 2-3 years
    6. Our research so far has not pinpointed an environmental source of *H. pylori* in Aklavik or other northern Canadian communities where *H. pylori* projects are being carried out

7. This is consistent with findings of research around the world: the evidence suggests that most people with *H. pylori* infection get it from direct contact with a person who has the infection

- Information from additional northern communities is needed to fulfill the CANHelp Working Group research goals
- The Inuvialuit Regional Corporation (IRC) asked the CANHelp Working Group to expand the research to additional ISR communities
- At the request of the ICR, the University of Alberta researchers of the CANHelp Working Group and the IRC executed a written research agreement for the ISR *H. pylori* Project
- The ISR *H. pylori* Project was launched in Tuktoyaktuk in February 2011
- In March 2013, University of Alberta gastroenterologists traveled to Inuvik to offer Tuktoyaktuk project participants upper gastrointestinal endoscopy at the Inuvik Regional Hospital as part of a pilot for expanding participation to other ISR communities
- To date, 107 Tuktoyaktuk residents consented to participate in the ISR *H. pylori* Project; approximately 90 participants completed questionnaire-based interviews; 104 were tested for *H. pylori* infection (proportion positive: 56%); 13 consented to upper gastrointestinal endoscopy, 13 had biopsies for culture and histopathology obtained, 25 have been assigned treatment and 13 enrolled in the treatment trial
- Long-term follow-up is ongoing in Aklavik and Tuktoyaktuk, as is analysis of questionnaire data and reporting research results back to the community
- The CANHelp Working Group has plans to facilitate participation in the ISR *H. pylori* Project to all interested ISR residents.

Objectives

Helicobacter pylori infection, linked to peptic ulcer disease and stomach cancer, is a health concern in northern Aboriginal communities, where people are aware of its health risks. Health care providers in the north view this infection as a major challenge because it is found in many patients with common stomach complaints and standard treatment is often ineffective in this setting. This research program seeks to generate knowledge about how health care decision makers can effectively manage *H. pylori* infection in a manner that addresses community concerns. While the research goals require data from multiple northern settings, the team conducted a pilot project as a starting point in Aklavik, NWT, where they found that a high prevalence of *H. pylori* infection, and among those infected, a high prevalence of precancerous stomach conditions.

This research program aims to:

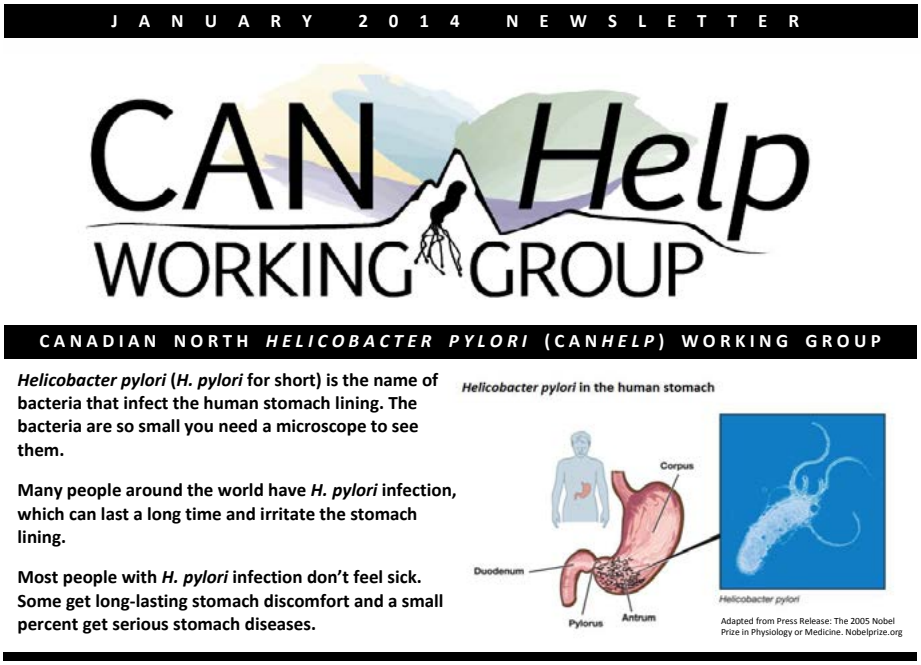
1. Expand the research to additional communities in the Inuvialuit Settlement Region to obtain representative data required for developing regional public health strategies pertaining to *H. pylori* infection;
2. Identify cost-effective and culturally appropriate *H. pylori* management strategies for northern communities;
3. Create knowledge exchange strategies to help community members understand *H. pylori* health risks and currently available solutions.

Introduction

Helicobacter pylori infection has been a health concern in some northern Aboriginal communities, where people are aware of its health risks. In many such communities, people worry about the link between *H. pylori* and stomach cancer, a cancer that is more common in this region than on average across Canada. Northern health care providers see this infection

as a challenge because it is found in many patients evaluated for stomach complaints, but treatment in this region is often ineffective. Public health authorities have identified the need for research to develop locally appropriate *H. pylori* control strategies.

This research program was developed at the request of the Inuvialuit Regional Corporation (IRC) on behalf of communities in the Inuvialuit Settlement Region (ISR) of western Canada. The goal is a comprehensive investigation of *H. pylori* infection in ISR communities so that such communities are represented in a broader research agenda that aims to develop public health strategies for *H. pylori* infection in northern Canada. This research seeks to generate knowledge about how northern health authorities can manage *H. pylori* infection in a manner that addresses community concerns about health risks. To achieve



JANUARY 2014 NEWSLETTER

CAN Help WORKING GROUP

CANADIAN NORTH *HELICOBACTER PYLORI* (CAN*HELP*) WORKING GROUP

***Helicobacter pylori* (*H. pylori* for short) is the name of bacteria that infect the human stomach lining. The bacteria are so small you need a microscope to see them.**

Many people around the world have *H. pylori* infection, which can last a long time and irritate the stomach lining.

Most people with *H. pylori* infection don't feel sick. Some get long-lasting stomach discomfort and a small percent get serious stomach diseases.

***Helicobacter pylori* in the human stomach**

Adapted from Press Release: The 2005 Nobel Prize in Physiology or Medicine. Nobelprize.org

Why northern Canada?

Helicobacter pylori (*H. pylori*) infection is common across Arctic communities and stomach cancer rates are relatively high in this region. *H. pylori* is a community health concern in northern Canada due to awareness of its link to stomach cancer.

The Canadian North *Helicobacter pylori* (CAN*Help*) Working Group was established in response to concerns expressed by community members in the Yukon (YT) and Northwest Territories (NT). Northern health authorities also sought information to improve clinical management of *H. pylori* infection and inform related public health policy.

The CAN*Help* Working Group is a collaborative team made up of researchers from the University of Alberta, and northern community leaders, as well as northern health providers and health officials. Our aims are to address community concerns about health risks from *H. pylori* infection and exchange knowledge with community members and decision makers to identify ways to reduce health risks from this infection.

Research Goals

Our research goals, based on the priorities of the participating communities and their health care providers are to conduct:

1. **Community-driven research projects to characterize the burden of disease from *H. pylori* infection**
2. **Policy analysis to recommend *H. pylori* control strategies**

Figure 1a. Example of the CANHelp Working Group newsletter for January 2014, page 1of 2.

these goals, the research team formed the Canadian North Helicobacter pylori (CANHelp) Working Group to link northern community organizations and health officials with University of Alberta researchers (Figure 1a and b).

To develop this research, the CANHelp team initiated a pilot project in Aklavik, NWT, focused on: investigating the burden of disease and risk factors associated with *H. pylori* infection in the Aklavik population; identifying effective therapies; and developing knowledge exchange strategies that address community concerns. This preliminary research has shown that 61% of Aklavik's project participants had *H. pylori* infection, and among those infected there was a high prevalence of severe inflammation and precancerous lesions in the stomach. In a trial to compare standard treatment against a new regimen in

J A N U A R Y 2 0 1 4 N E W S L E T T E R

Community Projects

Community Project	Participants Recruited	Urea Breath Tests Completed	Endoscopy Participants	Treatment Participants
Aklavik	376	333	200	113
Old Crow	200	193	65	70
Tuktoyaktuk	107	104	13	13
Fort McPherson	226	217	58	60

Community Project (Start Year)	Data Collection	*H. pylori*-Positive (By Urea Breath Test)	Gastritis Severity in *H. pylori*-Positive Participants[1]	Treatment Success[2,3]	Knowledge Exchange
Aklavik (2007)	Complete	58% (194/332)	Mild: 8% Moderate: 47% Severe: 43%	3-drug: 50% (24/49) Seq: 70% (28/40)	Ongoing
Old Crow (2010)	Complete	68% (126/186)	Mild: 3% Moderate: 32% Severe: 65%	Seq: 65% (13/20) 4-drug: 95% (20/21)	Ongoing
Tuktoyaktuk (2011)	Complete	56% (57/101)	Mild: 25% Moderate: 38% Severe: 38%	Seq: 50% (1/2) 4-drug: 100% (1/1)	Ongoing
Fort McPherson (2012)	In progress	57% (102/180)	Mild: 8% Moderate: 54% Severe: 38%	Seq: 86% (12/14) 4-drug: 100% (10/10)	Ongoing

[1]Gastritis: Chronic inflammation of the stomach lining; a pathologist graded the severity of gastric biopsies from endoscopy participants
[2]Reported to indicate project progress only; these estimates are highly uncertain due to small group sizes
[3]3-drug is short for Standard Triple Therapy; Seq is short for Sequential Therapy; and 4-drug is short for Quadruple Therapy

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Figure 1b. Example of the CANHelp Working Group newsletter for January 2014, page 2 of 2.

89 people who had not been treated before, cure rates were 73% of 40 on sequential therapy and 59% of 49 on standard therapy, a study size too small for precise estimates of the treatment effect size.

To generate study results with greater certainty, the CANHelp research program needs a larger number of participants representing additional northern communities. In addition to ISR projects, we have been conducting similar research in Old Crow, YT since 2010 and Fort McPherson NT since 2012. We have been working with the IRC since January 2010 on the expanding the research initiated in Aklavik to the remaining Inuvialuit Settlement Region communities.

This research addresses a health problem that imposes a disproportionate burden on northern communities relative to other groups in Canada. It aims to improve the management of *H. pylori* infection in northern communities, and reduce corresponding health risks. The research design conforms to principles of community-based participatory research, incorporates innovative approaches to knowledge exchange, and adheres to the ACUNS Ethical Principles for the Conduct of Research in the North and CIHR Guidelines for Health Research Involving Aboriginal People. The effectiveness of this research will be enhanced by the collaborative research team that links scientists across a comprehensive set of scholarly disciplines with decision-makers, industry partners, and community groups toward the common goal of improving community health.

Activities

Time frame and study area: Fieldwork and knowledge sharing activities were carried out throughout the year in the communities of Aklavik, Inuvik, and Tuktoyaktuk in the Northwest Territories (NT).

Research: The endoscopy and treatment components of the Inuvialuit Settlement Region (ISR) *H. pylori* Project was offered to residents of Tuktoyaktuk, as part of a pilot for expanding participation to other ISR communities. Planning for the expansion of the ISR *H. pylori* Project continued, but was delayed due another turnover in leadership at the Inuvialuit Regional Corporation (IRC). Diane Archie left her position as Executive Director of the IRC's Community Development Division, and was recently replaced by Evelyn Storr. Ms. Storr has kindly agreed to replace Ms. Archie as a member of the CANHelp Working Group, and we are taking steps to familiarize her with our research program's history and objectives. Additionally, a project aimed at testing water sources for the presence of living *H. pylori* organisms in and around Aklavik was piloted. Knowledge sharing activities were undertaken by members of the CANHelp Working Group throughout the year.

During 2013, the following activities were completed:

- Endoscopy and treatment components of the Inuvialuit Settlement Region (ISR) *H. pylori* Project offered to residents of Tuktoyaktuk
    * Temporary endoscopy clinic set up at the Inuvik Regional Hospital in Inuvik
    * Dr. van Zanten, Gastroenterologist, performed unsedated upper gastrointestinal endoscopy to examine the stomach for visible lesions and collect biopsies of stomach tissue
    * Participants with a confirmed diagnosis of *H. pylori* were prescribed treatment by Dr. van Zanten
- Dr. Girgis, Pathologist, microscopically examined the stomach biopsies collected during endoscopy to assess presence and density of *H. pylori* infection, degree of inflammation, and presence of gastric neoplasms
- Dr. Keelan, Microbiologist, cultured *H. pylori* from gastric biopsies and characterized strains according to virulence genotypes and antibiotic susceptibility
- Gastroenterologist Dr. van Zanten and MSc student Emily Hastings travelled to Aklavik to meet with project participants and present results

from Emily's MSc thesis research on association of *H. pylori* infection with environmental exposures

  * Project progress and preliminary results were presented on the local radio station; questions were also taken from community members who called in
  * They met in-person with community members at the local health centre
  * Follow-up urea breath tests were also offered to participants who had completed treatment with the project to ensure that the infection was cleared

- MSc student Emily Hastings traveled to Tuktoyaktuk to meet with project participants and share results from her thesis research
- PhD student Sally Carraher successfully defended her thesis titled "Never Say DIE! An Ethnographic Epidemiology of *H. pylori* Infection and Risk Perceptions in Aklavik, NWT"
- MSc student Emily Hastings successfully defended her thesis titled "Environmental Exposures, Helicobacter pylori Infection and Gastritis in Canadian Arctic Communities"
- PhD student Sally Carraher returned to Aklavik to meet with members of the Aklavik Health Committee and other community stakeholders and provide copies of her dissertation results to community organizations and the health centre
- Summer student Kate Williams (MSc student as of September 2013) traveled to Aklavik to pilot a chart review tool designed to collect data on antibiotic treatment histories in patients who had originally participated and provided consent to be included in the Aklavik *H. pylori* project
- Summer student Yashna Beesoon traveled to Aklavik to pilot a project aimed at testing environmental surface water samples and domestic treated water samples for the presence of living *H. pylori* organisms
  * Water samples were collected in triplicate from 20 sources, 10 were from indoor taps (treated water) and 10 were from untreated surface water
  * After the samples were transported to the University of Alberta, each set of the triplicate water samples were filtered, followed by DNA and RNA extraction
  * The filters were then cultured in an attempt to grow any *H. pylori* organisms present
- PhD student Emily Hastings (transitioned from MSc to PhD in September 2013) chaired a meeting with the Aklavik Health Committee to present an update on research findings and discuss plans for future research
- Postdoctoral fellow Arianna Waye carried out a systematic literature review examining studies of the cost-effectiveness of elimination of *H. pylori* infection and its effects on disease outcomes
- Members of the CANHelp Working Group met with Sabrina Broadhead, Director of the Division of Aboriginal Health and Community Wellness in the Government of the Northwest Territories (GNWT), and Andre Corriveau, Chief Public Health Officer in the Northwest Territories, to discuss project expansion and the development of a Community Engagement Facilitator position to be based at the GNWT offices in Yellowknife, NT
- Members of the CANHelp Working Group published five refereed papers (see publications)
- Members of the CANHelp Working Group published six extended abstracts in the International Journal of Circumpolar Health (see publications)
- Members of the CANHelp Working Group published one conference abstract in Gastroenterology, one in Helicobacter, and one in the International Journal of Circumpolar Health (see publications)
- Graduate students and staff of the CANHelp Working Group delivered presentations at 3

international conferences, 2 national conferences, 1 provincial conference, and 2 campus conferences (see publications)

- The CANHelp Working group was nominated for the Arctic Inspiration Prize by the Canadian Circumpolar Institute; for the nomination package, we were joined by our NT partners Diane Archie, Executive Director of Community Development for the Inuvialuit Regional Corporation, and Rachel Munday, Nurse-in-Charge of the Aklavik Health Centre
    * The CANHelp Working Group was one of six shortlisted nominees for the Arctic Inspiration Prize
- Billy Archie, collaborator and resident of Aklavik, was awarded travel funding from Inuit Tapiriit Kanatami (ITK) to attend ArcticNet's 9th Annual Scientific Meeting
- Graduate students Sally Carraher, Emily Hastings, and Kate Williams were awarded funding from the Nasivvik Centre for Inuit Health and Changing Environments to carry out community consultations on environmental health priorities in the Inuvialuit Settlement Region

Results

In total, 376 people have participated in the Aklavik *H. pylori* Project; thus the project has included over 60% of the Aklavik population (~600). To date, the project has yielded data on clinical factors from 345 participants, individual-level socio-environmental factors from 284, household-level socio-environmental factors from 145 households, results of breath test for detection of *H. pylori* infection from 333 participants (positivity=58%) and gastric biopsies from 194. Pathological examination of gastric biopsies focused on assessing the presence of abnormalities known to indicate increased risk of stomach cancer: severe chronic gastritis; glandular atrophy; and intestinal metaplasia. Of 129 participants with *H. pylori* detected by examination of gastric biopsies, 43% had severe gastritis and 47% had moderate gastritis, while 21% had gastric atrophy and 11% had intestinal metaplasia. Biopsies were also processed for culture of *H. pylori* and isolated strains were tested for antibiotic susceptibility: 25% of 120 *H. pylori* isolates were resistant to one drug and 7% were resistant to more than one drug. Antibiotic susceptibility testing results were taken into account for assignment of treatment regimen in our clinical trial component. The Aklavik trial showed that the standard therapy (a proton pump inhibitor, amoxicillin and clarithromycin for 10 days) used across Canada achieved cure in only 59% of Aklavik participants randomized to this treatment, in contrast to 80% effectiveness observed on average in Canada. A follow-up study was done in Aklavik to investigate the incidence rate of new cases of *H. pylori* infection and rates of reinfection in successfully treated participants. The incidence rate was estimated at 2.1% per year among participants aged 15 and older.

The ISR *H. pylori* Project started in Tuktoyaktuk with 107 participants. To date, this project has yielded data on clinical factors from 91 participants, individual level socio-environmental factors from 79, household-level socio-environmental factors from 57 housholds, results of breath tests from 104 participants (positivity=56%) and gastric biopsies from 13; 25 project participants have been assigned treatment, and 13 of them were enrolled in the treatment trial. With resources from other grants, the research team has conducted similar community projects in Old Crow, YT since 2010 and Fort McPherson, NT since 2012. The information from these two Gwich'in communities provide a basis for comparison with the Inuvialuit communities that are the focus of the ArcticNet project.

The Old Crow *H. pylori* Project enrolled 199 participants - around 80% of the Old Crow population (~250). To date, this project has yielded data on clinical factors from 138 participants, individual-level socio-environmental factors from 138, household-level socio-environmental factors from 86 households, results of breath tests from 192 participants (positivity=68%) and gastric biopsies from 63. Of 57

participants with *H. pylori* detected by examination of gastric biopsies, 65% had severe gastritis and 32% had moderate gastritis, while 74% had gastric atrophy and 35% had intestinal metaplasia. Due to the low effectiveness of standard treatment observed in Aklavik, the treatment trial for the Old Crow project used two alternative treatments: sequential therapy (a combination of a proton-pump inhibitor and amoxicillin for Days 1-5 and a proton-pump inhibitor, clarithromycin and netronidazole for Days 6-10); and quadruple therapy (a combination of a proton-pump inhibitor, Pepto-Bismol, metronidazole and tetracycline for 10 days). In this trial, a larger proportion of participants in the quadruple therapy group were treated successfully, but more data is needed for a precise estimate of the difference in treatment effectiveness of the alternate regimens. Our trials show a greater frequency of successful treatment among participants who had better adherence to the treatment regimen.

The Fort McPherson *H. pylori* Project has enrolled 226 participants since it launched in June 2012. To date, the project has yielded data on clinical factors from 172 participants, individual-level socio-environmental factors from 152, household-level environmental factors from 118 households, results of breath tests from 217 participants (positivity=59%) and gastric biopsies from 53 participants. Of 37 participants with *H. pylori* detected in gastric biopsies, 38% had severe gastritis and 54% had moderate gastritis, while 70% had gastric atrophy and 14% had intestinal metaplasia. The treatment phase of the Fort McPherson *H. pylori* Project is in progress.

A 2013 highlight comes from two projects we conducted to address community members' questions about whether water is a source of *H. pylori*. As part of her MSc thesis, Emily Hastings completed a data analysis to investigate indicators of transmission pathways using aggregated data from participating communities. The analyses showed a higher prevalence of *H. pylori* infection among participants who reported exposure to mice or mouse droppings in the home, although this exposure did not appear to be a major source of *H. pylori* in the participating communities given the small proportion of participants reporting exposure to mice or mouse droppings. This analysis also showed that consuming untreated or contaminated water did not appear to be associated with the prevalence of *H. pylori* infection. The second water-focused project was a pilot study conducted by summer student Yashna Beesoon to test samples of environmental surface water and domestic treated water taken from Aklavik for living *H. pylori* organisms. For this pilot, under the supervision of network investigator Monika Keelan, Ms. Beesoon developed an assay to detect *H. pylori* mRNA in water as an indication of living organisms. All water samples collected from Aklavik were negative for *H. pylori*, thus this pilot did not provide evidence that Aklavik water sources contain *H. pylori*, though it may be that limitations of the assay or the sampling locations impeded detection.

Discussion

Our research has estimated a high prevalence of *H. pylori* infection in Aklavik (58%), Old Crow (68%), Tuktoyaktuk (57%) and Fort McPherson (59%). We have also observed high prevalence of severe gastric inflammation in people with *H. pylori* infection, and a pattern of *H. pylori*-associated stomach disorders that indicates increased risk of stomach cancer. These findings confirm that community concerns about health risks from *H. pylori* infection are warranted.

Preliminary findings from our treatment trials show that the standard 3-drug therapy has poor effectiveness and an alternate, though more complex, 4-drug therapy may be more effective in the participating communities. While more data is needed for precise estimates of the treatment effectiveness of investigated treatment regimens, we have shown the need for changes in clinical practice pertaining to the treatment of *H. pylori* infection in the region.

Many factors influence *H. pylori* infection and disease risk in Arctic Aboriginal communities. Analysis of

data collected to date confirms the need to increase participation in this research program so that informative statistical analyses can be carried out. Results from gastric biopsy data showed important intercommunity differences in *H. pylori* disease burden, even between closely related communities such as Aklavik, Old Crow and Fort McPherson. The different distributions of these disorders across the communities confirm the importance of obtaining additional data from multiple communities in the region.

One question raised frequently by participating community members is whether water is a source of *H. pylori* infection. The research team has developed multiple approaches to address this question. Our initial results do not provide evidence that water is a source of *H. pylori* infection. We will continue working with the communities to make these results meaningful to them and to identify future research directions together.

The continuing development and expansion of our community *H. pylori* projects has allowed our team to develop expertise in research agreements between scientists and communities. This may serve as a model for future community-based participatory research in health science. Our research has also suggested a potential gap between the views of participants and researchers on health concerns about *H. pylori* infection. We will continue to develop knowledge exchange strategies that help community members understand *H. pylori* health risks as well as currently available solutions and unsolved challenges for reducing these health risks.

Conclusion

Our initial research in Aklavik provided a good start toward generating the information needed for developing regional public health strategies for reducing health risks from *H. pylori* infection. Analysis of data collected from Old Crow, Tuktoyaktuk and Fort McPherson provides a strong rationale for the need to expand this research to additional communities.

Our continued progress toward including additional communities in this research is allowing us to accumulate data from diverse Arctic communities. This will allow us to generate sufficient information conduct policy analysis to identify cost effective *H. pylori* management strategies that are ethically, economically, and culturally appropriate for northern communities.

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As the Aklavik *H. pylori* Project, from its inception in 2007, and other CANHelp Working Group research outside the Inuvialuit Settlement Region (ISR) provide important background for further research in the ISR as well as statistical power for informing regional policy recommendations, we would like to acknowledge all the funders and supporters of our research program:

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Publications

(All ArcticNet refereed publications are available on the ASTIS website (http://www.aina.ucalgary.ca/arcticnet/).

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