# Baseline Non-communicable Disease Prevalence in Nepal: A cross-sectional survey

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# Specific Aim:

Conduct door-to-door survey to establish baseline population characteristics and prevalence for adult noncommunicable diseases in five of the fifteen wards of Thaha municipality in Makawanpur District, Nepal. These include wards 11, 12, 13, 14 and 15 with a combined 2011 population of 7,675. Acupuncture Relief Project/Good Health Nepal, in collaboration with the Oregon College of Oriental Medicine (OCOM) in Portland, OR and Nepal Health Research Council in Kathmandu, Nepal will adapt the World Health Organization (WHO) STEPwise approach to noncommunicable disease risk factor surveillance instrument (STEPS) to collect data via a door-to-door cross-sectional survey.

Background and Significance:

Non-communicable diseases (NCDs), mainly cardiovascular disease, cancer, chronic respiratory disease and diabetes mellitus, represent a leading threat to human health and development (Banerjee K, 2016; Ricci G, 2017). Globally, chronic NCDs accounted for an estimated 36 million deaths, or 63% of the 57 million deaths that occurred in 2008 (World Health Organization, 2010). Furthermore, 80% of all deaths (29 million) from NCDs occurred in low-and middle-income countries (WHO, 2010), where rapid urbanization, increased globalization and an aging population contribute to rising prevalence (Miranda, 2008).

As one of the fastest developing countries in Southeast Asia, Nepal is currently in a transition from infectious diseases to NCDs as its major public health concern (Subedi YP, 2017). The most recent data suggests that NCDs account for 60% of all deaths (Aryal, 2015) and 80% of outpatient care (Mishra, 2015), with chronic obstructive pulmonary diseases (43%) and cardiovascular disease (40%) the most common, followed by diabetes mellitus (12%) and cancer (5%) (Bhandari, 2011). According to the WHO (World Health Organization, 2017), and a study by Bishwajit (2015), political instability, economic discrepancies, high unemployment, low education, unhealthy lifestyle behaviors, and indoor air pollution are all risk factors for NCDs in Nepal. Alcohol abuse and tobacco use are also particularly high (Ayral, 2015; Amundsen 2016). A 2011 paper by the the World Bank states "the accelerated urbanization [in Nepal] with limited resources, and a globalization of processed food contribute to the increase of unhealthy lifestyle habits that perpetuate the cycle of chronic illness, debt and poverty," (The World Bank, 2011) and indicates that addressing NCDs is the next major health challenge for Nepal.

In response to this rising burden of disease, the WHO outlined strategies for the management of NCDs for low-and-middle-income-countries such as Nepal in the 2008-2013 Action for the

Global Strategy for the Prevention and Control of Noncommunicable Diseases (World Health Organization, 2008). One strategy outlined in the publication is the implementation of "Lifestyle," or integrated clinics, designed to encourage a community-based approach to research, educate, prevent, and treat NCDs. In these clinics, primary healthcare workers are retrained to recommend nutritional and lifestyle counseling in an integrative, patient-centered care setting to promote an economically and socially favorable system of healthcare. (Mallawaarachchi, 2017). Countries in Latin America, Africa, Asia and South East Asia have successfully implemented Lifestyle clinics that address modifiable lifestyle behaviors based on the WHO model (Nissien, 2001, Siriwardhana, 2013). Extensive research also indicate a significant decrease in chronic disease mortality when behavioral risk factors are replaced with healthy lifestyle choices. (Ezzati, 2012; Yusuf, 2004; Knowler, 2002). A leading example is Sri Lanka, a South Asian island with similar regional challenges as Nepal. From 2009-2011, the Ministry of Health in Sri Lanka worked with the WHO to conduct a feasibility study establishing NCD interventions in primary clinics throughout the Badulla district (Mendis, 2012). Following the success of the study, 126 Healthy Lifestyle Centres (HLCs) were initiated, and in 2016, the number of HLCs increased to 826, resulting in a reduction of NCDs across its entire population. (Mallawaarachchi, 2017)

Given the rising burden of NCDs in Nepal and the success of Lifestyle clinics in similar countries, it is likely that the establishment of Lifestyle clinics in Nepal will be a valuable approach to manage the NCD crisis in Nepal. However, a number of barriers to the development and implementation of such clinics exist in Nepal, particularly in rural areas, including the lack of nationwide population data and insufficient government funding.(Mishra, 2015) The WHO STEPwise approach to NCD risk factor surveillance (World Health Organization, 2017) highlights the necessity of conducting baseline population surveys as a means of identifying the most pressing risk factors, and informing interventions for NCD control and prevention, including Lifestyle clinics. In particular, the collection of population data following a surveillance approach such as STEPwise allows for 1) the collection of data across and within countries, 2) comparisons over time and across countries and 3) health services to determine priorities and plan appropriate disease interventions. Therefore, the collection of robust survey data is a necessary first step for Nepal to begin the process of building a network of Lifestyle clinics.

As is the case in many low income countries (Nguyen, 2014), the initial NCD surveillance surveys are often conducted by well situated non-government organizations (NGOs) with the resources, regional understanding, and established relationships to enable the successful collection of data. In Nepal, one such NGO is Good Health Nepal (GHN) (Good Health Nepal, 2013).

GHN was founded in 2008 and currently operates clinics in Bhimphedi and Bajrabarahi in the Makawanpur District in central Nepal, an area where governmental health care service is limited or non-existent. The clinics serve a population of approximately 120,000 villagers who travel up to four hours by foot, each way, to receive treatment, urgent care, and medical referrals. The clinics are staffed by volunteers provided by Acupuncture Relief Project (ARP), a US 501(c)(3) nonprofit organization which works collaboratively with GHN. GHN/ARP, with a prioritization on patient education and prevention, have provided simple, practical, safe, low-cost and

sustainable treatments (including acupuncture and primary care) to more than 300,000 treatments patients within the clinic's catchment area in the Makawanpur District since it began.

Anecdotal evidence from GHN/ARP suggests that the burden of NCD is high in this region, however no data currently exists on the patient demographics, NCD type, prevalence, or regionally specific risk factors. Utilizing its resources, regional understanding, and established relationships with the local community, GHN/ARP will conduct a door-to-door survey to establish baseline population characteristics and prevalence for adult noncommunicable diseases in five of the fifteen wards in Makawanpur District, Nepal.

## Potential Benefits of this Research

Data and insights from this baseline survey will contribute to emerging NCD data for Nepal, and support the establishment and operation of future Lifestyle (Integrative) clinics in rural Nepal. Similar to other countries in the region (Mallawaarachchi, 2016; Siriwardhana, 2013, Sagner 2016), these lifestyle clinics will likely prioritize preventive health education, palliative care, dietary changes, exercise and other lifestyle modifications. Additionally, they will serve as primary care centers providing medical advice, diagnosis, and treatment for acute and chronic conditions. Once established, the clinic operations will likely be overseen by the following organizations: the National Health Research Center (NHRC), Health Professionals Council, District Office of Health Services (DOHS), and respective District Public Health Offices in Nepal.

## Methods

#### **Research Design**

This observational study will be a cross-sectional population survey to identify demographics and the burden of risk factors for NCDs. The survey is adapted from the WHO STEPwise approach to non-communicable disease risk factor surveillance (World Health Organization, 2017), and consists of questionnaire-based assessments, physical measurements and basic biochemical measurements.

A beta-test will be conducted with a convenience sample of ten households within the 12th Ward prior to the formal study. The beta test will identify necessary changes to question relevancy, coherency and consistency and assess feasibility and acceptability of the proposed survey. Findings from the beta-test will be used to streamline the formal survey prior to initiation of the study.

#### Study Population

This survey aims to capture household information and basic non-communicable disease assessments for all adult residents within wards 11, 12, 13, 14, and 15 in Thaha municipality in Makawanpu. These five wards occupy approximately 13 squares miles (18 acres) with 1,500 households (300 households in each ward) and a total population of 7,675 in 2011. Five survey teams will interview 10 households each day; we aim to interview 50 households daily for 30 days (1 month).

Inclusion critera:

- Adults nineteen years and older
  - The age cut-off of nineteen years is determined by traditional Nepalese counting methods for age and defines a population of adults who are eighteen years and older by traditional European counting methods for age

# Exclusion criteria:

- Children below the age of nineteen
- Inability of communicate directly with interviewers
- Non-consent

# Geographic Coverage

This survey will cover five of the fifteen wards of Thaha municipality in Makawanpur District located in the Hill Region of Nepal, approximately 65 km from Kathmandu. These include wards 11, 12, 13, 14 and 15 with a combined (2011) population of approximately 7,675.

# Household Identification and Tracking

An aerial grid map of the region will be employed to track households contacted and interviewed.

## **Survey Methods**

Two questionnaires along with physical and biochemical measurements will be used in in-person interviews to collect data on demographics and behavioral and physical risk factors. The survey questionnaires will be prepared in both paper and electronic forms. Five tablets loaded with an electronic version of the survey in REDCap will be available for use by the survey teams. Data collected on paper questionnaires will be entered by hand in the electronic database.

The interviews will be conducted by teams of two individuals staffed by the District Health Office in Suswaastya Nepal. Each household encounter will begin with a consent form and the household and dwelling questionnaire which is expected to take 20 to 30 minutes to complete. The household interview will be followed by individual questionnaires for all household adults and is expected to take 20 to 30 minutes to complete each. Each participant will be given the option of declining participation in this study. Individuals under 19 years of age will not be interviewed.

#### Overview of Questionnaire-based Assessments

Questionnaire items and content have been adapted from WHO STEPwise resources, previous population studies performed by the Patan Academy of Health Sciences, and National Institutes of Health's (NIH) Patient Reported Outcome Measurement Information System (PROMIS) questionnaires. The STEPS questionnaires have previously been translated into Nepalese and the remainder of the survey will be translated by Bhimsagar Guragain, the District Public Health Officer and Inspector of Makawanpur District prior to the initiation of the study.

#### Household and Dwelling Questionnaire

The household questionnaire (see Appendix 1) will collect data on each dwelling's description including construction materials, electricity, plumbing, kitchen and garbage management. This questionnaire will also ask about travel distance to the nearest healthpost, and hospital, and by

what method of transportation. Other household variables will include source and proximity to drinking water, technology and modes of transportation within the household, land ownership, livestock, food security, and recent deaths within the household. Items in the household questionnaire are adapted from the WHO STEPS and were used in the 2012-2013 Nepal NCD surveillance (World Health Organization, 2017).

## Individual Questionnaire

The individual questionnaire (see Appendix 2) will collect demographic data for adults 19 years and older. The data will include sex, Nepali and Western birth date, current age, general health, tobacco and alcohol use, medication use, healthpost or hospital use for common non-communicable diseases within prior two weeks or prior year, past acupuncture use and experience, ability to work, and individual health factors. The health factors include participant-reported paralysis, pain, diabetes, high blood pressure, mental health. Patient Reported Outcome Measurement Information Systems (PROMIS) tools will be included in the interview for general health (v1.2), pain interference and cognitive function (Short Form 8a). Within Thaha municipality, 93% of the population are within five ethnic groups. As a check box in the questionnaire, these categories include 'Tamang', 'Chettri', 'Newar', 'Brahmin', 'Gurung' and 'Other' to capture the smaller ethnic groups with a fill in the blank accompanying 'Other'. In each new municipality, these categories will change to include the ethnic groups

#### Physical and biochemical measurements

The interviewers will use standard practices to gather objective health measures. These include hip-to-waist ratio as an indicator for obesity, blood pressure, heart rate, normal blood oxygen saturation levels (SpO2), respiration rate, and random blood glucose.

# Data Collection Methods

## Training of data collection team

A week-long training will be organized for all study personnel prior to the start of data collection. Training will focus on interview techniques, sampling process, household and individual selection, use of the survey paper and electronic forms, and proper management of collected data.

## Interview Teams

Five teams of two individuals from the District Health Office in Suswaastya Nepal. Each team will be contacting households in one of the five wards. The study's physical base will be at Bajrabarah Clinic, the Good Health Nepal clinic in Bajrabarah, Makawanpur District.

### Field data collection

Interview teams will use tablets with versions of the questionnaires prepared in REDCap. Each team will have paper copies of each questionnaire for backup in the field.

#### Quality Control

Interview teams will be trained and provided with a GHN Field Manual (Appendix 3)

### <u>Timefram</u>e

This survey will occur during Nepal's mild weather season, either April 1st to June 1st or October 15th to Dec 15th

## Human Subjects Protection

- 1. Ethics
  - a. This study will adhere to the utmost of ethical standards including privacy, respect, and rights of the participants. It is the responsibility of the researchers is to maintain the dignity of all participants and in no way cause direct or immediate harm or any other potential action that will lead to an adverse consequence as a result of the study.
  - All individuals with elevated or unsafe biomarkers identified during the course of the survey will be referred to the local health post for further evaluation.
- 2. Participant Confidentiality
  - All participants are to remain anonymous and all of their information will remain confidential and secure. Maintaining the privacy and anonymity of participants will include:
    - i. All participants will be assigned a specific number that replaces their name to maintain anonymity. All of the names and corresponding numbers will be kept in a secure and encrypted database that only the PI and approved study personnel will have access to, and will not be exposed at any point during or after the study.
    - ii. All paper surveys will be returned to the central clinic from the field at the end of each day, and stored in a locked safety box. Only the PI and approved study personnel will have access to this safety box. In no

situation, shall the participants' personal identity or protected health information be shared or made public.

- iii. All paper and electronic survey data will be entered into an encrypted REDCap database housed on a HIPAA-compliant external server hosted by the Oregon College of Oriental Medicine.
- iv. All participants have the right to request their personal information be destroyed at any point during or after the study
- All participants have the right to decline participation in the survey, or withdraw from the survey at their free will. No one involved in the study shall coerce the participant into enter or remaining in the study.
- vi. All participants have the right to question the nature of the study without repercussion.
- 3. Informed Consent Procedure
  - a. All interview participants of the study will receive an Informed Consent. The Informed Consent will inform on the purpose of the survey, what is involved in participation, confidentiality, and who is organizing the study. The Informed Consent affirms that the interview participants understand that they can leave the study at anytime, clarifies the confidentiality and privacy of all of their information. Interview participants of the study **must** complete an Informed Consent prior to being interviewed.
- 4. Data Storage and Quality Assurance

a. Paper surveys will be transported from the field and stored in a securely locked cabinet at the end of each day. Only the PI and approved study personnel will have access this cabinet. All paper and electronic survey data will be entered into an encrypted REDCap database housed on a HIPAA-compliant external server hosted by the Oregon College of Oriental Medicine. All paper surveys will be shredded 3 years after the completion of the study.

## **Future Directions**

Data collected in this baseline survey will likely be published in academic journals, presented at conferences, and inform future health care development and research in Nepal.

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# Timeline and Budget Justification

Project and Evaluation Timeline: Baseline Adult Noncommunicable Disease Prevalence Survey (BANCD): A cross-sectional study proposal in Nepal

Project and Evaluation Activities	Month											
	1	2	3	4	5	6	7	8	9	10	1 1	12
Develop survey tool	X	X	X									
			X	X								
Obtain OCOM IRB Study Approval			X	X	X							
<i>Obtain Nepal Health Research Council (NHRC) Approval</i>			X	X	X							
Beta-test survey tool				X								
Train Interviewers					X	X						
Conduct survey						X	X					
Analysis of survey data								X	X	X	X	
Report Summary												X