Port Colborne

Community Health Assessment Project (CHAP)

Protocol "A":

Self-Reported Health Assessment of the Port Colborne Community

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Protocol Approval Signature Page

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Protocol Synopsis

TITLE	Self-Reported Health Assessment of the Port Colborne Community.
SPONSOR	INCO Corporation
STUDY SITE	Port Colborne, Ontario
PRIMARY OBJECTIVE(S)	To determine whether the overall perceived health status of the Port Colborne community is different than expected.
DESIGN AND METHODOLOGY	The Self-Reported Health Questionnaire will be offered to every resident in Port Colborne using a mail-out method. Alternative options (completing the questionnaire in a central location) will also be available. The Self-Reported Health Questionnaire consists of questions pertaining to: • identifying information • demographic information • perceived general health (health-related quality of life and general health questions) • child and adolescent health
POPULATION	Every resident of Port Colborne (approx. 18,450 individuals) is eligible to participate in this study. Adults (18+) will be asked to complete the Self-Reported Health Questionnaire. Parents/guardians will answer questions on the behalf of the children or adolescents currently residing with them
SUBJECT PARTICIPATION	The Self-Reported Health Questionnaire consists of a health-related quality of life questionnaire (SF-36) that includes 36 questions that will take approximately 5-10 minutes per individual to complete. The child and adolescent questionnaire is based on the National Longitudinal Children's and Youth Survey and the Canadian Community Health Survey. This will be filled out for each child in the household who is less than 18 years of age by their parent/guardian. The return of the completed questionnaire implies consent.
OUTCOME MEASURES	From the Self-Reported Health Questionnaire, the following will be obtained: • general health assessment of Port Colborne residents • demographic and general health data comparable to those obtained from validated health surveys
DATA COLLECTION & ANALYSES	The data that is collected from the Self-Reported Health Questionnaire will be analyzed using descriptive statistics. The SF-36 describes the health of participants in terms of 8 domains (physical functioning, role physical, bodily pain, general health perceptions, energy/vitality, social functioning, role emotional and mental health) and 2 summary scales (physical and mental components). The means and standard deviations for these 8 domains and 2 summary scales will be constructed across different age groups and for both males, females and both sexes combined. Comparisons will then be made to SF-36 scores obtained in general population surveys and between regions in Port Colborne. Direct age-standardization will be used to control for differences in the underlying age-distributions of the different populations. Similarly, responses to the child and adolescent questionnaire will be compared to the National Longitudinal Children's and Youth Survey and the Canadian Community Health Survey. Response rates will be constructed within geographical areas of Port Colborne to evaluate the potential for response bias based on levels of socioeconomic status and potential for exposure to Chemicals of Concern.

Abbreviations

CCHS	Canadian Community Health Survey
CHAP	Community Health Assessment Project
CoCs	Chemicals of Concern
IARC	International Agency for Research on Cancer
JWEL	Jacques Whitford Environmental Limited
MOE	Ministry of the Environment
NLSCY	National Longitudinal Study of Children and Youth
PLC	Public Liaison Committee
PSC	Publication Steering Committee
QoL	Quality of Life
SRHQ	Self-Reported Health Questionnaire
SF-36	Medical Outcomes Study Short-Form 36 (Questions)
SOW	Scope of Work
TSC	Technical SubCommittee
Ventana	Ventana Clinical Research Corporation

1.0 Rationale

The first step in CHAP is to assess the general health status of the entire community. To achieve this goal, each resident of Port Colborne will be afforded the opportunity to participate by completing the Self-Reported Health Questionnaire (SRHQ) (see Appendix 1). One component of this questionnaire will evaluate the perceived general health of the community using the Medical Outcomes Study Short-Form 36 (SF-36) module, a cross-validated tool used to assess health-related quality of life. This fairly brief and simple questionnaire contains 36 questions that cover 8 health concepts chosen on the basis of reliability, validity, and frequency of measurement in health surveys [1,2]. Two summary scores, mental and physical, have also been developed from the SF-36 [3]. Although there are only 11 numbered questions in the SF-36 module, the sum of all numbered and alpha notated questions is thirty-six.

The rationale for administering the SF-36 is in part due to the fact that while community surveys are frequently undertaken to either estimate the incidence of disease or the number of diagnostic tests performed, they provide limited information about the health of a community. Such surveys reveal little about aspects of a community's level of health, including dysfunction and disability that result from disease or other health problems. The health status of a community is now widely regarded to encompass several constructs [4]. With this in mind, several survey instruments have been designed to measure health status or health-related quality of life and have since been applied to both general and clinical patient populations. The SF-36 is one of the most widely used instruments to perform this measurement and has been shown to be sensitive to changes

in the health of the general population [5]. The administration of the SF-36 questionnaire will also permit comparisons across the 8 different domains to published results obtained in similar surveys conducted in the general population [7-12], and specifically for Canada [6]. Several studies have reported results in populations aged 18 years of age and older [8, 9, 12-15]. The SF-36 has also recently been applied to a community with concerns over putative exposure to chromium [16]. The Port Colborne community has similar concerns surrounding potential health conditions and exposure to environmental pollutants.

The SRHQ will capture an overall picture of the health status of adults in Port Colborne, which can then be compared to other populations of Ontario. Although laboratory measures and hospitalization records are important indicators of the need for treatment, they often correlate poorly to the way people feel. The SF-36 component of the SRHQ addresses the need to characterize this aspect of health within Port Colborne. In light of continuing concerns and anxieties of residents as they relate to the CoCs, and because quality of life issues are under researched in such settings, the application of the SF-36 to the adult population in Port Colborne represents an important initiative.

Although the SF-36 is a valuable tool used to assess the health status of adults, the application of this instrument to adolescents and children has limited application [17]. Therefore, the SF-36 of the SRHQ will be supplemented with a child and adolescent health questionnaire in order to evaluate the general health of Port Colborne residents who are less than 18 years of age. This questionnaire draws questions from the National

Longitudinal Youth Health Survey (NLSCY), and from the Canadian Community Health Survey (CCHS). The NLSCY data will permit comparisons between responses obtained from Port Colborne residents who are less than 12 years of age, while the CCHS allows comparisons to be made for those between the ages of 12 and 17.

The SRHQ is designed to evaluate the general health of the Port Colborne community relative to other populations, and also permits comparisons to be made across broadly defined regions within Port Colborne.

2.0 Objectives

The objectives of administering the SRHQ to the entire Port Colborne community are as follows:

1) To evaluate the perceived health status of the Port Colborne community so as to determine whether it is different than expected when compared to normative values in the general population.
2) To survey the health of children and adolescents and to investigate differences by comparing responses to those from the National Longitudinal Children's and Youth Survey and the Canadian Community Health Survey.

~~4.0~~3.0 Design and Methodology

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3.1 Overview

Ventana Clinical Research Corporation (Ventana) will undertake the planning and implementation of the data collection for the questionnaire. The questionnaire will be mailed out to all households of Port Colborne based on addresses obtained from an electronic file of phone listings. These phone listings are based on the most recently published available records that have been updated until January 1, 2002. Postal mailings may offer an advantage over face-to-face interviews, as they are less prone to suffer from social desirability bias. Specifically, it has been suggested that subjects may respond more accurately to SF-36 questions in the absence of an interviewer [18]. The phone list is sorted by area code, and includes phone, name and address for roughly 6,700 households. Based on most recent residential mailing information from Canada Post, this represents 85.3% (6,700 / 7,856) of households in Port Colborne.

3.2 The study instrument (SRHQ)

There are three sections to the SRHQ. The first collects basic demographic data from adult household members. The second, component is the SF-36 questionnaire. Finally, a parent or guardian, of residents of the household who are less than 18 years old are asked to complete a questionnaire for children and adolescents. Each of these three components is described:

3.2.1 Identifying information and demographic data

Demographic information, such as age, gender, average annual income, and education level, are routinely obtained in community surveys for the purpose of evaluating the data on the basis of socio-demographic factors, rather than simply the population as a whole. Such "stratified" analyses can reveal important underlying factors in the determination of health status in a diverse population, as well as identify potential at-risk subpopulations. The SRHQ will collect the following demographic information: age, sex, education, income, smoking status, length of residency in Port Colborne, and household size.

3.2.2 The SF-36

The SF-36 was chosen as the instrument to be used to measure health status for many reasons. These include: it's relative ease of use, its brevity and its successful application in a general population setting using the mail-out technique [19-21]. The validity and reliability of this instrument has been tested and established [22, 23]. The SF-36 includes one multi-item scale that measures eight health concepts. Bodily Pain (BP) evaluates limitations due to pain and the amount of pain experience. Physical Functioning (PF) evaluates the ability of an individual to perform physical activities. Role-Physical Functioning evaluates the extent to which physical health interferes with work or other regular daily activities. General Health evaluates personal health. Vitality measures levels of energy and vitality. Social Functioning evaluates interference with social activities due to physical or emotional problems. Role-Emotional evaluates problems with work or other daily activities due to emotional problems. Mental Health evaluates the extent of depression or anxiety. Two summary measures mental and physical, can also be

computed from these data; the physical component summary scale. The values range from 0 to 100 with higher scores equating to better Quality of Life (QoL).

3.2.3. The child and adolescent questionnaire

The Child and Adolescent Questionnaire draws on questions posed in both the NLSCY and the CCHS. The questionnaire is provided in Appendix 1. The questionnaire collects the following information: age, sex, body height and weight, general health, asthma, and skin conditions.

3.3 Sampling procedures

The sampling strategy is based on the principle that all current residents of Port Colborne will have the opportunity to take part in the Self-Reported Health Assessment. Ventana has been provided with a listing of all households based on phone listings obtained from Cornerstone. Cornerstone is one of Canada's leading suppliers of information-based marketing/research products and services. Cornerstone's divisions specialize in list, alternative media and Web-based brokerage and management, database construction and mining, data warehousing, donation and order processing and product sampling. Using the powerful list and media database of Cornerstone List Brokerage, they offer a broad range of list and database expertise. Duplicate addresses have been removed from the list in situations where there are multiple phone numbers within each household. Since this enumeration list is not 100 percent complete, the sampling procedure will allow for the removal and addition of names as the survey progresses. As mentioned previously, based on the most recent residential mailing information from Canada Post, the phone listing is

thought to reflect 85.3% of households. The communication strategy will encourage those individuals who have not received the first mail out post card to contact Ventana to be added to the mail out list.

The City of Port Colborne will be divided into five strata or regions. These regions are based on approximate estimates to levels of exposure to Chemicals of Concern (CoCs) within the city. These strata ensure that each subgroup of the population is represented, and thus the data obtained from the survey can be generalized to the entire community. They also allow for internal comparisons within the city to be made. The first area is west of the Welland Canal, and is bounded by Clarence and Augustine Road (Clarence is included). The second area is west of the Welland Canal, north of Clarence (excludes Clarence), is bounded by Minor Road and includes Rosedale Subdivision. The third area is east of the Canal, north the of Lake, south of Durham (includes Durham) and is bounded by Davis and Welland St. The fourth area is east of the Canal, south of the 2nd Concession, north of Durham (excludes Durham) and is bounded by Snider Road. Every other area not mentioned above will contribute to a fifth category, which will consist primarily of rural residences.

Residents who believe they have been omitted from the main list will be able to apply at a central facility that will be set up within Port Colborne for an opportunity to take part in the SRHQ. The address and phone number of the facility will be well advertised within Port Colborne. The electronic version of the list will be checked and, if necessary, the respondent's name and other key identifying information will be added to the main list.

The addition of new names will require a form of identification that confirms the respondent's address, such as a driver's license or a utility bill. This will allow for the geographic area they live in to be identified, thereby allowing data to be included in regional analysis within Port Colborne. It will also provide the opportunity to identify the duplication of questionnaire responses.

3.4 Study procedures

3.4.1 Questionnaire development

The SRHQ has been constructed using the validated SF-36 questionnaire. The child and adolescent questionnaire was designed based on relevant questions in the CCHS and the NLSCY. Questions were added to the SRHQ to reflect potential concerns related to childhood asthma and skin disorders. A unique household identification number will be assigned to each questionnaire in order to conduct regional analyses within Port Colborne and to examine whether there is differential response by geographic area. This will be useful in determining whether the results are representative of the entire Port Colborne community. This identifier will only allow the identification of residences within a region, it will not allow individual households to be identified.

3.4.2 Site and staff preparation

The clinical team will be based at 804 King Street, Port Colborne, Ontario. The site will be staffed by personnel that can supply additional questionnaires, clarify any questions on

the SRHQ, help with translation and update the questionnaire lists where appropriate, with individuals who were omitted from the phone listings.

Ventana will develop a communications strategy that will raise community awareness of the study within Port Colborne. This phase of the research, which will lay the groundwork for public support of the project, will be critical to the success of the study. The advertising and awareness campaign will outline the importance of citizen participation and inform the community that they will be asked to complete a questionnaire. It will also contain pertinent information on how residents can get more information on the questionnaire itself.

A mail out postcard will be the initial household contact which will be sent in mid August. The postcard will introduce the health assessment project and will indicate that a personal telephone call will be made at the end of August, notifying the household of the health assessment project and providing a 1-800 number for any questions relating to the process.

The postcard will contain dates of when the questionnaire mail out will commence, details of the Port Colborne facility, the 1-800 number and the closing date for the return of the questionnaire.

3.4.3 Administration of questionnaire

Using the phone list of 6,700 numbers, each household will be contacted via mail out postcard and telephone to inform them of the planned community health assessment

project. They will also be told to expect a questionnaire in the mail within one week from this phone call. Each household will be mailed 4 copies of the adult questionnaire and 2 copies of the child and adolescent questionnaire. The child and adolescent questionnaire will be formatted so that the responses for four children/adolescents can be written on one questionnaire. Each household will be provided with an envelope with return address and postage to facilitate the return of completed questionnaires and a phone number in the event that they require clarification about the survey, or about any of the questions posed. The return address will be Ventana Clinical Research Corporation, 340 College Street, Suite 400, Toronto, Ontario, M5T 3A9.

Each questionnaire will be assigned a uniquely defined household identification number. This number will be defined by the phone number, and will include a digit to identify the geographical area within Port Colborne where the household can be found.

Each adult member of the household (aged 18 and over) will be asked to complete a SRHQ. A parent/guardian will be asked to complete the questionnaire for children/adolescents.

The mailing of the questionnaires will occur immediately following approval by a Review Board (September 16, 2002). It is hoped that most respondents will agree to answer the questionnaire with the first mail-out, but up to two follow-up postcards will be mailed to encourage participation. These postcards will be sent out 2 and 4 weeks after

the initial mail-out. This will help to increase response rate. This will help to increase the response rate. The final date for receipt of the questionnaire is November 16, 2002.

The mailed questionnaire is preferable to phone interviews or face-to-face interviews for the following reasons:

- the participant can complete the questionnaire at his/her convenience
- there is less likelihood that the participant will be subject to social desirability response bias for the SF-36 questionnaire
- it is more economical and less time-consuming to mail-out the questionnaire than to train interviewers that go door-to-door to conduct face-to-face interviews
- the method is feasible because we are doing the questionnaire within the confines of a relatively small city and has been shown to be valid in similar settings
- the SF-36 has previously been employed in settings where there has been concerns about health effects resulting from occupational and residential exposure to environmental contaminants

The anticipated completion rate for mail-out questionnaires is approximately 65 percent. This number is dependent on: i) communications efforts launched to boost awareness of the research and an understanding by the community of the importance of participation; ii) potential respondents to the Port Colborne study having a vested interest in completing the SRHQ such that they are more likely to be interested in the process.

3.4.4 Inclusion of "Hard to Reach" residents

The high visibility of the project within the community of Port Colborne – through the communications campaign and its physical presence at Ventana's storefront location –

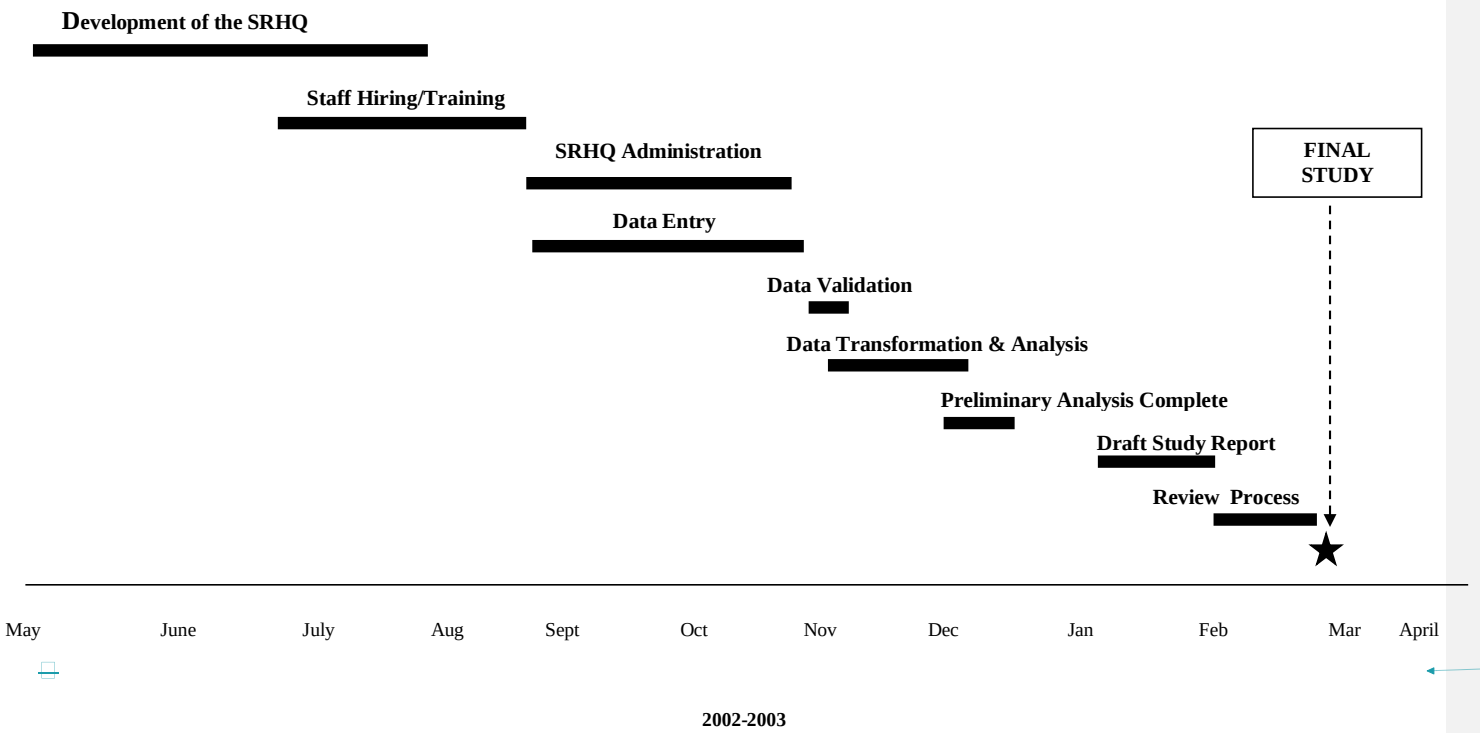
should preclude the possibility that someone who wished to be included in the SRHQ would not be able to do so because he/she was unaware of it or did not have a phone. Anyone visiting the central location will be given an opportunity to fill out the SRHQ. They will be asked to provide their address in order to ensure that no duplicate questionnaires were administered, and furthermore, so that the enumeration list, as based on phone records, can be made more complete.

Other studies that have used the SF-36 questionnaire administered through mail have demonstrated high response rates. For example, a UK study that collected community data in two postal questionnaire surveys conducted in 1991 and 1997 had response rates of 72% and 64%, respectively [19] . Elsewhere response rates of 82% were obtained in a community survey conducted among those 65 years of age and older [21], while a postal questionnaire survey of 3000 randomly selected 18 to 75-year-olds residing in 15 electoral wards and registered with two urban practices had a response rate of 73% [20]. Based on the results obtained from these similar studies, we believe with an accompanying communications plan, we feel that we can expect a response rate of at least 65%.

3.5 Duration

It is anticipated that the entire process of fielding the SRHQ; data analyses; and completion of the final study report will take place through to February 2003, subject to the study approval date. The schedule of dates is shown in Figure1.

Figure 1 – Proposed Timeline of Self-Reported Health Questionnaire Study



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3.6 Informed consent

A booklet will be provided with the questionnaire that will advise the respondent of all aspects pertaining to his/her participation in the study. The booklet will explain the self-assessment process and what information will be provided from this assessment in the community. It will explain how confidentiality is assured and provide guidance for completion of the questionnaire. Completion and return of the SRHQ implies that the respondent has given consent.

3.7 Confidentiality

According to the standards specified by The Personal Information and Electronic Documents Act, January 1, 2002.

- A respondent's personal data will not be used, disclosed, nor collected in any manner incompatible with the intended purpose of the research. Great care will be taken to keep the information secure, whether on hard copy, on computer or stored electronically.

Participants will be informed of the degree of confidentiality that will be maintained throughout the study during the process of obtaining informed consent. Moreover, individuals will be informed that under no circumstances will direct links exist between their names and their records or data. Instead, a unique identifier number will be assigned to each questionnaire, and will be carried through the data entry process until it becomes the first variable in the dataset. This unique identifier number will be permanently associated with the respondent's questionnaire. All versions of the database of

questionnaire responses will contain only the unique identifier – the respondent's personal identification information will be removed from all working databases, but it will be on files stored at Ventana. The uniqueness of the identifier number will be confirmed by running frequencies to ensure that there are no duplicates. Unless otherwise specified, only aggregate data, not individual data, will be published or released to the general public, as with any scientific study.

~~5.0~~4.0 Study Population

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4.1 Overview

All 18 000+ residents of Port Colborne, that is both adults and their children, will be eligible to participate in the SRHQ. An adult is defined as those 18 years of age and over. Parents or Guardians of children under 18 years of age will answer the "child-specific" component of the SRHQ on their child's behalf.

4.2 Participant selection criteria

4.2.1 Inclusion criteria

Participants may be included in the study if ALL of the following criteria apply:

1) They agree to complete the questionnaire (implied consent).
2) They are at least 18 years of age. Adults will answer questions on behalf of children currently residing in their household.
~~4)~~3) Their permanent residence is currently (as of September 1, 2002) within Port Colborne boundaries.

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4.2.2 Exclusion criteria

Participants may not be included in the study if:

1) They choose not to comply with the study procedures.

4.3 Premature withdrawal from the study

Individuals may withdraw from participation in the SRHQ at any time for any reason. If, for any reason, an individual chooses not to fully complete the SRHQ, their results will be used according to the following criteria:

1) Partial responses will be used and analyzed only if the participant consents to the use of such data (i.e., they mail back the questionnaire).
2) The SF-36 guide will be used to assist in determining whether enough fields have been completed to include the individual in the analysis [24].

4.4 Comparison/Control group(s)

Comparisons will be made between those participants that reside in the Rodney Street area to those that live in other areas of Port Colborne. Because of the large overlap of questions from the SRHQ with population-based surveys, a significant body of data exists for large populations for which comparison can be made against. Finally, comparisons of the study findings will be made to a recent study conducted in Canada [6].

~~6.0~~5.0 Outcome Measures

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The primary outcome measures expected from the administration of the SRHQ to the Port Colborne community are:

1) Perceived general health of individuals within the Port Colborne community.

~~3)~~2) Demographic and other health data, which can be compared to similar data from the CCHS, NLSCY, and the 1996 Canadian census.

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~~7.0~~6.0 Data Collection and Analysis

6.1 Sample size calculation

6.1.1 Overview

Sample size is an important consideration when designing a health questionnaire. When estimating the community rates of a certain characteristic or health condition, random sampling or chance may partly explain the findings. For example, if the overall smoking rate in Port Colborne were 30%, taking repeated samples of 10 individuals would not be expected to result in the finding of three smokers in every sample of 10 individuals. For this reason, a sufficient number of individuals must be sampled so that a reasonably accurate estimate of the health characteristics of the community can be obtained.

The term "Power" is used to describe the ability of a study to detect a true difference when making comparisons between two or more groups. If a study has a power of 50%, this means it has a 50-50 chance of detecting this difference. Typically studies aim for a power of at least 80%, as it would be unsatisfactory if there were more than 20% chance of missing this difference. The number of participants that are needed to ensure sufficient power are influenced by several factors including: the size of the difference that is to be detected; the prevalence of the disease or characteristic of the population that is being compared, the variance of the characteristic that is being examined; and the size of the

Type I error (probability of rejecting the null hypothesis when it is true). Each of these factors must be specified in order to estimate the power of a study.

The Power of a study may be calculated in order to ensure that the average value of a variable, or prevalence of a health condition within a community, is calculated with sufficient precision. This is referred to as a one-sample statistical test. Alternatively, the objective of the study may be to compare differences in disease rates between two communities. In this case, the study power is calculated to ensure that there are sufficient numbers of participants in both communities so that a meaningful statistical test can be constructed to allow comparisons between two communities. This is referred to as a two-sample test.

6.1.2 Power calculations

The primary objective of the study is to compare values obtained from the SRHQ to data obtained from similar population-based surveys conducted under similar settings. A secondary objective is to compare values obtained from the Rodney Street area of Port Colborne to values obtained from other Port Colborne residents. The SRHQ will be administered to as many residents as possible. Assuming that 60% of the Port Colborne residents are 18 years of age and older, and that the response rate is 65%, we anticipate that there will be 6,840 completed questionnaires among adults. Applying these proportions in the Rodney Street area, an estimated 324 adults will complete the SRHQ.

There are published Canadian normative data for the SF-36 health survey from which sample size calculations can be made [6]. We estimated the needed sample size by

applying the median standard deviation across the 8 domains of the SF-36 obtained from this study to the formula for the two-sample t-test as outlined by Rosner [25]. A minimum of 253 individuals would be needed in each of the two populations (Rodney Street vs. remainder of Port Colborne) in order to confer a power of 80% with a two-tailed level of significance to detect a difference in the health score of 5 points on the 100-point scales of the SF-36. This difference of 5 points is recognized as being clinically significant [24]. Therefore, given the anticipated response rates we will have sufficient power to make comparisons between SF-36 scores between residents in the Rodney Street area to other residents of Port Colborne.

6.1.3 Power calculations for comparisons to other populations

There are several published studies of SF-36 values obtained from mail-out questionnaire to the general population aged 18 years of age and older [8, 9, 12-15]. These sample sizes have typically exceeded 1,000 individuals, and therefore, this study provides sufficient power to make comparisons of the SF-36 values using the formula as outlined in 6.1.1.

6.2 Data collection and quality assurance

Subjects will be asked to return their questionnaires by mail in the pre-addressed stamped envelope provided to them. Opportunities for individuals to participate if they are not on the telephone listing or if there are language barriers will be available. Reminders will also be sent out to increase response rate.

All Data entry will occur at Ventana's head office in Toronto. The questionnaires will be entered into Phoenix Data Systems, a data entry application, using a double-data entry process. A data entry coordinator who will refer to the original questionnaire will reconcile differences between the first and second data entry. This method provides a reliable and accurate dataset. The data will be stored in an EXCEL data sheet which will then be converted to a SAS dataset for the purpose of statistical analysis.

6.3 Data analysis

For each participant, the values for each of the 8 dimensions of the SF-36 and 2 summary indices of the SF-36 (physical and mental component summary scores) will be calculated using previously defined methods Mean values and their standard errors will be calculated by age-grouping and gender. To facilitate comparisons with previously published Canadian data [6], subjects will be grouped into the following age categories: 25-34, 35-44, 45-54, 55-64, 65-74, 75+ and all age-groupings. For each age-grouping, comparison of mean values to the Canadian normative data will be done using unpaired t-tests. Direct age-standardization will be used to compare the means of the entire sample

to the Canadian values. This method will adjust for differences in the underlying age and gender distribution of the two study populations. As published data are not readily available for those between the ages of 18–25, comparisons will be made between survey data for this age group to other study populations and to scores from older age-groups in the Port Colborne survey.

Multivariate analysis of variance methods will be used to compare the mean values of the SF-36 scores among subjects in the Rodney Street area to those values for other Port Colborne residents. This method allows for a comparison to be made while controlling for the effects of potential confounding variables. These confounding variables include: age, gender, income level, and education. Analysis will be extended to determine whether the length of residency in Port Colborne is an important determinant of SF-36 scores. This will formally be tested using the likelihood ratio statistic, which can readily be obtained from analysis of variance methods.

The same methods of analysis will be applied to make comparisons of data obtained from the child and adolescent questionnaire of the SRHQ to responses obtained from the CCHS and the NLSCY and CCHS. Sample size constraints do not permit regional comparisons of asthma and skin disorders to be made within Port Colborne, however, summary questionnaire data for the prevalence of these conditions will be compared to national data.

Analysis will be undertaken to evaluate the potential for response bias. Response rates across regions of Port Colborne will be compared to determine whether there is differential response according to potential exposure to CoCs. Specifically, response rates between residents in the Rodney Street area will be compared to the remainder of Port Colborne. Response rates by age and gender will also be calculated. Testing for significant differences in response rates will be done using the Chi-Square test statistic.

Using sociodemographic and population data from the 1996 Canadian census, responses from the SRHQ will be examined to determine whether the sample appears representative of the entire Port Colborne community. Specifically, the distribution of responses according to age, gender and income will be compared to summary census measures for the Port Colborne region. Results obtained from the SRHQ will be interpreted in light of these potential response biases. All statistical analyses will be conducted by using SAS [26].

~~8.0~~7.0 Data Storage and Transfer

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The data will be stored at varying degrees of refinement. Hard copies of documents, including the questionnaires will be stored for five years. The storage will be at Ventana. Hard copy files will be archived within a secure, fire retardant facility.

8.0 Publication Policy

The study investigator(s) has the right to publish, present or otherwise disclose his/her findings in the scientific literature with respect to data generated by the Investigator(s) from the study, subject to the following criteria:

- All final draft manuscripts, based on whole or in part on the study, must undergo a review and be approved by a "Publication Steering Committee" (PSC), implemented in conjunction with the community.
- Submission to the PSC for review must occur at least 60 days prior to submission by the Investigator(s) of such manuscript for publication.
- No less than 12 months must elapse following completion of the final study report before submission for publication.
- Should the PSC determine the manuscript discloses confidential or proprietary information, the Investigator(s) will either remove it or modify the manuscript to the satisfaction of the PSC, so that publication of the revised manuscript may proceed.
- Should the PSC determine the manuscript discloses any discovery, invention, or other intellectual property, which the PSC wishes to protect, whether by preparing any patent or other intellectual property applications or otherwise, the Investigator(s) will, upon request by the PSC, delay submission for a period not exceeding 4 months from the date the PSC receives such manuscript from the Investigator(s).
- Restrictions may be imposed on where to publish, subject to discussion with the PSC.

9.0 References

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10.0 APPENDICES

10.1 Appendix 1 – SRHQ Adult Mail-out Questionnaire

SRHQ Adult Mail-out Questionnaire

🗁 indicates that the questions were derived from the SF-36
🗁 indicates that the questions were derived from the CCHS
🗁 indicates that the questions were derived from the NLSCY

EACH ADULT IN THE HOUSEHOLD SHOULD ANSWER THE FOLLOWING QUESTIONS (18+).

Household Information

1. How many people live in your household? _____

2. How many years have you lived in Port Colborne? _____

Demographics

3. What is your date of birth? DD/MM/YYYY 🗁

4. Please indicate your sex: 🗁
   Male
   Female

5. Highest grade of elementary or high school completed: 🗁
   ___ Grade 8 or lower (Quebec: Secondary II or lower)
   ___ Grade 9 – 10 (Quebec: Secondary III or IV; Newfoundland: 1st year of secondary)
   ___ Grade 11 – 13 (Quebec: Secondary V; Newfoundland: 2nd to 4th

year of secondary)

6. Highest degree, certificate or diploma:
   - ___ No postsecondary degree, certificate or diploma
   - ___ Trades certificate or diploma from a vocational school or apprenticeship training
   - ___ Non-university certificate or diploma from a community college, CEGEP, school of nursing, etc.
   - ___ University certificate below bachelor's level
   - ___ Bachelor's degree
   - ___ University certificate or diploma above bachelor's degree

7. Can you estimate in which of the following groups your household income falls?
   Was the total household income …
   - ___ Less than $20, 000?
     - ___ Less than $10, 000?
       - ___ Less than $5, 000?
       - ___ $5, 000 or more?
     - ___ $10, 000 or more?
       - ___ Less than $15, 000?
       - ___ $15, 000 or more?
   - ___ $20, 000 or more?
     - ___ Less than $40, 000?
       - ___ Less than $30, 000?
       - ___ $30, 000 or more?
     - ___ $40, 000 or more?
       - ___ Less than $50, 000?
       - ___ $50, 000 to less than $60, 000?
       - ___ $60, 000 to less than $80,000?
       - ___ $80, 000 or more?
   - ___ No Income

8. At the present time do you smoke cigarettes daily, occasionally or not at all?
   Daily
   Occasionally
   Not at all
   DK, R

General Health

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

9. In general would you say your health is… 🗁
   1 excellent
   2 very good
   3 good
   4 fair
   5 Poor

10. Compared to 1 year ago, how would you rate your health in general now? Would you say it is… 🗁
    1 Much better now than one year ago
    2 Somewhat better now than one year ago
    3 About the same as one year ago
    4 Somewhat worse now than one year ago
    5 Much worse than one year ago

11. The following questions are about activities you might do during a typical day. Does you health now limit you in these activities? If so, how much? 🗁
    a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

       1 Yes, limited a lot
       2 Yes, limited a little
       3 No, not limited at all

    b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.

       1 Yes, limited a lot
       2 Yes, limited a little
       3 No, not limited at all

    c. Lifting or carrying groceries.

       1 Yes, limited a lot
       2 Yes, limited a little
       3 No, not limited at all

    d. Climbing several flights of stairs.

       1 Yes, limited a lot

2 Yes, limited a little
3 No, not limited at all

e. Climbing one flight of stairs.

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

f. Bending, kneeling or stooping.

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

g. Walking more than a mile.

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

h. Walking several hundred yards (i.e. 10 minutes).*

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

i. Walking one hundred yards (i.e. a couple minutes).*

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

j. Bathing or dressing yourself. 🗁

1 Yes, limited a lot
2 Yes, limited a little
3 No, not limited at all

12. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? 🗁

a. Cut down on the amount of time you spent on work or other activities.

1 All of the time
2 Most of the time

3 Some of the time
4 A little of the time
5 None of the time

b. Accomplished less than you would like.

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

c. Were limited in the kind of work or other activities.

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

d. Had difficulty performing the work or other activities (for example, it took extra effort).

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

13. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? 🗁

a. Cut down on the amount of time you spent on work or other activities.
1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

b. Accomplished less than you would like.
1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time

5 None of the time

c. Did work or activities less carefully than usual.
   1 All of the time
   2 Most of the time
   3 Some of the time
   4 A little of the time
   5 None of the time

14. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
   1 Not at all
   2 Slightly
   3 Moderately
   4 Quite a bit
   5 Extremely

15. How much bodily pain have you had during the past 4 weeks. 🗁
   1 None
   2 Very Mild
   3 Mild
   4 Moderate
   5 Severe
   6 Very Severe

16. During the past 4 weeks, how much did pain interfere with your normal work (including both outside the home and housework)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Quite a bit
   5 Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give me the one answer that comes closest to the way you have been feeling.

17. How much of the time during the past 4 weeks …🗁

a. Did you feel full of life?
   1 All of the time

2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

b. Have you been very nervous?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

c. Have you felt so down in the dumps that nothing could cheer you up?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

d. Have you felt calm and peaceful?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

e. Did you have a lot of energy?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

f. Have you felt downhearted and depressed?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

g. Did you feel worn out?
   1. All of the time
   2. Most of the time
   3. Some of the time
   4. A little of the time
   5. None of the time

h. Have you been happy?
    1. All of the time
    2. Most of the time
    3. Some of the time
    4. A little of the time
    5. None of the time

i. Did you feel tired?
    1. All of the time
    2. Most of the time
    3. Some of the time
    4. A little of the time
    5. None of the time

18. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? 🗁
    1 All of the time
    2 Most of the time
    3 Some of the time
    4 A little of the time
    5 None of the time

19. How TRUE or FALSE is each of the following statements for you? 🗁

a. I seem to get sick a little easier than other people.
    1. Definitely true
    2. Mostly true
    3. Don't know
    4. Mostly false
    5. Definitely false

b. I am as healthy as anybody I know.
    6. Definitely true
    7. Mostly true
    8. Don't know
    9. Mostly false
    10. Definitely false

c. I expect my health to get worse.
    1. Definitely true
    2. Mostly true

3. Don’t know
4. Mostly false
5. Definitely false

d. My health is excellent.
    1. Definitely true
    2. Mostly true
    3. Don’t know
    4. Mostly false
    5. Definitely false

10.2 Appendix 2 – SRHQ Child & Adolescent Mail-out Questionnaire

SRHQ Child & Adolescent Mail-out Questionnaire

🗁 indicates that the questions were derived from the National Longitudinal Survey of Children & Youth (up to age 11)
🗁 indicates that the questions were derived from the CCHS (ages 12-17)
must design for 4 children / questionnaire

A PARENT/GUARDIAN IN THE HOUSEHOLD SHOULD ANSWER THE FOLLOWING QUESTIONS FOR ALL MEMBERS OF HOUSEHOLD (<18).

Demographics

1. What is your child's date of birth? DD/MM/YYYY

2. Please indicate your child's sex:
   Male
   Female

3. a) What is his/her height in feet and inches or in metres/centimeters (without shoes on)? 🗁🗁
   2. Feet and Inches
   3. Metres/Centimetres

If answered 1 to 3. a),
b1i) ____ feet
b1ii) ____ inches

If answered 2 to 3. a),
b2) __.____ Metres/Centimetres

4. What is his/her weight in kilograms (and grams) or in pounds (and ounces)? 🗁🗁
   4. Kilograms/Grams
   5. Pounds/Ounces

If answered 1 to 4. a),

b1) ____.____ Kilograms/Grams

If answered 2 to 4. a),

B2i) ____ Pounds

B2ii) ____ Ounces

General Health

5. In general, would you say your child's health is:?
    1. Excellent?
    2. Very Good?
    3. Good?
    4. Fair?
    5. Poor?

6. Compared to one year ago, how would you say your child's health is now? Is it:?
    1. … much better now than 1 year ago?
    2. … somewhat better now than 1 year ago?
    3. … about the same?
    4. … somewhat worse now than 1 year ago?
    5. … much worse now than 1 year ago?

7. Over the past few months, how often has he/she been in good health?
    1. Almost All the Time
    2. Often
    3. About Half of the Time
    4. Sometimes
    5. Almost Never

8. In your opinion, how physically active is your child compared to other children the same age and sex:

1. Much More?
2. Moderately More
3. Equally
4. Moderately Less
5. Much Less

9. a) The following questions are about asthma. Has your child ever had asthma that was diagnosed by a health professional? 🗁🗁*
    1. Yes
    2. No

   If yes, then

   b) Does this condition or health problem prevent or limit his/her participation in school, at play or any other activity normal for a child of his/her age? 🗁
        1 Yes
        2 No

   c) Has he/she had an attack of asthma in the last 12 months? 🗁🗁*
        1 Yes
        2 No

10. Has he/she had wheezing or whistling in the chest at any time in the last 12 months? 🗁
    1. Yes
    2. No

11. Does your child have any long term condition or health problems which prevent or limit his/her participation in school, at play, sports or in any other activity for a child of his/her age. 🗁
        1 Yes
        2 No

12. Does he/she take any of the following prescribed medication on a regular basis: Ventolin, inhalers or puffers for asthma? 🗁🗁**
    1. Yes
    2. No

13. a) Has your child ever had a skin condition that was diagnosed by a health professional?
    1. Yes
    2. No

    If yes, then

    b) Please specify the skin condition? _____