This is to certify that the
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IMPROVING SECONDARY PREVENTION OF CORONARY HEART DISEASE

USING DECISION SUPPORT INTERVENTIONS IN OUTPATIENT SETTINS;

A GRANT PROPOSAL SUBMITTED TO NATIONAL HEART LUNG AND BLOOD INSTITUTE

presented by

ADESUWA B. OLOMU

has been accepted towards fulfillment
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Matthew J Reeves
Major Professor's Signature

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Date

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IMPROVING SECONDARY PREVENTION OF CORONARY HEART DISEASE USING DECISION SUPPORT INTERVENTIONS IN OUTPATIENT SETTINGS; A GRANT PROPOSAL SUBMITTED TO NATIONAL HEART LUNG AND BLOOD INSTITUTE

By

Adesuwa B. Olomu

A THESIS

Submitted to
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ABSTRACT

IMPROVING SECONDARY PREVENTION OF CORONARY HEART DISEASE

By

Adesuwa B. Olomu

The proposed research will focus on improving secondary prevention of coronary heart disease (CHD) for both African American (AA) and low socioeconomic (SES) populations. AA have higher mortality and morbidity from heart disease than whites. They are less likely than whites to receive appropriate cardiac medications and basic clinical services.

Specific Aims of this project are to:

1) Develop and pilot test a patient-centered intervention, Office-Guideline Applied to Practice (Office-GAP) to improve the implementation of evidence-based guidelines for secondary prevention of CHD for both AA and low SES populations in an outpatient clinical setting. The intervention will include the use of Office-GAP tools as part of clinician workflow. The intervention will embed the content of secondary prevention into the care process. The principle of shared decision-making (SDM) will also be used to negotiate lifestyle/behavior change goals with the patient. Provider and patient educational modules will be developed and implemented.
2) Develop an Office-GAP follow-up program that will include reminders to reinforce secondary prevention goals.
3) Evaluate the implementation of Office-GAP using a cluster-randomized design at Ingham County Health Centers.

We believe that these decision support tools will translate research into practice and improve physician and patient adherence to evidence-based recommendations. This should lead to a decrease in cardiovascular morbidity and mortality for both AA and low SES populations. Elements of the proposed system can be applied to the treatment of other chronic diseases following successful implementation.

DEDICATION

To My Family

who encouraged, prodded, supported, sacrificed
and consoled through these years.

ACKNOWLEDGEMENTS

Special thanks to all those who helped me through this degree. In particular, I would like to thank Drs. Margaret Holmes-Rovner, Mathew Reeves, David Todem and Nigel Paneth, my mentors and committee members; students I have had the pleasure to work with over the years; and of course, my assistant, Jinie Shirey.

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KEY TO SYMBOLS OR ABBREVIATIONS

AMI	Acute Myocardial Infarction
AA	African Americans
ACC	American College of Cardiology
AHA	American Heart Association
ACEI	Angiotensin Converting Enzyme Inhibitor
CVD	Cerebrovascular Disease
CAD	Coronary Artery Disease
CHD	Coronary Heart Disease
DST	Decision Support Tools
GAP	Guideline Applied to Practice
HDL	High Density Lipoprotein
LDL	Low Density Lipoprotein
QI	Quality Improvement
SES	Socio-Economic Status

1. THE CANDIDATE:

A. BACKGROUND

My background demonstrates a consistent interest and commitment to research. Previous research experiences have expanded my knowledge base and research skills, as well as focused my research efforts on health services research, particularly in areas of prevention of cardiovascular diseases and quality improvement. I began my research career during my graduate training in Internal Medicine at the Queen Elizabeth Hospital and University of Birmingham, England, UK. Under the mentorship of Dr. Elwyn Elias, I successfully completed a research project and wrote a dissertation on gender differences in primary biliary cirrhosis. The results, published in the *New England Journal of Medicine*[1] and *Lancet*[(1)] furthered my interest in clinical research and studies involving patients with chronic disease.

On return to Nigeria from my medical training in England, I became involved in epidemiological studies among black populations before coming to the United States (US). Selected studies involving black populations, included, an epidemiological study of determinants of hypertension in blacks[(2)], body fat distribution and other anthropometric blood pressure correlates in a black elderly population[4], and the correlates of serum lipids in a lean black population[5]. These studies sharpened my skills in research design, data interpretation, scientific writing and presentation.

I did my residency in general internal medicine at Michigan State University (MSU), and soon after graduation, was appointed to the position of Assistant Professor in the Department of Medicine. With a keen interest in health services research, I became a member of an active health services research group engaged in the study of the process

and outcomes of care provided to patients with acute myocardial infarction. I gained substantial experience from involvement in the data analysis of the Michigan State Inter-institutional Collaborative Heart (MICH) study. MICH is an observational study of the process and outcomes of care for patients hospitalized with acute myocardial infarction in two mid- Michigan communities.

I am currently involved in studies determining the rate of use of recommended evidenced based medications in patients following acute myocardial infarction (AMI). Results of our studies revealed an under use of evidence-based medications for secondary prevention of heart disease. Furthermore, our results showed that African American patients were less likely than whites to be on daily aspirin at the time of admission. Findings from the MICH study, on the rate of use of beta-blockers and aspirin following AMI were presented at the Regional and National meetings of the Society of General Internal Medicine (SGIM) [6,7]. Another study, regarding changes in rate of use of beta-blockers following acute myocardial infarction was published in the *Journal of General Internal Medicine*, Oct 2004[8] (see Preliminary study 3 on pages 32-40). In addition, I am a co-investigator in "Translating Research Into Practice: Patient Decision Support and Coaching", a novel approach to improving the use of secondary prevention following hospitalization for myocardial infarction. Dr. Holmes-Rovner is the PI on this RO1 HS10531 from AHRQ. I am the clinical consultant on the project, and the lead investigator on minority health issues on the team.

I was awarded a minority supplementary grant *3 RO1 HS10531 from AHRQ*, based on the above RO1 parent grant. I am completing data analysis, assessing outcomes in patients with acute coronary syndrome. I have presented the following abstracts from

data analyzed so far: 1) "Evaluation and Treatment of High Cholesterol during Hospitalization for Acute Coronary Syndrome"[9] 2) "Self- Report Comorbidity Data and Functional Outcomes in Acute Coronary syndrome"[10] 3) "The Effect of Evidence-Based Cardiac Medication Use on Hospital Readmission for Post Acute Coronary Syndrome (ACS) Patients"[11]. 4) "Quality Improvement Efforts And Hospital Performance: Rates of Beta-Blocker Prescription for Acute Coronary Syndrome ".[12] These were at the Midwest Regional Meeting of Society of General Internal Medicine (SGIM) in October 2004 and at the National meeting of the SGIM in May 2005 and April 2006. Working on each of these abstracts improved my health services research skills and strengthened my interest and commitment to quality improvement and prevention of heart disease.

As I pursued my research interests, I became aware of the need to supplement practical research experiences with formal didactic training in clinical epidemiology and biostatistics. I successfully applied to MSU's NIH K30 program "Training Clinical Researchers in Community Settings (TRECOS)" to begin formal research training in epidemiology. The fellowship award has allowed me to pursue a Masters in Epidemiology at MSU while working on various research projects. I have completed 33 of 40 required credits towards the masters' program. The anticipated date of completion is December 2006. This program covers a broad range of topics relevant to clinical research including observational studies, controlled clinical trials, and survey research. It also provided training in biostatistics, epidemiology, statistical modeling and research management.

I am confident that, with the training, experience, and mentoring I will receive during a five-year NHLBI Mentored Minority Faculty Development Award, I will

become an independent investigator and a role model for minority medical students, residents and fellows in training.

Establishment of mentor relationship.

My research interests are in the area of health services research, specifically in the area of prevention, decision support, disease management and quality of care of cardiovascular disease among blacks and low-income populations. This interest has led me to work closely with Dr. Margaret Holmes-Rovner, the primary mentor for this application. Dr. Holmes-Rovner is a Professor of Health Services Research at MSU's College of Human Medicine. She is an internationally known expert in development and evaluation of decision support tools. She is a past president of the Society for Medical Decision Making and past chairperson of the AHRQ study section on Health Care Technology and Decision Sciences. We are currently working together in the MICH, the Heart After-Hospital Recovery Program (HARP) and minority supplementary projects. She has worked closely with me in the preparation of this application. I am also working closely with Dr. Kim Eagle, a co-mentor on this application, who is the Clinical Director of the University of Michigan Cardiovascular Center, and the principal investigator of the American College of Cardiology's Guidelines Applied to Practice (GAP) in Michigan. He is involved in the design of the quality improvement aspect of this proposal.

B. Career Goals and Objectives: Scientific biography

My career goal is to establish myself as an independent investigator in health services research with a focus on research to improve the quality of care of blacks and low-income populations with heart disease by translating research into practice. This is not traditional health services research, but is an emerging area that involves process

improvement and decision support for doctors and patients. To develop this career trajectory, I need additional knowledge and skills related to successful models of process improvement and decision support in order to design and implement the interventions. In addition, enhanced skills in epidemiology to evaluate the interventions and their impact on care of underserved populations are needed. My goal is to move to a tenure-track position from my present Human Health Program (HHP) medical track position and to achieve independence as a health services minority investigator.

My objectives are to:

1. Acquire health services research expertise that will enhance my clinical expertise and epidemiology training.
2. Gain new skills in improving clinical processes of care to improve outcomes for patients and increase the effectiveness of clinicians.
3. Gain new skills in qualitative research methodology and development of decision support tools.
4. Develop a research program of interventions and evaluation of their effect on patient health outcomes and quality of care in diverse primary care settings.
5. Disseminate research findings of the current proposal through presentations at local, regional and national meetings, peer- reviewed publications and through professional community health centers.

Completed postgraduate training relevant to this application: Masters Degree Courses in Epidemiology at MSU.

EPI 810 - Introduction to Descriptive and Analytical Epidemiology (3 credits).

Study of disease from a population perspective as the interaction of host, agent, and environment.

LCS 829 – Design and Conduct of Epidemiological Studies and Clinical Trials (3 credits)

Applied analytic methods in experimental design. Assessment of health and disease status of human populations. Risk assessment and interpretation of clinical trials.

STT 421- Statistics I (3 credits) and STT 422- Statistics II (3 credits).

Basic probability, random variables and common distributions. Estimation and tests for one, two and paired sample problems. Introduction to simple linear regression and correlation, 1-way ANOVA.

EPI 825- SAS Programming (3 credits).

A programming approach to plan and write simple SAS programs to solve common data management and data analysis problems in research settings.

EPI 815- Cardiovascular Disease Epidemiology and Prevention (3 Credits)

This course discussed the methodologies used in epidemiologic studies of cardiovascular disease. We reviewed genetic, environmental, and behavioral causes of cardiovascular disease as well as Surveillance and Validity issues. Approaches to the prevention and control of cardiovascular disease were emphasized.

EPI 812- Causal Inference in Epidemiology (3 Credits)

This course discussed causal models, criteria, and causality related to study design and analysis in epidemiology. Application of theoretical concepts to the design, analysis and assessment of epidemiologic research was also studied.

EPI 826 – Research Methods in Epidemiology (3 Credits)

Analyses of epidemiologic and clinical data applying statistical methods, based on logistic and survival models, using standard software was studied.

EPI 827- The Nature and Practice of Scientific Integrity (3 Credits)

Historical development of where and how science is practiced in the United States. Scientific culture, sociology, and ethical standards were discussed. Principles, standards, and practices which define scientific integrity and responsible research conduct were also discussed.

EPI 813- Investigation of Disease Outbreaks (3 Credits)

Principles of and practice in investigating disease outbreaks was discussed in this class.

EPI 935- How to write a Write a Grant Proposal (3 Credits)

This course discussed how to write a grant proposal and get funding. We developed a research proposal during this class and made a presentation at the end of the course.

C. Career Development Activities during Award Period

Objective 1. Acquiring health services research (epidemiology, decision making, and process improvement) expertise that will enhance my clinical expertise and epidemiology training.

Planned academic work

a. Epidemiology, Qualitative Methodology and Health Services Research Skills

i) EPI 820 – Evidence Based Medicine (3 Credits) Course at MSU. Instructor; Dr Mathew Reeves; MSU

The objective is to gain further expertise in methods of clinical epidemiology, health services and outcomes research. This course will cover the application of evidence-based

medicine. Topics will include: 1) Effectively searching the literature 2) General assessment of methodology and statistics. 4) Assessing the quality of reports of drug trials, diagnostic and screening tests, systematic reviews or meta-analysis, guidelines, economic analyses, qualitative research, and 5) implementation of evidence-based findings.

ii) Combining Qualitative and Quantitative Methods: Introduction and Overview (1.5 credits) 4 weeks course

Instructors: William Axinn, University of Michigan; Jennifer Barber, University of Michigan

In this course, we will become familiar with multiple methods of data collection and how to combine them within a single research project. We will focus on collecting data using unstructured or in-depth interviews, focus groups, participant observation, archival research, survey interviews, and hybrid methods. We will discuss the strengths and weaknesses of each approach, and we will focus on how each different method can contribute to the research question in unique ways. These skills will contribute to evaluating the fidelity and implementation of planned interventions.

iii) Qualitative Data Analysis: With and Without the Use of Computers (1.5 credits) 4 weeks course Instructor: Eben Weitzman, University of Massachusetts-Boston

This course will cover methods for organizing, interpreting, and drawing and verifying conclusions from qualitative data. The approach throughout will be active, participatory, and engaged with real data. We will learn how to make intelligent, individualized selections of software that best meet the needs of a particular research. We will apply what we learn to the analysis of real data, as we use selected software to enter,

summarize, and code data collected in the previous qualitative methods courses, ending in a research report.

iv) Qualitative Methods Workshop: Indiana University, Schuessler Institute for Social Research Intensive Program. Instructor: Sue E. Estroff, UNC-Chapel Hill. Intensive training in ethnography, in-depth interviewing, and other qualitative techniques. Opportunities for hands-on-research, one-on-one consultation.

v) Workshop in Focus Group Interviewing and Systematic Focus Group Analysis at University of Minnesota. Professor Richard Krueger will conduct the 5 days workshop. Professor Krueger is a member of the graduate faculty at the University of Minnesota and teaches course in program evaluation and research methods. He is a well-known expert in teaching and analyzing focus groups.

vi) The Michigan State University Health Services Research/Epidemiology Seminars/Research meetings. The Health Services Research Group sponsors 90-minute research meetings weekly. Topics are diverse and include presentation of research projects in various stages of development. We discuss grant proposals and review data and papers to be sent for publications. My mentor is the coordinator of these weekly meetings. In addition I will attend the bi-monthly seminars and weekly Journal club in the Department of Epidemiology.

b. Decision Making

Intensive short summer courses

i) Decision Making Models in Health care HMP 655 – 3 credits. Instructor: Mendez David.

I will take this intensive advanced short course at the University of Michigan. We will be exposed to Monte Carlo Simulation, Multiple Regression analysis, Discriminant analysis, Project Management, Integer Linear Programming and Multi-Criteria Optimization. Use of computers and spreadsheet modeling will be emphasized throughout the class. A better understanding of this discipline will inform the qualitative study and the development of the decision support tools.

ii) Society of Medical Decision Making Pre-conference Short Courses

The annual meeting of the society for Medical Decision Making and pre-conference short courses are the best resources available for advanced topics and new methodological advances in decision sciences for healthcare. I will attend annually throughout the period of the award. Examples of such courses are:

- Basic and advanced decision analysis
- Reducing bias in observational studies- propensity methods
- Decision quality-learning from common pitfalls of stated preference methods.
- Using information technology to improve safety and quality in the ambulatory setting

Objective 2. Gaining new skills in improving clinical processes of care in organizational settings. a) I plan to attend a learning section and participate in a conference on Improving Chronic Illness Care (ICIC) at the ICIC MacColl Institute for Healthcare Innovation, Center for Health Studies, and Group Health Cooperative at Seattle, WA. Edward Wagner is the leader of the group. This learning section will also offer me the privilege of meeting with the faculty of the Bureau of Primary Healthcare collaborative project. I am in contact with Connie Davis, ICIC's Associate Director for

Clinical Improvement regarding my interest. I will also learn more about the ICIC model by 1) joining the Ingham county new diabetic collaborative and 2) visiting the Detroit and Sterling community health sites that have completed the CHD collaborative and improvement model in the first year. This will allow me to learn the quality improvement model and become part of a process improvement team. In addition this will enable me to develop a model that builds on, and extends the patient decision support and reminder system within the ICIC/IHI model. The Michigan Primary Care Association (MPCA) Collaborative Coordinator Faye Theil and Ingham County administrator Sue Dumeney have approved my participation.

b) Annual National Forum on Quality Improvement in Health Care: I plan to attend annually the National Forum on Quality Improvement in Health Care (IHI), the premier "meeting place" for people committed to the mission of improving health care. Dr Donald M. Berwick is the President and CEO. IHI is a source of energy, knowledge, and support for a never-ending campaign to improve health care worldwide. The Institute helps accelerate change in health care by cultivating promising concepts for improving patient care and turning those ideas into action. Knowledge gained from this meeting will be helpful in the implementation of our research design. Future National Forum dates and Locations; Dec 9-12 2007 Orlando FL, Dec 7-10, 2008 Nashville, TN; Dec 6-9, 2009 Orlando, FL.

c) Forum on Quality of Care and Outcome Research in Cardiovascular disease and Stroke: I plan to attend annually this American Heart Association scientific program that gives attendees the opportunity to learn the most recent information on: 1) measuring and improving quality of care and outcomes for persons with or at risk for cardiovascular

disease and stroke. 2) new and innovative approaches to quantifying and improving clinical effectiveness. 3) efforts by national groups to assess and improve care. 4) new research with implications for improving clinical care and healthcare delivery. 5) methodological innovations in studying outcomes and conducting clinical research. The meeting occurs every year in Washington DC.

d) University of Michigan Cardiovascular Outcomes Research and Reporting Program (M-CORRP) Meetings. I will continue to attend the M-CORRP bi-monthly meeting at University of Michigan, Ann Arbor. The goal of M-CORRP is to improve the quality of cardiovascular care for patients. The research team led by my co-mentor Dr Kim Eagle studies common cardiovascular conditions and procedures among large populations; developing modern mathematical tools to assess risk and outcomes; promoting evidence-based care models which incorporate the best science into care itself by targeting physicians, nurses, and patients.

Objective 3. Gaining expertise in developing decision support tools. a) Dr. Holmes-Rovner has extensive experience in the development and evaluation of decision support tools (see preliminary studies). She will provide mentorship through our weekly meetings in which we will review progress, including my written work, and determine my tasks for the coming week. In addition, Dr. Kim Eagle, one of the leaders in the application of guidelines to practice of cardiovascular medicine will provide mentorship in this area through the bi-monthly M-CORRP meetings.

b) Ottawa Patient Decision Support Laboratory, Decision Center and Ottawa Health Research Institute.

Professor Annette O'Connor of the School of Nursing and Department of Epidemiology leads this program. Dr. O'Connor has developed a research program to understand and support decision making of practitioners and consumers facing a variety of health care choices. Dr. O'Connor has been involved in over 50 projects funded for over $8 million. I plan to visit the Health Decision center for 2 weeks, during the first two years of the grant to gain experience in the development of decision support tools and to obtain consultation on our draft decision support tools. Dr. O' Connor is a consultant for this project.

Independent Readings/Training

I will build on my formal learning experiences with on-going independent study both in my content area of cardiovascular prevention, theory and method of decision sciences, and quality improvement. I expect this activity to be partly guided by my mentors and partly based on my own searches of the literature. The program of independent readings/training designed by my mentors and myself includes:

1) Process of Care: MSU Cochrane Review of Patient centered care. Dr. Holmes-Rovner is the co-PI on an approved update of the Cochrane review, "Interventions for providers to promote a patient-centered approach in clinical consultations". I will participate as a reviewer. This review will provide methodological training in systematic reviews and content that will guide the design of the intervention. The results of the review of the relative effectiveness of interventions directed to 1) provider alone, 2) patient alone, 3) tool to both, or combinations of interventions will guide the implementation of our study.

2) Decision Support Tools: Review of tools for patient decision support in outpatient. Dr. Holmes-Rovner is a co-investigator on a second Cochrane Review, "Decision aids for

people facing health treatment or screening decisions" (2001, 2003). The current update is being completely re-reviewed, to test decision aids against new international standards. The two databases will be combined to form a subset of trials of tools designed to support patient decisions either as free-standing interventions, or in patient-centered consultations. Dr. Olomu will become the first author on a new review of decision support tools. She will evaluate specifically the evidence about use of tools in primary care, especially those designed to improve decisions and outcomes in cardiovascular disease. A second Cochrane Review, under the direction of Dr. O'Connor is being updated. Dr. Olomu will specifically evaluate the literature related to decision support tools in chronic disease.

3) Qualitative Methods: Readings under the supervision of Dr Linda Hunt; Associate Professor of Anthropology. This will involve weekly readings/assignments over the first one year of the award from the following texts:

Bernard HR. Research Methods in Anthropology: Qualitative and Quantitative Approaches, Third Edition AltaMira Press. 2001

Joseph A. Maxwell. Qualitative Research Design: An Interactive Approach. 2nd Ed. Sage Publications; 2004.

Objective 4. Developing a research program of interventions and evaluation of their effect on patient health outcomes and quality of care in diverse primary care settings.

In both Dr. Holmes-Rovner's and Dr. Eagle's research programs, I will be exposed to dynamic research laboratories with multiple related projects. This exposure will provide me with experience in on-going research and publication opportunities from existing data

sets. During the final 18 months of the award period I will write and submit an RO1 proposal for a randomized controlled trial to evaluate the proposed program's effect on patient health outcomes and quality of care in 20 diverse primary care settings. My Mentors, Dr. Holmes Rovner, Dr. Kim Eagle, will provide guidance and feedback on my proposal. Dr Nigel Paneth, one of my advisors that teaches a course in NIH grant writing at MSU has agreed to provide guidance for writing the RO1 proposal.

Objective 5. Dissemination of Research findings I will submit results of the several phases of the research to traditional research venues such as national and international meetings in cardiology and primary care, and cardiology specialty and general medical journals. In addition to the traditional dissemination venues of professional meetings and journals, I will work directly with "safety net provider organizations" to obtain feedback on the organizational implications of results of my pilot and planned studies. Two opportunities exist in Michigan for this process as a first step. The first is to work with the professional organization of Community Health Centers, the Michigan Primary Care Association (MPCA). Since they work constantly to improve the quality as well as productivity of their Centers, this will provide the first opportunity to incorporate the early results and determine the next steps toward an R01 grant of significance. Further, the Area Health Education Center (AHEC) is housed at Michigan State University. The AHEC director was formerly employed by MPCA, and the purpose of the AHEC is both to train health professions students in underserved areas, but also to incorporate the safety net providers into the faculty of Michigan State University. The AHEC has extensive experience working with both safety net providers (providers that deliver a significant level of health care to uninsured, Medicaid, and other vulnerable patients) and provider

organizations. They will work with us to further develop the research results of the K01 into a larger project. As we move beyond the local "proving ground" for real world dissemination, we will continue to learn from interacting with health professionals and communities in national and international venues as described above.

Additional Responsibilities. During all five years of the grant, I will spend 75% of my time in career development and research activities. In each year, 25% of my time will be devoted to patient care and teaching. Patient care will consist of seeing patients for 4 hours per week at the in the MSU Internal Medicine out patient clinic, and supervising 4 residents during a weekly 4 hours resident clinic. Teaching by outpatient, case management will occur in this setting. These activities will allow me to remain current in the provision of primary care to patients, which will include preventive medicine to both diabetic and cardiac patients. I will serve as a managing attending physician for in-patients, 6 weeks per year, during the grant period. This is a reduction of 75% from the usual duties of attending in my Division. The inpatient services will provide me with a unique chance to understand how evidence- based medicine in the area of cardiovascular diseases and diabetes are implemented in the community.

Time distribution for work effort

	Year 1	Year 2	Year 3	Year 4	Year 5
Training	**35%**	**35%**	**35%**	**40%**	**45%**
1.Formal course work and independent study	**25%**	**15%**	**10%**	**5%**	**5%**
2.Mentored decision tools development	**10%**	**5%**	**5%**	--	--
3. Mentored shared decision-making/quality improvement	--	**10%**	**10%**	**10%**	--
4. Presentations and publications	--	**5%**	**10%**	**10%**	**20%**
5. Mentored RO1 grant writing	--	--	--	**15%**	**20%**
Research Aims	**40%**	**40%**	**40%**	**35%**	**30%**
6. Patient care and clinical teaching	**25%**	**25%**	**25%**	**25%**	**25%**
Total	**100%**	**100%**	**100%**	**100%**	**100%**

D. Training in the Responsible Conduct of Research

EPI 827- Nature and Practice of Scientific Integrity (3 Credits) at Michigan State University

I received instruction on the overview of the historical development of where and how science is practiced in the United States with an emphasis on its culture, sociology, and ethical standards. There was emphasis on the principles, standards, and practices, which define scientific integrity and commitment to the responsible conduct of research. This course was completed in spring of 2005. I have attached a list of topics that were covered in the class in the appendix section.

RESEARCH PLAN

A. SPECIFIC AIMS

Project Overview

African Americans (AA) and low social economic status (SES) populations have a high prevalence of coronary heart disease (CHD), as well as a high CHD-related mortality[13-16]. African Americans are less likely than whites to receive appropriate cardiac medications[17] and are likely to receive a lower quality of basic clinical services[18]. These differences in medical care have been shown to be associated with increased mortality among AA patients[14-16, 19, 20]. Over recent years, the reduction of these racial differences has been a central aim of health policy in the US. Surveys and audits have documented failures of practitioners to comply with well-established clinical guidelines for the care of patients with CHD[21, 22]. The goal of this project is to test and evaluate the design and implementation of decision support tools (DSTs), in primary care practices, with the aim of facilitating adherence to key quality indicators. Quality indicators (ACC/AHA guidelines) include the appropriate use of aspirin/antiplatelets, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, smoking cessation, cholesterol assessment, and lipid lowering therapy during routine office visits. The study will serve as a foundation for a subsequent, randomized control trial to evaluate the program's effect on patient -oriented health outcomes and quality of care in diverse primary care settings. Achievement of our goal will improve physician and patient communication and adherence to evidence- based recommendations in primary care. This will improve secondary prevention of heart disease and should decrease cardiovascular morbidity and

mortality for the target population (blacks and patients of low SES). The specific aims are:

AIM 1. Develop and pilot test a patient-centered intervention, Office-Guideline Applied to Practice (Office-GAP) to improve the implementation of evidence-based guidelines for secondary prevention of CHD for both African Americans and low socio-economic populations in an outpatient clinical setting. To accomplish this aim, we will

a) Develop Secondary Prevention of Myocardial Infarction Decision Support Tools that will contain guideline oriented standard orders for secondary prevention of CHD. The Hospital-based Guideline Applied to Practice (GAP) Tool kit will be adapted to primary care and will be called the Office-GAP Tools. Office-GAP DST will be incorporated into routine office visit for use by patients and physicians. The DST will provide Quality Improvement (QI) infrastructure to build a systems-based approach to helping physicians, nurses and patients remember to take advantage of the proven therapies that national guidelines recommend.

b) Develop and implement provider education modules that include interactive educational meetings to implement the evidence-based patient-centered method for communication and tool use.

c) Develop and implement a patient education module. This will include sharing recommendations with patients and requesting documentation from the patients themselves about barriers to following clinical recommendations.

AIM 2: Develop an Office-GAP follow-up program to reinforce secondary prevention goals

The follow up program will include a systems-based Office GAP follow up telephone call by the research assistant after the first visit and use of reminders to inform overdue appointments and reinforce compliance with set goals. It is anticipated that reminders will include postcards, e-mail, and telephone contact.

Hypothesis Follow-up program will reach > 70% of patients enrolled in Office -GAP project, using a research assistant dedicated to the project.

AIM 3: Evaluate the implementation of Office-GAP using a cluster-randomized design. This will include:

a) Pre and post evaluation of rate of use of aspirin/antiplatelets, beta-blockers, ACEI, cholesterol assessment and treatment and smoking counseling/status in both the intervention and control arms of the study.

b) DST utilization rate and acceptability of the intervention by the clinic and medical staff in the intervention arm of the study.

c) Patient perception of the physician participatory decision style before and after program implementation.

Hypothesis: Successful implementation of the program will: a) Increase the proportion of patients on aspirin/antiplatelets, beta-blockers, cholesterol lowering agents, and ACEI.

b) Increase the proportion of patients having cholesterol assessed, attaining LDL-cholesterol $\leq$ 100 mg/dl, and increase in rate of smoking counseling and reduction in proportion of patients smoking.

c) Lead to at least 75% of patients having documented evidence that the Office Gap Tools were used during the study window and DST will be acceptable to the clinic and medical staff.

d) Improve patient perception of physician participatory decision style.

B. BACKGROUND AND SIGNIFICANCE

B. 1.1. Racial Disparity in Coronary Heart Disease Mortality in the United States

Despite advances in diagnosis and treatment, CHD remains the leading cause of death in African Americans (AA) and whites in the US. More than 12 million patients are known to have CHD in the US alone. It accounts for 1 in 3 US deaths. The economic cost for the evaluation and care of patients with acute coronary syndrome is estimated to be $100 to $200 billion a year[23]. The 2010 Progress Review of Heart Disease and Stroke by the Acting Assistant Secretary of Health in April 2003 estimated the burden of heart disease and stroke to be more than $351 billion in 2003 and to grow in the decades immediately ahead. Among racial/ethnic groups, blacks showed the greatest disparity from the average in 2000, with a CHD death rate of 243 deaths per 100,000. The goal for the Healthy People 2010 is 166 per 100,000 for the entire population.

On average, CHD develops about 5 years earlier and has a higher associated mortality rate among blacks than among whites of the same age, at least through age 64 for men and age 74 for women[24, 25]. Although the age-adjusted CHD death rate in the US has been declining, the rapid rate of decline is less for African Americans than for whites[26]. From 1992 to 2000, age adjusted heart disease death rates remained 29% higher among AA. Myocardial infarction (MI) declined 28% among whites but only 19% among AA. Studies have also confirmed higher mortality and morbidity among persons of lower SES[27, 28]. Higher rates of several cardiovascular risk factors[26, 29, 30], compounded by delays in obtaining care[30], underutilization of acute perfusion therapies[26, 29, 31], lower usage of invasive cardiac interventions[18, 20, 29, 31, 32] and difficulties for black patients in accessing longitudinal care[25, 32-36] have all been previously documented. Racial factors

also affect health care utilization patterns, and there is considerable underutilization of preventive health services among black populations[37].

SES appears to influence cardiovascular disease prevalence by affecting health care utilization patterns, environmental stress, and health risk behaviors[38, 39]. Low income affects medical care choices and reduces the likelihood of utilization of preventive health care. Dietary habits associated with lower education levels and poverty increases CHD morbidity and mortality[40]. SES significantly affects outcomes in AMI patients. Low-income AMI patients had less favorable outcomes than the higher income patients, irrespective of the type of health insurance. The overall goal of this proposal is to deliver the right medical care to AAs and patients of lower SES with heart disease on a reliably basis in routine clinical practice. This should lead to a reduction in the gap that exists between AAs and whites in area of cardiovascular morbidity and mortality.

B. 1.2. Increasing Numbers of Patients are Surviving Acute Myocardial Infarction

Since the mid-1960's, short-term mortality (30 days) from AMI, has decreased from approximately 30% to 6.5%[41]. Modern therapy for AMI has led to an increasing number of patients surviving AMI, creating a growing group of high-risk individuals, often elderly, who need further treatment and care. The survival rate among the approximately 1million cases of AMI that occur annually is approximately 70% to 80% [42, 43] in the first year. *The rate of recurrent events in this population remains high.* Almost half a million patients with prior myocardial infarction have a recurrent infarction. A history of cardiovascular disease (CVD) increases the relative risk of subsequent premature cardiovascular morbidity and mortality by 5 to 7 times [44, 45]. Among survivors of a first MI, the rate of subsequent MI is increased 3 to 6 times, and

risk of any cardiovascular event may be as high as 80%[46]. Approximately 70% of CHD deaths and 50% of MIs occur in patients who have previously established coronary artery disease[47]. A major challenge in taking care of these patients is trying to prevent progression and recurrence of clinical events. During the past two decades, major improvements in survival of post myocardial infarction patients are related to medical therapy that attenuates the threats of recurrent ischemia and reinfarction. Much of the advantage is a matter of consistent use of available therapies.

B. 1. 3. Diabetes Mellitus is Associated with an Increased Risk of Cardiovascular Disease

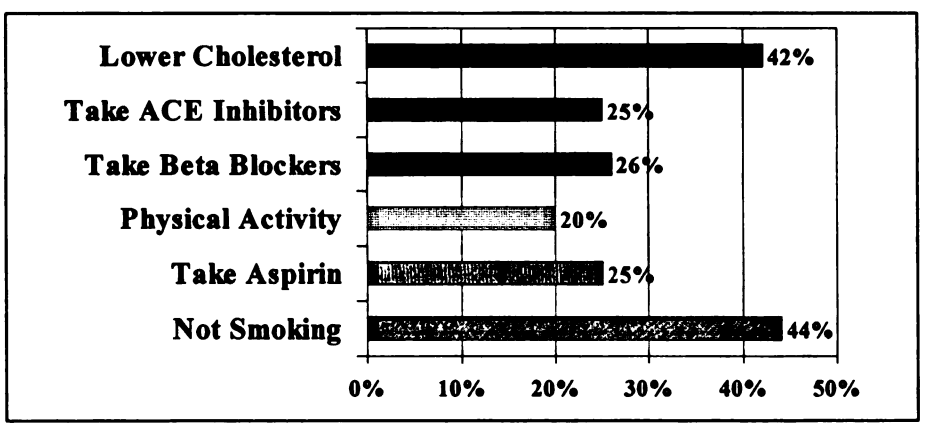
Type 2 diabetes mellitus is an independent risk factor for future cardiovascular events[48.50]. The risk of cardiovascular event is as high among patients with diabetes as among nondiabetic patients who have had a cardiovascular event[51, 52]. Cardiovascular risk factors such as hypertension, obesity, dyslipidemia, also tend to be more common in patients with diabetes. Accordingly, it may be advantageous to target risk reduction strategies in these patients. In a study by Haffner et al the seven-year incidence rates for myocardial infarction in nondiabetic subjects with and without prior MI at baseline were 18.8% and 3.5% respectively ($P < 0.001$) [48]. The seven-year incidence rates of MI in diabetic subjects with and without prior MI at baseline were 45% and 20.2%, respectively ($P < 0.001$). Recent clinical trials of lipid therapy and intensive blood pressure control have demonstrated significant reductions in cardiovascular outcomes among patients with diabetes[51-54]. Treatment guidelines recommend aggressive control of both dyslipidemia and hypertension in diabetic patients that is consistent with recommendations for patients

with known cardiovascular disease[55]. Therefore, diabetic patients will be included in the proposed project to decrease their risk for developing myocardial infarction.

B. 1.4. Effectiveness of Secondary Preventive Therapy

The efficacy of heart disease related medical and behavioral secondary prevention is well established. The evidence is summarized in several guidelines, including the Agency for Health Care Policy and Research (AHCPR) Cardiac Rehabilitation Guidelines[56-58], American College of Cardiology/American Heart Association Guidelines (ACC/AHA)[57, 59], and the NHLBI Consensus Statements on physical activity and cardiovascular health. The use of aspirin[60], cholesterol-lowering agents[61], beta-blockers[62], angiotensin-converting enzymes[63], physical activity[64], and smoking cessation[65] have all been shown to decrease the risk of recurrent ischemia and reinfarction following AMI, as shown in Figure 1.

Figure 1. Effectiveness expressed as Percent Risk Reduction of Recurrent Heart Attack through Secondary Prevention.



B. 1.5. Under-Utilization of Secondary Prevention in Heart Disease

Surveys and audits have documented failures of practitioners to comply with well-established guidelines for the clinical aspects of care of patients with hypertension[66],

diabetes[67], CHD[22, 68], frailty in the elderly[69], and other chronic conditions. National Study of Physician Awareness and Adherence to Cardiovascular Disease Prevention Guidelines in 2005 revealed that only 40% - 50% of primary care physicians and cardiologist incorporate guidelines into clinical practice[22]. Recent studies have shown that African American and less educated patients were less likely to receive cholesterol-lowering therapy after AMI; despite most having insurance that covers this therapy[70]. Similar differences have been demonstrated for other effective cardiac drugs. For example, studies that have analyzed large Medicare data sets have documented racial disparities in beta-blocker prescription post AMI at discharge[71, 72]. Hayward et al 2005 reported in their paper *"Sins of Omission"* that getting too little medical care may be the greatest threat to patient safety. They found that the overwhelming majority of substantive medical errors identifiable from the medical records were related to people getting too little medical care, especially for those with chronic medical conditions[73]. These findings underscore the ongoing need to monitor, improve and evaluate the use of effective therapies for appropriate patients.

B. 1.6. Interventions to Improve Chronic Illness Care

There are three overlapping initiatives in the effort to improve the management of chronic illness: the Report card initiative[74], Disease management[75], and "Chronic Care Model" [76]. The report card initiative provides report/feedback to institutions regarding their specific performance on clinical quality measures, addressing the management of specific diseases like AMI, diabetes or heart failure. Wagner defined disease management as a population based approach to health care that identifies patients at risk, intervenes with specific programs of care and measures outcomes[75, 76].

The third of the three initiatives proposes the Chronic Care Model (CCM)[77] to assist provider organizations in chronic care improvement. The CCM is like an evidence-based guideline because it represents a synthesis of system changes used to guide quality improvement. Its feasibility and acceptability in helping to improve quality of care in health care organizations has been reported[77]. However, disease management programs like CCM can be costly to develop, implement, and evaluate. According to the Disease Management Association of America, an estimated $1 billion was spent in 1999 to develop and implement disease management programs[78]. Despite the investment, evidence supporting their effectiveness is sparse[79]. In addition, commercial disease-management programs target only the "high-risk" patients, and do not address the inadequacy of care for the millions of other "low risk" Americans with chronic diseases.

The proposed project builds on components of the CCM and our previous research in patient decision support, to encourage implementation of secondary prevention strategies by patients and physicians *within the primary care system.* Our program, "Office Guideline Applied to Practice (Office-GAP)" will target all CHD patients and diabetic patients regardless of risk status. Should the program prove successful, it could serve as a prototype delivery vehicle for other evidence-based interventions during routine office visits. Unlike disease management programs that are offered mainly in staff-model HMOs or as a carved-out service by pharmaceutical-benefits management firms, this program would operate within the structure of most primary care offices.

B. 1.7. Decision Support Interventions

Decision Support Interventions (DSIs) grew out of expected utility theory[80] and shared decision –making (SDM) [81] approaches. Effective DSIs or "decision aids" are designed to promote clinical care that is consistent with scientific evidence and patient preferences. They 1) integrate evidence-based guidelines into daily clinical practice, 2) share evidence-based guidelines and information with patients to encourage their participation, 3) use proven provider education methods, 4) integrate specialist expertise and primary care[77]. The value of evidence-based guidelines or protocols, if integrated into practice and supported by effective provider training and behavioral change methods, is widely recognized[82-84], but generally not practiced[22]. The DSI approach assists patients making personal treatment choices consistent with evidence about consequences of medical alternatives and making use of their own values. DSI formats have included workbook/guidebook[85], video[86], computer[87], and interactive video formats. We will use a guidebook and video format in this intervention, the materials will be adaptable to audio and Internet formats.

B. 1.8. Improving Clinical Practice Using Clinical Decision Support Systems (CDSS)

A nation wide audit assessing 439 quality indicators found that US adults receive only about half of recommended care[88] and the US Institute of Medicine has estimated that up to 98,000 US residents die each year as the result of preventable medical errors[89]. To address these deficiencies in care, health care organizations are increasingly turning to CDSS, which provide clinicians with patient-specific assessments and recommendations to aid clinical decision-making[90, 91]. CDSS is defined as any system designed to aid

directly in clinical decision-making, in which characteristics of individual patients are used to generate patient-specific assessment or recommendations that are presented to clinicians for considerations[90]. Examples include manual or computer based systems that attach care reminders to the charts of patients needing specific preventive care services, and computerized physician ordering systems that provide patient –specific recommendations as part of the order entry process. Such systems have been shown to improve prescribing practices[92-94], reduce serious medication errors[95, 96], enhance the delivery of preventive care services[97, 98] and improve adherence to recommended care standards [90, 21, 99, 100]. These systems have been shown to be more effective and more likely to result in lasting improvements in clinical practice compared with other approaches[74, 79, 101-105]. CDSS do not always improve clinical practice. They improved clinical practice in 68% of 70 trials (77% in outpatient settings) reviewed by a study designed to identify features critical to success [91]. They identified four features as independent predictors of improved clinical practice: automatic provision of decision support as part of clinician work flow, provision of recommendation rather than just assessment, provision of decision support at the time and location of decision making and computer based decision support[91]. This proposed project will incorporate these features in the development and implementation of Office GAP for our target population. Where computer-based decision support is not possible, paper and pencil tools will be used. The Ingham County Health Department is planning to install a new electronic medical record into all the clinics.

B. 1.9. Optimizing the Provider-Patient Relationship

The need for change in how physicians interact with minority patients was so important that the Institute of Medicine (IOM) report on unequal treatment[106] suggested that economic incentives should be considered for practices that improve provider-patient communication and trust, and reward appropriate screening, preventive and evidence-based clinical care. The IOM further suggested that both patients and providers could benefit from education. Provider-patient relationships can influence patient satisfaction, adherence to treatment and health outcomes positively.

Existing models of physician-patient relationships reflect one of three approaches to clinical management; Paternalism, informative, or shared decision- making (SDM). The degree of patient participation in medical decisions varies widely across different models of the physician patient relationship. According to the paternalistic model, the physician knows best what is in the patient's interest; patient participation is limited. This model clearly does not take into account patients' autonomy and desire for information. In contrast, the informative model claims that the patient can make his/her own decisions while the physician role is restricted to providing him or her information. However, patients expect their doctors not to be only technical experts, but also caring persons. In SDM, both the physician and patient engage in an open discussion about the values the patient could and should pursue. The physician is allowed to present his or her preferences, and conflicting values are discussed explicitly. Thus, the patient is empowered to choose between alternative treatments. A recent study demonstrated that patients and physicians will use SDM instruments in their clinical encounter and they attributed multiple functions to the instrument (reference tool, organizes discussion,

develops concordance, customizes care, improves education, motivational tool), especially as a tool to facilitate agreement with treatment goals and plans[107].

This study will build on the work to optimize the provider patient relationship, through shared-decision-making conducted by Braddock[108], Elwyn[109], Towle and Godolphin[110]. The study will use the established Smith patient-centered physician interviewing method (described in section D. 4.3.) developed and tested and in current use in our Internal Medicine Residency Program at MSU[111]. Dr. Smith is a consultant for this application. The patient centered approach provides the appropriate first skills for shared decision-making. Our proposed study is sensitive to physician time constraints and need for physician autonomy. We will also emphasize the importance of flexibility in the way that providers structure the decision-making process so that individual differences in patient preferences can be respected.

B. 1.10. Patient Education and Empowerment

Increasingly, researchers are recognizing the important role of patients as active participants in clinical encounters[112]. With a few exceptions, the tested interventions do not include long-term support for patient self-management or efforts to engage the primary care team. A wealth of educational tools and resources such as materials online, in print, and on audio, and decision support videos that present information to help individuals understand complex medical issues will increase patient's confidence in making the changes to improve and maintain his or her health. Decision support videos may be more acceptable for people of low literacy that are unable to read. While evaluation data on decision support materials are limited, particularly with respect to racial and ethnic minority patients, preliminary evidence suggests that patient education

can improve patients' skills and knowledge of clinical encounters and improve their participation in care decisions. The IOM recommended implementation of patient education programs to increase patients' knowledge of how to best access care and participate in treatment decisions[106]. Thus, we propose the current study to integrate patient education and empowerment into routine clinical practice using a system approach.

B. 1.11. Reminder Systems

Patient safety is an increasingly important focus of quality improvement activities[113]. Most interventions to improve safety focus on preventing errors of commission (doing the wrong thing) [114] yet arguably more damage is done by errors of omission (not doing the right thing). For example, recent reports have shown under prescription of aspirin and beta-blockers following AMI [11], errors of omission that could cost more lives and cause more disability than errors resulting from negligent practice[114]. In caring for patients with chronic conditions, errors of omission might be reduced by physician adherence to simple rules or algorithms based on well-documented efficacy studies[115-118]. Failure to adhere to accepted guidelines and practice standards can be due to the complexity of the health care system, medical decisions[119, 120], difficulty in applying available clinical knowledge[121, 122], physicians' idiosyncrasies[123] and human errors[124]. In a recent meta-analysis of disease management programs for patient with chronic illnesses, Weingarten et al. found that programs using education, feedback, or reminders for healthcare providers produced significant improvements in provider adherence to care guidelines[79].

B. 1.12. Moving Research into Practice

It is crucial that research findings are implemented in outpatient clinics if high quality care is to be achieved. As described by Wagner et al. high quality medical care for chronic illness must accomplish three objectives[76]: 1) assure the delivery of those interventions that have been shown by rigorous evidence to be effective, 2) empower patients to take responsibility for the management of their condition, and 3) provide information, support, and resources to assist patients in self -management tasks. The proposed project will be designed to fulfill these goals.

B. 2. Significance

One of the goals of the President's Race and Health Disparities Initiative is to eliminate by year 2010 the differences in outcomes and health status for racial and ethnic minority populations in six clinical areas including cardiovascular disease. The proposed research will develop and evaluate the implementation of office based decision support tools designed to facilitate adherence to evidence-based treatment recommendations for AAs and low socio-economic status populations in primary care. The patient centered approach of the program aims to improve effective patient - physician collaboration, while the strengthening of physician-patient communication through the use of shared decision-making, should improve the use of secondary prevention among patients with heart diseases.

Should this project succeed, it may help to close the gap that exists between the rate of use of medications in-hospital and post discharge. Furthermore, improved secondary prevention of heart disease should decrease cardiovascular morbidity and mortality for AAs and low socio-economic status populations. It is expected that the

quality of life of these patients would improve and the cost of their health care decrease. Elements of the proposed system can be applied to the treatment of other chronic diseases. In addition, the program provides an opportunity to collect essential descriptive data about where problems occur in the system and the roles of patients and providers in creating and eliminating problems.

C. PRELIMINARY STUDIES:

C. 1 Overview

Our core research team has established working relationships and complementary expertise to undertake the project we propose. Our on-site primary research team consists of Dr. Ade Olomu, PI, Dr. Margaret Holmes-Rovner, a health service researcher with whom Dr Olomu has worked on a weekly basis for the past 5 years, Dr Mathew Reeves, an epidemiologist, and Dr David Todem, the statistician on Dr Olomu's pilot studies. The consultants include Dr Olomu's mentors and teachers in medicine and epidemiology: Dr Robert Smith, an expert in patient centered interviewing skills at MSU, Dr Kim Eagle, Professor of Internal Medicine and Cardiology at the University of Michigan and co-mentor on this application, and Dr Annette O' Connor, director of the Ottawa Patient Decision Support Laboratory, with whom Dr. Holmes-Rovner has collaborated for the past 20 years. The prior work of our team provides both the rationale and methodologies for the research proposed. The team has the appropriate depth and breath of research and clinical knowledge to undertake this project.

C. 2. Prior Work Done by Members of the Team Regarding Under-Use of Evidence-Based Medications in Secondary Prevention.

The proposal builds directly upon previous work conducted by our team, and it combines the interests of the team in health services research, development and testing of decision support systems, use of practice guidelines in cardiovascular care, risk assessment and outcome analysis as follows.

Preliminary study 1. *Under-Use of Aspirin following Acute Myocardial infarction in Community Hospital.* Funded by the Blue-Cross Blue-Shield of Michigan

Foundation and MSU Foundation. ***Dr. Olomu, Dr. Holmes-Rovner,*** The MSU Inter-Institutional Collaborative Heart (MICH) Study group determined the rate of use of Aspirin following Acute Myocardial Infarction (AMI) in five hospitals, in two Michigan communities (1994-1995). The MICH Study was a hospital study of management and outcomes following AMI. 1,163 patients were enrolled; 1,021 were ideal candidates for aspirin therapy. In the index hospitalization 80.4% received aspirin, and only 72.6% were discharged on aspirin. *Logistic regression showed that AA patients with previous AMI were less likely than white patients to be on daily aspirin, at the time of admission (OR 0.36%, 95% CI 0.15-0.86). AA patients were less likely to be discharged on aspirin (OR 0.48, 95% CI 0.03-0.077).* We found a significant underutilization of this potentially life-saving therapy in our community hospitals in patients following AMI. This was especially true for AA patients and underscores the need to improve awareness of the benefits of aspirin in AMI among practicing physicians and patients. The PI presented this finding at the National Meeting of the Society of General Internal Medicine (SGIM) in May 2002[6] at Atlanta Georgia.

Preliminary study 2. *Under-Use of Beta-blockers following Acute Myocardial infarction in Community Hospital,* ***Dr. Olomu, Dr. Holmes-Rovner.*** The MICH Study group studied Beta-blocker (BB) use in community hospitals in Michigan. Out of 1,163 AMI patients, we found 347 patients were ideal candidates for BB therapy. Of these, 81 had a previous AMI and only 26% of them were on BB at the time of admission. During their hospitalization, only 54% received a BB, and only 34% were discharged on BB. In conclusion, we found significant under-utilization of this relatively inexpensive but efficacious medication. This finding again, further highlighted the need to designs ways

of increasing the use of these medications following AMI. PI also presented this paper at the National Meeting of the Society of General Internal Meeting in May 2002[7].

Preliminary study 3: *Changes in rates of Beta-blocker Use in Community hospital patients with acute myocardial infarction.* ***Dr. Olomu, Dr. Margaret Holmes-Rovner.*** This study, aimed to determine change in beta-blocker use on admission, in hospital, and at discharge between 1994-1995 (MICH I) and 1997 (MICH II) in patients with acute myocardial infarction (AMI) in two prospectively enrolled cohorts from five mid-Michigan community hospitals, prescription of BBs to ideal patients with AMI increased in patients with previous history of myocardial infarction on arrival at the hospital, (12.5% vs. 36.0% p = 0.01), in-hospital (47.0 vs. 76%; p< 0 .01) and at discharge (34.0% vs. 61.9%; p<0.01). The increase BB use is most likely the result of regional and national quality improvement initiatives in these hospitals. Our results suggest that outpatients programs to insure continued use of BB post AMI are urgently needed. (**Olomu AB,** et al "Changes in Rates of Beta-blocker Use in Community Hospital Patients with Acute Myocardial Infarction"). J Gen Intern Med 2004; 19 (Issue 10): 999-1005). The findings from our preliminary studies 1-3 led to the current proposal.

C. 3. Decision Support Tools

Preliminary study 1. *Women's judgment of estrogen replacement therapy,* funded by the National Center for Nursing Research from 1986-1994. M. Rothert, PI. Co-investigator, M. Holmes-Rovner. This work sought to understand how women make judgments to take hormone therapy (HT) or not. It showed that people often find mortality and morbidity information difficult to use in reaching a decision. The experimental study[125-127] tested a formal program to teach decision-making skills. Three

groups were compared, 1) lecture/workshop, 2) lecture/only, and 3) an educational booklet control group. The unanticipated result was that all three groups were significantly more able to make a decision that they felt reflected both their own values and the research evidence after intervention than before. *The booklet designed as an information-only control was also a powerful intervention, in fact, the most efficient route to teaching patients the outcomes data and how to structure the decision process*[128, 129]. The knowledge gained from this study will be used to guide the design of our decision support tools.

Preliminary study 2. *Greater Flint Shared Decision Project*, funded by the Blue Cross Blue Shield of Michigan Foundation, 04/1/97 to 8/31/99. M. Holmes-Rovner, PI. This study evaluated decision supports (in-depth interactive videodisks) developed by the Foundation for Informed Medical Decision Making (FIMDM). This project attempted to implement them in office practices and was only marginally effective[130]. We learned that use of decision aids alone, outside the office visit is insufficient. For that reason, we will develop a tool kit that can be integrated into routine office practice, and can be supported by follow-up and reminders.

Preliminary study 3. *The Shared Decision-making Forum 2000: Oxford,* funded by the Nuffield Trust, 1/1/2000-8/1/2000. PI. A Coulter, Co-investigator, Dr. Holmes-Rovner. This grant brought together the Oxford, Cardiff, MSU, Ottawa, and Dartmouth decision aid development groups in a six-month "think tank" in Oxford to further develop the field of shared decision-making and decision aids. The group extended their collaboration, contributed to the book, Evidence-Based Patient Choice[131] and proposed future direction for the field[132]. This work established collaborative relationships with

primary care faculty in the UK that led to an international standards-setting process (results forthcoming in BMJ). Those standards and the consultation with Dr. O'Connor at the University of Ottawa will guide toolkit development. Dr. O'Connor is the PI of the Cochrane Collaboration decision aid review. She has developed extensive training programs in shared decision-making. She will provide access to all decision aids being evaluated in the Cochrane Collaboration[128, 133, 134].

Preliminary study 4. *Developing Patient Decision Support Materials for Prostate Cancer Treatment,* funded by the Centers for Disease Control and Prevention, 4/1/02-4/30/03. Holmes-Rovner, PI. This project developed new decision support materials for men with prostate cancer. The Prostate Cancer Action Committee of the Michigan Cancer Consortium developed new decision support tools[132] that use plain language and apply principles of effective communication with limited literacy audiences in the design of a new decision support prototype booklet. The prototype attempts to optimize inclusion of quantitative treatment evidence and patient-centered personal and social contextual issues. Formative evaluation studies are in progress. The booklet and an Internet version and an audio tape/CD version can be found at www.prostatecancerdecision.org. Our proposed Office-GAP guidebook will be designed in a similar manner to meet the need of low literacy populations.

Preliminary study 5. *Shared Decisions to Manage Diabetes,* funded by the Blue Cross Blue Shield of Michigan Foundation, 02/01/2004 to 01/31/2005. B. Corser, PI. M. Holmes-Rovner, Co-Investigator. This pilot study, Shared Decisions to Manage Diabetes (SDM-D), teaches patients to use a decision support booklet, and teaches resident doctors to engage patients in shared decision-making within the clinical encounter. While the

diabetes study did not develop the full toolkit for quality improvement, it provides experience in implementing a shared decision-making program in primary care and will guide the development of our training program for providers. Dr. Olomu supervised residents in the project as the Residents' Clinic Attending.

C. 4. Quality Improvement in Cardiovascular Disease

Dr. Kim A. Eagle, a Co-mentor, has worked extensively in various studies, improving the Quality of Care for AMI. Dr. Eagle has been the principal investigator of the American College of Cardiology's Guidelines Applied into Practice (GAP) project in Michigan studying the application of guidelines to care processes for patients with ACS in 33 Michigan hospitals. This work has shown that by embedding key priorities of guideline-based care into care itself, that both process indicators and outcomes can be improved. Most recently, Dr. Eagle presented the overall experience of the GAP initiative for acute MI care in Medicare beneficiaries in Michigan showing that guideline based care resulted in 21% to 26% reduction in both 30 day and one year mortality in patients being admitted to Michigan hospitals[135]. He will provide his wealth of experience in the development and implementation of the proposed project. The proposed project combines the hospital GAP principles with our experience in outpatient decision support to produce the *new Office GAP intervention.*

Preliminary study 1. Improving Quality of Care for Acute Myocardial Infarction-In hospital: The Guideline Applied in Practice (GAP) Initiative[21, 136-138]. PI Kim A. Eagle. The Gap project tested the implementation of a structured initiative to improve care of patients with AMI in 10 acute-care hospitals in southeast Michigan. The project developed a multifaceted intervention aimed at key players in the care delivery

triangle: the physician, nurse, and patients. **Results:** Increases in adherence to key treatments were seen in the administration of aspirin (81% vs. 87%; P = .02) and BB (65% vs. 74%; P = .04) on admission and use of aspirin (84% vs. 92%; P = .002) and smoking cessation counseling (53% vs. 65%; P = .02) at discharge. Evidence of tool use during chart review was associated with a very high level of adherence to most quality indicators[136, 100]. This initial in-hospital GAP project provides a foundation for this proposal, which aim to reinforce and continue quality improvement issues on out patient basis.

Preliminary study 2. Translating Research Into Practice: *Patient Decision support and Coaching Project.*

RO1 HS10531-01 A1 from AHRQ Jan 2001 – 6/31/04. PI Dr. Margaret Holmes-Rovner. Co-investigator, ***Dr. Olomu***. This study was a patient-level randomized trial to compare the effectiveness of the combination of decision support and the hospital GAP quality improvement intervention with GAP alone to improve medication use, patient health status and physical activity in the 8 months following acute coronary syndrome (ACS)[139, 140]. The study was done at 5 hospitals in two Mid-Michigan communities. The intervention, Heart After Hospital Recovery Program (HARP), was a brief nurse-managed telephone intervention. It engaged the patient and HARP nurse in reviewing evidence about medical and behavioral secondary prevention strategies and developing a plan for the patients' recovery. The nurse counselor, made follow up telephone calls at 1, 2, 4 weeks to help solve problems and reinforce decisions made using a decision support tool, the HARP booklet. The PI, Dr. Ade Olomu presented three abstracts from this project at the National SGIM meeting in New Orleans May 2005 (detailed in the

biographical sketch). Our study on "*The effect of evidence-based cardiac medication use on hospital readmission for post coronary syndrome patients*" **Yang** et al, 2005[11] revealed that in addition to the prescription of effective discharge medications timely and appropriate medication changes in outpatient settings appears to improve health outcomes in acute coronary syndrome patients. In April 2006 **Dr. Olomu** presented *"Quality Improvement Efforts And Hospital Performance: Rates of Beta-Blocker Prescription for Acute Coronary Syndrome*" at the National meeting of SGIM in Los-Angeles[12].

C. 5. Approach to Modules and Tools

The patient and physician modules to be adapted for this project are drawn directly from previous work by our collaborators and us. Office-GAP will adapt the hospital GAP tools to the outpatient setting. In the present project, we will work with providers in the Community Health Center setting to develop standard orders, and a patient contract, and involve a physician champion and a nurse champion in implementation in ways that fit their level of electronic data collection and organization. The decision support tools will be adapted from an existing video for secondary prevention of CHD developed by our colleagues at the Foundation for Informed Medical Decision Making (FIMDM). FIMDM was founded by Dr. Jack Wennberg, Director of the Center for Evaluative Clinical Sciences at Dartmouth Medical School and Dr. Albert Mulley, professor of Medicine and Health Policy at Harvard Univ. and Scientific Director of FIMDM. Working independently and collaboratively with others, including our consultant, Dr. Annette O'Connor, we have developed a consistent approach to content and approach to decision aids that has resulted in international standards[141]. We will use an updated version of the FIMDM video that is included in the review packet as part of

our patient educational module. The video itself is presently being updated (see support letter from Dr. Levin). Dr. Holmes-Rovner will supervise Dr. Olomu in the adaptation of the accompanying booklet to plain language to address the needs of patients with limited literacy. We will incorporate the Office-GAP contract and follow up telephone call by a research assistant in a package that can be systematically used in primary care clinical settings.

C. 6. Summary. We have built this project on our team's prior research in shared decision-making, goal setting, disease management, and application of guidelines into care processes for patients with acute MI. Since patient empowerment rarely occurs spontaneously, we propose to use decision aids to assist patients to understand evidence-based guidelines and adhere to it, directly address the pros and cons of treatment, address their values and negotiate a plan for management of their heart disease.

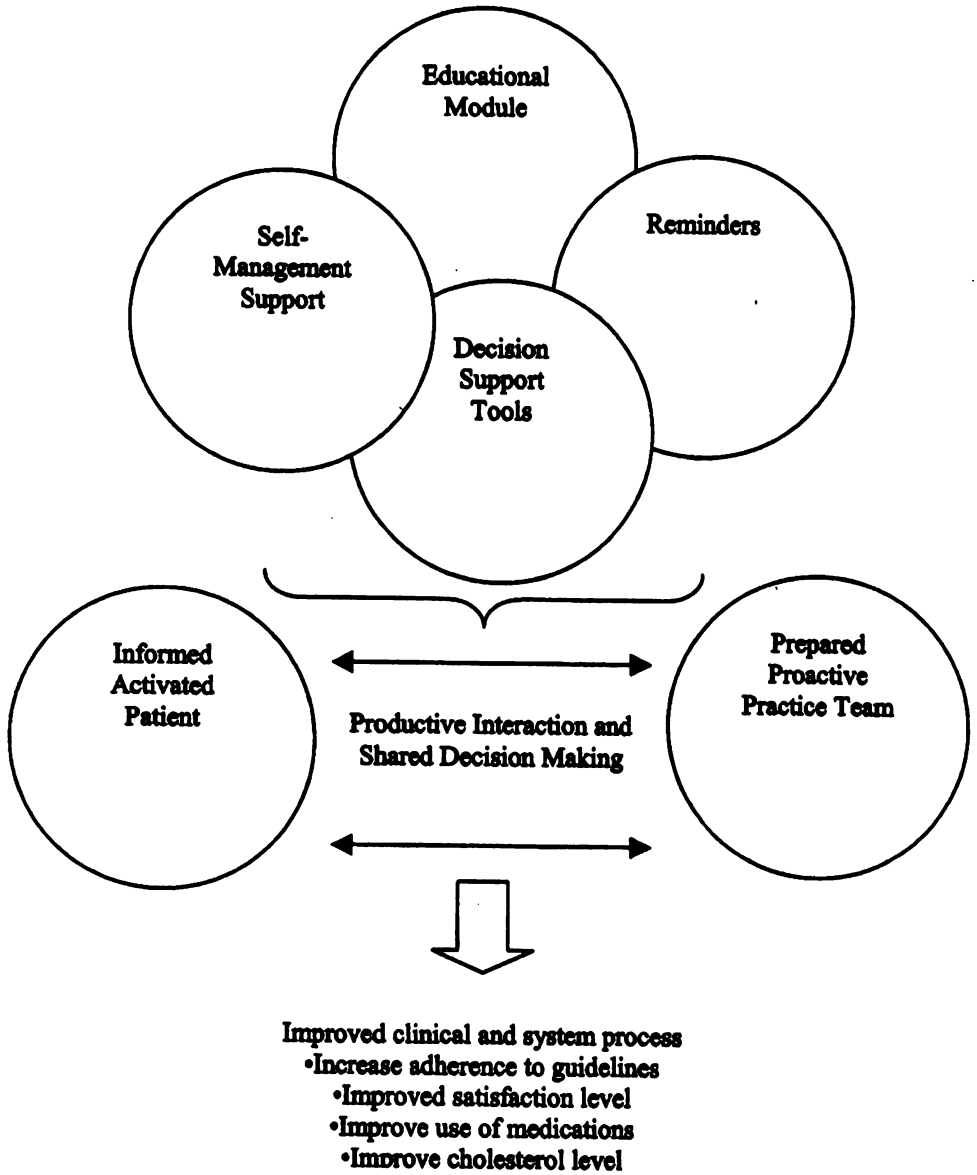
D. RESEARCH DESIGN AND METHODS

D. 1. Overview

This study will develop and evaluate the design and implementation of decision support tools for secondary prevention of coronary heart disease in outpatient settings for AA patients and low socio-economic status populations using a small cluster randomized trial. The study will lay the foundation for a full-scale randomized control trial to evaluate the program's effect on patient health outcomes and quality of care in diverse 20 primary care settings. The emphasis of this study design is on establishing the feasibility of embedding evidence-based knowledge into the process of care, teaching patients and healthcare providers how to use decision support tools that will remind caregivers to consider evidence-based therapies in every patient. Development and evaluation will be done collaboratively with patients and providers using both qualitative and quantitative approaches to developing decision support interventions.

D. 2. Conceptual Model

Figure 2. Conceptual Model to Facilitate Adherence to Guidelines Within Primary Care



Our conceptual model in figure 2 provides the context for this project. It builds on components of the Chronic Care Model[76] that includes decision support tools (DSTs), educational modules, self management support, and reminders and our previous research in patient decision support and shared decision-making[130, 132, 142, 143], to produce productive interactions between the informed activated patient and prepared proactive practice team *within primary care settings.* We anticipate that DSTs, will promote clinical care that is consistent with scientific evidence and patient preferences. It will embed evidence-based guidelines into daily clinical practice. Self-management will empower and prepare patients to manage their health and health care. Self-management support strategies include assessment, goal setting, and action planning, problem solving and follow up. Provider/patient educational modules will assist in producing an activated patient and a prepared provider. Reminders should help to reinforce the system. The productive interactions, will likely lead to better adherence to guidelines, achieve better disease control, and higher patient satisfaction.

D. 3. Study Sites

The study will be conducted at Ingham County Healthcare Centers. Ingham County is located in the south central portion of Michigan's Lower Peninsula and includes the capital city of Lansing. The Ingham County Health Department Adult clinics are currently comprised of three facilities, the Health Center at Sparrow Hospital, the Adult Health Center at South Cedar, and the Ingham County Health Center at St Lawrence Hospital. The three healthcare Centers are all within 15-20 minutes drive from each other. The Centers have one overall medical director and a nursing administrator. The medical records and data systems are the same, which will ease the conduct of the

research project. The Healthcare centers deliver primary health care and diagnostic/screening services to citizens in mid-Michigan. These services include general primary medical care, as well as preventive services targeted at specific patient groups with Cancer, Diabetes, Cardiovascular Disease, HIV/AIDS, and Mental Health conditions. During 2003, a total of 3,025 clients (47.9% Male, 31% over 40 years of age) received care at these three facilities, with 91.6% of these clients at or below federal poverty levels, 56% were non-white, and 70% were uninsured or covered by Medicaid. A total of 8,442 general medical service encounters were recorded during 2003. In 2003, 1,595 patients with either cardiovascular disease or diabetes received care at these centers. We will recruit 182 patients from this population into the study. Our targeted patient population table shows the estimate of the ethnic distribution of the patient population (Table 2, page 80). The professional health care staffs at the clinics currently include family practice physicians, internal medicine physicians, nurse practitioners and nurses.

D. 3.1. Eligibility criteria

The eligibility criteria in our study are designed to recruit as large a number of patients as possible who will benefit from secondary prevention for CHD. Eligibility criteria include AA, and low-income populations aged 18 or older, seeking care at any of the three health centers. With at least 1 of the following:

1) Inpatient, outpatient or emergency department diagnosis of coronary artery disease, angina, or myocardial infarction at any time in the past. The diagnosis must be documented in the patients' chart.

2) Definitive diagnostic test (e.g., cardiac catheterization, an echocardiogram or scintigram showing segmental abnormalities in the left ventricular wall, an electrocardiogram demonstrating significant Q-waves, or results of cardiac enzymes studies) indicating acute myocardial injury at any time.
3) Diabetes mellitus, type 1 or type 2

In addition, patients must be able to speak English and able to provide informed consent. Low SES will be based on patient's income, number of people in the household and insurance status. SES data will be obtained through self-report and from chart abstraction. Many of the patients that attend the Ingham County clinics have neither job nor insurance.

Exclusion Criteria include cognitive impairment, dementia, psychosis, and inability to understand spoken English. The race/ethnicity of each patient will be determined by self-report. The study team is experienced in recruiting participants for decision-making and qualitative research in clinical and community settings. We do not anticipate much difficulty recruiting our sample. We will compensate participants with $35 for their time during their 6 months visit to the clinic.

D. 3.2. Recruitment strategy

Two Ingham Health Centers will be randomized to receive intervention and a third will be used as control site (as described in section D. 6.1). The research plan proposes to enroll 182 patients diagnosed with CAD or Diabetes Mellitus from the 3 health center (91 from the 2 intervention sites and 91 from the control site). Patient recruitment will proceed as follows: Eligible patients will be identified from the clinic registry using ICD 9 codes for CAD and Diabetes Mellitus (e.g. ICD 9; 410- 414 for

CHD and ICD 250 for diabetics). The ICD 9 codes are used for coding patient medical diagnosis and also used for billing purposes after the office visits. The clinic nurse will screen each chart to ensure eligibility of the patient. A letter will then be sent to the eligible patients from their primary care physician to invite them to participate in the study. Those who are interested will be given a self –addressed envelope to return to the clinic indicating their interest in the study. Interested patients will also be given the opportunity to indicate their interest in the study by calling the clinics. Those who are not interested will be asked to return a stamped self-addressed card. Those that did not return the card will be contacted by telephone and offered opportunity to participate. Clinic nurse will log all responses positive and negative. The PI and/or research assistant will obtain informed consent from all patients that agree to participate during their first office visit with the physician after the invite or just before the focus group or patient educational session. We will enroll 91 consecutive eligible patients that agree to participate into the interventional arm of the study from the 2 interventional health centers, and 91 consecutive patients will be enrolled into the control arm of the study from the control health care center. After patients' recruitment PI and trained Research Assistant will give initial training and further explanation of the study.

D. 3.3. Orienting Physician Practices

All health professionals i.e., internal medicine/family practice physicians, nurse practitioners, nurses, social workers, public health nurses and other health care workers at Ingham County health centers will be recruited into the study. Members of staff work only at one location, they do not move from site to site. All the providers at the healthcare centers randomized into the interventional arm of the study will be expected to participate

in at least one of the physician/healthcare worker orientation/interactive educational meetings that will be provided. Interactive educational meetings are one of the consistently effective interventions shown to promote behavioral change among health professionals[103].

The PI and the project team will prepare the physicians and their office staff to implement the program into their daily practice pattern during the developmental phase. We have had a series of discussions and meetings regarding this project with Director and staff of Ingham county health centers and they have pledged their support for this project.

D. 3.4. Methods for Aim 1. Develop and pilot test a patient-centered intervention, Office-Guideline Applied to Practice (Office-GAP) to improve the implementation of evidence-based guidelines for secondary prevention of CHD for African Americans and low socio-economic populations in an outpatient clinical setting.

To accomplish our objectives, it will be crucial to understand the factors relevant for collaborative care based on the needs of patients and their providers. We will conduct patient focus groups. The focus groups are expected to yield enhanced insights into patients' decision-making, their needs, what motivate them and what the barriers are, that will assist in the modification of DSTs. The type of information that patients need in their guidebook will also be determined.

The intent is to use findings from patient focus groups and physician educational interactive meeting to modify the DSTs development and implementation.

The *rationale* for use of the patient focus groups is that any successful intervention must be relevant to both the providers of such intervention and the recipients. Consequently, to

foster collaboration among patients, their providers, and the health care system, understanding the perspectives of all groups is mandatory.

D. 4. Programs to achieve Aim 1. Table 1.

Table 1. PROGRAMS TO ACHIEVE AIMS 1-3

PROGRAMS TO ACHIEVE AIM 1

- **Patient focus group**
- **Development of decision support tolls**
  - **Office –GAP contract**
  - **FIMDM Video**
  - **Patient Office – GAP Guidebook**

PROGRAMS TO ACHIEVE AIM 2

Reminders

- **Nurse phone calls**
- **Postcard mail/letter**
- **Email reminder**

PROGRAMS TO ACHIEVE AIM 3

- **Pre and post evaluation of rate and use of evidence-based medications, in both the study and control group**
- **LDL cholesterol and smoking counseling/status**
- **Office-GAP Tool Utilization**
- **Assessment of Patient perception of Physician Participatory Decision Style**
- **Evaluation of the program effect on other aspects of patients' care and acceptability of intervention**

D. 4.1. Program 1a. Focus Groups

Focus groups are qualitative research methods that provide an in-depth understanding of social and behavioral attitudes of individuals[144]. They are a cost-effective and successful way to obtain in-depth information about a homogenous group, and to develop interventions to reduce the risk of chronic diseases[145].

There will be 4-patient focus groups comprised of 8 participants in each group. There will be 2 all black focus groups and 2 all white focus groups matched with

facilitators of the same race to maximize candor and trust. Moderator or facilitators will be chosen based on three criteria, including familiarity with the subject matter, expertise in leading focus groups and acquaintances with the group dynamics. The focus group participants will be recruited from the group of patients from the intervention arm of the study that meet our eligibility criteria and agreed to participate. The themes to be explored in the patient focus groups are beliefs and attitudes about heart disease self-management, barriers to receiving culturally sensitive care, perceptions about medication use, facilitators/barriers to medication use, health care providers and the health care system, beliefs about patient autonomy and shared decision-making. Participants' will be shown the DSTs and asked for example: ***"How might the DSTs help or hinder your discussions with your physicians?*** and ***"What changes would you make?" "What were your first impressions of the patient Guidebook mailed to you? "What is the book trying to say?" "How will you describe Office- GAP guidebook to your family?"***

Standardized probes to encourage elaboration and discussion of the participant initial responses will be used[146]. Each focus group will last for about an hour. Focus group interactions will be recorded and transcribed for detailed review and analysis. The PI will observe all focus groups and take notes. Participants in the focus group will not be excluded from the study because they are part of the interventional arm of the study.

4. 2. Program 1b. Development of Decision Support Tools

4. 2.1. Office-Guideline Applied to Practice - Contract (Office-GAP Contract)

The Guideline Applied to Practice (GAP) hospital discharge contract for patients following AMI will be adapted for the design of the Office-GAP Contract. The discharged contract improved the quality of care for patients post AMI in hospital and

significantly increased the rate of use of secondary preventive agents[21, 135, 136]. The Office-GAP Contract will contain guideline oriented standard orders. It will be designed to aid patients and physicians in considering the use of all the evidenced based medications for secondary prevention. The patient will be asked to check whether they are taking each medication currently and if not they will be required to document the reasons why they are not on it. Similarly the practice of healthy life style (e.g. exercise, health diet) will be documented (a copy of the Office-GAP contract is included in the appendix). Both the patient and the physician/nurse will sign the Office-GAP Contract form. It will provide decision support at the time and location of decision-making for both patients and physicians/nurses and serve as a reminder. Office-GAP-Contract form will be attached to the front of patient's chart and reviewed with patients by the physician/nurse during the patient's office visits. Its use will be documented in the patient chart. Finally, the patient will be given a copy to take home.

4. 2.2. Office-Guideline Applied to Practice – Video and Guidebook (Office-GAP - GB)

The updated version of the FIMDM video for secondary prevention of CHD developed by our colleagues "Living With Coronary Artery Disease-Doing Your Part." will be used as part of our patient educational module. The video will prepare patients to make informed values-based decisions with their provider. The 37 minutes video discuses in plain language what CAD is, how to manage CAD, how medications helps, common side effects of the medications, managing cholesterol and Blood pressure, quitting smoking, managing exercise and stress and how much benefit the patients gets from participating in each of these preventive measures. The video will particularly be helpful

for patients of low literacy who cannot read. Dr. Holmes-Rovner will supervise Dr. Olomu in the adaptation of the accompanying booklet to plain language to address the needs of patients with limited literacy. (See Appendix G for accompanying booklet). In addition, a *Tracking sheet (TS)* will be developed as part of the Office-GAP-GB. The specific components include; a) patient-provider management goals for their BP, LDL, and evidence-based medication use (ASA, Beta-blocker, lipid lowering agents, ACEI) smoking cessation, and physical activity and b) a reminder document for each subsequent office visit. The Office-GAP Video/CD and -GB will be mailed to the patient at home for review before their attendance at the focus group or the patient educational session. Patient who cannot watch the video at home will have the opportunity of watching the video during the educational section.

D. 4.3. Procedures to Achieve Aim 1b

Provider educational module

A four–hour orientation for CME credit will be conducted for providers in the interventional arm. This will be done in three sessions to meet the schedule needs of the providers. This is not traditional CME, but is CME in the context of community physicians participating in a research study. Our team used this technique, in both the MICH and HARP studies. The activities to be provided by Dr. Olomu, Dr. Holmes-Rovner and a local cardiologist, Dr. Prieto will include: 1) Limited didactic presentations on evidence for the effectiveness and cost-effectiveness of medical therapy and behavioral changes in the management of heart disease. The ACC and AHRQ and other guidelines will be reviewed as well as other recent data on secondary prevention. 2) Limited didactic teaching concerning the theories, concepts and design of the program.

Participants will be shown the DSTs and there will be discussions regarding the best way to implement their use in their practice. Smith evidence-based[111] patient-centered method for communication and establishing the provider-patient relationship[147, 148] to optimize providers' ability to integrate patient-centered method with goal setting and screening - oriented protocol with patients during office visit will also be discussed. We are fortunate to have Dr. Smith, who described this published method in our institution as a consultant on this project. He has agreed to teach this approach during the educational session with the providers.

The Smith approach supplies the patient-centered foundation for this project. In addition, shared decision-making skills by Braddock[108], and Elwyn[109] will be included. The draft sequence of skills we will teach is:

1. *Setting the stage* for the clinical encounter by welcoming the patient, using the patient's name, assessing the patient's readiness to be interviewed and ensuring privacy, and remove any communication barriers to put the patient at ease.
2. *Assessing the patient's agenda* by setting time limit, obtaining information about what the patient would like to discuss, and negotiating their chief complaint.
3. *Non-focused and focused open-ended interviewing* to obtain the history of present illness through open-ended questions and skills focused open-ended questions, closed ended questions and obtaining information through non-verbal cues.
4. *Transition to goal setting,* including checking progress in the guidebook on past goals, trouble shooting barriers, exploring ideas, fears and expectations of possible options, portrayals of physician equipoise, checking how patient is taking their

medications, exercise activities, diet, smoking cessation is being done. New goals can be negotiated.

5. *Reminders* about laboratory test and any referrals.

The nurse/nursing assistant responsible for taking the patient vital signs and getting the patient ready for the physician/practitioner will be responsible for going over the guidebook/ tracking sheet with the patient and making a stick-on note for the physician/practitioner regarding areas of care that need to be discussed with patient, medications that need to be prescribed or cholesterol that need to be checked. This will help the physician/practitioner to use limited time more efficiently with the patient. Providers will complete a pre- intervention survey at the onset of the meeting to determine their perceptions regarding the use of DSTs in their clinical practice.

D. 4.4. Procedures to Achieve Aim 1c.

Patient / Support Person Training Program

We will offer a series of training sections during the day for small groups of patients (n-8) from the interventional arm of the study that meet our eligibility criteria and agree to participate through out the recruitment period. The training program will consist of 1) showing the FIMDM video 2) teaching patients how to set their heart disease management goals using the Office-GAP- guidebook, 3) training in shared decision-making and how to use the Office-GAP-Contract and 4) the role of the doctor and patient in shared decision-making. Patients will have opportunity to ask questions. This small group meeting can be adapted for a group office visit with physician. Physicians can bill for this form of group visit. This will encourage physicians' continued practice of the process. At the end of the patient educational module, all participants will

complete a self-administered written survey asking patients to rate all aspects of the DSTs, their perceived barriers to self management and the best time they will like to be contacted after their visit with their provider. The PI and the Research Assistant will assist patients in completing the questionnaires if help is needed. The training session will be scheduled for one and half hours. Patients in the control site will not be involved in the focus group or any of patient training programs. Neither the video nor the Office-GAP book will be mailed to the patients. However, the American Heart Association (AHA) handouts for patients with CAD or the American Diabetes Association handouts for healthy life style will be mailed to patients with CAD and diabetics respectively.

D. 4.5. Expected results

At the completion of the objectives for aim 1, adequate information on the components that the patients and providers expect in the collaborative care of patients with CHD in AAs and patients of low SES will become available. In addition, DSTs will be developed. Both providers and patients will become familiar with the use of the DSTs and its application using the principle of SDM to negotiate life style/behavior change goal. The results of this section will not only foster provider-patient collaboration; it will emphasize the need to include the ultimate recipients of care (patients), in the decision-making process and system design for the outpatient care of patient with CHD.

D. 5. AIM 2: Develop an Office-GAP Follow-Up Program to Reinforce Secondary Prevention Goals

A research assistant/nurse will provide reinforcement through a brief (10-15min) structured," Nurse Initiated telephone contact" within a week of the first doctor's visit. She will obtain information on the following a) how the visit went, b) if goal setting

occurred, c) if the patient has any questions regarding the medications, d) if needed laboratory tests were done, e) if he/she has any questions about any aspect of the visit, f) if the next doctor visit has been scheduled and date recorded in the guidebook, g) if more reminders are necessary and how often? Patients will be informed of their follow up appointment.

The research assistant will document each encounter with the patient and detail the issues discussed and problems solved. The research assistant will report to the PI any problems that she could not solve over the phone. PI will follow up on all unresolved issues. The PI will review all documented encounters with patients on a weekly basis for purposes of program improvement, as well as reinforcement. The phone calls will provide individualized information, support and problem solving around barriers based on the patients' ongoing report of goals and problem areas. Other reminders will include the use of post card mail/letter as some patients may not have access to a phone and /or E-mail reminder, for some patients that may prefer to be contacted through the Internet. Study patients who fail to keep their appointments will be contacted by phone or sent letters. In general when the research assistant/nurse experiences an unforeseen situation that is new she will contact the PI who will be "on call" for such occurrences. Standard responses will be developed at weekly meetings and incorporated into the developing Office-GAP manual.

Chart stickers: We will design a sticky note to flag the patients' charts. This will be placed in front of each patient's chart. The goal is to remind providers and office staff of patient's participation in the project, to use the DSTs, to sign the Office-GAP Contract and to review the patient-tracking sheet.

D. 6. AIM 3: Evaluate the Implementation of the Office-GAP Using a Cluster-Randomized Design

Office-GAP will be implemented at the 3 Adult Health Centers at Ingham County described above. Evaluation will include:

a) Pre and post evaluation of rates of use of evidence-based medications (aspirin, beta-blocker, ACEI, cholesterol assessment and treatment and smoking counseling/smoking status in both the intervention arms and the control group. Cholesterol and smoking has high impact on mortality.

b) DST utilization rate and acceptability of the intervention by the clinic and medical staff.

c) Patient perception of the physician participatory decision style in the interventional centers.

d) Determine the impact of the program on other aspects of patient care.

Patient charts will be reviewed for relevant data and evidence of DST use during chart abstraction. We will look for the presence of Office-GAP contracts in the charts. Documentation that patient came into the clinic with his/her Office-GB and tracking sheet. Details are described in section D.8 under data collection. Throughout the study the PI and the research assistant will take notes and document barriers to use of DSTs and the impact on patient flow. Providers' views regarding the effects of the DST and intervention will be determined through the use of a survey that will be administered pre and post the intervention. To determine the beneficial or detrimental effects that this focus on patients' cardiovascular care could have on other aspects of patient care; pre and post intervention rates of colonoscopy, flu vaccine, pneumovax, and stool occult blood

test in both the interventional and control arms will be determine through chart abstraction data. We expect that the program implementation will make communication more efficient and lead to enhance care in other areas.

D. 6.1. Study Design

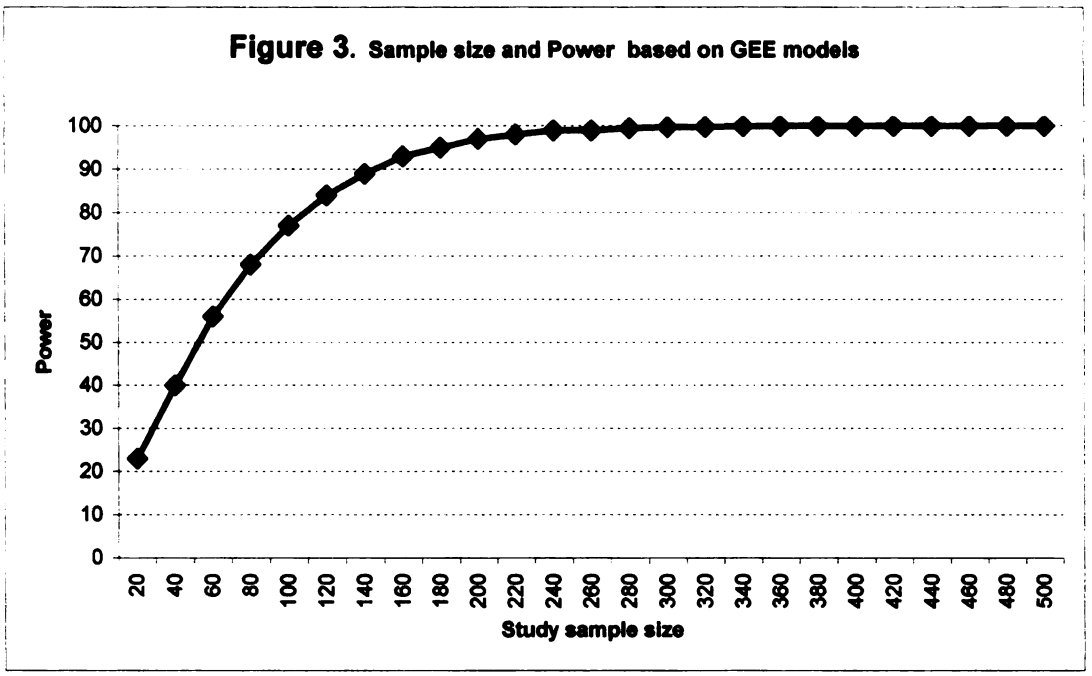
The study to be conducted during the KO1 training will be a pilot study; a two-arm cluster randomized interventional trial will be designed to test the feasibility of implementing the program (Aim 3) at three health care centers in Ingham County, Michigan. Based on the results of this pilot study, the PI anticipates submitting an RO1 proposal for a full scale randomized controlled trial to evaluate the program's effect on patient health outcomes and quality of care in twenty health care centers providing primary care to underserved populations in Michigan.

We considered 3 possible options for the randomization of patients into the study: patient level, physician level or center level. Randomization at the patient level would result in the possibility of a physician managing both the intervention patient and the control patient at the same time resulting in significant contamination and bias. Randomization at the physician level would also lead to a degree of contamination since both the interventional physicians and the control physicians would be at the same center and their patients would cross over and be seen by other physicians. Randomization at the center level means that all the physicians and patients at one center will either be in the interventional arm or control arm of the study. This will minimize the risk of contamination and greatly improve the feasibility of delivering the intervention. Two centers will be in the interventional arm of the study and the third one in the control arm. By incremental accrual patients with CVD or Diabetes Mellitus will be enrolled into the

study at both the interventional and control centers. The providers at the intervention centers will participate in the provider educational module as described above. The patients at the intervention center will be invited to participate in the patient educational module that includes the use of DSTs, education, use of contracts and reminders similarly described above. The physicians and their patients in the control center of the study will continue with their usual care but patients be mailed the AHA handouts on living a healthy lifestyle. The usual care at all three centers currently does not include the use of educational modules for either providers or patients or the use of DST. All patients will be followed for 6 months. Patients will be expected to visit their primary care physician at baseline, 3 months and at 6 months.

The following 6 primary outcome measures: aspirin, beta-blockers, ACEI, assessment of cholesterol or lipid panel, use of lipid lowering agents, and smoking counseling/status will be determined at baseline (before any intervention), and after six months for patients at both the interventional centers and control center from chart review The same information will be obtained over the telephone at 6 months if the patient was unable to keep his/her 6 months follow up appointments.. The effectiveness of the intervention will be measured by comparing the differences in the rate of use of these medications (from baseline to the end of the study) between the intervention arm and the control arm.

D. 6.2. Sample Size Calculation



Sample size calculations for the pilot study assume the simplest case of a binary exposure (intervention /control group) without any covariate adjustment. The primary outcome related to beta-blocker (BB) intake, one of the most important outcome variables was used to compute the minimum sample size using 80% power. Due to the longitudinal design of the study, a Generalized Estimating Equations (GEE) model is used to compute the sample size. Specifically, the GEE model for an outcome w_{ijk} for example taking BB (w_{ijk} =1 if BB is taken and 0 if otherwise), for a subject i at time point j=1 (baseline), or 2 (6 months) in the group k, (k=T for the treated group and k=C control group), can be written as $\log\left(\frac{pr(w_{ijk}=1)}{1-pr(w_{ijk}=1)}\right)=\beta_{jk}$, where

β_{jk} is the log odds of taking BB for group k at time point j. Let us denote by p_{jk} the probability $pr(w_{ijk}=1)$. The intervention effect can be measured by the ratio $\frac{p_{2T}/p_{1T}}{p_{2C}/p_{1C}}$, which represents the ratio of improvement rates between the intervention and the control groups. Note that the ratio p_{2k}/p_{1k} represents the improvement in the group k between the baseline and the follow-up time.

If the intervention has a positive effect we have $p_{2T}/p_{1T} > p_{2C}/p_{1C}$ or equivalently, $\log\left(\frac{p_{2T}/p_{1T}}{p_{2C}/p_{1C}}\right) > 0$. Although, we expect the alternative to be a one sided when the intervention is effective, the sample size calculations are based on a two-sided test. Therefore, the intervention effect can be measured by the interaction between the time component and the intervention variable represented by the term $(\beta_{2T}-\beta_{1T})-(\beta_{2C}-\beta_{1C})$. Hence, if there is no intervention effect, we have $(\beta_{2T}-\beta_{1T})-(\beta_{2C}-\beta_{1C})=0$, which represents the null hypothesis. For inferences, due the longitudinal nature of the binary outcomes, the standard error of an estimate of $(\beta_{2T}-\beta_{1T})-(\beta_{2C}-\beta_{1C})$ is computed using the sandwich estimator approach. Based on this methodology, our sample size calculation shows that to detect an intervention effect based on $p_{1T}=50\%$, $p_{2T}=80\%$ (increase from

50% to 80% in the intervention arm), $p_{1C} = 50\%$ and $p_{1C} = 60\%$ (increase from 50% to 60% in the control arm), which corresponds to $(\beta_{2T} - \beta_{1T}) - (\beta_{2C} - \beta_{1C})$ = log (.8*.6/(.2*.4))=1.79, at 80% power and at 5% significance level, we need about 55 subjects in each arm (See Fig 3 above).This then corresponds to 110 patients for the entire study. Although we anticipate that about 30% of patients will drop prematurely from the study, we will however recruit 182 patients to make up for any possible higher attrition rate. Our assumption of a 30% increase in rate of use of medications was based on our recently completed HARP study "Outpatient medication use and health outcomes in post acute coronary syndrome patients" in which we demonstrated a 35% increase in the rate of beta-blocker use among 323 patients that were followed up for 8 months in an outpatient telephone intervention study [11].

D. 7. Study Measures

D. 7.1. The Primary Objective of this Proposal

To determine the influence of the program on the rate of use of key quality indicators. We will determine:

a. Change in proportion of patients on aspirin, beta-blocker, cholesterol lowering agents, and ACEI.

b. Change in proportion of patients that have their cholesterol accessed LDL-cholesterol ≤ 100 mg/dl, smoking counseling, and reduction in proportion of patients smoking. Information regarding medication use will be abstracted from the chart or per patient self report. Patient will be asked to read the name of their medications off the containers.

D. 7.2. The Secondary Objective of This Proposal

To ensure that physicians/other healthcare providers can implement the program. We will look for documentation of:

a. Use of the Office-GAP Contract, Office-GAP guidebook and tracking sheet.

b. Documentation of patient goals, regarding medication use, exercise, blood pressure, smoking cessation, and weight control.

c. Documentation of laboratory test and results e.g. cholesterol.

D. 7.3. Patient Perception of Physician Participatory Decision Style

Participatory Decision Style (PDS) is a 3-item scale developed in the Medical Outcomes Study[149]. It is completed by patients to describe their physicians' propensity to: a) Involve them in treatment decisions b) Give them a sense of control over medical care, c) enable them to take some responsibility for their own care. Participatory decision-making style has been shown in the Medical Outcomes Study and subsequent studies to predict provider switching[149]. It is positively related to patient satisfaction and loyalty to the physician and length of office visits. While our program is not anticipated to increase the length of the office visit, it constitutes care provided before the office visit (patient educational modules) and provides a structure for patient/physician collaboration in secondary prevention planning. The PDS will measure the extent to which the outcome of the program is patient perception of increased involvement, control and responsibility for care of their heart disease. All patients will complete the patient perception of physicians PDS questionnaire during their enrollment at the group meeting and at the end of the study, during their 6-month's physician office visit. The

questionnaire will be administered over the phone for patients that are unable to keep their follow up appointment.

D. 7.4. Effect of Program on Physician Practices and Barriers to Program Implementation

A pre and post survey of patients and physician/nurse practitioner/staff perception of the use of DSTs in outpatient settings will be completed. In addition, a survey of the impact of the program on the practices will be determined at frequent intervals. We will also document any barriers to implementation of the program. The information will assist in the design and implementation of the subsequent RCT to evaluate the program's effect on patient health outcomes.

D. 8.1. Data Collection

After the group meeting (focus group/educational meeting) patient will complete a baseline questionnaire to collect information on age, gender, race/ethnicity, income, education, marital/partner status, insurance, insurance coverage of secondary prevention, and number of people in the household. In addition information on risk factors, coronary heart disease history, and comorbidities will be obtained. Types of reminders that patients prefer (e.g. phone calls, postcards, etc) will also be ascertained and information regarding barriers and facilitators to medication use will be obtained. The best time for patient to be called by the nurse after the doctor's visit will also be obtained. Patients will complete questionnaire about DST. The PI and the research assistant will assist any patient that needs help to complete the questionnaires.

D. 8.2. Questionnaire Development and Modification

Prior to being used in our study, our questionnaire will be field tested for clarity, ease of use and accuracy of data responses among 20 English-speaking patients at another clinic site, the MSU Internal Medicine Clinic. The MSU Internal Medicine Residents' Clinic provides services for low- income indigent populations similar to those seen at Ingham County Healthcare Centers.

D. 8.3. Chart Abstraction

We will set up a centralized data-coordinating center at MSU. Patient charts will be abstracted in the clinic at baseline and at 6 months i.e. before and after implementation of the program. Information will include, use of aspirin, Beta-blockers, ACEI, smoking counseling/ status, cholesterol assessment and treatment. Other data to be abstracted from the chart will include cardiac procedures and treatment, comorbidities and hospital admissions. Severity of coronary artery disease (number of vessels occluded, ejection fraction), previous surgeries, including cardiac bypass, height, weight, blood pressure and contraindication to medications will also be abstracted. All completed forms will be forwarded to the study office, at the clinical center, Department of Medicine, where the information will be entered into a database. A paper print out of a summary of the chart abstraction will also be kept in addition to the chart abstraction form for each patient. All confidential patient information will be entered into a separate secure database to protect patients' identity. A patient study record number will link confidential patient information to the patient identifier.

D. 8.4. Medications Prescribed

Patient medications will be obtained at baseline, and 6 months post program implementation. Current medications will be enquired about during their routine office

visits at baseline and at 6 months. If a patient forgets to bring in his/her medications to the clinic, patient will be requested to call in their medications to the clinic nurse over the telephone.

D. 8.5. Cholesterol

Fasting Low-density lipoprotein (LDL) cholesterol, total cholesterol (TC), and triglyceride will be gathered from the outpatient chart review, pre and post-implementation of the program. Cholesterol will be measured as increase in the proportion of patients who have their cholesterol measured and are at or below the target values for patients with coronary heart disease established by the National Cholesterol Education Project (NCEP, ATP III), LDL $\leq$100mg/dl, and TC $\leq$200 mg/dl. Triglyceride < 200mg/dl [150]

D.8.6. Data Entry of Survey Questionnaires

The PI and Research Assistant will scan for missing responses at the time the completed surveys are turned in. They will ask that the subject complete any missing items. At the stage of data entry, double entry verification will be used to minimize data entry error. An access database will be used. A paper print out summary of the data collected will also be kept.

D. 8.7. Quality Assurance

The PI and the research assistant will train the medical record chart abstractors on specific chart abstraction protocols for the project. Acceptable inter-rater reliability (kappa >. 8) will be achieved for all new chart abstractors before independent chart abstraction will occur. For quality assurance purposes data will be reabstracted by the trained chart abstractors from a 10% random samples of chart at both baseline and

remeasurement. Intra-rater and inter-rater reliability will be determined. The goal is to have a kappa coefficient > 0.8.

Treatment fidelity strategies (strategies to ensure that the content of the intervention is being delivered as specified) will be included in our research design and implementation in order to monitor and enhance the reliability and validity of our behavioral interventions. A high degree of treatment fidelity is needed for successful replication and dissemination of the project. We will adopt the treatment fidelity framework by Borrelli et al[151]. The areas of focus will include, 1) DST design, 2) training providers, 3) delivery of educational modules and DST, 4) receipt of DST and educational modules, 5) enactment of intervention skills. We will ensure that the content of the intervention was being delivered as specified e.g. by development of treatment manuals, protocols, check list and conduct weekly meetings of the research team. We will include mechanism to assess if the provider actually adhered to the intervention plan by a follow -up phone call to the patient and check for use of DST.

D. 8.8. Data Back-Up

Periodically, an encrypted back up copy of electronic data will be created and stored in a secured location in the in the Department of Medicine.

D.9. DATA ANALYSIS

D. 9.1. Creation of Study Database

Datasets for statistical analyses will be created and cleaned after merging data from different data sources. We will define ranges for each variable collected and examine the accuracy of outliers. We will check for internal consistency of inter-related and calculated variables and resolve inconsistencies by reviewing primary data sources.

We will complete a series of descriptive statistical analyses to profile the study sample in terms of demographic and clinical characteristics. All analyses will be performed using the statistical program SAS (Statistical Analysis System, version 9.1 Inc, Cary NC). The research analytic sequence will vary according to the type of data and study outcome being analyzed. Qualitative type-recorded data will be analyzed on an on-going basis.

D. 9.2. Focus Group Analysis

Data will be obtained from multiple close readings of the transcripts of focus group interactions; the moderator/facilitator notes and from the notes kept from observations of the PI. The unit of analysis for Specific Aim 1 is a thematic unit [146]. Thematic units for this study are the recurring systems of beliefs or explanations that emerge from the patient focus groups describing attitude towards heart disease self-management, medication use, patient autonomy, SDM, use of DSTs, and collaborative care across racial and provider groups. Emphasis will be placed on recurrent themes regarding attitudes towards heart disease self-management, SDM and collaborative care across racial groups. To be considered a theme, a topic will have to be mentioned by more than one participant across provider groups and across racial categories of patients. Sampling within thematic units will be done to provide themes that are representative of the beliefs of the study populations. Emergent themes will be used to classify the content of focus group interactions into categories. The categories will be organized so that the meanings of discussions are maintained.

Coding: Initial coding categories will be created and refined by a team comprised of Dr. Holmes-Rovner, the PI, and the moderators of the focus groups based on the literature and personal experiences with the study populations. These coding categories

will then be applied to part of the focus group data to check for relevance and consistency. Finally, a separate group of coders will apply the refined categories to a subset of the data to determine the reliability of the coding categories. Once reliability is established then coding of the focus group data will be done.

Qualitative Analysis: Since Specific Aim 1 is exploratory in nature, content analysis and resulting statistics will be descriptive. We will summarize emergent themes in order of decreasing frequency. Relationship between themes will be determined by cross-tabulation of the frequencies of co-occurrences. Images, discriminant analysis, and association analyses will be conducted to determine the uniqueness of the information from the patient focus groups. Our findings will provide a rational and culturally sensitive framework on which to develop interventions in these populations. The focus groups are expected to produce data that captures the perceptions of patients that are impossible to accomplish through close-end question surveys.

D. 9.3. Office-GAP Follow-Up Program

We will determine the increase in the proportion of patients adhering to recommended medications in response to our interventions and reinforcement with reminders. Analysis is as described in next section.

D. 9.4. Data Analysis for Aim 3

Assessment of the influence of the Office-GAP implementation on the rate of use of key quality indicators.

In our preliminary descriptive analyses, the outcome variables related to likelihood of use of aspirin, beta-blockers, ACEI, and cholesterol assessment and treatment, smoking counseling/status will be considered. We will begin our analysis by

computing the sample proportion at each single time point and for each treatment group, together with the corresponding sample standard deviation. Because the study involves repeated measurements on the same subject, we will compute measures of association between time-point responses of a given outcome. Specifically, we will use pairwise odds ratios and Pearson correlations to measure the temporal association between two different time points. These measures of association will provide an indication on how the association between responses of a given outcome could be modeled over time in the regression models. It is widely known that putting some structure on the working correlation matrix, improves efficiency for time dependent covariates in GEE models.

To assess the intervention effect on the outcome variables, we will use regression models for which their specification will depend on the format of the outcomes under investigation. We will use GEE models with explanatory variables, which include the time variable, the intervention variable and their interaction. We will also adjust for the clinics effects in order to account for unmeasured clinics' specific differences. GEE models, which are specified in the sample size calculation section, for binary outcomes is an extension of the classical logistic regression model that takes into account the correlation of an outcome measured repeatedly over time within a subject[146]. They treat the within-subject association as a nuisance parameter and assume a "working correlation" structure which needs not be the correct correlation structure. The standard errors are robustly computed using the sandwich-based approach which takes into account the correlation within a given subject. Since the marginal probabilities are modeled as those of a classical logistic regression, the slope estimates from the model have, a population-averaged interpretation. However, these models may produce biased

inferences when the completely missing at random assumption (MCAR) is violated. A weighted GEE model or likelihood methods for correlated binary data such as that based on the Multivariate Plackett distribution can then be invoked for their robustness against any violation of the MCAR assumption in the direction of the Missing at random (MAR) mechanism [147]. For model diagnostics, all model fits will be evaluated for individual and systematic departures of the observed and fitted values using informal (e.g. inspection of residuals) and formal methods (e.g. based on Wald tests for extra parameters).

Handling and treatment of missing data and intention to treat analysis

It is most likely that we will have missing data in the course of the study. The missing data are mostly dropouts in that some participants will be lost to follow-up as the study progresses. The primary concern in analyzing the resulting (unbalanced) data rests on the nature of the missing data. Using terminology from Rubin and Little[152], missing data mechanisms are classified as missing completely at random (MCAR), missing at random (MAR) and missing not at random (MNAR), if missingness is allowed to depend on (1) none of the outcomes, (2) the observed outcomes only, or (3) unobserved outcomes as well, respectively. The models proposed above (weighted GEE models) are known to provide valid inferences when the missingness mechanism depends on the observed outcomes and not on the unobserved ones. However, when the missingness mechanism depends on the unobserved outcomes, these models may yield biased inferences. In this context, we can assess the impact of this class of missingness process on inferences through sensitivity analyses. We will then formulate a non-ignorable model that takes into account the missing data indicator and the measurement data into a unified likelihood. We will then use this model to study how the missingness process influences

the inferences.

Intention to treat analysis

It is likely that there will be some non-compliance in the study in that some participants randomized to the intervention arm may not comply with instructions of the intervention. To address this issue, we will consider an intention to treat analysis, i.e. participants will be analyzed according to the group they were randomized to, regardless of whether they actually comply with the intervention process. Due to the nature of the delivery of the intervention, we do not expect participants on the control arm to have access to the intervention.

D. 10. Quantitative Patient Perception of Physician Participatory Decision Style (PDS)

The difference between pre and post intervention data will be used to create a composite ***PDS score differences for*** each study patient. Statistical significance will be tested at the 0.05 level using a series of matched pair test. The anticipated sample size will provide an adequate level of statistical power to test these differences.

D. 10.1. Baseline Patient Characteristics

To be used as ***Covariates*** are age, sex, race, income, insurance status, marital status, number of people in the household, comorbidity as measured by Charlson Comorbidity Index (CCI) [153], severity of coronary heart disease (number of vessels diseased, ejection fraction <40), history of coronary heart disease and cardiac procedures, (coronary artery bypass graft, angioplasty, diagnostic catheterization), hospitalizations after implementation of the program.

D. 10.2. Anticipated Problems/Study Limitations

*1) **Patient Recruitment**:* We propose to enroll 182 patients. We do not anticipate significant difficulties in recruiting our sample. The study team is experienced in recruiting participants for decision-making and qualitative research in clinical and community settings. The PI has held a series of meetings with the medical director, health administrator and the physicians at the health centers. However, we have allowed ample time to extend recruitment if necessary.

2) ***Physician Recruitment:*** We have assumed that all the physicians and nurse practitioners at a given site would participate. However, some may not be able to do so for scheduling and other unanticipated reasons. The PI has met with all the physicians/nurse practitioners that work at the health centers and they expressed their interest in the study and willingness to cooperate with the team to ensure that the program succeeds.

3) ***Focus groups:*** A concern that is often raised is the validity of focus group analyses. Based on the exploratory nature of the study question, focus groups when conducted properly are most likely to provide the desired results. Dr. Holmes-Rovner, Dr. Smith and Dr. Hunt are skilled in the conduct, analysis and interpretation of focus group data. The availability of these mentors, skilled at qualitative analysis, will ensure that valid and reliable inferences can be deduced at the completion of Specific Aim 1.

4) ***Decision support tools (DSTs)*** and reminder systems: While DSTs and reminders have been previously shown to affect physicians' ordering of recommended medications and tests, they don't always work. In a recent study by Tierney et al. computerized reminders were mostly ignored, and did not affect any patient

outcomes[154]. However, the Guideline Applied to Practice Tools by Dr. Eagle and his team were very successful in increasing secondary prevention for inpatients. We propose to adapt these tools for outpatient use in our study. Dr. Eagle, a co-mentor is actively involved in the design of this program. In addition, involvement of both patients and physicians in designing the system will increase the chances of successful implementation. Patients follow up program should help to reinforce the system.

5) ***Limitation of Cluster randomized trials:*** One of the limitations of cluster randomized trial is that it may have substantially reduced statistical efficiency relative to trials that randomize the same number of individuals.

6) ***Ability to meet relevant timetables:*** We have ample time for patient recruitment and data collection, and we do not anticipate a significant deviation from the schedule. Timeline is attached in the appendix.

E. HUMAN SUBJECT RESEARCH

E. 1. Risks to the Subjects

E. 1.1. Human Subjects Involvement and Characteristics

The research plan proposes to enroll 182 patients with coronary heart disease and diabetes mellitus from the three health centers at Ingham County. The eligibility criteria in our study are designed to recruit as large a number of patients as possible, who will benefit from secondary prevention for CHD. Eligible patients will be African Americans and other low-income populations attending any of the three health centers, aged 18 or older, with 1 of the following:

1) Inpatient, outpatient or emergency department diagnosis of coronary artery disease, angina, or myocardial infarction.
2) Definitive diagnostic test (e.g., cardiac catheterization, an echocardiogram or scintigram showing segmental abnormalities in the left ventricular wall, an electrocardiogram demonstrating significant Q-waves, or results of cardiac enzymes studies indicating acute myocardial injury or
3) Coronary Heart Disease risk equivalent - Diabetes mellitus

   In addition, patients must be fluent in English and able to provide informed consent. Low SES will be based on patient's income, number of people in the household, (using the US poverty thresholds 2005 levels as defined by the US Census Bureau, Housing and Household Economic Statistics Division) and insurance status.

Patients will be excluded if there is any evidence cognitive impairment, dementia, psychosis, and inability to understand spoken English. The race/ethnicity of each patient will be determined by self-report.

We will conduct 4 patients' focus groups. Each group will consist of 8 subjects. The sample composition will consist of women and men.

No patient is denied care in this study. All patients will receive usual care for heart disease and diabetes and patients and providers will only be expected to respond to interview questions, participate in focus groups and educational modules with emphasis on improving secondary prevention of heart disease.

E. 1.2. Sources of Research Materials

Data obtained specifically for research purposes will include personal opinion information from focus groups, surveys, and interviews. Some information such as demographics and clinical status and list of medication use will also come from medical records.

E. 1.3. Potential Risks

This study poses no additional risk to patients or providers. The subjects will have the option of withdrawing from the study at any time without jeopardizing access to care.

E. 2. Adequacy of Protection Against Risks

E. 2.1. Recruitment and Informed Consent

Subjects will be recruited from the three health centers in Ingham County. Patient recruitment will proceed as follows: A letter will be sent by patients' primary care physicians or his clinic nurse/ clinic research assistant (RA) to patients with evidence of

CHD or diabetes that meet the eligibility criteria in the interventional centers at Ingham County health centers inviting them to participate in the study. The letter will include a stamped addressed post card that interested patients can return to the research office indicating their interest to participate in the study. Clinic Nurse/ clinic RA will log all responses positive and negative and will follow up with a phone call from the clinic in 2 weeks to patients that did not respond. In addition a phone number to a phone with a voice mail in the research office or clinic will also be included that patients can call to indicate their interest in participating in the study. Those who would like to discuss the program further will be offered an appointment unless one had already been scheduled as part of routine care. PI and Research Assistant will obtain informed consent from all patients that agreed to participate after their office visit with their physician or before the focus group or patient educational section. Consistent with HIPPA regulation patient identifiers will not be obtained by research team for recruitment purposes without patient consent. After patients' recruitment PI and trained Research Assistant will give initial training and further explanation of the study. Consent to participate in the study will also be obtained from all the providers who will participate in the study. IRB Preliminary human_subjects' approval has been obtained (attached in the Appendix). Full IRB approval will be obtained before the onset of the study. All recruitment procedures are consistent with present HIPAA regulations, and no individual data will be obtained prior to patient consenting to join the study.

E. 2.2 Protection Against Risk

The project team will establish a uniform procedure for handling patient questions regarding their continued participation in the study or expressed desire to withdraw from the study addressed in a confidential manner.

Data obtained from participants will be linked to personal information only through identification codes that will be stored in a locked drawer separate from the data. Access to data will be restricted to the research team. Reported data and publications will list patients in groups and will never report information that is personally identifiable. We expect these precautions to be effective safeguards against the risks imposed by participation in this research.

Michigan State University's Human Research Protection Programs

Michigan State University is dedicated to the highest standards of ethical research conduct and the protection of human subjects in research. The Human Research Protection Programs at Michigan State University (MSU) are fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). MSU has an FWA on file with the Office of Human Research Protection (# 00004556). When appropriate, MSU develops collaborating relationships with other institutions holding an FWA through IRB Authorization Agreements and with individual investigators in non-FWA institutions through Individual Investigator Agreements. Michigan State University has three Institutional Review Boards with expertise relevant to each focus area: Biomedical and Health IRB (BIRB), Social Science/Behavioral/Education IRB (SIRB) and the Community Research IRB (CRIRB). MSU provides extensive required and supplemental human subject research education for

faculty, staff and students, including conferences, seminars, guest lectures and online training. MSU requires that investigators and all key personnel complete the MSU online tutorial and then six CITI modules, or equivalent, every 2 years. The MSU HRPP conducts random and performs audits on a regular basis of all categories of review (exempt, expedited and full board) to ensure compliance with University policies and federal regulations. In addition, MSU has a university [HIPAA] Privacy Board and follows and enforces the HIPAA law for the protection and confidentiality of protected health information. If there are any questions about the MSU HRPP please contact Peter Vasilenko, PhD, the Director of the MSU Human Research Protection Programs at 517-355-2180 or irbchair@ores.msu.edu.

E. 3. Potential Benefits of the Proposed Research to the Subjects and Others

The potential benefit to the participants is the possibility that they may find it helpful learning how to best prevent occurrence/recurrence of coronary heart disease by improving the rate of use of evidence-based medications, maintaining healthy lifestyle and improving their self-management skills. The research may lead to learning better ways of improving secondary prevention of coronary heart disease for AA and low socio-economic status populations within primary care.

E. 4. Importance of the Knowledge to be Gained

It is hoped that knowledge gained from the patients and providers' participation in the proposed project will assist in the development of decision support tools that will be adaptable for use within primary care. This is likely to enhance adherence to evidence-based treatment recommendations for African Americans and low socio-economic status populations in primary care. Elements of the proposed system can be applied to the

treatment of other chronic diseases. In addition, the program provides an opportunity to collect essential descriptive data about where problems occur in the system and the roles of patients and providers in creating and eliminating problems. We are confident that the possible benefits of this research clearly outweigh the risks to subjects.

E. 5. Collaborating Sites

None.

E. 6. Women and Minority Inclusion

This project will include both men and women. About 52% of patients that attend Ingham County clinics are women. We anticipate that this proportion will be reflected in our recruitment of subjects. This study is specifically for AA and low-income populations; we anticipate the enrollment of the minority population, the elderly and patients with chronic illnesses.

Table 2. Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Improving Secondary Prevention of Coronary Heart Disease

Total Planned Enrollment: 182

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	9	17
Not Hispanic or Latino	93	72	165
Ethnic Category: Total of All Subjects *	101	81	182
Racial Categories			
American Indian/Alaska Native	1	0	1
Asian	5	3	7
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	46	38	84
White	50	40	90
Racial Categories: Total of All Subjects *	101	81	182

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories"

E. 7. Inclusion of Children

Children will not be included as this study pertains to patients with CHD and Diabetes who are aged 18 or older.

E. 8. Priority Populations

This entire project focuses entirely on priority populations. African American and low socio -economic status populations are the focus of this research. The elderly and patients with chronic illnesses are included. Our study populations are patients with history of previous MI or CAD and patients with diabetes.

F. VERTEBRATE ANIMALS

Not applicable.

G. SELECT AGENT RESEARCH

Not applicable.

APPENDIX A: RESOURCE SHARING PLAN

Data Sharing Plan

While the proposed work does not request greater than $500,000 in any year, and does not propose to develop a model organism, we expect to share all data generated by this proposal as follows:

Presentations at regional and national meetings:

From the project it is expected that approximately four to six presentations will be generated during the research project. The PI will submit abstracts of the initial findings and data analysis at the regional and national meetings of the Society of General Internal Medicine. This meeting is designed and implemented to meet the educational and professional needs of the primary care general internist community. The meeting offers an unparallel opportunity to network with the community of scholars devoted to primary care internal medicine and research. The PI will also submit her work at the Society of Medicine Decision Making and Annual meeting of the American Heart Association.

Annual Meeting of the Training Clinical Researchers in Community Settings (TRECOS)

TRECOS is MSU's NIH K30 program that provides training for community physicians. The TRECOS program conducts a one-day meeting of all current and past TRECOS fellows from MSU. During the meeting, fellows present their ongoing projects for evaluation and feedback. Fellows interact with other colleagues and the Board of Directors of the program. The PI is a TRECOS fellow and will present the results of her findings during the annual meeting throughout the five years.

In addition, if our decision supports tools are successfully implemented in the outpatient setting, we will plan to publish our findings in J. Gen Intern Medicine, Annals of Intern Med, and Health Services Research. In addition, we will share these tools directly with other practices. Since our work will be conducted in Community Health Center (CHC) settings, our first dissemination effort will take place in other CHCs, serving low-income and minority populations. The Michigan Primary Care Association (MPCA) is the professional association of CHCs in Michigan. We will work through the MPCA to make these tools available and to plan for evaluating them further.

MICHIGAN STATE
UNIVERSITY

Renewal Application Preliminary Approval

September 15, 2006

To: Adesuwa OLOMU
B329 Clinical Ctr.

Re: **IRB # 04-730** Category: PRELIMINARY PRELIMINARY
Renewal Approval Date: **September 15, 2006**
Project Expiration Date: **September 14, 2007**

Title: IMPROVING SECONDARY PREVENTION OF CORONARY HEART DISEASE

The Institutional Review Board has completed their review of your project. I am pleased to advise you that the renewal for Preliminary Approval has been approved.

Preliminary Approval allows investigators to open their Contracts and Grants account and spend funds for certain purposes, develop study instruments or procedures, or may be needed to submit certain grant applications.

Under Preliminary Approval you cannot contact human subjects or collect data from them. Prior to implementation of the research, the investigator must submit a complete *Application for Initial Review* for approval.

Renewals: IRB approval is valid until the expiration date listed above. If you wish to continue Preliminary Approval of your project, you must submit an ***Application for Renewal*** at least one month before expiration. If the preliminary approval is no longer required and you do not plan to submit an initial application, please submit an ***Application for Permanent Closure***.

When you submit a subsequent application, please use the IRB number listed above, even in a new Initial Application. Also refer to that number in any correspondence with the IRB office.

Good luck with your project. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

Peter Vasilenko, Ph.D.
BIRB Chair

c: Margaret HOLMES-ROVNER
C 203 E. Fee Hall

APPENDIX C

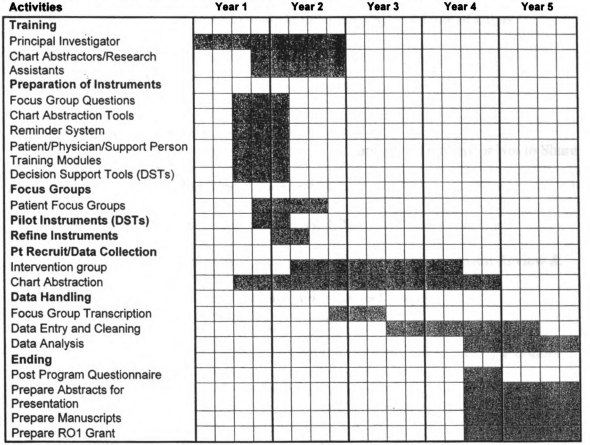
Physician Participatory Decision Making (PDM) Style questionnaire

Physician Participatory Decision Making (PDM) Style **"People who are experiencing depression symptoms may be considering various options for what to do. If anything, about managing or taking care of their symptoms. Thinking about your <u>past experience</u> with your health care provider: if there was a choice between treatments for your depression symptoms:**	
"Would your health care provider ask you to help make the decision?" • Read the response options to the participant. • A participant may indicate that s/he has more than one health care provider. As the participant to answer the questions for the health care provider who suggested/prescribed treatment, or would be most likely to do so. Make a note here of who the participant is making the ratings for; i.e., "primary care doctor," "nurse practitioner," etc.	☐ Definitely no ☐ Probably no ☐ Maybe ☐ Probably yes ☐ Definitely yes ☐ Don't know ☐ Refused
"How often does your health care provider make an effort to give you some control over your treatment?"	☐ Never ☐ Seldom ☐ Sometimes ☐ Often ☐ Very often ☐ Don't know ☐ Refused
"How often does your health care provider ask you to take some of the responsibility of your treatment?" • If the participant asks what "taking responsibility" means, examples of the HCP asking the patient to assume roles in "carrying out" treatment can be given (examples should be tailored to the history of treatment the patient has already provided, if possible). For example, HCPs may ask patients to follow through with taking prescribed medications, record response of symptoms to prescribed treatments, report new symptoms, openly discuss with the HCP beliefs about possible causes of symptoms, etc. One or two examples that the patient may have already mentioned can be used.	

APPENDIX D

Project Timeline

The major tasks for the proposed research will be scheduled over 5 years as follows:



APPENDIX E

Training in the Responsible Conduct of Research

The Nature and Practice of Scientific Integrity

Spring Semester 2005

Beginnings:

- Integrity in research and scholarly activities: an educational imperative
- Introduction, Overview, and "The Issues"

US Support of Science and Technology

- US public support for research & development, including education and training
- Academic Freedom and National Security in a Time of Crisis

Strategic Planning & the Future of Science

- The US Federal Budget Process

Lapses in the Name of Science

- Significant Examples
- Whistleblowing

Modern Science – Relevance, Meanings & Purpose

- The Beneficiaries of Science & Technology – To Share or Not to Share

The Practice of Science

- Program Planning & Proposal Writing
- The NIH Process
- The Human Subjects Process at MSU

Responsible Conduct of Science

- Research Initiatives Requiring Institutional and/or Federal Review & Approval: Can Scientists do Whatever They Want?
- The role of the IRB in the human subject process
- Research in International Settings
- The Role of the IACUC in the Animal Subject Process
- Scientific Misconduct; Integrity in the Research Record: Laboratory Notebook & Data Management; Quality Control
- Conflict of Interest; Objectivity in Research
- Publication Practices & Responsible Authorship
- What is Science? Analogies from the Law

In-Class Mock Review Boards

- Humans
- Animals

APPENDIX F

American College of Cardiology Foundation, Guidelines, Applied in Practice, Acute Myocardial Infarction – Heart Attack Discharge form

OFFICE GAP PROJECT

HEART ATTACK PREVENTION CONTRACT

To decrease my risk of having a heart attack, I need to do the following:

1. **TAKE MEDICINE. I understand that there are certain mediations which may help to prevent a future heart attack and may help to extend my life.**

a. Aspirin _____ mg daily ☐ Yes ☐ Does not apply to me because: _____

b. ACE inhibitor ____ ☐ Yes ☐ Does not apply to me because: _____

A measure of how well my heart is pumping is my *ejection fraction.*
My ejection fraction = _____%. ☐ I do not know my ejection fraction.

c. Beta blocker _____ ☐ Yes ☐ Does not apply to me because: _____

d. Cholesterol lowering _____ ☐ Yes ☐ Does not apply to me because: _____

My cholesterol values are as follows:

Total Cholesterol (TC) = _____ (goal: less than 200)

Low Density Cholesterol (LDL) = _____ (goal: less than 100)

High Density Cholesterol (HDL – good cholesterol) = _____ (goal: between 40-96)

Sublingual nitroglycerin tablets _____ ☐ Yes ☐ Does not apply to me because: _____

2. QUIT SMOKING. I understand that smoking increases my chances of suffering from a future heart attack and that smoking causes other illnesses which may shorten my life.

a. I smoke and have been counseled to stop. ☐ Yes ☐ I do not smoke.

b. I will stop smoking by (date) _____. ☐ I am not ready to stop smoking yet.

c. I have been given medication to help me stop: _____.

d. Referral to smoking cessation classes: Call: _____ at phone _____.

---

3. EAT A LOW-FAT DIET. I understand that a diet that is low in cholesterol and fat may help to reduce my chances of suffering a future heart attack.

a. I have received counseling about a low fat diet. ☐ Yes ☐ No ☐ Does not apply to me because: _____

b. Nutrition Services Contact: Call _____ at phone _____.

---

4. EXERCISE REGULARLY.

a. I have received activity instructions. ☐ Yes ☐ No

b. I walk, jog, or run at least 40 minutes to 1 hour, 5 to 6 times a week ☐ Yes ☐ No

c. I have received information regarding exercise opportunities in my community. ☐ Yes ☐ No

---

5. LEARN ABOUT HEART DISEASE.

a. I have seen the video on heart disease prevention ☐ Yes ☐ No

b. I have received cardiac education (office GAP) booklet in the mail. ☐ Yes ☐ No

c.. I have received instructions on how to use my medications at home. ☐ Yes ☐ No

---

6. FOLLOW UP WITH MY PHYSICIAN.

a. I have a follow-up appointment made with my physician. ☐ Yes ☐ No ☐ Does not apply

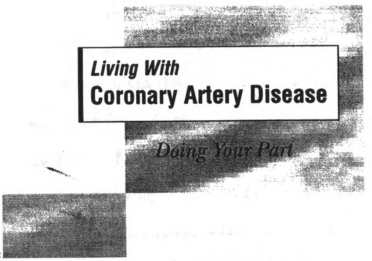
b. The number to call if I have not received a follow-up appointment in 2 weeks is _____ - _____.

Nurse/Physician Signature / Date: **Patient Signature / Date:**

_____ _____

APPENDIX G

FIMDM GUIDEBOOK "LIVING WITH CORONARY ARTERY DISEASE: DOING YOUR PART"



A Shared Decision-Making® Program

The Foundation for Informed Medical Decision Making

CAD002B V02

Table of Contents

About This Program

This program is intended for people with coronary artery disease. If you have had a heart attack, experienced episodes of angina, or have had a procedure such as angioplasty or coronary bypass surgery, this video program and booklet contain information that may be valuable to you.

This program is not intended for:

- People with congenital heart disorders
- People with heart valve disorders
- People with cardiomyopathy
- People with congestive heart failure not due to coronary artery disease
- Pregnant women

This booklet summarizes the information presented in the video. In addition, the booklet contains many of the numbers that summarize the benefits of medication and lifestyle changes so you can take time to review them.

This program is intended for your individual use as part of a multi-faceted Shared Decision-Making® (SDM) support system provided by Health Dialog through your health service. SDM programs are designed to support an informed dialog with your doctor as you work together to make important decisions about your healthcare.

SDM programs are based on medical evidence researched and evaluated by the Foundation for Informed Medical Decision Making. The programs are regularly reviewed to ensure they contain the most current and accurate information, and each program is updated as necessary. If you have received this program from a source other than your health service, it may be out of date and should not be used.

Information on Health Dialog program editions and updates can be found on our Web site—www.healthdialog.com—or you may call 800-966-8405.

Please use the product number located on the videotape label for all inquiries.

Shared Decision-Making

Making decisions about how to manage coronary artery disease can be challenging. Depending on the specifics of your case, you may be asked to consider making a lot of changes to your lifestyle. Decision which of these changes make sense and understanding how they may benefit you will take time and effort.

The choices you make about smoking, diet, exercise, and managing stress as well as taking medications can significantly affect your risk for future heat attacks and death.

But all of these choices involve tradeoffs. The decisions you make will probably depend on how you feel about those tradeoffs and how much risk you are willing to live with.

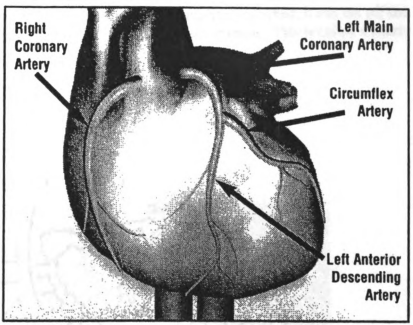
Although many people believe their doctors should decide which choices are right, you own point of view is very important. Once you understand these choices, you and your doctor can make decisions together. If you do this, you may be more satisfied with your decisions and the outcomes of your treatment.

This approach is called **shared decision-making**.

Coronary Artery Disease

Coronary artery disease results when deposits (called plaque) made up of fat, cholesterol, and calcium build up in one or more of the coronary arteries, which supply blood to the heart muscle itself. Although you can't see this happen, you can sometimes feel what it does to your heart. Plaque can narrow the arteries and interfere with the heart's supply of blood and oxygen. This can cause symptoms, called angina, such as chest pain or discomfort, or pain or pressure in the arm, shoulder, or neck.

Heart and Coronary Arteries



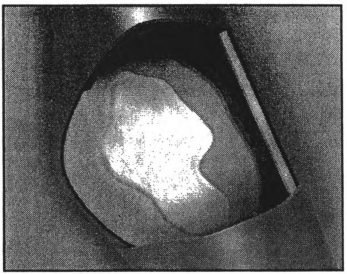
*The **coronary arteries** supply the heart muscle with blood and oxygen. Plaque can build up inside the arteries.*

Angina sometimes comes on predictably, such as when you climb a flight of stairs or when you are emotionally upset. Resting or taking prescribed medications often relieves it. But if angina pain is new or different, or if it doesn't respond to rest and medication as it has in the past, it can signal a major heart event, such as a heart attack.

Not everyone has the same symptoms of angina, so it's important that you know how to recognize and respond to your heart symptoms. Your plan might include taking medications, calling your doctor, or calling emergency medical services. Being prepared will help build your confidence and lower your anxiety.

If the blood flow through a coronary artery is completely blocked, it can cut off the supply of blood and oxygen to a portion of the heart muscle. This is called a heart attack.

Complete Blockage

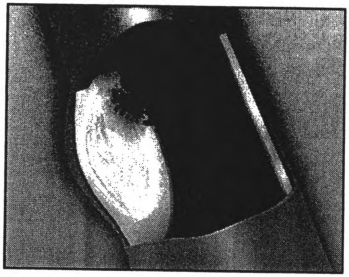


*Some heart attacks occur when a large **plaque** completely blocks a **coronary artery**.*

Scientists used to believe that most heart attacks happened when a large plaque completely blocked blood flow in a coronary artery. But not all plaques are alike. In fact, it now appears that large plaques are responsible for only about 15% of heart attacks.

Many heart attacks involve a different kind of plaque. In these cases, it's not the size of the plaque that's the main problem, but rather its tendency to break open or rupture. When this happens, even if the plaque is small, it can trigger a blood clot that causes a heart attack. Our new understanding of these "unstable" or "vulnerable" plaques helps explain why some heart attacks occur in coronary arteries that are only partially narrowed by plaque.

Plaque Rupture



*Many heart attacks occur when a **plaque** of any size breaks open (ruptures), causing a **blood clot** that blocks an **artery**.*

Doctors have increasingly focused their attention on plaque—why it builds up, how it behaves, and how to control it. There are many different ways to reduce or slow down the buildup of plaque. Controlling cholesterol is one important way. Medications help, and so do a healthy diet and regular exercise.

Managing Coronary Artery Disease

Living with coronary artery disease often means taking medications and changing some parts of your lifestyle. What is the goal of these lifestyle changes?

- Relieve symptoms
- Reduce risk of heart attacks and death
- Reduce need for procedures such as angioplasty or bypass surgery
- Reduce need for medications
- Prolong life

Many people have procedures such as angioplasty or bypass surgery to treat their coronary disease. But although these procedures help relieve symptoms, prevent heart attacks, and may prolong life, they do not address the underlying problem. Fortunately, medications and lifestyle changes do. In fact, one of the most effective ways to control coronary artery disease is to live a "heart-healthy" lifestyle. That means:

- Taking prescribed medications
- Lowering cholesterol
- Controlling blood pressure
- Quitting smoking (if you smoke)
- Getting regular exercise
- Reducing stress

Each of these lifestyle changes can help you feel better or live longer – or both. But they can present challenges for some people.

How Medications Help

Medicines are very helpful for managing coronary artery disease. Some medications relieve symptoms or help reduce blood pressure or cholesterol. Others help stabilize plaque or prevent blood clots. Some medications have multiple benefits. The list at the back of this booklet includes some common heart medications, but it's not a complete list. Depending on your situation, you may be taking one or more of these medications, or others that are not listed.

Many medications have possible side effects. Not everyone has side effects, but they can be bothersome for people who have them. It's important to know that if a medication causes side effects, your doctor can often prescribe a different one. Don't stop taking any medication without talking with your doctor, and tell your doctor about any bothersome symptoms that start soon after you start taking any medication. Some medications have rare but serious side effects, so make sure you know what to watch for.

ACE inhibitors

- Lower blood pressure

- Stabilize plaque
- Help prevent heart attacks

In addition to lower cholesterol, statins have other benefits. They help make plaque smaller and less likely to break open (rupture), which helps lower the chance of heart attack. In fact, statins can lower the risk of heart attack and deaths related to coronary artery disease by 24 to 30 percent, or even more in some people.

A Common Misconception

Taking a cholesterol-lower medication does not make it "ok" to eat unhealthy foods. People taking statins still need to stick to a heart-healthy diet of lean meats, vegetables, fruits, and whole grains.

Possible side effects:

- Dry cough
- Dizziness
- Diarrhea

Angiotensin receptor blockers (ARBs)

- Lower blood pressure
- Help prevent heart attacks

Possible side effects:

- Dizziness or lightheadedness
- Headache, muscle aches, back pain
- Cough, congestion, runny nose, sore throat

Beta blockers

- Lower blood pressure
- Slow heartbeat and help prevent irregular heartbeats
- Help prevent heart attacks

Possible side effects:

- Fatigue
- Depression
- Reduced sex drive
- Impotence (erectile dysfunction)
- Cold hands and feet
- Shortness of breath

- Vivid dreams
- Difficulty sleeping

Calcium channel blockers

- Lower blood pressure

Possible side effects:

- Ankle swelling
- Constipation or diarrhea
- Headache
- Dry mouth
- Flushing, feeling warm

Fibrates or fibrinic acid

- Lower cholesterol
- Increase "good" or HDL cholesterol

Possible side effects:

- Nausea or diarrhea
- Stomach pain, gas, or heartburn

Aspirin or other platelet inhibitors

- Help prevent blood clots and heart attacks

Possible side effects:

- Stomach pain or heartburn
- Headache, muscle aches, or back pain
- Bleeding (occasionally serious)

Nitrates

- Improved blood flow to heart
- Relieves symptoms

Possible side effects:

- Headache
- Dizziness or lightheadedness
- Flushing of face and neck

Statins

- Lower cholesterol
- Stabilize plaque
- Help prevent heart attacks

Possible side effects:

- Muscle and joint pain
- Stomach pain, heartburn, or nausea
- Constipation or diarrhea

Managing Cholesterol

Cholesterol is a natural substance found in the blood stream. The liver normally creates all the cholesterol the body needs. Certain kinds of foods high in saturated fats, however, can significantly increase cholesterol levels. Too much cholesterol in the blood contributes to the buildup of plaque in the coronary arteries.

Doctors measure cholesterol with a blood test called a "cholesterol" or "lipid" profile. The types of cholesterol are referred to by their initials:

- **LDL** stands for low-density lipoprotein cholesterol.
- **HDL** stands for high-density lipoprotein cholesterol.

LDL is the bad cholesterol. HDL is the good cholesterol. Triglycerides are another type of fat found in the blood.

Recommended cholesterol targets for people with coronary artery disease are:

- Total cholesterol: below 200.
- LDL (bad) cholesterol: less than 100 (a goal of less than 70 may be reasonable for some people at very high risk).
- HDL (good) cholesterol: above 40 (higher is better).
- Triglycerides: less than 150.

Managing cholesterol means reaching your target cholesterol numbers for LDL and HDL cholesterol and for triglycerides. Not everyone with coronary artery disease has high cholesterol or high triglycerides, but if you do, there is a lot you can do to help improve your numbers. Diet and exercise can help, but most people whose LDL cholesterol is higher than 129 also need medications to reach their target of 100 or lower.

What kind of diet helps lower cholesterol?

- Low in total fat (less than 30% of daily calories), saturated fat (less than 7% of calories), cholesterol (less than 200 mg per day), and trans-unsaturated or trans fats (found in partially hydrogenated oils).
- High in soluble fiber (10 to 25 grams per day) from vegetables, fruits, beans (legumes), oat bran and whole-grain cereals, breads, and pastas.
- Replaces butter or margarine with polyunsaturated or monounsaturated oils (such as canola, flaxseed, olive, and safflower oils) or with margarines or spreads that contain plant sterol ester (1.3 grams per day) or stanol esters (3.4 grams per day).

Read labels carefully on "diet" foods. Some may be low in fat but contain a lot of sugar and just as many calories per serving as the regular food. Extra calories from sugar can be a particular problem for people who are trying to lower their triglycerides, and for people with diabetes who need to manage their blood sugar levels.

What kinds of foods should you avoid, or enjoy only once in a while, in small portions? Those that are high in saturated fat, such as:

- Fatty meats, such as sausage and cold cuts
- Fast food sandwiches
- Fried foods such as French fries or fried chicken
- Baked goods such as donuts, cookies, cakes, and pies
- Cheese, cream, butter, and ice cream

Diet and Your Heart

There's intriguing evidence that certain dietary patterns, such as diets that include more vegetables, fruit, fish and olive oil, may dramatically reduce the risk of certain fatal heart attacks. In particular, eating two servings per week of fish that contains omega-3 fatty acids, such as salmon, trout, mackerel, and albacore tuna, has been strongly linked to a lower risk of death in people who have had heart attacks. And in at least one study, fish oil supplements (about 1000 mg per day) also helped prevent certain heart-related deaths. Other good sources of omega-3 fatty acids include flaxseed oil and walnuts.

Alcohol in Moderation

If you already drink, you will be happy to know that for many people, moderate drinking has heart benefits. But if you have high triglycerides, it's usually recommended that you avoid alcohol. People with heart failure also need to avoid alcohol because it can decrease the heart's pumping function. Drinking too much can contribute to other health problems, too. So, moderation is important, which means no more than one ounce per day for men and 0.5 ounce per day for women and lighter weight men. Take time to find out if alcohol is safe for you and your heart.

Exercise and Cholesterol

Exercise can help increase HDL (good) cholesterol levels. It also helps lower blood pressure, helps maintain a healthy body weight, and many people find it helps them manage stress.

Cholesterol-Lowering Medication

Some people can't reach their target cholesterol levels with diet and exercise alone. Medications called statins are often prescribed to further reduce cholesterol levels. Other medications, such as fibrates or nicotinic acid may be prescribed for some people, either instead of or in addition to statins.

Controlling Blood Pressure

Blood pressure is the amount of force your bloodstream exerts against the walls of your blood vessels. Over time, if high blood pressure (hypertension) goes untreated, it can harm the heart and blood vessels, which increases the risks of coronary artery disease.

What should your blood pressure goal be?

- Less than 140/90, if you have coronary disease
- Less than 130/80, if you have diabetes

Regular exercise is one of the most effective ways to lower blood pressure. For some people, daily exercise may be as good as medication for lowering blood pressure. But many people also need medications. ACE inhibitors, beta blockers, and calcium channel blockers, as well as other medications, help lower blood pressure. Some of these medications have other benefits, such as helping to stabilize plaque. ACE inhibitors and beta blockers can reduce the risk of heart attack and death from coronary artery disease by about 25% or more in some people.

Quitting Smoking

If you smoke, quitting is one of the best ways to reduce your risk of future heart problems. People with coronary disease who continue to smoke face a much higher risk of heart attack and other heart problems. Within about a year of quitting smoking, heart risks drop by about 50%.

Now, maybe you've tried to quit smoking before. Most people try several times before they succeed. Here are some proven ways to help you quit:

- Nicotine replacement therapy – the nicotine patch, chewing gum, lozenges, or nasal spray
- Prescription medication called buproprion (Zyban)

Up to 30% of people who use these methods while taking part in support groups are successful at quitting smoking.

Managing Exercise and Stress

Daily exercise is one of the most important lifestyle changes for people with coronary artery disease. Getting 30 minutes of exercise most days of the week can help lower blood pressure, keep weight within a healthy range, and relieve stress.

The best place to begin an exercise program is under the guidance of coronary disease specialists, such as the nurses and providers at a cardiac rehab or wellness program.

There are many different ways to fit exercise into your life. A brisk walk, gardening or yard work, dancing and other activities that you might already do also count as exercise.

Stress

Exercise also helps relieve stress. Stress doesn't cause coronary disease but it does affect the body in ways that can make it harder to manage. It can increase stress hormones that affect the heart and blood vessels, increase blood pressure, make the heart work harder, and may even affect cholesterol levels.

There are many stress – reduction techniques. Here's one of the easiest.

- Sit or lie with a pillow at the small of your back.
- Breathe in or out slowly, pushing your belly out as you breath in.
- Exhale slowly, and let your belly relax.
- Repeat 10 times with slow, deep breaths.
- Practice several times a day.

What's in it for You?

So, what's in it for you? How much benefit might you get from taking medications, managing your cholesterol and blood pressure, quitting smoking, or exercising regularly? In part, it depends on your risk of future heart problems, such as heart attack, heart failure, or needing a procedure such as angioplasty or bypass surgery. And that risk depends on a number of things:

You're at higher risk if:

- You have had one or more heart attacks, especially if a previous heart attack damaged a lot of heart muscle
- You have diabetes or heart failure

You're at lower risk if:

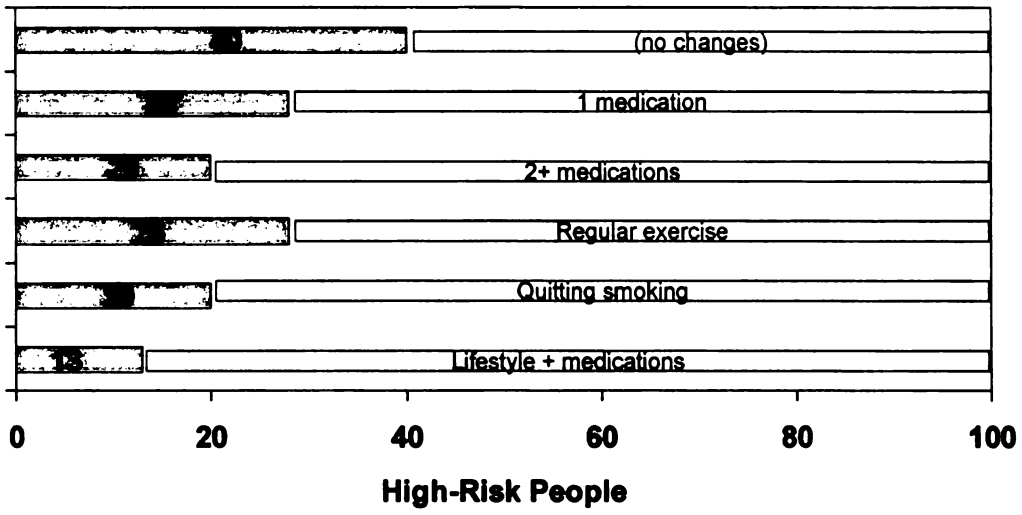
- You have not had a heart attack, or a previous heart attack did not damage a lot of heart muscle
- You do not have diabetes or heart failure

If you're at higher risk, you have more to gain. If you are at lower risk, your benefit will be smaller. In either case, what's in it for you also depends on how you feel about the tradeoffs involved in making changes. In the tables on page 113, you can review the numbers for people at high and low risk of future heart problems. The darker grey part of the bars show how many people will have a heart attack or die of heart-related causes within 5 years. The lighter grey shows how many people will not.

Whether you are in the higher-risk group or the lower-risk group – or somewhere in between – you can reduce your chance of future heart problems. But you have more to gain if you are at higher risk to start with.

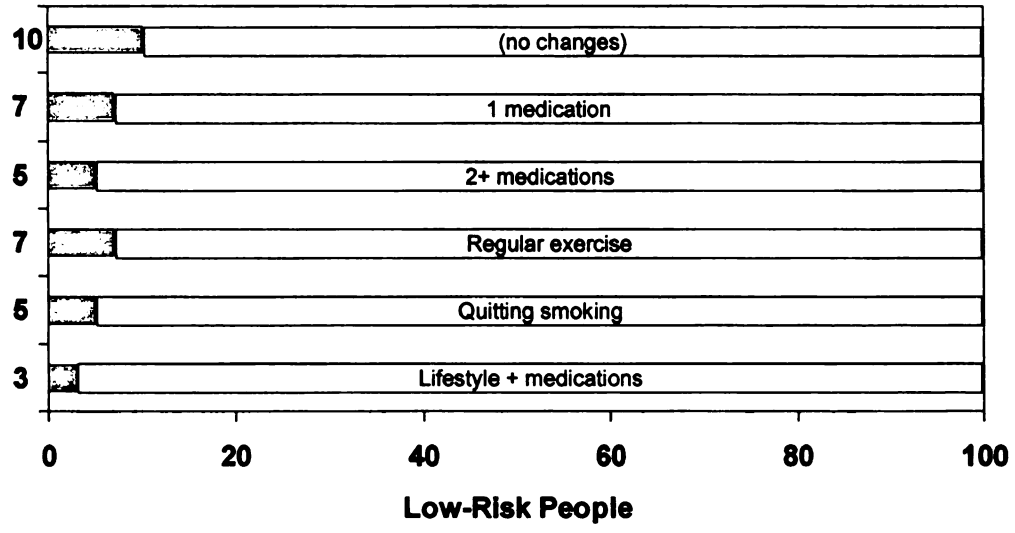
Chance of Heart Attack or Heart-Related Death Within 5 Years (%)

Effect of Medications and Lifestyle Changes (Exercise, Healthy Diet, Quitting Smoking)



Chance of Heart Attack or Heart-Related Death Within 5 Years (%)

Effect of Medications and Lifestyle Changes



What's Best for You?

How much you stand to gain also depends on what's important to you, and what tradeoffs you are willing to accept now in exchange for possible benefits in the future. Everyone's different.

For some people, the right choice means making all the changes mentioned in this booklet and video. For others, it means making only those changes that make sense to them. Some people have an easy time making changes. Others find it more difficult. Changing habits such as what you eat, how much exercise you get, and whether you smoke can be challenging. Medications sometimes have bothersome side effects, and remembering to take them every day is hard for some people.

Is it worth it to you to give up some things you enjoy, or do some things you may not enjoy, so that you can live a healthier or longer life? Your doctor would probably say "yes". Doctors feel strongly about lifestyle changes, because every day they see the bad things that can happen to people who have coronary disease. But you are the one who has to make the choices every day – to take the medication, choose healthy foods, avoid cigarettes, or find time to take a walk. So, you have to decide if it is worth it to you. Be honest with your doctor about what you are willing to do, and explain why.

Once you've decided which changes are right for you, look for resources that can help you succeed. The Internet is a good source of information, and some helpful Web sites are listed at the end of this booklet. Your doctor and other healthcare professionals, such as cardiac rehab specialists, can also recommend tools and techniques that can help you get started and help you stay on track.

One final note: You can't control everything about coronary disease even if you make all the changes in this program. People who do all the "right" things can still have heart attacks or need heart procedures – in fact, you probably know someone like that. If it happens to you, it doesn't mean you failed. The important thing is that you don't give up on living a heart-healthy life.

Medical Terms

ACE Inhibitors: Medications that lower blood pressure and help stabilize plaque in the coronary arteries.

Angina: Pain or pressure in the chest, arms, shoulder or jaw, often during exercise or emotional stress. Angina is a symptoms of coronary artery disease. It's caused by reduced blood flow to part of the heart muscle.

Angioplasty: A catheter procedure that compresses plaque against the wall of a coronary artery.

Angiotensin-II Receptor Blockers (ARBs): Medications that lower blood pressure through the cardiovascular and renal systems by affecting salt and water balance.

Arrhythmia: Irregular heartbeat.

Beta Blockers: Medications that lower blood pressure and help prevent irregular heartbeats.

Blood Clot: Blood clots normally help stop blood loss due to injury. A clot that occurs in a coronary artery can cause a heart attack.

Blood Pressure: The pressure of blood against the walls of the arteries. Systolic blood pressure is the amount of pressure when the heart pumps. Diastolic blood pressure is the amount when the heart is at rest between beats.

Bypass Surgery: See Coronary artery bypass surgery.

Cholesterol: A type of fat fond in the blood stream. High cholesterol levels can contribute to the buildup of plaque and increase the risk of coronary artery disease.

Cholesterol Profile: A report on the levels of various types of cholesterol and triglycerides in the blood. Also called lipid profile.

Coronary Artery Bypass Surgery: An operation that takes healthy blood vessels from the leg or chest to reroute blood flow around portions of the coronary arteries that are blocked or narrowed by plaque.

Diabetes: A chronic disease that occurs when blood sugar levels are too high. Diabetes increases the risk of coronary artery disease.

HDL (High-Density Lipoprotein) Cholesterol: The "good" or protective cholesterol. HDL levels above 40 are desirable.

Heart Attack (Myocardial Infarction or MI): Heart attacks occur when blood flow to a portion of the heart muscle is complete blocked by ruptured plaque and/or a blood clot.

LDL (Low-Density Lipoprotein) Cholesterol: The "bad" cholesterol. High levels of LDL cholesterol increase the risk of heart attack. LDL levels below 100 are desirable for people with coronary disease.

Lipids: See Cholesterol.

Plaque: A buildup of calcium, and other substances within the walls of an artery. Plaque in the arteries that supply blood to the heart is called coronary artery. Plaque can also buildup in other arteries such as those in the legs and pelvis.

Platelets: A particle in the blood that is involved in forming blood clots. Some medications act on platelets to help prevent blood clots that can cause heart attacks.

Saturated Fats: A type of fat the body converts into cholesterol.

Side Effects: A secondary, usually unwanted effect or symptom caused by a medication or treatment.

Statins: Medications that lower cholesterol levels and help stabilize plaque. Statins help prevent heart attacks.

Stress: Any emotional or physical factor that causes tension.

Trans Fats: A type of dietary fat that increases LDL cholesterol levels.

Triglycerides: A type of fat found in the blood stream. Triglyceride levels below 150 are desirable.

Unstable Plaque: A type of plaque that has a tendency to break open or rupture, which can trigger a blood clot and cause a heart attack. Medications such as ACE inhibitors and statins help stabilize plaque.

Common Heart Medications

ACE inhibitors	Accupril (quinapril) Aceon (perindopril) Altace (ramipril) Capoten (captopril) Lotensin (benazepril) Mavik (trandolapril) Monopril (fosinopril) Prinivil (lisinopril) Univasc (moexipril) Vasotec (enalapril) Zestril (lisinopril)
Angiotensin receptor	Atacand (candesartan) Avapro (irbesartan) Benicar (olmesartan) Cozaar (losartan) Diovan (valsartan) Micardis (telmisartan) Teveten (eprosartan)
Beta blockers	Betapace (sotalol) Blocadren (timolol) Cartrol (carteolol) Coreg (carvedilol) Corgard (nadolol) Inderal (propranolol) Kerlone (betaxolol) Levatol (penbutolol) Lopressor (metoprolol) Normodyne (labetalol) Sectral (acebutolol) Tenormin (atenolol) Toprol (metoprolol) Trandate (labetalol) Visken (pindolol) Zebeta (bisoprolol)

Calcium channel blockers	Adalat (nifedipine) Calan (verapamil) Cardene (nicardipine) Cardizem (diltiazem) Covera (verapamil) Dilacor (diltiazem) Diltia (diltiazem) DynaCirc (isradipine) Isoptin (verapamil) Norvasc (amlodipine) Nimotop (nimodipine) Plendil (felodipine) Procardia (nifedipine) Sular (nisoldipine) Tiazac (diltiazem) Verelan (verapamil)
Fibrates or fibrinic acid	Clofibrate Lopid (gemfibrozil) Tricor (fenofibrate)
Platelet inhibitors	Aggrenox (aspirin & dipyridamole) Aspirin (many brands) Clopidogrel (Plavix)
Nicotinic acid	Niacor (niacin) Niaspan (niacin)
Nitrates	Imdur (isosorbide) Ismo (isosorbide) Isordil (isosorbide) Nitro-Dur (nitroglycerin) Nitrostat (nitroglycerin)
Statins	Crestor (rosuvastatin) Lescol (fluvastatin) Lipitor (atorvastatin) Mevacor (lovastatin) Pravachol (pravastatin) Zocor (simvastatin)

Resources

American Heart Association National Center
www.americanheart.org
7272 Greenville Avenue
Dallas, TX 75231
1-800-AHA-USA-1
(214) 373-6300 or contact your local chapter.

The American Heart Association provides print, video, and Web-based materials on all aspects of coronary artery disease. Some materials are available in Spanish.

Mended Hearts is a support organization affiliated with the American Heart Association. Local chapters provide help, support, and encouragement to heart disease patients and their families.

National Heart, Lung, and Blood Institute (NHLBI)
www.nhlbi.nih.gov

The NHBLI Web site provides information on coronary artery disease, including high blood pressure, cholesterol, exercise, heart-healthy eating, and weight control. Some materials are available in Spanish.

FDA Heart Health Site
www.fda.gov/hearthealth

This site provides information about products used to prevent, diagnosis, and treat coronary artery disease.

Check with your doctor for resources other than those listed above.

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