An evaluation of Community Health Workers screening for CVD in the community in four NHLBI/United Health Centers of Excellence

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[1] RESEARCH PLAN

1.1 ABSTRACT

The utilization of Community Health Workers (CHWs) in many low and middle income countries (LMICs) has been largely focused on infectious disease management and maternal and child health[1, 2]. Effective screening and appropriate management of patients who are at high risk for chronic disease in low-resource settings cannot be accomplished due to limited levels of trained personnel and scarce financial resources to conduct lab-based assessments for non communicable disease (NCD) risk factors such as lipid levels[3]. Lay health workers have increasingly been targeted to help shore up the human resource gaps as part of larger efforts to prevent, reduce and manage chronic diseases, including cardiovascular disease (CVD)[3].

This study proposes to train CHWs to use a non-lab based risk assessment tool to identify persons at high risk for CVD in community settings in South Africa, Bangladesh, Guatemala, and Mexico. The risk tool developed in the US population and tested with good performance in several South African cohorts, uses age, gender, BMI, blood pressure, smoking status, and history of diabetes mellitus (DM) to calculate an absolute risk score for developing CVD[4]. The CHW-generated risk scores will then be compared for agreement to risk scores generated by a trained health professional. If there is significant overlap in the percent agreement between the two sets of scores, it will demonstrate that low-level health workers such as CHWs can be adequately trained to screen for, and identify, those at high risk for CVD. The referral pattern for high-risk patients from CHWs to a trained health professional at a community health clinic will also be assessed. Finally, CHW knowledge levels and retention of knowledge about CVD and its risk factors will be evaluated.

Demonstrating success in this study in LMICs will show that this approach can be effectively translated to other low resource settings and can free up trained physicians and health professionals to perform other higher-level functions.

1.2 SPECIFIC AIMS

The burden of NCDs in low and middle income countries (LMIC) is very high and compounds the effects of the already high burden of infectious diseases[5]. The WHO has noted the critical importance of investing in the prevention of NCDs, as well as the importance of community screening – both for its ability to reach large segments of the population in a cost-effective manner and for building community-based models of care for disease management, which is key in ensuring success in reducing and managing NCDs[6]. However, effective screening and appropriate management of patients who are at high risk for NCDs in low-resource settings cannot be accomplished due to limited human and financial resources[3]. There are inadequate numbers of trained personnel in these settings to conduct effective screening of the population in either the primary care setting or with the numbers of trained personnel available.

Task-shifting from physicians to nurses in managing NCDs has been shown to be effective in several countries. A review of the evidence regarding nurse-led interventions reveals that nurses are effective at the management of diabetes in primary care, outpatient, and community settings[14] and in reducing hospitalizations, days spent in hospital, multiple readmissions, patient care, and cost-savings, even after factoring in the cost of the intervention[15]. Still, the lack of human resources in LMIC overall, negatively impacts the ability of nurses to manage NCDs and the deployment of CHWs to offset this burden on nurses.

Currently, the utilization of CHWs in many low and middle income countries has been largely focused on infectious disease management. In addition to the human resources challenge, the scarcity of resources to conduct lab-based assessments for NCD risk factors such as lipid levels, provide an additional challenge to effective screening for high-risk persons at the population level. Where CHWs have been used in NCDs, it has largely been for improving adherence, improving lifestyle choices, or screening for cancer. To date, no one has evaluated the effectiveness of CHWs in screening for cardiovascular disease (CVD) risk and referral for those at high CVD risk for care at primary health

centers. Finally, the WHO has also articulated the explicit recommendation (#17) for the existence of, referral systems as part of managing care and for the appropriate training of health workers to use them [7]. The proposed specific aims of the study address all of these important aspects of screening for, and managing, NCDs in low resource settings.

Furthermore, current funding and health care policy structures often do not recognize the need to prevent and manage the burden of NCDs effectively in low resource settings. This study will contribute to the evidence base required to make this paradigm shift to recognize the burden and importance of managing chronic disease effectively[8].

1.2.1: To determine how well CHWs correctly identify persons who are at high risk for CVD, using a risk prediction tool, by comparing the CHW-generated risk score to a risk score generated by a trained health professional.

Primary outcome: The percent agreement between CHW-generated risk scores and trained health professional-generated risk scores.

Secondary outcome: The cost of screening by CHWs and nurses, including training costs and delivery of the screening program.

1.2.2: To assess if patients, once identified as high risk, are adequately referred and attended to.

Primary outcomes: The proportion of high-risk participants who obtain a referral for a clinic visit.

The proportion of referred high-risk patients who schedule and attend a clinic visit.

1.2.3: To determine the effectiveness of training of CHWs to inform their knowledge of CVD and its major risk factors.

Primary outcome: CHW knowledge level about CVD risk factors after training in the use of the risk prediction tool.

1.3 RESEARCH STRATEGY)

1.3.1 SIGNIFICANCE

Currently, the double-burden of infectious diseases and NCDs in LMICs is compounded by the lack of funding directed at NCD care, lack of adequate health systems infrastructure to tackle the problem, a lack of evidence for the best models for care and human resource challenges[1, 9, 10]. This study will address two important aspects of the latter set of challenges: (1) can a simple risk assessment tool be effectively utilized by CHWs to screen for individuals who are at high risk for CVD in a community setting and, (2) can CHWs adequately identify those at high risk and effectively refer these patients for further assessment and management at a community health center? Together, evidence from these two questions will provide important information about the effectiveness of using a simple risk tool, as well as the value and effectiveness of task-shifting from trained health professionals (most often nurses) to CHWs, as part of a team approach for managing NCDs in a community setting. Both goals have been identified by the WHO as important for making progress in managing NCDs in LMICs for the next two decades[6].

We know that health worker shortages are 'the greatest impediment to health in Sub-Saharan Africa', where the proportion of trained health workers in the region who intend to migrate ranges from 26-68%[11, 12]. This challenge also extends to other LIMC settings. For example, the range of trained health professionals in Sub Saharan Africa (SSA) varies from a regional average of 15.5 physicians and 73.4 nurses/100,000 population, to 25.1 physicians and 140 nurses/100,000 population in South Africa. In the Asia-Pacific, health personnel estimates range from 29.1 physicians, 14.4 nurses and 3 lab health workers/100,000 population in Bangladesh, to 237 physicians, 816 nurses, and 97 lab health workers in New Zealand[13].

Vital alternate delivery mechanisms (e.g. community-based) for health services should be identified to reduce the burden on the health personnel already in place. This approach is consistent with

the goal of training CHWs to screen for those at high risk of CVD and, in so doing, reduce the work load of the trained health personnel at community health centers.

CHWs or Promotoras de Salud (PdS) in Mexico for example, have become important in promoting health in low socioeconomic populations, due to their closeness and knowledge of local communities and health systems and in functioning as cultural brokers and public health advocates. In three of the four sites (Bangladesh, Guatamala, and South Africa), CHWs or Promotoras de Salud (PdS) participate in programs largely related to infectious diseases, maternal and child health and vaccination campaigns. It is only in the United States * Mexico Border area that CHWs have been engaged in activities related to NCD prevention and where specific NCD training programs for CHWs have been initiated through individual projects, although some pilot work has been conducted in two of the other sites. However, in none of the sites has the CHWs ability to screen for CVD and make adequate referrals for high risk individuals been evaluated.

The WHO CVD Risk-Management package provides 1 of 3 scenarios geared specifically to the non-physician health worker and involves 3 visits to a clinic[2]. This is perfectly aligned with the proposed study as it involves non-invasive risk factor assessment (with the exception of urine sugar levels which are optional, based on resources for lab testing) and suited to CHW training.

This study is a concrete way to put this scenario to the test by evaluating the CHWs ability to effectively conduct screening and has the added advantage of performing it in a community setting. In addition, the ability to measure against the gold standard of the health professionals, evaluate training effectiveness and articulating knowledge and use of the referral system is in line with other recommendations related to effective training of human resources.

Population-based approaches are a critical aspect of public health and particularly suited to the needs of low resource settings, which face resource shortages (both human and fiscal) and require community support and involvement to ensure improved health outcomes[16]. Lay health workers are not

well trained and often lack the tools required to manage NCDs[8]. In addition, a focus on prevention is often missing and the communities served by the health care system are often not involved in tackling their own health care challenges[8]. This study will assess the ability of CHWs to use a simple tool effectively to promote prevention through community screening for those at high risk of CVD.

1.3.2 RESEARCH APPROACH

Study Design

This **pilot study** utilizes a quasi-experimental design. Ten CHWs who reside in the same catchment area in each participating site will be identified and undergo a training over two weeks to use the screening tool. Each CHW will then screen at least 100 persons at a local community location over a 4 to 6 week period. The data they generate will then be used by a study health professional to calculate risk for the individual comparisons. The **study population** will be drawn opportunistically from the catchment area served by the local community health center in each of the participating sites. Participants will be given a refreshment after their participation in the screening. Those whom the CHWs identify as being at high risk for CVD will be provided with information pertaining to CVD and it major risk factors, and they will be properly guided to schedule an appointment with a health professional at the clinic. Any disagreement between the CHW and trained health professional's assessment of low-risk or high-risk will be reviewed by the site investigator to determine if these participants should be notified of their risk status and invited to set up a clinic visit for further management.

CHW Identification by Site

South Africa

In 2009 after the launch of the Expanded Public Works programme (EPWP), Provincial health departments received a mandate to identify non-governmental organizations (NGO) that would employ and implement CHW programs. This was on the premise that the government would finance certain NGO costs, including monthly stipends. Numerous NGOs operate in communities around the country. Since

2002, the School of Public Health (SOPH) at UWC, a member of CDIA, has been working with CHWs employed by an NGO in Site C, Khayelitsha, an urban black township in the Western Cape, in a participatory action research project for primary prevention of NCDs. The study will take place in this area.

Guatemala

In Guatemala, the health system, particularly, the primary health care system frequently employs CHWs to support programmes related to infectious diseases, maternal and child health and vaccination campaigns in low-income communities. CHWs usually work as volunteers and are trained and coordinated by primary health care centres. Sometimes, they receive a monetary incentive to keep them motivated. Currently, in Guatemala there are no formal schools for training CHWs and they have not previously been used to work in NCD prevention programmes. Last year, the COE research group completed a pilot study assessing the impact of a cardiovascular health promotion programme delivered by CHWs. The present study will take place in the peri-urban communities adjacent to Guatemala City (Villa Nueva and Mixco).

United States Mexico Border

The Center of Excellence (COE), through its member institutions, provides quality education and training for health professionals and CHW with emphasis on chronic diseases prevention, control and management needs in border populations. For example, the COE, along the U.S.-Mexico border's member institutions, is currently implementing *Pasos Adelante/Steps Forward*, an educational curriculum facilitated by CHW/PdS which focuses on chronic disease prevention and walking groups. The study will take place in Reynosa, Juarez or Tijuana

Bangladesh

Community Health Workers (CHWs): CHWS in Matlab are all female, with varied educational qualifications, ranging from high school certificate to master's degree. Since 1966, CHWs have been collecting data on various demographic and health issues, six times a year (bimonthly). They are the representative of the local people. Each has a specific geographical area to work (catchment area), to collect health and demographic data from the people of specific ages. Currently, 36 CHWs are working in Matlab, where this study will be located.

Methods: (Working protocol attached)

Selection of the sample to be screened

Eligibility Criteria

Men or women aged 25 or older who are present in the community space during the 4-6 week period set for screening in each site. Those who are not able to speak or understand the CHW's language will be excluded. Furthermore, those with a prior history of treatment for hypertension, diabetes, or known CVD (stroke, myocardial infarction, or angina) will be excluded, as these patients would have been referred to or treated in the primary health centers before.

Community Screening and Referral

At least ten trained CHWs will screen participants in a community setting over the course of 4-6 weeks. Informed consent for participation will be obtained and CHWs will then take the appropriate measurements (blood pressure, height, weight) and record them, along with other risk factor information (age, gender, smoking status, history of DM), onto a pre-formatted, data collection instrument. Demographic information (name, address, telephone, ID number) will also be collected. Each participant will be assigned a study identifier (noted on the front of the data sheet) to maintain confidentiality. After screening and calculating the risk score (which will be noted on the back of the participant data sheet), the CHW will inform the participant of their possible risk level and invite those deemed at high risk to set up a visit with a trained health professional at the clinic. To facilitate this visit, the CHW will provide the

participant with the pertinent information noted on an index card. If the participant is illiterate, the CHW will offer to share the information with a proxy who can make an appointment for the participant.

CHW Training

At least ten CHWs will be recruited from those currently employed or actively collaborating with the local health authorities. They will undergo a training session to educate them about the risk factors for CVD and how to use the risk assessment tool, including using the questionnaire for medical history; how to measure blood pressure,using an automated blood pressure cuff: how to measure weight and height and calculate BMI. There will be a pre and immediate post training assessment of their knowledge of CVD and its risk factors. Three months after completion of the community screening, assessment will be repeated to test retention of knowledge of CVD and its risk factors, in addition to the skills mentioned above.

CHW Data Entry

Upon completion of each day's screening, the research team will copy the data sheets completed by the CHWs. The front page of the copies will be passed to the trained health professional for re-scoring, while the originals will be locked away in a secure cabinet. CHWs will transfer all the screened participants' risk scores to a pre-formatted record book, together with information on which individual participants were referred to a health professional, based on their calculated score.

Health professional Scoring

The health professional will use the copies of the original data sheets to duplicate the calculation and notation processes followed by the CHWs, noting their scores and recommendations for referrals in a separate, pre-formatted notebook. A unique identifier (numeric) will be assigned to each CHW and each health professional, respectively. These risk scores will be generated on the same day as completion of the screening.

At one and six months after the screening, a study assistant will review clinic appointments to determine which participants who had been invited to attend a clinic visit did in fact schedule and attend the center for the visit. The precise method to be used for this ascertainment may vary by site, but will be facilitated by using the contact and identifying information provided on the data sheet at screening. The study health professional may also review these same participant files for initiation of management of hypertension, CVD event occurrence, and any other NCDs diagnoses that occurred since screening.

DATA COLLECTION AND COORDINATION:

The CDIA based in Cape Town will serve as the coordinating center for the multi-center pilot. After the completion of the community assessment, CHW scores, health professional scoring, and testing of CHW post-training knowledge levels, all data will be sent to the coordinating center for entry into a central database. Data from all centers will remove unique patient identifiers prior to submission to the coordinating center. The coordinating center will provide data sets for analyses, as requested, to individual centers. The coordinating center will also be responsible for study-wide analyses and will work closely with individual centers to clarify any data discrepancies. Similarly, 7-8 months after completion of the community screening, the data relating to the high risk subjects referral to and attendance at the community health centre will be collected and sent to the co-coordinating centre. Individual sites will complete the necessary procedures to ensure compliance with their respective institutional review boards policies for guaranteeing the protection of confidentiality for study participants for all phases of the study, including recruitment and follow-up efforts.

COST INFORMATION

To measure costs, we will adhere to a common set of costing principles to ensure comparability across the diverse sites and with other costing studies. Identification and measurement of resource use will be the foundation for the costing analysis. Where applicable, we will adopt a micro-costing approach, in which the costs of different components of the intervention and its implementation will be aggregated to form its

total cost. To account for inflation, all costs will be converted to constant dollars using the equivalent of the Consumer Price Index for each country. We will also estimate program/policy costs, based on identifying, quantifying and valuing each category of resources used in planning, implementing, and monitoring the program. These categories routinely include personnel involved in planning, administration and execution; rent, maintenance and depreciation of buildings, vehicles and other capital resources; costs of training; advertising and other media costs; and the net costs associated with subsidies and enforcement of regulation, taxation or legislation.

ANALYSIS

Data from all participating centers will be pooled for global analyses and all such analyses will be stratified by individual centers to identify trends or between-center differences.

Aim 1: A one-tailed t-test will be conducted to determine if the CHW-generated risk scores are significantly different from the health professional-generated risk scores. Mean costs for training and implementing the screening program overall will be evaluated and compared across centers.

Aim 2: To assess if patients, once identified as high risk, are adequately referred.

ANOVA analysis will be conducted to assess if there is a significant difference in the number of patients referred and the number who scheduled and attended the clinic visit.

Aim 3: To determine the effectiveness of training of CHWs to inform their knowledge of CVD and its major risk factors.

Design: O_1 - - - - - - - X - - - - - - - O_2 - - - - - - - O_3

O_1 = Pre-training knowledge; X = Training program experience; O_2 = Immediately post-training; O_3 = 3 months after training.

ANOVA analysis will be conducted to assess if there is a significant difference in knowledge retention levels. Since this is a non-randomized design, the results could potentially be biased due to pre-test measurement error (attenuation of the regression lines) or nonequivalence between the measures. This will require using a more conservative estimate like Crohnbach's Alpha.

PUBLICATION PLAN AND PROPOSED AUTHORSHIP STRUCTURE*:

The following is the proposed order of publication priority for proposed analyses:

1. A paper covering all centers, followed by individual center papers focused on Aim 1
2. A paper covering all centers followed by individual center papers focused on Aim 2.
3. A paper covering all centers followed by individual center papers focused on Aim 3.
4. A potential paper addressing the costing differential between the use of trained health personnel vs. community screenings with CHWs, covering all centers and at individual centers.

***Any additional analyses, either across all centers or at individual centers, will require the submission of a short proposal for review and approval by all center investigators. The review process will be coordinated through CDIA and successful proposals will specify specific authorship and publication requirements.*

PROBLEMS/CHALLENGES

Obtaining weight measures using conventional scales can be challenging to do if health care workers have to engage in door-to-door campaigns. Therefore, locating the screenings in community meeting places and venues (e.g. places of worship, outdoor markets) reduces these logistical challenges to reaching recruitment goals.

PROPOSED TIMELINE:

	Months 1-3	Months 4-6	Months 7-9	Months 10-12	Months 13-15	Months 16-18	Months 19-21	Months 22-24
Hire staff								
Design training materials								
Set up data management systems								
Conduct screenings								
Follow-up								
Data Cleaning								
Analysis								
Writing								

[3] APPENDICES

APPENDIX 1: REFERENCES

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APPENDIX 1: PROTECTION OF HUMAN SUBJECTS

No intervention or fieldwork will commence until such time that the proposals are approved by all the collaborating site and Developed Country Partner IRBs as well as NHLBI of NIH.

Risk of Adverse Events

The risks of the study to the trial participants are minimal. This is not a trial where we are testing new treatments for NCDs. Rather we are evaluating whether CVD screening can be improved through the provision of simplified screening tool by CHW. Participants may be newly identified as being at risk for an acute cardiovascular event through study procedures, namely blood pressure, BMI, and smoking or known diabetes status and will be referred for to the local clinic for management. Given that this information has the potential for emotional stress, the CHWS will counsel the participants. Participants with a systolic blood pressure > 180mmHg or a diastolic blood pressure > 110mmHg will be referred to a trained health practitioner acutely if they have persistently elevated blood pressure or if they are clinically unwell.

APPENDIX 2: DATA AND SAFETY MONITORING PLAN

To protect confidentiality, a unique number will be assigned to each participant. The identity number will not be linked to names or telephone numbers, except in a log which will be kept locked in the trial manager's office. Identifiers will be destroyed after the data are entered into the computer and the data collection process is complete.

All the data collection procedures will be conducted by trained fieldworkers both in the methodologies to be used as well as the required confidentiality procedures.

For patients from participating clinics for whom a NCD prescription is processed during the trial period, we will adhere to the ethical principles for use of medical records without patients' consent (Haines 2000), as follows. The research has a clear public benefit. We will obtain approval for this analysis from the University of Cape Town's Faculty of Health Research Ethics Committee, and from the Western Cape Department of Health and each participating site's IRB. Use of the data for research will not influence decisions about individuals' care. Only a small number of data managers will access to personal identifiers. Anonymised unlinked data (without names or national identity numbers) will be provided only to selected members of the research team – the principal investigators and the trial statistician.

APPENDIX 3: TARGETED/PLANNED ENROLLMENT

The four sites will be expected to enroll 4,000 patients – 100 patients per CHW in each of the four countries – using 10 CHWs for screening over a 4-week period. Of the 4,000 screened patients, it is anticipated that 10% of participants (400 persons) will have a calculated risk score of $\geq$ 20% and will require a referral.

APPENDIX 4: CONTRACTUAL ARRANGEMENTS

The CDIA at the South Africa Center of Excellence will serve as the administrative and data coordinating center that will be responsible for all project communications, generation of appropriate reports, collection and collation of data from all centers, and activities related to data analyses. The Harvard site will be responsible for coordinating project-wide activities in conjunction with the CDIA, including the collection of costing data at Brigham and Women's Hospital.

APPENDIX 5: WORKING PROTOCOL

AN EVALUATION OF COMMUNITY HEALTH WORKERS SCREENING FOR CVD IN THE COMMUNITY IN FOUR NHLBI/UNITED HEALTH CENTERS OF EXCELLENCE

WORKING PROTOCOL

3rd November 2011

COMMUNITY HEALTH WORKER SELECTION AND TRAINING

INCLUSION/EXCLUSION CRITERIA FOR CHW

1) Must be drawn from the communities where opportunistic screening will occur.
2) Must speak the language of the communities where opportunistic screening will occur.
3) Must have the minimal level of education specified by each site:
    a. Bangladesh: typically grade 8 at least.
    b. Guatamala: typically equivalent to high school at least
    c. Mexico: Minimal, no formal requirement
    d. South Africa: Typically grades 8-12.

SOURCE AND SITE OF CHW RECRUITMENT

	BANGLADESH	GUATEMALA	MEXICO	SOUTH AFRICA
RECRUITMENT SOURCE	CHW will be recruited from the existing pool of CHW in the Matlab region.	CHW will be drawn from the communities picked as the trial site which have existing	CHW will be recruited from existing pool in the northern Mexico Border	CHW will be drawn from the existing pool of CHW serving the area.

	BANGLADESH	GUATEMALA	MEXICO	SOUTH AFRICA
		cadres of *promaturas* active in these communities.	cities.	
TRIAL SITE	**RURAL** Matlab region – approximately 55 km from the capital city that has served as surveillance site for the past 40 years.	**RURAL** 2 predominantly Mayan Indian communities approximately 60km from Guatemala City.	URBAN Predominantly from northern Mexico Border cities (Reynosa, Juarez or Tijuana)	**PERI-URBAN** Khayelitsha - an informal township approximately 32km from Cape Town.

CHW TRAINING

a. 10 -15 CHW recruits will be identified at each centre for training.
b. CHWs will be assessed on their knowledge of CVD risk factors prior to training.
c. CHWs will be trained to measure blood pressure, weight, height, waist circumference, to apply the study questionnaire and calculate the risk score.
d. CHWs will be assessed on their knowledge of CVD risk factors and ability to perform the risk screening after training.
e. CHWs who fail this post-training test will not be retained for the population screening.
f. If the maximum number of CHWs (15) passes this test, individual centers will utilize all the CHW and adjust their recruitment schedules accordingly.
g. CHW will be assessed on their retention of knowledge of CVD risk factors 3 months after training.

SCREENING OF PARTICIPANTS

LOCATIONS FOR SCREENING

BANGLADESH	GUATEMALA	MEXICO	SOUTH AFRICA
Likely to be home visits.	Home visits or community screenings – will depend on CHW recruited.	Community setting screenings and self help group home meetings.	Home visits or community screenings – will depend on CHW recruited.

INCLUSION/EXCLUSION CRITERIA FOR PARTICIPANTS

INCLUSION

1. Men or women aged 25 or older who are present in the community space during the 4-6 week period set for screening in each site.

EXCLUSION

a. Those who are not able to speak or understand the CHW's language will be excluded.
b. Those with a prior history of treatment for hypertension, diabetes, or known CVD (stroke, myocardial infarction, or angina) will be excluded, as these patients would have been referred to or treated in the primary health centers before.
c. Those whose systolic blood pressure is $\geq$ 180 mmHg when measured at the opportunistic screening.

PROTOCOL FOR CHW TO OBTAIN TRIAL DATA

RECRUITMENT:

CHW recruits participant for screening in the community, at a community event or in a home by:

a. Explaining the purpose of the screening
b. Give the information sheet to the participant
c. If the participant agrees, a written consent form is given to the participant for review and signature.
d. After the participant signs the consent form, the CHW starts to obtain the non- physical measurements using a study questionnaire.
e. If the participant reports any exclusion criterion even after signing the consent form, thank them for their participation and explain why they will not be included in the study, but offer to continue with the physical measurements
f. Then take the physical measurements, explaining each step before taking the measurement.

OBTAINING NON-PHYSICAL MEASUREMENTS:

These measures are obtained using a study questionnaire instrument. The proposed format of the questions is listed below.

STUDY QUESTIONNAIRE

1. AGE[1]

a. How old are you now? _____ years
b. What is your date of birth? _____ (day/month/year)

2. SMOKING HISTORY[2]

a. Do you currently smoke cigarettes? _____**YES/NO**

→ **IF YES:**

i. On average, how many of the following cigarette products do you smoke each day?
   1. Manufactured cigarettes _____
   2. Hand-rolled cigarettes (bidis) _____

[1] From the 2003 DHS survey for South Africa
[2] From the 2003 Standard DHS survey for South Africa

b. In the past, did you ever smoke cigarettes daily? _____**YES/NO**

→ **IF YES:**

1. When did you quit? _____ (month/year)

3. <u>HIGH BLOOD PRESSURE</u>[3]

a. Has a doctor or nurse or health worker at a clinic or hospital told you that you have high blood pressure?

_____**YES/NO/DON'T KNOW**

b. Have you had your blood pressure measure in the last 12 months?

_____**YES/NO**

c. Do you know what your blood pressure is?

_____**YES/NO**

→ **If YES:**

1. What is your blood pressure number?

_____mmHg (Systolic/Diastolic)

d. Is it high, normal or low?

_____

_____**HIGH/NORMAL/LOW**

e. Do you use any medicine regularly for your high blood pressure that has been prescribed by a doctor or nurse?

_____**YES/NO/DON'T KNOW**

→ **IF YES:**

a. Can you name the medication? _____**YES/NO**

→ **IF YES:**
WRITE DOWN THE NAMES OF THE MEDICATION(S):

_____

_____

_____

4. <u>HISTORY OF DIABETES</u>

a. Has a **doctor** or **nurse** or **health worker** at a **clinic** or **hospital told you** that you have or had diabetes or blood sugar?

_____**YES/NO/DON'T KNOW**

→ **IF YES:**

b. Do you use any medicine regularly for your diabetes that has been prescribed by a doctor or nurse?

_____**YES/NO/DON'T KNOW**

→ **IF YES:** Can you name the medication? _____**YES/NO**

[3] From the 2003 DHS survey for South Africa

→ **IF YES:**
WRITE DOWN THE NAMES OF THE MEDICATION(S):

_____
_____
_____

5. HISTORY OF HEART DISEASE

c. Has a **doctor** or **nurse** or **health worker** at a **clinic** or **hospital told you** that you have or had a stroke, myocardial infarction (heart attack), or angina?

YES/NO/DON'T KNOW

→ **IF YES:** Which of these conditions were you told you suffered from?

_____
_____

d. Do you use any medicine regularly for these conditions that has been prescribed by a doctor or nurse?

YES/NO/DON'T KNOW

→ **IF YES:** Can you name the medication? _____**YES/NO**

→ **IF YES:**
WRITE DOWN THE NAMES OF THE MEDICATION(S):

_____
_____
_____

IF THE PARTICIPANT HAS REPORTED A HISTORY OF HIGH BLOOD PRESSURE TREATMENT, DIABETES TREATMENT OR HEART DISEASE TREATMENT S/HE IS NOT ELIGIBLE TO PARTICIPATE

BUT OFFER TO TAKE THE PHYSICAL MEASUREMENTS.

IF THE PARTICIPANT HAS NOT REPORTED A HISTORY OF HIGH BLOOD PRESSURE TREATMENT, DIABETES TREATMENT OR HEART DISEASE TREATMENT, PLEASE PROCEED TO TAKE THE MEASUREMENTS AS INSTRUCTED BELOW.

C. OBTAINING PHYSICAL MEASUREMENTS:

a. BLOOD PRESSURE

i. Participant is asked to sit down.
ii. CHW determines the appropriate cuff size for the participant.
iii. CHW measures SBP and DBP using the automated blood pressure cuff (Omron) and equipment .
iv. CHW records the measurements while the patient remains seated for 5 minutes.

v. CHW takes a second set of measurements after 5minutes.
vi. CHW records the second set of measurements.
vii. CHW calculates the measurements average SBP and DBP.
viii. CHW records this average measurement.

3 SETS OF SBP AND DBP MEASUREMENTS SHOULD NOW BE RECORDED ON THE STUDY INSTRUMENT

IF THE PARTICIPANT'S AVERAGE SYSTOLIC BLOOD PRESSURE (SBP) IS ≥ 180 mmHg, OR THE DIASTOLIC BLOOD PRESSURE (DBP) IS ≥ 110 mmHg, S/HE IS NOT ELIGIBLE TO PARTICIPATE. THEY NEED TO BE REFERRED FOR REVIEW AT A CLINIC OR PRIVATE DOCTOR ON THE SAME DAY

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b. BODY MASS INDEX (BMI)

i. For participants with a SBP of < 180 mmHg and diastolic< 110 mmHg, the CHW continues to proceed with obtaining the measurements required for calculation the BMI.
ii. CHW notes that the participant is ELIGIBLE for the trial.
iii. CHW asks the participant to remove his/her shoes and heavy outer clothing, step onto the scale and then records the weight.
iv. CHW measures the participant's height and records it.
v. CHW calculates the BMI using the formula provided and an electronic calculator or performs a hand calculation using the formula.
vi. CHW notes the BMI.

c. WAIST CIRCUMFERENCE (WC)

i. CHW measures the participant's waist circumference using a tape measure.
ii. CHW notes the WC.

CHW REFERRAL PROCESS:

IDENTIFYING PARTICIPANTS WHO REQUIRE REFERRAL FOR TREATMENT

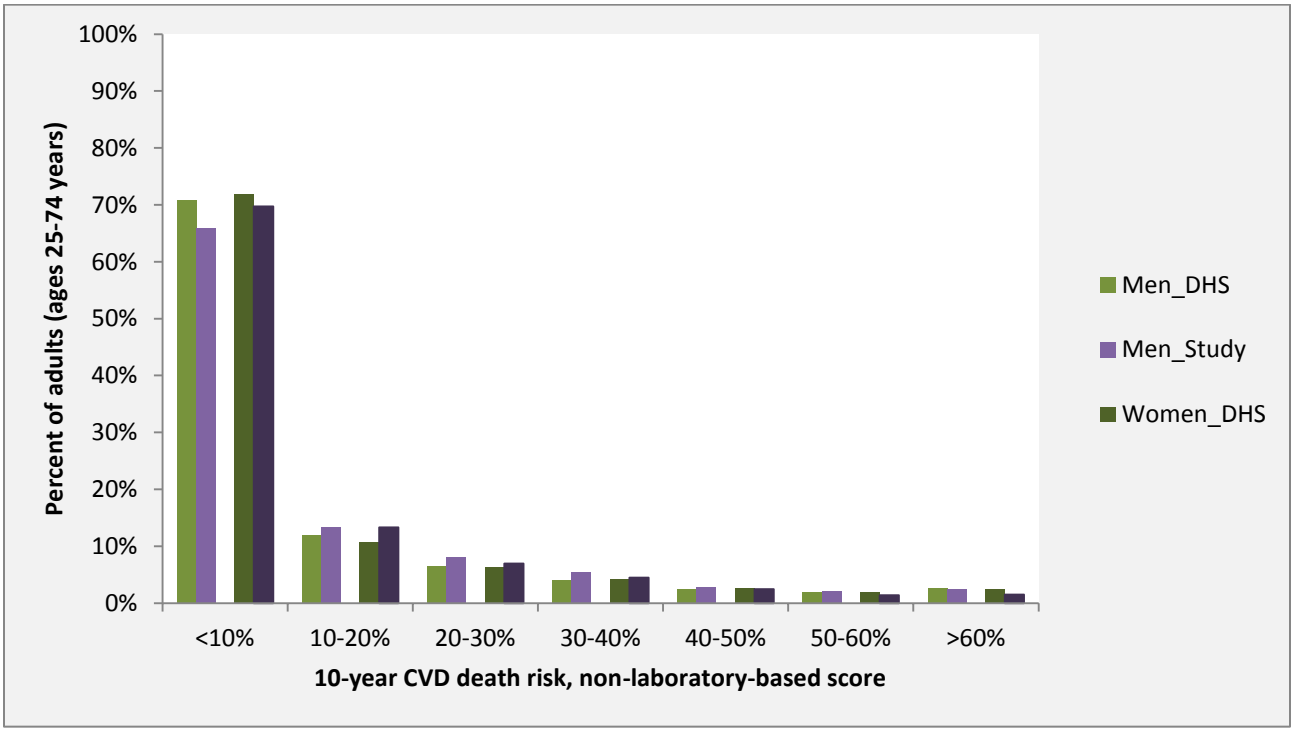
iii. Participants with a repeated blood pressure of ≥180/110 require same day referral
iv. Participants with an average blood pressure of>140/90 but < 180/110mmHg require referral
v. CHW calculates the risk score.
vi. Participants with scores of 20% or greater require a referral.
vii. Participants who are referred will receive counselling by the CHW at the time of referral.

DEFINITION OF HIGH-RISK PATIENTS

High-risk patients are those who have a calculated risk score of ≥ 20%.

This definition is based on the distribution in Figure 2 below and agreement by the study investigators that this threshold will yield an adequate sample size of participants[4].

Figure 2. Histograms of 10-year non-laboratory-based CVD death risk are plotted for the aggregate study population and the representative DHS (South Africa, 1998) populations by sex for adults ages 25-74 years (age-adjusted for WHO Segi "world" reference population). The study population has a slightly higher risk profile compared to the DHS population in the lower ranges (<10% to 30-40%), although the overall distributions of risk are mostly similar between these populations for both men and women.



PROTOCOL FOR HEALTH PROFESSIONAL TO CALCULATE RISK FOR VERIFICATION

1) CHW notes the calculated risk score for the participant on a paper instrument.
2) CHW passes the paper instrument to the health professional for review.
3) The Health professional re-calculates the risk score and compares it to the score assigned by the CHW – within 48 hours of CHW screening.
4) If any High-risk patients are identified by the health professional but not the CHW, the latter will be requested to contact the participant and provide a referral note to a primary health care clinic.

WHERE WILL PARTICIPANTS BE REFERRED

[4] Each study site will have a CHW sample size of 10.

This will vary in the different sites

	BANGLADESH	GUATEMALA	MEXICO	SOUTH AFRICA
CURRENT PRIMARY HEALTH CARE CLINIC	A government or ***icddr, b*** clinic where physicians and nurses are on site during specific days of the week when primary care and specialty services are made available.	A government clinic where physicians and nurses are on site during specific days of the week when primary care and specialty services are made available.	Government physicians and nurses are on site during all week days, primary health care available.	A government clinic where physicians and nurses are on site during specific days of the week when primary care services are available.
CURRENT AND PROPOSED REFERRAL SYSTEM TO PRIMARY CLINIC	None exists for NCD. Study team will make a temporary arrangement by employing a physician for the study referrals.	Most CHW work in collaboration with a primary health care center and this mechanism will allow for referrals to be made.	CHW works with health center and when a risk person is identified coordinates an appointment and often goes with the person, fills out a referral slip. This will take place for the study	Most CHW work in collaboration with a primary health care center where they steer patients to a RN for appropriate referral visits. Participants requiring referral will be referred to the nearest local clinic

TOOLS REQUIRED FOR OBTAINING MEASUREMENTS AND CALCULATIONS

1. Questionnaires
2. Omron Automated BP cuff and machine
3. Digital scale
4. Height measure
5. Tape measure
6. Risk charts
7. Study book to record participants screened
8. Pen/pencils
9. Referral notes

RISK PROFILE ASSESSMENT TOOLS

NON-INVASIVE RISK PROFILE ASSESSMENT TOOL: GAZIANO

a. WOMEN

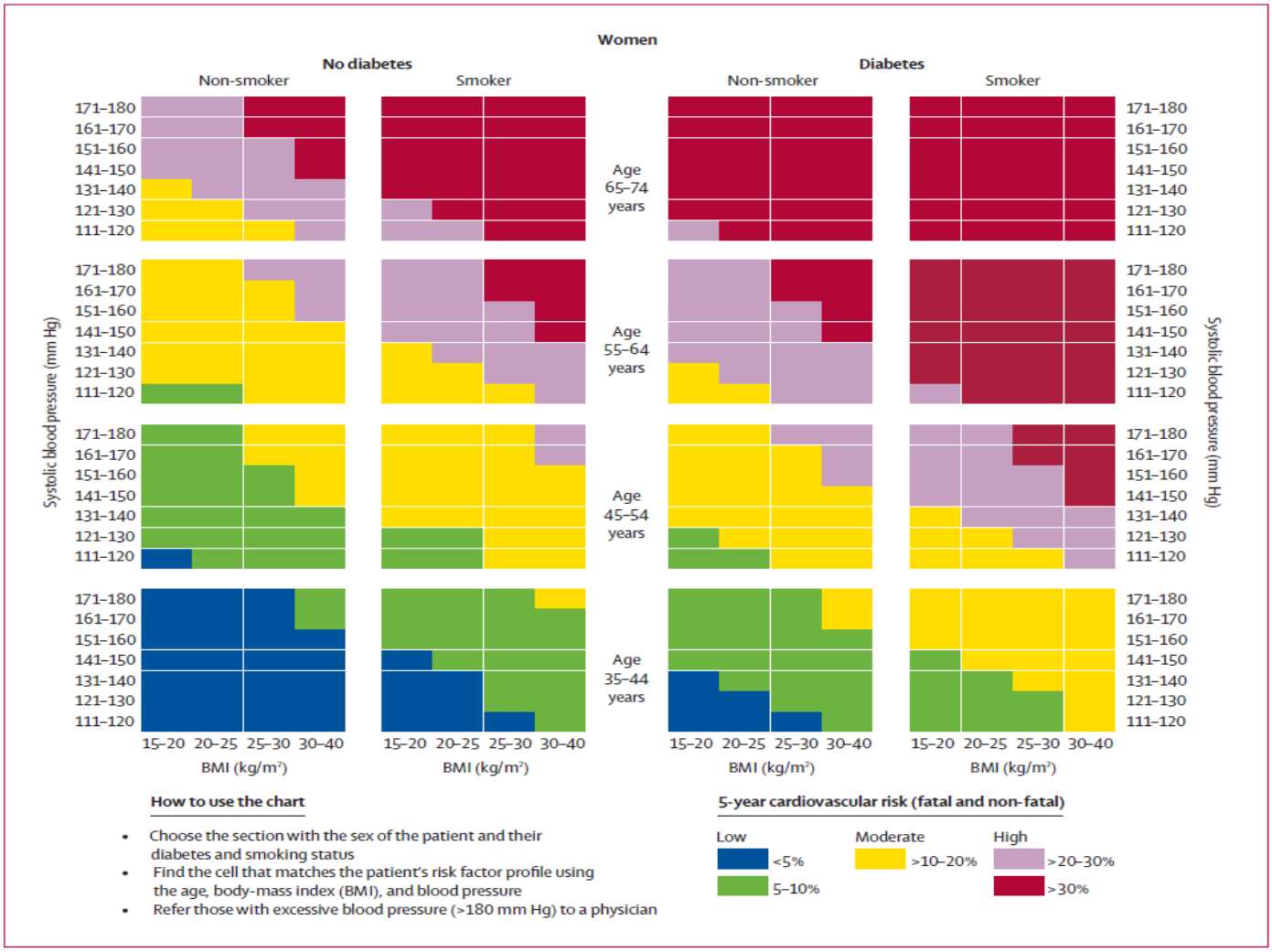


Figure 4: **Risk prediction chart for cardiovascular disease using non-laboratory-based measures (women)**

b. MEN

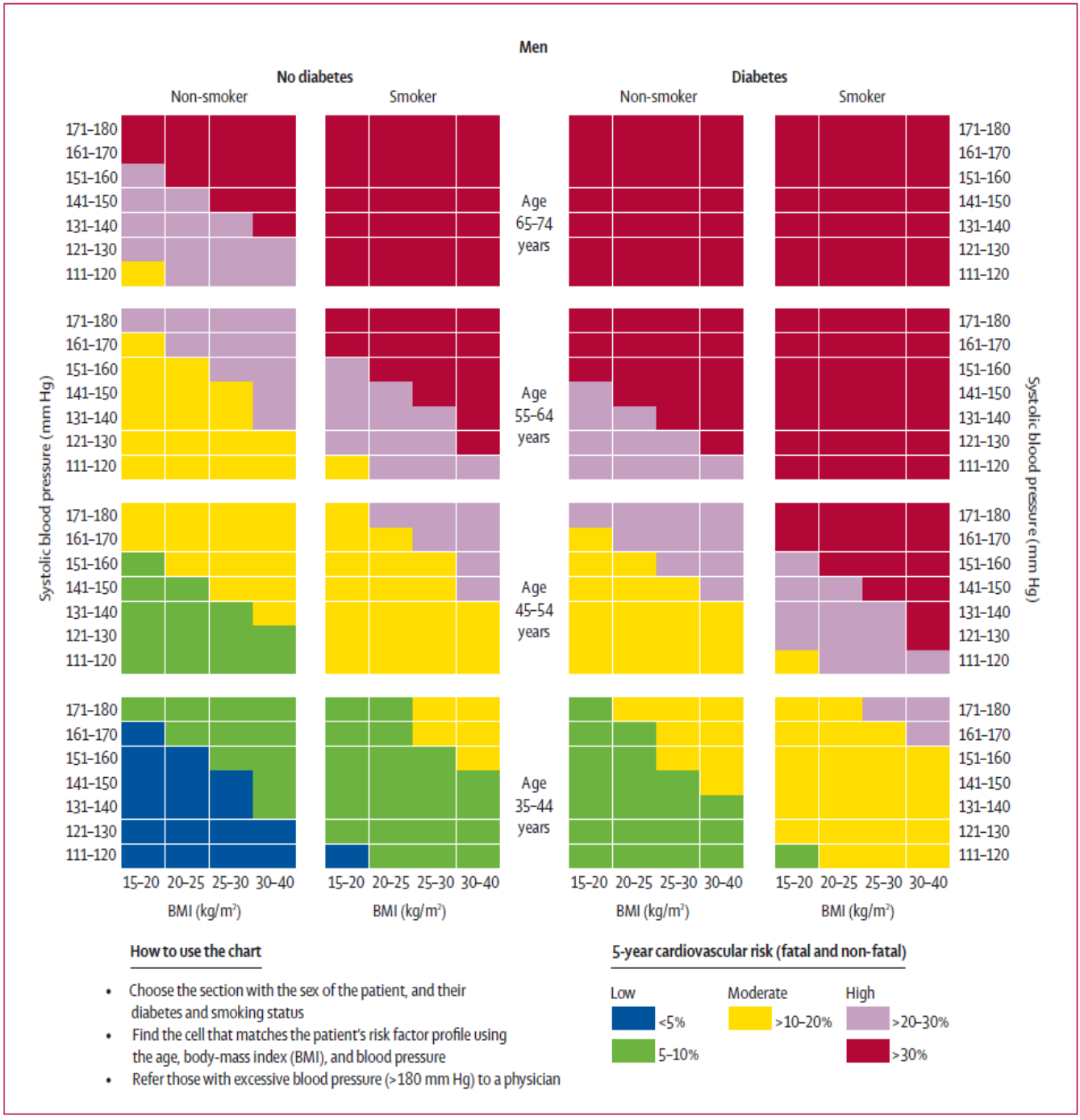


Figure 5: **Risk prediction chart for cardiovascular disease using non-laboratory-based measures (men)**

VERIFICATION OF CLINIC VISITS

The health professional and PI in each site will be responsible for developing an accurate process for obtaining the following data:

1. Did the clinic visit take place
2. What was the outcome of the clinic visit
3. What was the experience of the participant when attending the clinic

PROTOCOL SUMMARY

Title: **Community Health Worker Focus Group Substudy: (Supplement) An evaluation of community health workers screening for CVD in the community in four NHLBI/UNITED Health Centers of Excellence.**

Subcontract: **BWH**

PI: **Gaziano, Thomas**

Type: **New Protocol for Substudy (Protocol Exemption # 2011P002794 previous granted)**

IRB PROPOSAL #: 2012D001151

Study Staff:

Gaziano, Thomas: Principal Investigator, Division of Cardiology, Department of Medicine at BWH.

Abrahams-Gessel: Research Manager, Division of Cardiology, Department of Medicine at BWH.

SUMMARY

Current status:

An exemption to this study was obtained in 2011 as the activities at the BWH (subcontract) was limited to analyses using de-identified data only and coordinating trial-wide activities that did not require participant contact or handling identifiable data.

Request for protocol approval for substudy to accommodate planned BWH staff contact with community health workers and others who are research subjects in the study

Study investigators at the 4 international sites in Bangladesh, Gautemala, Mexico and South Africa are now planning on interviewing the community health workers (CHWs) who conducted field work, clinic administrators and others to obtain a qualitative assessment of their experiences of the trial for a policy analysis. Each site is in the process of obtaining amendments to the protocol from their individual IRBs and, once obtained, the coordinating center at the University of Cape Town in South Africa will file all amendment approvals with the funder, the NHLBI/United Health Centers of Excellence network, as required.

There will still be no direct contact between BWH study staff and research subjects. However, Ms. Abrahams-Gessel will be the only BWH staff member to now have direct interaction with the interviewees (CHWs and others) as she will be assisting with the qualitative data collection effort at the South Africa center.

Dr. Gaziano will have no role in conducting the interviews.

Participation and Informed Consent

Potential focus group participants and interview subjects will be invited to participate with an invitation letter signed by the study investigators in Cape Town, Drs. Noami Levitt and Thandi Puoane. Agreeing to participate and attending the focus group or participating in a scheduled interview will constitute informed consent.

Domains / Areas of Inquiry

The study questionnaire is under development and will inquire about experiences in the following domains using open-ended questions:

- The CHWs' experiences of the training curriculum, structure and interaction with peers and trainers.
- The CHW's experiences of field work, including interactions with study participants, staff at referral clinics and study support staff.
- The experiences of clinic supervisors and administrators of the training, interaction with study staff, supervision of CHWs post-training and their opinions about the planned integration of CHWs into their organizations.

Data collection

Data will be collected in the form of transcripts of audio recordings from focus group sessions and in-person interviews.

Audio recordings will be transcribed in a secure location at each site and will be secured for storage in a location accessible only to study investigators, until it is destroyed in accordance with the IRB requirements at each individual site. Audio files will not be sent off site, including to the data coordinating center. On-site transcription of the audio tapes will be performed by qualified, local study staff and transcripts sent to the coordinating center for use in approved analyses.

Transcripts of the audio recordings will not contain any personal identifiers such as the interviewee's name, title, etc. Individual speakers will have generic identity numbers assigned to them only to distinguish between individuals in the transcript.

Study investigators and staff will analyze these de-identified transcripts for thematic content using either manual and/or software designed for qualitative data analyses. Any publications resulting from these analyses will therefore not be able to be linked to any individual interviewed.

Specific changes to RESPONSE TO REVIEW FORM responses dated 12/29/2011 (Protocol # 2011P002794)

The following are updates to the responses for specific questions on the RESPONSE TO REVIEW FORM that is necessitated by this request to a change in the previously exempted protocol:

Question 3:

Ms. Abrahams-Gessel will interact with interviewees as described during a site visit in November/December 2012 but, as noted, she will continue to have no contact with the 1,100 enrolled participants in the study.

Question 5b:

Ms. Abrahams-Gessel's role will be expanded to include participating in the qualitative data collection in the form of focused groups and in-person interviews, as described above.