DESIGN AND DEVELOPMENT OF A CORONARY HEART DISEASE DECISION SUPPORT TOOL

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Abstract

We are developing a decision support tool to help clinicians and policy makers estimate the impact of various coronary heart disease (CHD) treatments on disease outcomes for populations. We have created seven modules that correspond to states commonly encountered with CHD, that is, congestive heart failure, tachyarrhythmia, stable angina pectoris, acute coronary syndrome, bradycardia, postmyocardial infarction, and postcoronary artery bypass grafting, and a healthy individual module. Within each module, we created event-decision- intervention-outcome flow pathways to simulate risk of a clinical event and the expected outcome as the result of a particular intervention. We will combine disease state probability estimates based on the experience of the Olmsted County, Minnesota, population and estimates of intervention efficacy based on clinical trial data to estimate the impact of interventions on a population. We plan to make this tool available to the public through the internet.

Keywords: Stochastic process, Coronary heart disease, Biomedical technology assessment, Computer simulation, Forecasting

There are more than a dozen interventions of proven efficacy that improve outcomes when applied along the continuum of coronary heart disease (CHD) risk and clinical events (see Table 1). These range from preventive interventions like treatment of at-risk, healthy individuals with HMG Co-A reductase inhibitors (statins) or angiotensin converting enzyme inhibitors to implantable defibrillators for individuals who have experienced ventricular fibrillation and cardiac transplantation for individuals who are dying of congestive heart failure. These interventions are applied at different stages of the disease, are applied to differing proportions of the population, and are of varying levels of efficacy. Without decision support tools, it is difficult to estimate their impact on populations. For example, an intervention that might be interpreted as weak, for example, a 10 % lowering of total serum cholesterol, has been shown to have a far greater expected impact on population mortality rates than interventions that might be interpreted as much more powerful, for example, implantation of automatic defibrillators or heart transplantation (5). Although simulation

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Table 1. Interventions for Prevention and Treatment of Coronary Heart Disease That Will Be Included in the Model

- Resuscitation from out-of-hospital cardiac arrest
- Coronary artery bypass graft surgery
- Rescue angioplasty during acute myocardial infarction
- Pacemaker insertion
- Thrombolysis
- Glycoprotein IIb/IIIa inhibitors for acute coronary syndrome
- Aspirin and heparin for acute coronary syndrome
- Beta-blockers for acute coronary syndrome
- Beta-blockers after myocardial infarction
- Aspirin after myocardial infarction
- Smoking cessation
- Advice to quit smoking
- Treatment of elevated blood pressure
- Dietary change to improve serum lipid levels
- Pharmacologic treatment of elevated serum lipid levels
- ACE inhibitors for left ventricular dysfunction
- Beta blockers for left ventricular dysfunction
- Cardiac transplantation
- Automated external defibrillators
- Pacing cardioverter devices
- Daily physical activity

has been used to estimate the impact of risk factors and treatment interventions on disease incidence, prevalence, or outcomes, none of the software is available to the public for use as an interactive planning resource. In this document, we describe our progress toward creating a valid decision-making tool that will be publicly available to assist the medical and health policy community in the effective and cost-effective application of CHD prevention and treatment interventions.

DEVELOPMENT OF THE MODEL

Our goal is to design and develop a tool that informs policymakers, clinicians, and researchers about the probable population effects of CHD treatments. To create this tool, we divided the universe of possible CHD events and treatments into eight "modules," each one a distinct decision model for a specific condition that may be encountered by a patient and clinician. Each module relates to a clinically important state of presenting symptoms or events: (1) Healthy Individual, (2) Congestive Heart Failure (CHF), (3) Tachyarrhythmia, (4) Stable Angina Pectoris, (5) Unstable Coronary Syndrome, (6) Bradycardia, (7) Postmyocardial Infarction (MI), (8) Postcoronary artery bypass graft surgery (CABG). We have created a flow chart of decisions, interventions, and outcomes for each module. The modular, flowchart design not only allows us to define the treatment decisions and outcomes for specific conditions, it allows us to modify the decision support tool as the availability of interventions and indications for use change.

Every node (i.e., box) in each module has at least one probability associated with it (see Figure 1). For example, in Figure 1 (a typical module), node 1.8 asks whether a CHD event occurs for the healthy individual. To answer that question, each possible pathway out of node 1.8 (i.e., 1.8.1 through 1.8.7) has a definable probability of occurring and these probabilities sum to 1.0. Depending upon the node, the probabilities, or model parameters, are the likelihood of having specific demographic characteristics (e.g., age, gender), risk factors (e.g., smoking status), disease prevalence, treatment candidacy, treatment application, or treatment efficacy. Setting the parameters for each node in the model defines a set of probabilistic decision rules for determining CHD events for a person of a particular gender, age, and combination of risk factors.

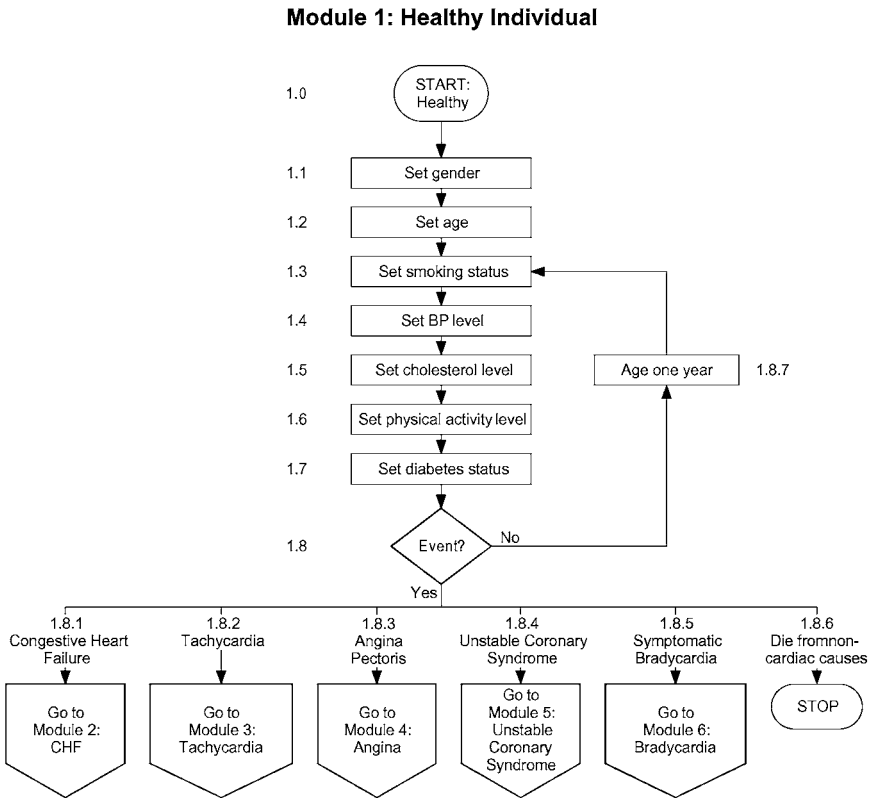

Figure 1. Module 1: The Healthy Individual Module. The Healthy Individual Module is typical of all 8 modules. The module allows the levels of all parameters related to the outcomes in the module to be set. The possible outcomes in the module are both exclusive and exhaustive. That is, one and only one outcome is possible at each decision node.

We simulate development and progression of CHD in a defined population by summing the experience of individuals over a period of years. Such a simulation "run" will involve the following steps: (1) create a simulated population of a specified size and demographic make-up by randomly assigning demographic and risk characteristics (e.g., age, gender, cholesterol level) according to desired distributions; (2) run each individual in the population through the treatment model, making decisions probabilistically according to the node parameters that have been set; (3) age each individual in the population by one year; (4) repeat steps 2 and 3 for as many years as desired (typically 20 to 40); (5) extract desired outcome measures (e.g., prevalence and mortality rates by age, gender) from the simulated population; (6) perform steps 1 through 5 many times. This process generates a distribution of outcome values with a known mean and variance. By varying the parameters of the model, we can isolate and test the effect of different interventions in a population.

Parameter estimates will come from several sources. We are using risk functions from the Framingham study (1;4) to simulate the impact of risk factor levels on the probability that there is a transition from healthy to diseased. The Rochester Epidemiology Project (3) will allow us to generate population-based event probabilities for events such as out-of-hospital cardiac arrest, incidence of congestive heart failure, and acute coronary syndrome. We will use the clinical trial literature to set the parameters that define the probability that an intervention will be successful. When data from clinical trials are not available, we will use cohort or case-control data. Where no empirical data are

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available, we will estimate parameters based upon the informed opinions of experienced cardiologists.

We will subject all parameter estimates to sensitivity analysis by testing error ranges (when known), reasonable ranges, and theoretically bounded ranges. The purpose of the sensitivity analysis will be to test whether conclusions are sensitive to observed or plausible differences in disease incidence rates, levels of intervention application, and rates of intervention efficacy. Parameters whose exact values do not significantly affect the final outcomes can remain as the estimates used in the preliminary model, regardless of their source or quality; more sensitive parameters may require further research. As we complete parts of the computerized model, we will be able to use simulated populations matching the proportion of age, gender, and risk factors of Olmsted County, Minnesota, to test the validity of the model. By aging this population within the model and comparing the model incidence and mortality rates to those observed in Olmsted County, problems with the model can be identified, analyzed, and corrected.

DISCUSSION

We are developing a decision support tool that permits comparison of multiple primary and secondary interventions, and we plan to make the tool available through the Internet. This tool will become increasingly valuable as health care resources become increasingly scarce and the need for rational application of health resources increases (2).

We face several challenges in developing the tool. The software is complex and requires that sufficient computer power is available. However, our experience indicates that modern desktop computers are sufficient to handle the computing tasks. The model must be amenable to change as new technologies are introduced and new indications are introduced for technologies that are already available. The modular design of the model makes this possible. Perhaps the biggest challenge is to define the model parameters. We are aware that reliable data may not be available for all subsets of the population. This awareness may be true both for a particular state probability and for the probability that an intervention is successful when applied to an individual in that state. When reliable data are lacking, we will have to rely on expert opinion. We will subject all probability estimates to sensitivity analysis.

Our eight-module model is limited by simplifying assumptions, and our experience with model building indicates that we need to start with a model that addresses problems that can be solved and that provides answers that can be understood. Once we achieve this level of modeling, we can increase the complexity of the model as needed. We also plan to address cost, quality of life, and individual preferences with the decision support tool in the future. Although the issues discussed above indicate that the development of our proposed model will be challenging, we believe that development of the decision support tool is not only possible, it is essential if we are to have informed decision making as we try to prevent and treat coronary heart disease.

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