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Ira S. Ockene, MD
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January 30, 2014

Philip Barter, M.D.
President, International Atherosclerosis Society

Dear Dr. Barter;

It is a pleasure to submit our proposal entitled "Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems" in response to your RFP entitled "Reducing Cardiovascular Risk Globally Through Improved Dyslipidemia Awareness and Treatment". We have a very strong team involving the University of Massachusetts Medical School in Worcester, Massachusetts and the Universidad de las Américas Medical School in Quito, Ecuador. We have extensive experience in all of the areas of importance to this project: behavioral counseling for patient risk factor change, physician training for patient-centered counseling to reduce cardiovascular risk and particularly to reduce lipid levels, improving adherence to both medication and needed behavior change, and carrying out studies in Latino populations, with many of these studies supported by NHLBI, NIDDK, and NIMH. Furthermore, the relationship between our Ecuadorian and US colleagues goes back many years, with Doctors Zevallos and Chiriboga having done research fellowships at UMass, and Doctors Baldeón and Fornasini both having done Fulbright fellowships at UMass. Likewise, Doctors Ockene and Rosal have worked and taught in Quito on a number of occasions, and have been involved in three different symposia going back eight years. We have the very strong collegial relationship that is required to carry out this type of innovative project.

As described in our abstract and in the detailed project description, we will carry out a two-year controlled trial to assess the feasibility of training primary care physicians in an evidence-based, patient-centered counseling program combined with an office support program designed to improve the ability of Ecuadorian primary care physicians to reduce their patients' CVD risk. The study will include 32 physicians and 200 patients at high risk of diabetes. We will assess feasibility, patient satisfaction with the intervention, and a number of clinical outcomes, with a special focus on LDL, for which the study will be powered, together with feasibility. We will also carry out a cost analysis to make this project as relevant as possible to developing nations. This is made somewhat easier in Ecuador as they utilize the American dollar as their currency.

We have made every effort to keep the budget as low as possible and have reduced the budget by over $100,000 from the initial description in our letter of intent. We believe that at this level we can carry out a project that will deliver meaningful results that we can then extend to larger scale studies and disseminate both to Ecuador at large and also to other developing nations in Latin America and elsewhere throughout the world.

Both of our institutions have institutional review boards which will of course review and approve the entire research proposal should it be funded.

We would be most pleased to answer any further questions that you might have.

Sincerely,

Ira S Ockene, FACC, FAHA

A. COVER PAGE

TITLE: Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems.

ORGANIZATIONS INVOLVED: The University of Massachusetts Medical School, Worcester, Massachusetts (UMMS): Divisions of Cardiovascular Medicine and Preventive and Behavioral Medicine; the Universidad de las Américas Medical School (UAMC), Quito, Ecuador; and The International Atherosclerosis Society (IAS) of Ecuador.

PRINCIPAL INVESTIGATORS: Ira S. Ockene, MD (UMMS); Manuel Baldeón, MD, PhD (UDLA).

IAS-Pfizer Grant 11538663

ABSTRACT: We will assess the feasibility of an evidence-based patient-centered counseling plus office support program intervention model to improve the ability of Ecuadorian primary care providers (PCPs) to reduce their patients' CVD risk. In a two-year study we will randomize, by site, 32 PCPs and 200 of their patients free of CVD but at high risk of diabetes to either an intervention (IC) or usual care (UC) condition. The goal is to reduce the high risk of cardiovascular disease to which these patients are subject. Feasibility will be measured by level of implementation of a patient-centered counseling algorithm and office support system as assessed by Patient Exit Interviews (PEIs). We also will assess patient satisfaction with the intervention, as well as the effect of the intervention on patients' risk factors, including: improvement in LDL, weight, fasting blood sugar, HgbA1C and insulin resistance (HOMA); and self-reported health behaviors: diet, physical activity, and medication adherence. The study will be powered for change in PEI and LDL. The project will be a collaboration between the University of Massachusetts Medical School and the Universidad de las Américas Medical School in Quito, Ecuador. Disseminatable products of the study will include a validated patient-centered physician counseling training package as well as all of the ancillary materials provided as office support for the physician seeing at-risk patients.

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G. Staff Biosketches

- Ira S. Ockene, M.D., Principal Investigator
- Milagros C. Rosal, Ph.D., Co-Principal Investigator
- Manuel E. Baldeón, M.D., M.Sc., Ph.D., Subcontract Principal Investigator

H. Letters of Commitment

- Alfredo Borrero, M.D., Dean, Faculty of Health Sciences, Universidad de las Americas – Quito
- Jaime Ocampo, M.D., Chief Executive Officer, SIME – USFQ, Diego de Robles s/n y Pampite, Clinica Universitaria
- Juan Carlos Peñafiel S., Chief Executive Officer, MetroRed
- David Chiriboga, M.D., Consultant (in kind)

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C.1. Overall Goal and Objectives

We will assess the feasibility of our evidence-based intervention model involving physician-delivered patient-centered counseling plus office support to improve the ability of Ecuadorian PCPs to reduce their patients' CVD risk. In the proposed two-year study we will randomize 8 sites with 32 PCPs, and will recruit 200 of their patients free of CVD but at high risk of diabetes (as defined below), to either intervention (IC) or usual care (UC) conditions. Feasibility (**primary goal**) will be measured by level of implementation of a patient-centered counseling algorithm both initially and with increasing time (up to 15 months) from the initial training, as assessed by Patient Exit Interviews (PEIs). [20,21] We will assess patient satisfaction with the intervention. We will assess the effect of the intervention (**secondary goals**) on patient risk factor outcomes, including: improvement in LDL, weight, fasting blood sugar, HgbA1C and insulin resistance (HOMA); and health behaviors: diet, physical activity (PA), and medication adherence.

Primary goal hypotheses:

Hypothesis 1a: IC physicians will deliver a greater number of patient-centered counseling steps as compared to UC physicians.

Hypothesis 1b: IC patients will report greater satisfaction with the care received from their PCPs as compared to UC patients.

Secondary goal hypotheses:

Hypothesis 2a: IC patients will have lower LDL levels as compared to UC patients.

Hypothesis 2b: IC patients will have improvement in other risk factors including FBS, HbA1C, HOMA-IR, and weight as compared to UC patients.

Hypothesis 2c: IC patients will have improved self-reported behavioral risks including dietary and physical activity behaviors and medication adherence, as compared to UC patients.

We will assess the cost of the intervention (per patient) and will measure the cost per incremental LDL improvement in the IC. These measures will be critical for documenting the feasibility of disseminating the intervention to other sites in Ecuador.

Note: Power calculations are presented for hypotheses 1a and 2a, as the most important of our primary and secondary goals. (*See C.2.d.*)

C.2. Technical Approach

C.2.a.1. Current Assessment of Need:

Ecuador, as other Latin American countries, is transitioning as part of a worldwide trend linked to rural-to-urban migration and related changes in lifestyles. [1-5] There is now a high prevalence of hyperlipidemia, obesity, hypertension and smoking in Ecuador,[1,6,7] and a national health and nutrition survey published by the Ecuadorian Ministry of Public Health in December 2013 shows an increasing prevalence of most cardiovascular risk factors among the Ecuadorian population.[8] (Table 1.)

Table 1. Cardiovascular risk factors in Ecuadorian adults (%)

Variables	Age groups		
	30 – 39	40 - 49	50 - 59
Total Cholesterol >200 mg/dL	29.7	38.4	51.1
LDL-C >130 mg/dL	24	31.4	40.5
Triglycerides >150 mg/dL	35.6	44.7	43.1
Total Cholesterol/HDL-C >5	31.6	38.4	39.4
Hypertension	7.3	13.5	22.7
Diabetes	1.9	5.4	10.3
Smoking	23	29.4	50.8

Table 2. Metabolic factors associated with CVD in the Ecuadorian adult population (%)

Variables	Age groups		
	30 – 39	40 - 49	50 - 59
Overweight	45.6	45.4	42.4
Obesity	22.7	28.4	32.7
Metabolic syndrome	36.8	47.1	53
Insulin resistance/HOMA	42.1	44.3	43.2

Table 2 indicates the prevalence of other metabolic conditions associated with CVD. Close to two thirds (62.8%) of 20-60 year-old Ecuadorians are overweight or obese, approaching adult US rates (69%). Further,

for this age range, prevalence rates of metabolic syndrome (27.7%) are higher than those reported in the US adult population (22%) in 2010. The same national survey also indicates that 45% of Ecuadorian adults engage in low levels of physical activity,[8] and that medication adherence rates are less than optimal (48.9% of hypertensive patients reported not taken their medication). In addition, Type II diabetes is a major risk factor for CVD, the primary cause of death in Ecuador.[15] We have previously shown that awareness of diabetes risk factors and prevention strategies is quite low in low-income U.S. Latinos with no known diagnosis of diabetes.[9] Based on these realities, helping primary care providers (PCPs) and health care systems to implement CVD risk factor reduction interventions is crucial to improving the health of the Ecuadorian population. However, no models exist in Ecuador for PCP-delivered risk-reduction interventions.

Our team has demonstrated the efficacy and effectiveness of a combined physician-delivered patient-centered counseling plus office support intervention model. We tested this model in several NIH-sponsored trials for helping PCPs promote patient behavior change, including smoking cessation, dietary and physical activity change and high-risk drinking. [10-12] We also have successfully used patient-centered approaches in community settings in Latino patients with elevated diabetes risk and patients with type 2 diabetes.[13,14] The training of PCPs to learn and implement the model is sustainable and scalable in a variety of settings, and we believe that adoption of this program by Ecuadorian PCPs will reduce patient CVD risk. We also have considerable research experience with Latino prediabetic patients.[13] As a result we have decided to recruit prediabetic patients, who represent about 28% of Ecuadorians between 20 and 60 years of age, and have a high prevalence of lipid abnormalities and hypertension.

C.2.a.2. *Preliminary Research Leading to the Proposed Application*

The WATCH study (RO1-HL44492)

Study Design: WATCH evaluated the efficacy of physician-delivered patient-centered nutrition counseling, alone and in combination with office support, on dietary fat intake and serum LDL-C of patients with serum LDL-C levels in the highest 25th percentile. Forty-five primary care internists at a central Massachusetts health maintenance organization were randomized by site into 3 conditions: Condition I - Usual Care; Condition II - Physician counseling training; and Condition III - Physician counseling training plus office support. Participants were 1278 patients with. At baseline and 12 months lipids, diet, weight, and psychosocial factors were measured.

Physician-delivered Counseling Component: patient-centered counseling is grounded in social cognitive theory [23] and involves a brief assessment (in this case related to diet) of six content areas: 1) desire and motivation to change behavior; 2) experience with change; 3) barriers to change; 4) resources for change; 5) goal and plan for change; and 6) problem-solving. The physician is taught to inform patients regarding the relationship of the risk factor to CVD; to help patients develop a plan for change; to provide educational materials to patients; and to arrange follow-up for behavioral change. The intervention algorithm guides PCPs to follow the intervention steps, including scheduling of follow-up PCP visits.

Physician training: PCPs in conditions II and III were taught to implement the 7-10 minute patient-centered counseling protocol involving these steps and to do a follow-up intervention at return visits, assessing accomplishments and readiness to change, reinforcing changes made, and setting up new behavioral goals as needed. The 2-session training consisted of a 2.5 hour small group session and a second 30-minute individual follow-up tutorial. The small group sessions included: a) a didactic component teaching the relationship of elevated serum lipid levels and other risk factors to CVD; b) introducing the counseling algorithm and discussion of a videotape demonstrating its implementation; c) filling out a dietary and activity risk assessment (DARA) and learning how to use it with patients (to identify problem dietary habits and develop

nutrition and physical activity change goals); d) role-playing the counseling algorithm in triads with fellow internists; and e) a question and answer period. Physicians were provided with the algorithms for the initial and follow-up counseling interventions, a sample script, and a DARA. After the small group training, the individual follow-up tutorial was carried out in the physicians' offices by a simulated patient and audio-taped. A blinded evaluation of audio-taped physician-patient interactions showed that physicians' use of dietary counseling steps increased significantly (mean pre=5.4, mean post=9.2; p<0.001). They also had increased confidence in having an effect on their patients' behavior.[21]

Office Support Component: Office support involved a folder that was attached to the patient's chart each time the physician saw a study patient. This folder contained: 1) the patient's most recent lipid levels, with a prompt indicating that the LDL-C level was in the highest quartile; 2) a DARA form to be filled out in the waiting room by the patient before seeing the physician (*see Appendices*); 3) dietary goal sheets to use with the patient; 4) the counseling algorithm (*see Appendices*); and 5) a copy of the national cholesterol management guidelines.

Intervention Fidelity Evaluation: After the initial physician-patient encounter, a random quarter of the patients in the three conditions were given a ten-item patient exit interview (PEI) to assess whether the physician provided advice; assessed past changes, barriers and resources; negotiated specific plans and goals; provided patient materials; and developed plans for follow-up. We found that condition III physicians implemented significantly more of the counseling sequence than did physicians in either of the other two conditions (PEI by condition (max. = 10): I = 4.09; II = 4.05; III = 6.28 (P<.0001). Higher PEI scores in condition III were stable to three years beyond training. We concluded that PCPs, when provided with training in counseling and office support, will counsel patients appropriately, but training alone is not sufficient.[21]

Primary Endpoint Measures: The primary outcome measures at one year of follow-up included change in percent calories from fat and saturated fat; BMI and weight; and blood LDL-C levels. Significant improvement was seen in all primary outcome measures in condition III, compared to Conditions I and II. There was a 6.9 mg/dl decrease in LDL-C (p=0.05). As compared to condition I, condition III pts had an 8% decrease in calories from fat (p=0.04), a 12% decrease in calories from saturated fat (p=0.02); and a loss of 6.3 lb. (p<0.0001). The time spent by physicians in delivering the intervention was estimated using the PEIs. Physicians in condition III spent a mean of 9.2 minutes discussing diet, as compared to 4.3 and 6.2 minutes for physicians in conditions I and II, respectively. We have previously shown that patients see physician counseling very positively, even when they do not plan to adhere to the advice given, and they may perceive the visit as longer than it actually is.[11] We concluded that brief patient-centered nutrition counseling delivered by physicians can produce beneficial changes in diet, weight and lipids, but only if combined with a supportive office environment.

The Lawrence Latino Diabetes Prevention Project (LLDPP) (NIDDK R18 DK067549-01). In this RCT we tested the effectiveness of a community-based, literacy-sensitive, and culturally tailored lifestyle intervention on weight loss and diabetes risk reduction among low-income, Spanish-speaking Latinos from Lawrence, Massachusetts at increased diabetes risk, defined as a 7.5 year likelihood of becoming diabetic of >30% as predicted by the Stem formula.[19] We randomly assigned 312 participants to lifestyle intervention care (IC) or usual care (UC). The intervention was implemented by trained Spanish-speaking individuals from the community. Each participant was followed for 1 year. *Results*: The participants' mean age was 52 years; 59% had less than a high school education. The 1-year retention rate was 94%. Compared with the UC group, the IC group had a modest but significant weight reduction (–2.5 vs 0.63 lb; P=.04) and a clinically meaningful reduction in hemoglobin A1c (–0.10% vs. –0.04%; P=.009). Likewise, insulin resistance (HOMA-IR) improved significantly in IC vs. UC. Because of the precision of the measurement, small changes in HgbA1C can be quite significant. The significant

HgbA1C change of 0.1% in the LLDPP, validated by an equally significant change in insulin resistance, was slightly greater than the 0.09% one-year HgbA1C reduction seen in the multicenter Diabetes Prevention Program.[24,25] The IC also had greater reductions in percent calories from total and saturated fat. We concluded that an inexpensive, culturally sensitive diabetes prevention program resulted in weight loss, improved HbA1c, and improved insulin resistance in a high-risk Latino population.[13]

Diabetes Management for Low-Income Hispanic Patients (NIDDK R18 DK065985). This RCT tested the efficacy of a culturally-tailored literacy-sensitive intervention (Latinos en Control) designed by our team[26] to enhance adherence to diabetes self-management behaviors and improve glycemic control (HbA1c) among low-income Spanish-speaking patients with type 2 diabetes. We randomly assigned 252 patients from five urban community health centers to IC or UC conditions. The intervention was delivered at community sites by trained lay individuals. Patients were assessed at baseline, 4- and 12-months with a retention rate of 93%.[27] *Results:* A significant difference in HbA1c change between the groups was observed at 4 months (IC -0.88 vs. UC -0.35, P < 0.01), although this difference decreased and lost statistical significance at 12 months (IC -0.46 vs. UC -0.20, P = 0.293). There were significant improvements at 12 months in diabetes knowledge (P = 0.001), self-efficacy (P = 0.001), blood glucose self-monitoring (P = 0.02), dietary quality (P = 0.01), kilocalories consumed (P= 0.001), percent calories from dietary fat (P = 0.003), and saturated fat (P = 0.04). These changes were in turn significantly associated with HbA1c change at 12months.[14]

Clinical research experience in Quito: The Ecuadorian team has carried out a number of clinical trials. They have studied the hypoglycemic effects of L. Mutabilis (an Andean legume) in normal participants and in patients with the metabolic syndrome, hypertension, and diabetes.[28] Sample sizes range from 60 to 100 and the mean follow up period has been 3 months. The team has successfully recruited and retained participants, with a participation rate of over 70%. Similarly, the team has recruited patients into a number of pharmacological clinical trials, again with a participation rate of approximately 70%.

C.2.b. Intervention Design and Methods

Overall study plan: The proposed study will utilize intervention and assessment methods of the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH) in which we found that a physician-delivered patient-centered counseling plus office support intervention, resulted in significant beneficial changes in patients' diet, weight, and blood lipid levels at one year of follow-up, described in detail below.[16] Eight primary care sites with 32 PCPs in Quito, Ecuador will be randomized to one of two conditions: an intervention condition (IC) in which the site PCPs receive training in patient centered counseling methodology and receive office system prompts to deliver the intervention, and a usual care condition (UC) in which the sites will continue their usual practice. Randomization by site will ensure that all PCPs in a given clinic will be in the same condition, decreasing the possibility of contamination. There are no local lipid-lowering medication guidelines, with Ecuadorian physicians generally using American guidelines. Thus, to facilitate the test of the intervention in the present absence of guidelines, we will distribute the U.S. guidelines for the management of lipids to ALL PCPs in the IC as well as the UC sites. [17,18] It should be noted that even in the U.S. the most recent iteration of the guidelines is based on data from White and African-American populations and it is an extrapolation to use these guidelines in Latino-Americans in the U.S. and elsewhere. Given the above considerations, the use of American lipid-lowering guidelines in this study is reasonable and will be accepted by PCPs. IC PCPs will additionally receive training in patient-centered counseling and will be prompted to counsel their patients via an office support system. Two hundred patients will be recruited into the study, 100 in each condition. Patients will be eligible to participate if they are at increased risk for the development of diabetes (but not yet

diabetic), defined by a $\geq$30% risk of developing diabetes within 7.5 years as judged by the Stern predictive equation, which includes age, gender, Hispanic or no, FBS, systolic BP, HDL, BMI, and family history of diabetes.[19] The study primary goal, Feasibility, will be evaluated via physician adherence to the counseling protocol both initially and with increasing time (up to 15 months) from the initial training, measured by PEI's,[20,21] medication adherence will be measured by self-report.[22] Secondary goals, evaluation of the intervention effects, will assess patient clinical and behavioral outcomes measured at baseline and six months, including direct LDL-C, weight, HDL, HgbA1C, FBS and insulin levels (allowing calculation of HOMA-IR), and diet and PA. Relevant psychosocial and demographic variables also will be assessed and intervention costs will be tracked.

Phases of the investigation and timeline: There will be four phases in the proposed study, described below (Table 3).

Table 3: *Phases of the investigation*		
Phase	Months	Activity
I	1-2	Hiring and training of staff, refinement and pretesting of the protocols for recruitment and intervention; development and testing of evaluation materials, training of physicians
II	3-16	Recruitment and follow-up for the study
III	17-22	Follow-up only
IV	23-24	Close-out, data analysis, manuscript preparation

Rationale for Patient Population Chosen: The clinic patient population is essentially lower middle class; 90% of the patients are adults. These are largely individuals who have health insurance and do not use the public hospitals. Approximately 80% of the patients have private insurance, 10% have social security coverage and 10% are uninsured patients. We considered using the public hospital facilities, but physicians and patients change very frequently, medication availability is variable, and the public hospital clinic infrastructure is insufficiently developed to permit good control of a study. The eight clinics have been matched to IC and UC conditions so that both physicians and patients are similar. Clinics also were matched by geographic location in the Quito metropolitan area. Clinic location is associated with population socio-economic conditions.

Patient Eligibility and Exclusion Criteria: Included in this RCT will be 200 primary care patients, evenly randomized into the 2 conditions and blocked by gender, physician, and two age intervals (30-50, 31-70). A patient will be eligible if he or she meets the following criteria:

1. Has a 7.5 year likelihood of becoming diabetic of $\geq$30% as predicted by the Stem formula[19]
2. Is $\geq$ 30 - 70 years of age; and 3. Has a BMI > 24 kg m^2

A patient will be excluded if he/she has any of the following characteristics:

1. an inability or unwillingness to give informed consent;
2. is presently or has within the prior year been on specific lipid-lowering medication (e.g., resins, fibric acid derivatives, HMG-CoA reductase inhibitors, nicotinic acid); or on metformin (sometimes used in pre-diabetes, although rarely in Ecuador)
3. has known coronary heart disease
4. has a secondary cause of hyperlipidemia (e.g., hypothyroidism, pregnancy);
5. plans to move out of the area within the study period;
6. has a psychiatric illness which limits ability to participate; or
7. has no telephone.

Patients with known CHD will be excluded to maintain the primary care paradigm of the study. Patients on drugs that can affect lipid levels (e.g., thiazide diuretics, hormone replacement

agents) will not be excluded, provided that they have been on a stable dose of medication for at least 6 months. Use of such medications, will be tracked, and considered in the analysis.

Patient Recruitment: All participating clinics have electronic clinical record systems. A search algorithm based on an upcoming PCP appointment, factors of the Stern formula (BMI >25, HBP, HDL, FBS), and the inclusion and exclusion criteria will be developed to obtain a pool of likely eligible patients, who will be invited for screening, where a lipid profile and FBS will be drawn. Screening staffing (and budget) anticipate a 1/2-1/3 final eligibility based on the Stern formula and inclusion/exclusion criteria. From this pool of eligible patients, we will over the course of the study select 110 per treatment group, anticipating no more than a 10% drop out rate over the 6 month patient participation. In the LLDPP we had a 94% retention rate at one year in a very low income/education pre-diabetic Latino population.[13] The clinic populations far exceed the numbers needed, and given the high rate of hyperlipidemia, overweight/obesity, and metabolic syndrome, we anticipate no difficulty recruiting the needed cohorts. Once identified as interested and qualified, the patient will sign an informed consent. Subsequently, patients will have baseline lab work that will include a fasting lipid profile (total-cholesterol, direct LDL-C, HDL-C, and triglycerides), glucose, insulin, and HbA1c. The screening laboratory data will not be used in the actual study data set to avoid regression to the mean. Upon inclusion of the patient, staff will administer the baseline survey instruments.

Patient Follow-up: At the initial PCP visit a PEI will be administered following the physician-patient encounter. Patients see the same PCP in follow-up. At the 6-month follow-up final blood studies will be taken and survey instruments administered.

Retention of study patients: To enhance study retention, recruitment and final assessment visits will be scheduled on a date convenient to the patient. Reminder calls will be made the day before the scheduled visit. Patients who no show will receive a call from the RA on the same day to discuss the importance of their participation, problem-solve their challenges to attending the session, and re-schedule the session. We have successfully used these retention strategies in our previous studies and achieved retention rates of 94% with hard-to-reach U.S. Latinos.[13,27] Patients will receive a $10 incentive after completing each assessment.

Cardiologist members of the International Atherosclerosis Society will play an important role in this project. Dr. Ockene, the principal investigator, is a long-standing member of the IAS, and Juan Carlos Zevallos, the Ecuadorian cardiologist who will lead the training of the PCPs and cardiologists, is also an IAS member. The Quito IAS cardiologists also support the study; will themselves be trained in the counseling intervention, and will serve as "champions" of the program both during and after the intervention training. Their active participation and promotion of the intervention will be of great value.

Description of the Intervention condition: The intervention to be tested will be similar to the Condition III intervention in the WATCH study (described in section C.2.a.2. above), consisting of *Physician-delivered Counseling Training plus Office Support*. However, in addition to the nutrition counseling used in WATCH, this study will also train physicians to counsel patients to increase their physical activity, with an emphasis on walking and provision of a step counter, and in the appropriate prescription of statin therapy.

Physician-delivered Nutrition, Physical Activity, and Statin Use Counseling Training Component: As in WATCH, physicians will be trained in the patient-centered counseling model. As described above (see C.2.a.2) the protocol "walks the PCP through" each counseling step. The entire algorithm is delivered at the first visit in 7-10 minutes. The algorithm for the follow-up visit is shorter, primarily assessing and reinforcing changes made by the patient and readiness for additional change, and setting up new behavioral goals as needed.

Training of physicians at the intervention sites will involve an intensive four-hour session led by Drs. Ockene, Rosal and Zevallos. As in WATCH, the training will consist of a didactic component teaching the relationship of behavioral and cardiovascular risk factors to CVD and a review of the guidelines for statin therapy. Subsequently, physicians will be introduced to patient-centered counseling, the patient-centered counseling algorithms, a diet and physical activity assessment tool (DARA), and the statin use algorithm per the latest U.S. guidelines.[18] Physicians will be taught to use these materials with their patients using video and live examples followed by role-playing with fellow PCPs, with alternating roles as clinician, patient and observer. Physicians will receive a training binder with the training slides; the counseling intervention algorithms, a sample script, and other intervention materials (diet and exercise goal sheets, the DARA, and the statin use algorithm); and patient education materials and step counter.

Using translated and adapted assessment tools from WATCH, we will conduct pre- and post-training assessments to document physician changes in knowledge about diet, physical activity, lipid therapy, and attitudes about their intervention and counseling skills. In addition, a follow up 30-minute individual tutorial will be carried out within the subsequent 2-4 weeks in the physician's office by a simulated patient. Additional training will be provided by the study team to physicians who demonstrate errors of omission or commission in delivering the counseling intervention (this additional training has been available in our previous studies but has not been needed). After successful completion of the training, PCPs and cardiologists will receive a training certificate (CME) issued by UMMS.

Office Support Component: As in WATCH, physicians at the intervention sites will be prompted to deliver the intervention by providing them with a packet, affixed to each study patient's chart each time he/she is seen by the PCP through 6 months. The packet will include statin therapy guidelines, a full-color patient diet and physical activity guide, and a pedometer. The clinic personnel will track patients due for a visit, prepare patients' packets and insert them into their charts (as they do for other materials, e.g., lab reports, consult notes). They will give the DARA to the patient upon arrival in the clinic, to be filled out in the waiting room prior to their visit with the PCP, and will administering the PEI when the patient leaves the PCP's office.

Usual care condition: Providers at the UC sites will be provided with the U.S. guidelines for statin therapy (rationale described above in section C.2.b.).[18] These will be distributed to physicians by the administrators at each practice. Physicians at these sites will deliver care as usual and their patients will participate only in the study assessments.

C.2.c. Evaluation design

The study evaluation plan will determine whether the proposed intervention model (physician-delivered patient-centered counseling plus office support), shown effective for CVD risk factor reduction in the U.S., [10,11,13,16] is feasible and effective in Ecuador. Feasibility is defined as the degree to which the counseling algorithm is implemented by the PCP, and by patient satisfaction; both will be assessed via PEIs on all patients. The effectiveness of the intervention will be determined based on patient lipids (LDL) and other risk factor outcomes. Patient assessments (clinical and survey measures – see table 3 below) will be conducted by trained clinic coordinators at baseline and at 6-month follow up. A tracking system will prompt the coordinators to contact patients due for an assessment via phone to schedule their visit. All assessments will be conducted at the clinics, with patients in a fasting state.

Table 4. Outcomes and Data Sources for Evaluating the Study Primary and Secondary Goals.	
Outcome	**Measure/Method**
Primary Goal: Feasibility	
Patient Exit Interviews (PEIs)	The PEI is a brief measure of a patient's perception of content and quantity of an intervention received from their PCP and are used to assess the degree to which clinicians

	deliver each of the counseling algorithm steps. Responses are summarized in a PEI index score. The PEI will be administered to patients immediately following their PCP visit.
Patient satisfaction with care	Patient satisfaction is an important measure of health care quality, and a critical component of intervention feasibility. It will be measured using the same tool utilized in WATCH: The 2-item Overall Evaluation of Quality Scale, evaluating 1) overall quality of care, and 2) outcome of care. Pts use a 5-point rating scale, with the score the mean of the two items.[29]

Secondary Goals: Effectiveness

Physiological

Serum lipids; FBS; HbA1C; insulin	Venous blood samples from an antecubital vein will be collected in the morning after a 12 hours fast. Samples are centrifuged to harvest serum within 2 hours. Serum glucose, total cholesterol, triglycerides, HDL, and direct LDL-C will be measured using colorimetric-enzymatic methods (Roche-Diagnostics) in a Hitachi Roche-917 full-automated analyzer system. Serum insulin will be determined by an electro-chemiluminescent immunoassay using an automated ELECSYS 2010 analyzer system (Roche/Hitachi, Quito); HbA1c will be measured by inmunoturbidimetric methodology (Roche-Diagnostics. Blood biochemistry will be carried out at NetLab Laboratory; NetLab maintains an internal and external quality control system (College of American Pathologists, Brazilian society of Clinical Pathologists). All assays will meet criteria of the CDC-NHLBI Lipid Standardization Program. [30,31]
Insulin resistance	The widely used homeostatic model assessment (HOMA) will be used to yield an estimate of insulin sensitivity from fasting plasma insulin and glucose concentrations. [32-34]
Blood pressure (BP)	Blood pressure will be measured in a standardized manner in the right arm after 15 minutes of quiet sitting. A Dinamap XL automated BP monitor will be used.[35,36]
Weight and Body mass index	Body weight and height will be measured twice (and averaged) with the individual wearing light clothing and no shoes. Portable digital scales and stadiometers will be used. Body mass index (BMI) will be calculated as weight (kg)/height squared (in meters).

Behavioral

Dietary behaviors	The Latino Dietary Behaviors Questionnaire (LDBQ) [37] will be used to assess multiple areas of dietary behaviors, providing a general index of healthy eating.The LLDBQ has adequate psychometric properties including internal consistency, concurrent and convergent validity (association with 24-hour nutrient intake and clinical measures: lipids, HbA1c and blood pressure), and sensitivity to change over time. We will pre-test and adapt the LDBQ for local food habits, as needed.
Physical activity (Walking)	We will use selected culture-appropriate items from the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire, a self-report measure of physical activity shown to be valid, reliable, and sensitive to change [38]
Medication adherence	Self-reported medication adherence will be measured by the Morisky Adherence scale (MMAS),[22] a widely used 8-item instrument with adequate reliability and validity.

Other variables and co-variates

Costs	We will track all data on staff time in each intervention-related activity using time sheets with itemized tasks. We also will track cost of all intervention materials (quantities and cost).
Depression	The Center for Epidemiological Studies Depression Scale (CES-D),[39,40] a 20-item survey assessing frequency of depressive symptoms (cognitive, affective, behavioral and somatic symptoms and positive affect) in the previous week will be used. This measure is available in Spanish and we have used in in our previous studies with various Latino subgroups.
Sociodemographics and health status	Education, income, employment, race/ethnicity, age, marital status, living situation, smoking, and chronic conditions will be assessed.

C.2.d. Power estimates and Analysis:

Power Estimates: <u>LDL</u>: Based on WATCH I study the SD for change in LDL was 28.2 mg/dl. The study will have approximately 100 patients per arm (train+support vs control) and approximately 15 physicians per arm (one arm may have slightly more). For power estimates we assumed different levels of intraclass correlation (ICC) within physician. Prior studies have shown ICC for cholesterol to between 0.02[41] and 0.048.[43] For a difference in change in LDL of 15 mg/dl between the groups and an ICC of 0.05 there is 92% power for α=0.05.   80% power for difference of 12 mg/dl if ICC=0.02. Calculations assume equal number of patients per physician. Guittet et al has shown unequal clusters reduces power 2-4%.[42]

<u>PEI at first visit</u>: Based on WATCH I, SD for PEI score was 2.9. The ICC for PEI is likely to be high within physician.   Most ICC estimates are less 0.2 . [41,43] As a conservative estimate we assumed ICC=0.3. There is 84% power for a PEI score difference of 2 between the two arms.

<u>PEI maintenance</u>: Within the intervention arm PEI score over time will be estimated. There will be power of at least 80% for a decrease of 2.7 points in PEI over the study period. This is under the assumption of no correlation within physician. As ICC increases power increases. Simulations indicate power of 80% or more as ICC approaches .15 for decrease of 2.2.

Analysis: Patient characteristics between the two arms of the study will be compared to examine balance after randomization by site. The primary outcomes are change in LDL and PEI scores.   Mean outcomes will be compared between the two arms using a linear mixed model framework with random intercepts to account for two levels of clustering (physician and site). Prior experience has shown that clustering on one level (e.g., physician) may be sufficient.   If there is imbalance (a standardized difference >0.1) between the two arms in characteristics associated with the outcomes, the models will adjust for those factors. Within the intervention arm mean PEI over time will be estimated with a linear mixed model, clustering by physician and site with random intercepts and slopes (PEI vs time).   Test of the slope of PEI over time equal to zero will provide the test of maintenance of PEI.

<u>Cost analysis</u>**:** Cost information associated with the implementation of the intervention by research staff and PCP and medical office staff will be combined into a single cost analysis table for each activity. Only the costs that would be incurred if the intervention were to be implemented outside the context of the research project will be counted as intervention implementation costs. These will include program costs (training of PCPs and administrative staff) and unit costs (efforts to reach patients, patient contact time). The unit costs of each activity will be estimated and a total cost of the intervention per patient will be determined. We will also evaluate the cost of incremental statin usage in the IC condition vs. UC, and will calculate the cost of incremental changes in LDL.

C.2.e. Data management: Dr Daniela Rosero, the UDLA Project Director, will be responsible for overseeing adherence to data collection procedures. The data generated in each clinic will be collected every week and exported in an Excel format. Dr. Rosero will send all data to Dr. Fornasini and copy Dr. Baldeón. Dedicated UDLA computers are used exclusively by the team and require a private log-in to gain access. Dr. Fornasini will keep a separate password protected hard drive to back up the information every 15 days. He will update a master SPSS data base with clinic information. Subsequently, Dr. Fornasini will send an encrypted master SPSS data base to the UMMS Project Director (Mr. Phil Merriam) and Dr. Ira Ockene every 15 days, All the hard copies of the forms for the study will be stored in a locked metal cabinet that can be accessed only by Dr Baldeón.

<u>Participant Tracking</u>*:* A participant tracking system will be created in Microsoft (MS) Access to track the recruitment process and the baseline and follow-up assessments at the 8 participating clinics. The information will be entered by each clinic coordinator. The data includes: (1)

identified eligible individuals; (2) recruitment disposition; (3) completion of the baseline assessments (including completion status, date of completion or reason for non-completion); and (4) completion of the six-month follow-up assessment (including completion status, date of completion or reason for non-completion). All files will contain unique subject identification numbers. Separate files will contain participant identification linked to a study-specific ID number. All files and data will be stored on a password-protected network, with regular back-up onto cd-roms and accessible only to study personnel

Data entry: Data will be entered directly into EpiInfo programs by the clinic coordinators . Data will be transferred to Stata data files for analysis. STATA data manipulation techniques will be used for merging. All participant identifiers will be removed from analytic datasets, and datasets with identifiers will be password-protected. Frequent exploratory analyses will detect unusual or erroneous values. Ongoing comparisons will be made of data entered and tracking system indication of data collected.

Quality Control Measures: Dr. Fornasini and Dr. Reed will structure the primary datasets, data-linking procedures, variable-naming conventions, codebooks, and documentation. They will monitor data quality, preparation and documentation of all final analytic datasets. Password-protected study directories will be created and will serve as the central repository for all final Stata datasets at UDLA and UMMS.

C.3. Detailed Work Plan and Deliverable Schedule:

	2014									2015		
	April	May	June	July	August	Sept	Oct	Nov	Dec	Jan	Feb	March
Year 1	1	2	3	4	5	6	7	8	9	10	11	12
start-up	X	X										
contacting pt		XX	XX		XX	XX		XX	XX		XX	XX
screening			XX	XX		XX	XX		XX	XX		XX
baesline				XX			XX			XX		
6 month assess										XX		
										2016		
Year 2	13	14	15	16	17	18	19	20	21	22	23	24
start-up												
contacting pt		XX	XX									
screening	XX		XX	XX								
baseline	XX			XX								
6 month assess	XX			XX			XX			XX		
analysis											X	X
	* 5 waves: 40/wave; 100/condition)											

Deliverables of the project will include a validated patient-centered counseling training package that includes PowerPoint slides, video and audio files, and all of the office support program materials. Deliverables will also include a cohort of IAS cardiologists who are program "champions" and in addition to the program directors and staff will be available for further training and dissemination of the study results.

F. REQUIRED DOCUMENTATION

- University of Massachusetts Medical School (UMMS) agreement letter

- University of Massachusetts Medical School (UMMS) statement of intent

Department of Medicine
Division of Cardiovascular Medicine

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Ira S. Ockene, MD
David and Barbara Milliken Professor of
Preventive Cardiology
Director, Preventive Cardiology Program

January, 27, 2014

Dear Sir and Madam:

We are submitting a proposal in response to the RFP, Reducing Cardiovascular Risk Globally Through Improved Dyslipidemia Awareness and Treatment, a collaboration of the International Atherosclerosis Society (IAS) and Pfizer. It is focused on improving care for patients with medium or high levels of cardiovascular risk, with a particular focus on dyslipidemia.

Our submission titled, Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems, is in collaboration with colleagues from the Universidad de las Americas – Ecuador.

We look forward to your review of the proposed project.

Sincerely, yours,

Ira S. Ockene, M.D.
David and Barbara Milliken Professor of Preventive Cardiology
Director, Community Engagement Section,
UMass Center for Clinical and Translational Science

Diego Vazquez
Assistant Provost
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Research Funding Services

University of
Massachusetts
UMASS. Medical School

STATEMENT OF INTENT TO ESTABLISH A CONSORTIUM AGREEMENT

A. **APPLICATION TITLE:** Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems

APPLICANT INSTITUTION: University of Massachusetts Medical School - Worcester

PRINCIPAL INVESTIGATOR: Ira S. Ockene, M.D.

COOPERATING INSTITUTION: Universidad de las Américas Medical School in Quito, Ecuador
   DUNS number: NA
   Congressional District: NA

CO-INVESTIGATOR: Manuel E. Baldeón, M.D., Ph.D.
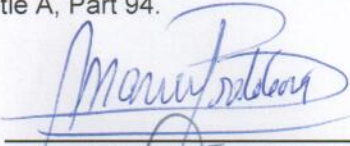
TOTAL PROJECT COSTS: $ 153,298

PROPOSED PROJECT PERIOD: April 1, 2014 – March 31, 2016

In signing below and offering to participate in this research program, the Cooperating Institution certifies that to the extent applicable under the law neither they nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; they are in compliance with the Drug Free Workplace Act of 1988; they are in compliance with the U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying; they have filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; they have filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); they are in compliance with PHS policy governing Program Income; they have established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that they are in compliance with applicable federal and/or sponsor guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the PHS-NIH consortium grant policies and are prepared to establish the necessary inter-institutional agreement(s) consistent with those policies. In signing below, the Cooperating Institution certifies that it has implemented and is enforcing a written policy on Conflict of Interest that is in compliance with the provisions of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94.

_____   _____   _____   20-01-2014
Ira S. Ockene, M.D   Date   Manuel E. Baldeón, M.D., Ph.D.   Date
Principal Investigator   Co-Investigator

_____   _____   _____   01/20/2014
Signature of   Date   Carlos Larreategui   Date
Authorized Institutional Official   Authorized Institutional Official
Janice Lagacé, Assistant Director   Universidad de las Américas Medical School
UMass Medical School

I. APPENDICES

- Abbreviations

- References

- Algorithm for Initial Physician-Delivered Lipid Intervention

- Algorithm for Follow-up Physician-Delivered Lipid Intervention

- WATCH Diet and Activity Risk Assessment

- Patient Exit Interview

Abbreviations

Intervention condition	IC
Usual care condition	UC
Primary care provider	PCP
Homeostatic model assessment	HOMA
Patient exit interview	PEI
Worcester-Area Trial for Counseling in Hyperlipidemia	WATCH
Physical activity	PA
Dietary and activity risk assessment	DARA
Body mass index	BMI
Fasting blood sugar	FBS
Hemoglobin A1C	HbA1C
Patient	pt

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Algorithm for Initial Physician-Delivered Lipid Intervention

CLINICAL EVALUATION (history, physical exam, lab tests)
* Evaluate for secondary cause
* Evaluate for familial disorder
* Consider influences of age, sex and other CHD risk factors

---

1. ADVISE LOWERING DIETARY FAT

"Your cholesterol is high. High cholesterol increases your risk of heart attack. Usually high cholesterol is related to eating too many high fat foods such as meat, fried foods, cheese and other dairy products such as ice cream, butter and sour cream, as well as baked goods. So, we need to work on lowering your risk of heart attack by cutting down on the amount of fat that you eat and replacing foods that are high in fat with foods that taste good but are low in fat."

---

2. ASSESS:
- Past Experience
- Current Diet
  (Dietary Assessment Form- DAF)

- Have you ever tried to lower the amount of fat and cholesterol in your diet?
  What changes did you make?
- What kinds of problems did you have making your changes?
- What kinds of things helped?
- (If possible, patient should fill out DAF before visit.)

---

3. PRIORITIZE AREA(S) OF HIGH FAT INTAKE

*Meats*Snacks/Side Dishes*Dairy*Spreads/Dressings

- Reinforce positive dietary habits

- What problems would you expect in making these changes? (e.g. I eat out a lot; Someone else buys/ prepares food; My family won't eat this eay; I'm too busy to eat right; I don't have will power.)

---

4. NEGOTIATE PLAN
- Ways to deal with expected problems
- Cholesterol goal
- Dietary goal
- Provide Dietary Goal Handout(s)
- Refer to nutritionist (>90% LDL)

- How do you think you could deal with them? (SEE BACK FOR SUGGESTIONS TO ADDRESS CONCERNS)
- Negotiate cholesterol and dietary goal with patient.
- Give patient dietary goal handout on specific area of change and packet of additional information.

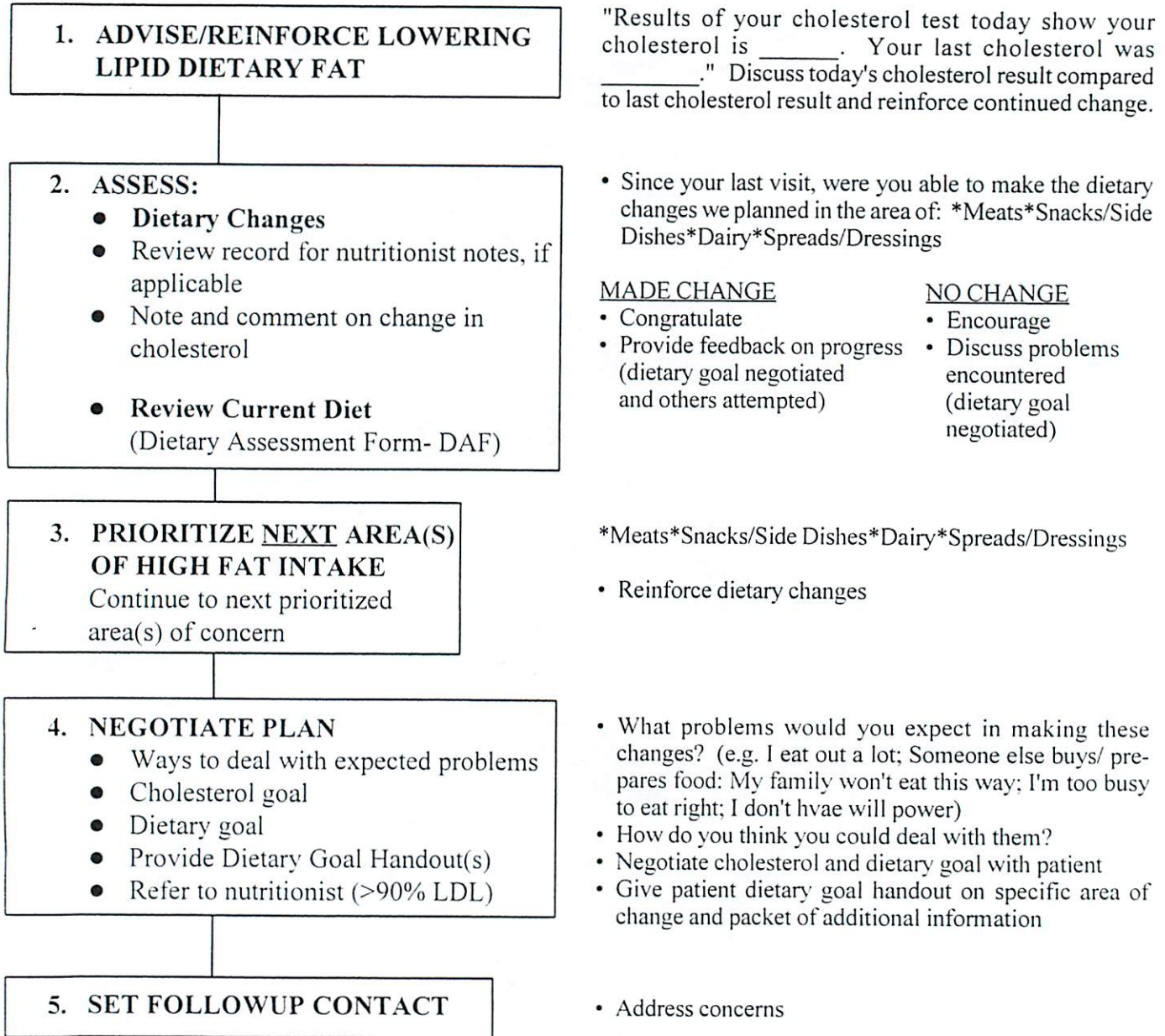**5. SET FOLLOWUP CONTACT**

75-90% LDL-C	> 90% LDL-C	
Return Visit 4-6 weeks and/or 3 months as appropriate	Refer immediately for Nutrition Counseling Return visit 4-6 weeks and/or 3 months as appropriate	• Address concerns.

Followup Algorithm for Physician-Delivered Lipid Intervention

1. ADVISE/REINFORCE LOWERING LIPID DIETARY FAT

"Results of your cholesterol test today show your cholesterol is _____. Your last cholesterol was _____." Discuss today's cholesterol result compared to last cholesterol result and reinforce continued change.

---

2. ASSESS:
- **Dietary Changes**
- Review record for nutritionist notes, if applicable
- Note and comment on change in cholesterol

- **Review Current Diet**
  (Dietary Assessment Form- DAF)

- Since your last visit, were you able to make the dietary changes we planned in the area of: *Meats*Snacks/Side Dishes*Dairy*Spreads/Dressings

MADE CHANGE	NO CHANGE
• Congratulate	• Encourage
• Provide feedback on progress (dietary goal negotiated and others attempted)	• Discuss problems encountered (dietary goal negotiated)

---

3. PRIORITIZE <u>NEXT</u> AREA(S) OF HIGH FAT INTAKE
Continue to next prioritized area(s) of concern

*Meats*Snacks/Side Dishes*Dairy*Spreads/Dressings

- Reinforce dietary changes

---

4. NEGOTIATE PLAN
- Ways to deal with expected problems
- Cholesterol goal
- Dietary goal
- Provide Dietary Goal Handout(s)
- Refer to nutritionist (>90% LDL)

- What problems would you expect in making these changes? (e.g. I eat out a lot; Someone else buys/ prepares food: My family won't eat this way; I'm too busy to eat right; I don't hvae will power)
- How do you think you could deal with them?
- Negotiate cholesterol and dietary goal with patient
- Give patient dietary goal handout on specific area of change and packet of additional information

---

5. SET FOLLOWUP CONTACT

- Address concerns

Diet and Activity Risk Assessment

Worcester Area Trial for Counseling in Hyperlipidemia

Name: _____   **Date**: _____   **MRN**: _____   **ID#**: _____

The questions on the following pages ask how often you eat certain foods.
Please answer the questions based on how you **usually** eat, rather than *how you would like to* or *think you should* eat.

Please read the questions carefully and circle the most appropriate answer.

Example:

How many times a week do you eat......
1. Bacon, sausage, or ham   0   1   (2)   3   4+

---

1. How interested are you in improving your diet?

   Not at all   Very Much
     1   2   3   4   5

2. How confident are you that you will be able to make changes to improve your diet?

   Not at all   Very Much
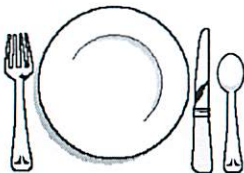   1   2   3   4   5

3. Are you following a particular diet now? (check the appropriate boxes)

   No θ   Yes θ (please specify below)
                                 θ A program such as Weight Watchers, Jenny Craig
                                 θ weight loss
                                 θ low salt
                                 θ diabetic
                                 θ low fat/low cholesterol

   θ other_____

4. Would you like assistance to improve your diet?   Yes   No

5. About how many meals or snacks do you eat <u>out</u> each week?

   None   1-3   4-6   7-10   10+

   - Which meals do you eat away from home the most? (Circle all that apply)

   Breakfast   Lunch   Dinner   Snacks or treats

6. Is there someone who would help you change your diet and stick to it?   Yes   No

7. Who does <u>most</u> of the cooking in your home?

   Myself θ   Spouse or Partner θ   Both θ   Other: _____

PROTEINS

**If you eat meat,
how many times a week do you eat.....**

Goals
set by
MD ↓

No.	Item					Goal
1.	Regular bacon, sausage, ham, hot dogs, kielbasa, lunchmeats like bologna or salami	0 1	2	3+		☐
2.	Do you ever eat low-fat bacon, sausage, ham, hot dogs, kielbasa, lunchmeats like bologna or salami	0 - 2	3 - 4	5+		☐
3.	Regular hamburger, including hamburger meat in dishes like meatloaf or spaghetti	0 1	2 3	4+		☐
4.	Lean hamburger, including hamburger meat in dishes like meatloaf or spaghetti	0 - 3	4 - 5	6+		☐
5.	**Red meats**					☐
	- Beef - like roast, stew meat, ribs, or steak	0 1 2	3 4+	5+		
	- Cuts of pork, like chops, ribs, roasts, BBQ	0 1 2	3 4+	5+		
	- When you eat meat, is the fat usually trimmed?	Yes	Sometimes	No		
	- Is your serving larger or smaller than a pack of cards?	Smaller	Same	Larger		
6.	**If you eat chicken or turkey**					
	- Is the chicken usually fried?	No	Sometimes	Yes		☐
	- Do you usually eat the skin?	No	Sometimes	Yes		
	- Which part of the poultry do you usually eat?	White meat	Both	Dark meat		
7.	Fish including tuna fish and shellfish	2+	1	0		☐
	- Is the fish usually fried?	No	Sometimes	Yes		
8.	Vegetables such as split peas, lentils, pinto, kidney, navy, or garbanzo beans, tofu or soy products?	2+	1	0		☐
	- Do you ever eat vegetables instead of meat?	Yes	Sometimes	No		
9.	How often do you eat regular peanut butter or nuts?	0 - 1	2	3+		

SNACKS and SIDE DISHES

How many times a _WEEK_ do you eat.....

							Goals
1.	Tossed salads	4+	3	2	1	0	☐
2.	"Regular" sweets, including pies, cakes, cookies, donuts, sweet rolls, muffins or chocolate candy	0	1 2	3 4		5+	☐
	"Low-fat" sweets, including pies, cakes, cookies, pastries, muffins or chocolate candy	0	1 2	3 4		5+	
3.	"Regular" crackers, snack chips, potato chips, Fritos ™, Cheetos ™, or tortilla chips	0	1 2	3 4		5+	☐
	"Low-fat" snack chips or crackers	0 - 3		4 - 5		6+	
4.	Side dishes cooked or baked with cheese or cheese sauce	0 1		2		3+	☐
5.	"Regular" cereal, toast, English muffins or bagels	4+	3	2	1	0	☐
	"Low Fat" or "High Fiber" cereal, toast, English muffins or bagels	4+	3	2	1	0	
6.	Rice, noodles, and other grains	5+	4	3	2	1	
7.	Bread or rolls, including sandwiches	2+		1		0	☐
	- Do you eat whole wheat bread?	Yes		Sometimes		No	

How many times a _DAY_ do you eat or drink.....

					Goals
8.	Fruit or fruit juices	2+	1	0	☐
	Vegetables of any kind (excluding FRIED vegetables)	2+	1	0	

DAIRY and EGGS

If you consume dairy products, how many times a _WEEK_ do you eat or drink.....

					Goals set by MD
1.	Whole milk (as a drink or in cereal)	0 1	2	3+	☐
	2% milk	0 1	2 3	4+	
	1% milk, buttermilk	0 2	3 4	5+	
	Skim	1+	0		
2.	"Regular" cheese, like cheddar, Swiss, American, or cream cheese - including cheese in other dishes or sandwiches	0 1 2	3 4	5+	☐
	"Low-fat" cheese, like part-skim mozzarella, Ricotta, or cottage cheese	0 - 3	4	5+	
	Do you eat "fat free" alternatives?	Yes	No		
3.	"Regular" ice cream (including ice cream bars, etc)	0 1	2	3+	☐
	"Low-fat" ice cream, ice milk, sherbet, or frozen yogurt?	0 - 2	3 - 4	5+	
	Do you eat "fat-free" alternatives?	Yes	No		
4.	Cream, half & half in coffee or tea	0 1 2	3	4+	☐
5.	How many whole eggs do you eat each week?	0 1 2	3 4	5+	☐
	Do you ever eat Egg Beaters ™ No Yes				
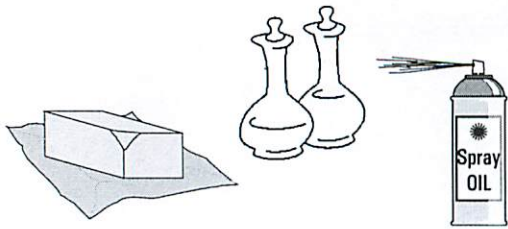
BUTTER, MARGARINE and OILS

Goals set by MD ↓

1.	Do you usually eat OR cook with margarine or butter?	No, rarely	Sometimes	YES	☐
	- If you use margarine, is it tub, liquid, or stick?	LIQUID/SPRAY	TUB	STICK	
2.	How many teaspoons (pats) of margarine or butter do you add to food at the table each day?	0 1 2	3	4+	☐
3.	Do you use the following oils for baking or cooking in your home?	Fat-free or low-fat spread or spray, Canola oil, olive oil	Other vegetable oils	Pork fat, butter, lard, shortening, stick margarine	☐
4.	How is your food <u>usually</u> flavored?	Nothing Salt/Pepper Herbs/Spices Spray Oils	Reduced fat sauces, etc.	Sour Cream, Meats, Butter/Marg., Cheese sauce Cream sauce Bacon fat	☐

How many times a <u>WEEK</u> do you eat.....

5.	Gravy or meat drippings	0 1	2	3+	☐
6.	"Regular" mayonnaise (including sandwiches such as tuna or egg salad) or salad dressing	0-2	3-4	5+	☐
	"Low-fat" mayonnaise, or salad dressings (including sandwiches as above)	0-4	5	6+	
7.	Foods that are fried, like French fries, onion rings, fried dough, chicken, fried clams and/or other seafood	0 1	2 3	4+	☐

PHYSICAL ACTIVITY

The following questions ask you about your level of physi[cal]
at work
(include volunteer work), at home, and during leisure-time.

Occupational activity

1. Are you currently working (include volunteer work)   Y   N
   If yes, how many hours per week do you work or volunteer?   1-8 9-16 17-24 25-40 40+ hrs/wk

If you <u>are</u> currently working, **which of the following categories best describes the amount of physical activity required on your job and/or volunteer work? (please circle <u>one</u> category)**

1	2	3	4
Mainly sitting with slight arm movements. [Examples: office worker, watchmaker, seated assembly line worker, computer worker]	**Sitting or standing with some walking.** [Examples: cashier, general office worker, light tool and machinery worker]	**Walking with some handling of materials generally weighing less than 50 lbs.** [Examples: mailman, waiter/ waitress, construction worker, heavy tool and machinery worker]	**Walking and heavy manual work often-requiring handling of materials weighing over 50 lbs.** [Examples: lumberjack, stone mason, general laborer]

MODERATE ACTIVITIES

In a typical week, on <u>how many days</u> do you participate in the following types of activities <u>for at least 30 minutes in a day?</u>

2. Moderate household activities (e.g. vacuuming, scrubbing floors or windows, sweeping garage)	5-7	4	2-3	1	0
3. Walking for exercise	5-7	4	2-3	1	0
4. Moderate recreational or leisure activities (e.g. gardening, recreational cycling, golf, softball, skating)	5-7	4	2-3	1	0
5. Strengthening and flexibility exercise (e.g. calisthenics, weight lifting, stretching, yoga)	5-7	4	2-3	1	0

VIGOROUS ACTIVITIES

In a typical week, on <u>how many days</u> do you participate in the following types of activities <u>for at least 20 minutes in a day</u>?

6. Vigorous leisure activities (e.g. running, lap swimming, aerobics, basketball, x-country skiing)	5-7	4	2-3	1	0
7. Heavy household or gardening activities (e.g. chopping wood, shoveling snow, digging in garden)	5-7	4	2-3	1	0
8. **How many <u>months per year</u> do you typically participate in any of these household, recreational, or leisure-time activities <u>at least 3 days per week</u> ?**	11-12 mos	9-10 mos	6-8 mos	3-5 mos	0-2 mos

PATIENT EXIT INTERVIEW

Date: ____/____/____ MM DD YY Name: _____ M.D._____	Clinic: _____ Study ID:_____ MD ID:_____	Time: Appointment: _____am/pm Exit: _____am/pm Exit interview: _____ minutes In person? _____ By telephone? _____ PEI #: _____

Interview instructions:

- All the questions are about TODAY'S visit with your doctor.
- This is not a questionnaire from your clinic.
- This information is collected for research purposes only and will be kept confidential.

	YES	**NO**

1. Did your doctor talk to you about your cholesterol level TODAY?

2. Did your doctor talk to you about your diet as it relates to your cholesterol TODAY?

   If YES, about how many minutes did your doctor spend TODAY discussing your diet as it relates to your cholesterol?

   _____ minutes

3. During TODAY'S visit, did your doctor advise you to make or continue making changes in your diet to lower your cholesterol?

   If YES, what goal(s) did you set?

   _____

   If NO to questions # 2 and 3, skip to question #8

4. Did your doctor discuss your past efforts to change your diet to lower your cholesterol?

5. Did you and your doctor discuss problems you might have making changes in your diet?

   If NO to question #5, skip to question #7

6. Did you and your doctor discuss any solutions to these problems?

7. Did you and your doctor agree on specific dietary changes or goals?

8. Did your doctor give you any written education materials during TODAY'S appointment?

   If YES,

   _____ standard WATCH materials packet, including goal sheets,

             tip sheets and recipe booklet)

   _____ goal sheet(s)

   _____ tip sheet(s)

   _____ recipe booklet

   _____ other: Specify: _____

9. During TODAY'S visit, did your doctor discuss beginning or maintaining an exercise program?

   If YES, what goal did you set?

   _____

10. Did your doctor schedule a follow up visit to talk about your progress with your diet and lowering your cholesterol?

    If YES, when is your next appointment with your doctor?

                     ____/____/____

                     MM   DD   YY

    Were you referred to another professional for help with your diet or cholesterol?

    If YES, who?

    _____ a nutritionist or dietitian

    _____ other: Specify: _____

<div align="center">Thank you!</div>