



Fort McPherson *H. pylori* Project Progress Report

1 Apr 2015



The Fort McPherson H. pylori Project arose from a collaborative effort of the Canadian North Helicobacter pylori (CANHelp) Working Group to investigate H. pylori infection in northern Canada with goals of addressing community concerns, improving clinical management, and reducing health risks.

Report Date: 1 Apr 2015

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Overview of Project Timeline and Findings

What has been done so far?

- Completed components of the project include *H. pylori* screening by breath test, collection of questionnaire data, endoscopy, and treatment.

What remains to be done?

- Short-term treatment follow-up is ongoing, as is analysis of questionnaire data and reporting research results back to the community.
- Long-term follow-up will be carried out over the next several years.

What have we learned?

- Of participants screened by breath test, 59% were positive for *H. pylori* infection.
- Of those who had a scope test and whose stomach biopsies revealed *H. pylori* when examined by a pathologist, 92% had moderate to severe chronic inflammation of the stomach; this frequency of moderate to severe chronic inflammation is consistent with an increased risk of stomach cancer in this community.
- Of treatments investigated in Aklavik, Old Crow, and Fort McPherson, 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.
- Available treatments for eliminating *H. pylori* infection are burdensome and more research is needed to find out how to make them more effective.
- Follow-up *H. pylori* testing in Aklavik suggests that most people who were successfully treated remained *H. pylori*-free for 2 years or longer.
- CANHelp Working Group research so far has not pinpointed an environmental source of *H. pylori* in Aklavik or other communities where *H. pylori* projects are being carried out; 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.



Fort McPherson *H. pylori* Project Timeline

- | | |
|---|-------------------|
| • Wave 1 data collection | |
| • Recruitment, <i>H. pylori</i> screening by breath test, questionnaires (health, participant, household) | Jun to Sep 2012 |
| • Endoscopy and treatment | Mar 18 to 21 2013 |
| • Pathology | May 2013 |
| • Pathology results reported to participants | May 2013 |
| • Short-term treatment follow-up | Ongoing |
| • Research results reported to community | Ongoing |

Participation and Data Counts

- Participants recruited: 236
- Interviewer-administered health questionnaires completed: 175
- Breath tests completed: 228 (209 have a positive, negative, or borderline result)
- Fort McPherson residents consenting to endoscopy: 59
- Fort McPherson residents completing endoscopy: 57 (53 completed with biopsies)
- Biopsies available for *H. pylori* testing: 52
- Interviewer administered participant questionnaires:
 - 154 individual respondents
 - 121 household respondents (reporting household data for 185 individuals)
- Participants consenting to treatment: 83
- Participants assigned treatment: 79
- Treatment trial participants: 68
- Post-treatment breath tests completed: 54 (53 have a positive, negative, or borderline result)
- Interviewer-administered post-treatment questionnaires completed: 55

Findings to Date

- Proportion positive on breath test: 59% (124/209)
- Endoscopic findings from 53 Ft. McPherson residents:
 - Gastritis: 15% (8/53)
 - Gastric erosions: 11% (6/53)
 - Gastric ulcer: 4% (2/53)
 - Duodenitis: 4% (2/53)
 - Duodenal erosion: 2% (1/53)
 - Duodenal ulcer: 0
 - Esophagitis: 11% (6/53)
 - Barrett's esophagus: 0



- Pathology findings (Sydney classification) from 53 Ft. McPherson residents:
 - Chronic gastritis: 83% (44/53)
 - Severe: 26% (14/53)
 - Moderate: 38% (20/53)
 - Mild: 19% (10/53)
 - Atrophic changes: 49% (26/53)
 - Intestinal metaplasia: 11% (6/53)
 - *H. pylori* positive: 70% (37/53)
 - Among 37 *H. pylori*-positive participants:
 - Chronic gastritis: 100% (37/37)
 - Severe gastritis: 38% (14/37)
 - Moderate gastritis: 54% (20/37)
 - Mild gastritis: 8% (3/37)
 - Atrophic changes: 70% (26/37)
 - Intestinal metaplasia: 14% (5/37)
- Microbiology findings from 52 Aklavik residents:
 - Culture positive: 58% (30/52)
 - Antibiotic susceptibility tests were performed on 28 isolates obtained from culture:
 - Resistance to any antibiotics tested: 68% (19/28)
 - Metronidazole: 46% (13/28)
 - Clarithromycin: 29% (8/28)
 - Ciprofloxacin: 7% (2/28)
 - Rifampicin: 4% (1/28)
 - Amoxicillin, nitrofurantoin, tetracycline: 0
 - Resistance to multiple (2 or 3) antibiotics: 18% (5/28)
 - Clarithromycin + Metronidazole: 14% (4/28)
- Treatment success among 46 treatment trial participants with post-treatment UBT results:
 - Sequential therapy: 83% (24/29)
 - Quadruple therapy: 100% (17/17)

The breath test prevalence (proportion positive) of 59% is a better reflection of the prevalence of *H. pylori* infection in Fort McPherson than the 70% positive by pathology (or the 58% positive by culture) among those with biopsies from endoscopy. Since residents who were informed of positive breath test results were motivated to undergo endoscopy, there are proportionally more positives in the latter group.

Summary of On-going and Previous Project Activities

On-going Project Activities

1.1 Recent Activities

MSc student Kate Williams traveled to Fort McPherson June 2014 to collect antibiotic exposure histories from medical charts of participants who had *H. pylori* cultured from stomach biopsies and tested for antibiotic susceptibility and/or were treated and completed a post-treatment breath test. For each of these participants, information was collected for the five-year period before project enrolment on: demographic factors; frequency of antibiotic prescriptions; type of antibiotics prescribed; and reason for prescription. Kate will use this information for her MSc thesis, to estimate associations of antibiotic exposures on two health outcomes: 1) the prevalence of antibiotic-resistant *H. pylori* infection and 2) success of treatment to eliminate *H. pylori* infection.

1.2 Upcoming Activities

Additional trips will be made throughout 2015 to offer post-treatment breath tests to participants who had treatment to eliminate *H. pylori*, and to develop and implement additional knowledge exchange activities to inform community members of study progress and findings.

Previous Project Activities

2.1 First Wave of Data Collection (Jun 2012)

Community Projects Lead Amy Colquhoun, Fieldwork Lead Laura Aplin, Fieldwork Coordinators Emily Hastings and Monica Sierra, and Community Research Assistants Maria Peterson and Donna Koe initiated data collection in Fort McPherson in June 2012. A project launch event was held on Wednesday, June 6 at the Recreation Complex to mark the start of the Fort McPherson *H. pylori* Project. Activities included a community dinner, an information session, and a viewing of "Never Say Die: The Aklavik *H. pylori* Project." On June 15, the project team announced the winner of the logo contest on CBQM, the local radio station. The contest was open to all school-aged children attending Chief Julius School. Students were asked to draw a logo representing the Fort McPherson *H. pylori* Project. The winner of the contest was Johanna Edwards for her very creative drawing depicting *H. pylori* throughout the local environment.

Recruitment of participants took place via radio announcements and door-to-door outreach for the month of June. During this time, project staff obtained informed consent and screened participants for *H. pylori* infection using the urea breath test. They also interviewed participants using individual and household risk factor questionnaires and health questionnaires. Project staff created a phone list and map of the community to track coverage of households. Regular radio announcements on CBQM were also used to encourage participation throughout the recruitment and data collection processes and to respond to commonly asked questions. In

September, project staff returned to Fort McPherson to report the first set of breath test results to project participants.

2.2 Community Response to Initial Recruitment Efforts

Initial recruitment efforts were met with a positive response from the community. Most residents contacted indicated a desire to participate. The biggest challenge was getting potential participants to follow through on scheduled appointments to complete the informed consents, breath tests, and surveys.

2.3 Returning UBT Results (Sep 2012)

Fieldwork Lead Laura Aplin returned to Fort McPherson in September 2012 to report breath test results and continue project enrollment. She continued recruitment efforts primarily through radio announcements and speaking to the public during the Community Health Representative's weekly radio program. She also recruited participants through information stands at the local radio station, flyers posted around the community, and door-to-door visits. In mid-September, Ruby Koe joined the project team as a Community Research Assistant. Ruby continued to offer breath testing and interviews in Fort McPherson until the endoscopy and treatment components of the project in mid-March.

2.4 Endoscopy and Treatment (Mar 18-21, 2013)

The endoscopy and treatment phases of the Fort McPherson *H. pylori* Project took place during Monday, March 18 through Thursday, March 21, 2013. Endoscopy participants were recruited through the local radio station, CBQM, and phone calls to project participants who had expressed an interest in having a scope test on the health questionnaire.

For the endoscopy component of the project, gastroenterologists Amy Morse, Adriana Lazarescu, and Sander van Zanten traveled to Fort McPherson to perform upper gastrointestinal endoscopies at the William Firth Health Centre in temporary endoscopy units equipped with rented endoscopy towers and gastroscopes, with technical support from Olympus Canada. Experienced Alberta Health Services endoscopy nurses and service workers assisted the gastroenterologists. Endoscopy protocols developed for the Aklavik and Old Crow *H. pylori* Projects were adapted for use in Fort McPherson. Study participants 15+ years of age who wished to undergo endoscopy were eligible, as were children whose parents requested that they be included, at the gastroenterologist's discretion. During 4 days, the team completed 58 endoscopies; 1 participant was not able to complete the procedure, and biopsies for culture and histopathology were obtained from 53 participants. No adverse effects occurred during the endoscopy procedures.

During this time, for participants who consented to treatment, gastroenterologists Amy Morse, Adriana Lazarescu, and Sander van Zanten evaluated eligibility for the project treatment trial and oversaw the administration of therapy. Participants who were not eligible for the trial were prescribed treatment outside the trial protocol as appropriate. Consent for

the treatment trial was obtained from 50 participants and 49 received medications as part of the trial, which was designed to compare sequential and quadruple therapies, two of the best available treatment regimens for eliminating *H. pylori* infection. The duration of both therapies was 10 days. Sequential therapy consisted of a proton pump inhibitor and amoxicillin for days 1-5, followed by a proton pump inhibitor, clarithromycin and metronidazole for days 6-10. Quadruple therapy consisted of a proton pump inhibitor with bismuth, metronidazole, and tetracycline for days 1-10. Participation in the treatment trial has remained open; to date, 87 participants have consented to treatment and 71 have participated in the trial.

For the treatment phase of the project, gastroenterologists Amy Morse, Adriana Lazarescu, and Sander van Zanten evaluated eligibility for the project treatment trial and oversaw the administration of therapy. Participants who were not eligible for the trial were prescribed treatment outside the trial protocol as appropriate. Consent for the treatment trial was obtained from 51 participants and 47 received medications, 41 as part of the trial, which was designed to compare sequential and quadruple therapies, two of the best available treatment regimens for eliminating *H. pylori* infection. The duration of both therapies was 10 days. Sequential therapy consisted of a proton pump inhibitor and amoxicillin for days 1-5, followed by a proton pump inhibitor, clarithromycin and metronidazole for days 6-10. Quadruple therapy consisted of a proton pump inhibitor with bismuth, metronidazole, and tetracycline for days 1-10. Participation in the treatment trial has remained open; to date, 83 participants have consented to treatment and 68 have participated in the trial.

Lead Gastroenterologist Sander van Zanten and Fieldwork Lead Laura Aplin coordinated treatment follow-up activities from the William Firth Health Centre and, later, from the project offices in Edmonton. This included phone reminders to participants during the course of treatment as well as collection of bubble packs to count unused medication and administration of a post-therapy questionnaire.

2.5 Biopsy Data

Dr. Safwat Girgis, team Pathologist, completed pathologic assessment of the gastric tissue biopsies in May 2013. Later that month, Sander van Zanten, Laura Aplin, and Emily Hastings contacted endoscopy participants individually to report pathology findings. William Firth Health Centre staff assisted Dr. van Zanten in making arrangements for any participants who required a follow-up endoscopy.

2.6 Treatment Follow-up

Laura Aplin and summer student Kristina Lea visited Fort McPherson during July 8-20, 2013 to collect remaining bubble packs and administer additional post-therapy questionnaires. They offered follow-up breath testing to participants who had completed treatment at least 4 weeks prior to see if their therapy was successful. Those who still tested positive by breath test were prescribed a second treatment by one of the project physicians. At least 1 week



before the visit, community members were informed of the upcoming trip through flyers and radio announcements on the local radio station, CBQM.

Additional trips were made throughout 2013 to evaluate participants' post-treatment *H. pylori* using the urea breath test, and to develop and implement additional knowledge exchange activities to inform community members of study progress and findings.

2.7 Chart Review – General

Several team members, including Community Projects Lead Laura Aplin, Lab Manager Richelle Redekop, and summer students Melissa Power and Emelie Gustafson, carried out chart reviews at the William Firth Health Center during June and July 2014. The chart review collected information for each participant for the 5 years preceding project enrolment on digestive complaints as well as testing and treatment for *H. pylori* infection. The chart review information will enhance the completeness of the health questionnaires and help the project better estimate the burden of digestive diseases among residents of Fort McPherson.