Cardiology, Health Care Reform, and a New Treatment System

A White Paper

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Introduction

Today's discussion about health care reform is driven by escalating costs and occurs against a challenging background of economic, political, demographic, and medical issues and questions. Behind this discussion is the widespread recognition that, for better or worse, the practice of medicine and how it is paid for will change significantly in the coming years.

Today nearly 47 million Americans are uninsured or underinsured for health care, an issue that the Obama campaign used effectively to argue for political change during the 2008 campaign. The current recession has only heightened awareness and concern over the future of health care, as the number of uninsured increases with each round of layoffs and business failures.

All these factors highlight the need for new approaches that could slow or halt the rapid rise of health care costs, making this an appropriate time to consider the role that innovation should play in reshaping the American healthcare system.

This white paper describes one such innovation in detail, a new approach to the management of coronary artery disease (CAD). The method proposed, if implemented widely, has the potential to reduce the direct and indirect costs of CAD treatment in the United States by $41 billion per year, from $165 billion to $124 billion per year, while at the same time providing patients with better care, and providing physicians with greater control over the treatment they provide to their patients.

These savings will come primarily from three changes in how CAD patients are treated:

1. A significant reduction in unnecessary Emergency Room (ER) visits and hospitalizations for patients experiencing recurrent cardiovascular symptoms,
2. More effective control of cardiovascular symptoms by meticulous drug treatment, and
3. A reduction in the frequency of acute coronary syndromes (ACS) through preventive drug treatment.

The principles underlying this approach may also be applicable to many other chronic conditions including stroke, pulmonary disease, and cancer, suggesting that significant cost savings across a wide spectrum of chronic conditions may be readily achievable.

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Reformulating American health care to be more accessible and cost-effective addresses three of the major problems that affect health care delivery in general. We will examine them here in the specific context of coronary artery disease:

1. An inflexible, inefficient and costly mode of care delivery,
2. A paucity of health information tools (HIT) in treatment practice, and
3. A disconnect between the processes of care delivery and outcomes analysis.

The public, the medical profession, and policy makers have all expressed support for reform that provides quality health care without compromising the traditional doctor-patient relationship, if it can be done at lower cost than the present system allows for.

From the author's point of view this is not merely a theoretical exercise, as the proposed system for treating CAD that is described in this white paper already exists, and it has proven remarkably effective in achieving cost reductions of 50-80% in trial patient populations. All indications are that the system is readily scalable and could address these issues on a national scope.

Part 1:

The Present System Of Care For Patients With Coronary Artery Disease

The experience of patients with established coronary artery disease (CAD) provides a window into the broader American health care system. CAD is a common and chronic condition that affects about 17 million Americans (1), and many of the systemic issues that affect CAD patients are also pertinent to other chronic medical conditions.

The costs and consequences of CAD are significant. More than 1.2 million Americans experience a heart attack annually, and 150,000 of these die (11). Treatment of CAD carries an annual price tag of approximately $165 billion (1).

To create cost-effective alternatives to the present system of care will require not only an understanding of the biology of the disease, but also a deep understanding of the system that is used to treat it. A brief summary of the biology is presented below, followed by a detailed discussion of the treatment system, and then a proposed solution.

The Biology of Coronary Artery Disease

Coronary artery disease (CAD), also known as coronary atherosclerosis, results from an accumulation of plaques, similar to fat-filled blisters, on the inner lining of the coronary arteries that nourish the heart. The symptoms of CAD result from the plaques that impede blood flow.

The slow accumulation of plaques reduces the effective diameter of coronary arteries to the point that the heart does not receive sufficient blood flow. This restriction, known as myocardial ischemia, is clinically manifest as angina pectoris, which patients experience as a squeezing discomfort in the chest that occurs during exercise, and is relieved by rest.

The plaques may also rupture their fatty contents into the coronary arteries, which causes total or near-total interruption of blood flow to the heart. This is associated with chest discomfort similar to that of angina pectoris but generally more severe and unrelenting, and often associated with faintness, nausea, and shortness of breath.

If the resulting oxygen deficiency is prolonged, it irreversibly damages the heart muscle, resulting in myocardial infarction or heart attack. Individuals experience these symptoms in varying degrees, constituting a clinical spectrum ranging from transient angina pectoris to severe heart attack. The spectrum is described in the medical literature as "acute coronary syndrome" or ACS.

Treatment of CAD

While the health care system suffers from a general lack of coordination between health care providers, no aspect of health care delivery better exemplifies the need for coordination than the management of patients with CAD. In the Emergency Room (ER), physicians routinely manage acute cardiovascular issues in patients with whom they are unfamiliar and whose Primary Care Physicians (PCPs) and cardiologists usually do not participate in the decision making process during emergency treatment (2). Further, the medical data that are readily available in the PCP's office or the cardiologist's office are generally unavailable to ER staff (3) .

As a result, medical histories and lab results are deficient or entirely missing for nearly one-third of patients who arrive at the ER. In about half of all cases, these data are essential to care , and these information gaps result in delays in hospital care for ACS patients, and poorer treatment outcomes (4).

Many patients with established CAD who are clinically low risk are nevertheless hospitalized because ER physicians are concerned that these patients will fail to undergo follow up evaluation (5) or visit their regular physicians in a timely manner following discharge

The transition from hospital to home following treatment of ACS also has gaps. There is a general lack of communication between ER and hospital physicians and the patient's PCP (6). Because the physicians who provide hospital care are often different from those providing post-discharge care, and there is no electronic medical record system in place (EMR), follow-up risk assessments are often omitted, prescriptions lapse, tests are not ordered or followed up, and patients are often discharged with inadequate medication regimens (6).

Three Fundamental Problems

This situation exposes that the "system" as it presently operates embodies three fundamental problems.

Problem 1:
Inadequate Mode of Care Delivery

The most significant fundamental shortcoming of the present system is that it relies on the patient to visit a health care facility such as a clinic or ER for all their care. Because "the visit" enables the patient and physician to interact in person, and for the transaction to be recorded, it has become the basic unit of health care delivery. But total reliance on these visits is systemically inefficient, costly, and ineffective.

An astute observer of systems once noted that you can discern the structure of a system by following the trail of the money. In this regard, "the visit" is essential to the physician because that is how the physician is paid. From the physician's point of view, queuing of patients for visits is the most efficient way to maximize billable hours, and promotes a constant flow of clinically stable patients to the outpatient clinic, while providing the side

benefit of encouraging clinically unstable (and therefore disruptive) patients to go elsewhere, i.e., to the ER.

This is not to disparage the idealism or dedication of physicians; it is, however, an indictment of a system of care that has oriented itself over the last forty years to providing a steady cash flow to medical professionals as a primary system objective.

From the vantage of the patient, the visit represents an inflexible, inefficient, and costly experience. It is the patient who queues, not the physician, and while the needs of the patient may span a broad range, from elective advice to urgent intervention, the format of the visit itself is astonishingly inflexible.

From the vantage point of society as a whole, the inflexible nature of "the visit" is a significant driver of escalating health care costs, because it effectively requires all patients in need of urgent care to go instead to the ER, where the cost of treatment is much higher.

In the case of CAD, however, fully half of all patients with suspected ACS who visit the ER are discharged home following evaluation, meaning that they didn't need to come to the ER in the first place

Further, among the half who are hospitalized, a heart attack is documented in fewer than 20%, or ten percent of the total (7). While the ER visit is entirely appropriate for patients who are high risk, it is needlessly complex, inconvenient and expensive for the majority of patients, who are at moderate or low risk. At present, however, there is no way to screen patients between low, moderate, and high risk prior to the ER visit, so everyone ends up there, half of them unnecessarily.

From a systems perspective it is obviously inefficient to process 100 patients through the ER, a time consuming and very costly process, to identify the 10 who are experiencing a heart attack.

For every 100 CAD patients who visit an Emergency Room, an additional 20 who experience cardiovascular symptoms choose *not* to visit the ER and these self care decisions are frequently incorrect. Why incorrect? Patients at high risk of death or nonfatal MI, require immediate treatment, yet many delay seeking care and many of them die (8). Those who delay treatment experience suboptimal outcomes of percutaneous coronary interventions and thrombolysis (9).

Despite numerous large public health campaigns focused on reducing the time delay between the onset of symptoms and patients' arrival in the ER, this interval has not diminished in twenty years (10). This tells us that systemic issues related to the ER experience, such as overcrowding, are inhibiting some people who do need care from promptly seeking it (11). From all this we see clearly that the system is producing adverse outcomes for a significant percentage of patients, and for society as a whole.

Problem 2:
Lack of Health Information Technology (HIT) in American Healthcare

In addition to the issues described above surrounding the visit and the lack of access to telephone support, there is also the topic of medical records to address. Fewer than 15% of American physicians had implemented an electronic medical record (EMR) for outpatient care by 2005 (12) and fewer than 25% of hospitals had implemented an EMR by 2008 (13). And even when electronic medical records are in use, the clinic, ER and hospital operate autonomously, without coordination between them.

Wide scale implementation of HIT offers the potential to improve the quality and enhance the cost-effectiveness of American health care, but it cannot achieve these goals unless we also change the process of care delivery by making full use of the information captured by HIT from all healthcare venues, including the home, throughout the care process.

The guidelines that have been incorporated into HIT primarily concern care provided in hospitals. Few guidelines have been developed for treatment of outpatients, and fewer still for patients in their homes, even though the home is where people spend 50-90% of their time, and where the onset of symptoms usually happens. Any systematic approach to HIT will therefore need to address these coordination problems, as well as the necessity of using HIT in the home, as we have done with the Stanford CMS System.

Problem 3:
Disconnect Between Healthcare Delivery and Outcomes Assessment

The third key problem is that the results of care delivery are not measured effectively. The objective of cost-effectiveness analysis is to guide allocation of resources, but this type of analysis is not widely used outside of hospitals, largely because the health care system lacks the resources and staffing for ongoing, systematic capture and analysis of data about healthcare costs and outcomes.

Because the Stanford CMS System is an integrated HIT application, it readily incorporates sophisticated analytics.

Summary of Part 1: Treating CAD: The Failure of the Current System and the Attributes of an Ideal System

With tongue only slightly in cheek, let us now restate the problems and offer some solutions:

1. All clinical strategies for managing ACS begin when a patient experiencing symptoms of chest discomfort reports his or her symptoms.

   A patient experiencing a heart attack requires immediate evaluation in a facility equipped to provide cardiac defibrillation and the full range of diagnostic and treatment options, and thus there is no practical alternative to an ER visit.

   After recovering from the heart attack, the same patient rarely requires an office-based follow up evaluation because the diagnosis has already been established and treatment is focused on preventing another heart attack.

2. If this post-hospitalization patient does experience any symptoms of discomfort, a simple telephone contact with the cardiologist would quickly establish the need for additional diagnostic tests or a change in the medical regimen.

   But contacting the cardiologist by phone is presently not an option. Instead, every patient is routinely herded into a queue for a follow up visit at a future time, because this is the only option for continuing surveillance. If the patient remains clinically stable until the time of the office visit, the medical rationale for the visit (other than reassuring the patient and the physician) is nonexistent. But if the patient experiences recurrent symptoms prior to the scheduled follow up visit, then there is no alternative to a repeat visit to the ER.

   In an ideal system, the patient could immediately contact the cardiologist by phone to determine if a visit to the ER is actually required (which, as noted above, is not needed in 50% of all cases).

3. One reason that the patient's cardiologist is unavailable by telephone (which could eliminate the need for an ER visit) is because he or she is already committed to meeting with patients in the clinic queue, most of whom are clinically stable. In effect, then, patients who are clinically stable displace those who may require immediate attention to their needs.

   In the ideal system, clinically stable patients would not need to visit the clinic.

4. Patients are presently left to their own devices to decide whether their symptoms are life-threatening, requiring an ER visit, or simply a recurrence of non-threatening symptoms they have previously experienced.

   In an ideal system, any patient experiencing symptoms could get immediate advice concerning their symptoms without visiting the ER.

5. Even if a patient were to reach his or her cardiologist by telephone, the cardiologist would probably not have immediate access to the patient's medical record, and would not therefore be in a position to propose a course of treatment.

   A HIT system should be universally accessible.

6. Patients who follow recommended procedure and elect to visit the ER out of concern that they are suffering from a potentially life-threatening cardiac problem must compete for the attention of ER staff with a large number of other cardiac patients, approximately half of whom (unbeknownst to themselves or the staff) are not in fact suffering from an urgent condition (14).

   Screening out those who don't need to be there would be a big improvement for everyone.

7. As individual patients are unknown to the ER staff, it is necessary to undertake a costly cardiovascular evaluation for each one, generally in the absence of the patient's medical record.

   The ER staff should have access to each individual's complete records to avoid unnecessary procedures, costs and delays in treatment.

8. Conversely, patients experiencing cardiovascular symptoms who elect not to seek ER care are in fact at risk for death or nonfatal MI. Statistically speaking, those who delay in seeking ER care experience worse health outcomes than those who arrive soon after the onset of symptoms.

   If these people could get sound advice by phone, they would immediately decide to go to the ER to receive needed treatment.

9. Because ER physicians are generally unfamiliar with the individual patients, and also lack access to their medical records, they are inclined by caution to hospitalize every patient presenting with almost any cardiovascular symptoms, even though the actual risk of a heart attack is about 10%.

   Better information about individual patients will enable ER physicians to avoid unnecessary hospitalizations.

10. The ER physician also generally chooses hospitalization because he or she lacks confidence that patients who were discharged home would actually undergo the recommended tests, treatments, and follow up visits with their physicians. In addition, their subsequent telephone contact with patients is limited or nil.

    If they were assured that patients would receive effective follow up care from their primary physicians, ER physicians could feel confident that hospitalization was unnecessary, thus avoiding significant costs.

It is therefore no exaggeration to characterize this "system" as an unintended comedy of errors that is inevitably prone to progressively escalating costs, even without showing any historical improvement in treatment outcomes over the last twenty years. It is unsustainably expensive and dramatically underperforming. Indeed, it is high time for a thoughtful, systematic redesign.

Part 2:
A New Treatment System

To begin a redesign we should make sure that we're focusing on the right questions.

The current system derives its data on ACS based on visits to the ER. The published literature therefore addresses the question: "What was the outcome of patients presenting to the ER for evaluation of suspected ACS?"

But chest discomfort experienced by a patient who does not present to the ER for evaluation goes unrecorded unless it is reported during a clinic visit at a later time. Since those who did not visit the ER are not included in the data, the data themselves must be considered suspect.

Hence, a more salient question is: "What was the outcome of patients experiencing symptoms of suspected ACS, irrespective of whether they visited the ER or not?"

This tells us that the present operation of the health care system is informed by a one-dimensional experience: it knows only about those individuals who enter its field of vision, and its field of vision is limited to the ER.

The conversation above describes the rationale for an approach that the current system does not allow for, a three-tiered treatment strategy designed to provide better care for patients at lesser cost to themselves and society as whole.

First, primary prevention of CAD is achieved by addressing and mitigating the key coronary risk factors, physical inactivity, hypertension, hyperlipidemia, and smoking.

Second, treatment of those whose initial manifestation of CAD is in the form of cardiac arrest is achieved through traditional measures, such cardiac defibrillation, ER visits, and hospitalization.

These are the accepted methods of treatment.

The third aspect is different, as it concerns what happens after patients are treated and released from the hospital.

As presently understood, the mission of the hospital is to provide excellent care on its premises, while the mission of the physician is to provide continuity of outpatient care. But because patients are often treated by many physicians during hospitalization, this sometimes leads to miscommunication between the hospital-based physicians and those responsible for follow-up care (6). As hospitals have no obligation to coordinate follow-up care, the patient's regular physician(s) may or may not receive a discharge summary from the hospital.

Because ERs provide no systematic follow-up, the onus is on the patient to call the ER or return to the ER in the event of a subsequent problem. ERs are also under no obligation to contact the patient's physician to apprise him or her of the patient's ER visit. Consequently, the patient's physician is likely to remain unaware that the patient has visited the ER unless the patient broaches the topic.

For the patient who suffers recurrence of symptoms, the only option is to ignore the symptoms, which is risky, or return to the ER.

Given these gaps in communication, can we design a system to provide more proactive care for ACS patients following their initial treatment and discharge? Can we eliminate 1.2 million unnecessary ER visits each year, costing $7.2 billion dollars, and 600,000 unnecessary follow-on hospitalizations costing an additional $7.2 billion?

In our ideal model, patients have access to expert telephone advice 24 hours a day so they can receive immediate advice whenever they experience symptoms or have a question or a concern that is not specifically symptom-related.

On the other end of the phone line is a trained nurse care manager who uses a sophisticated medical information system to record all the information provided by the patient. This system incorporates a diagnostic algorithm, developed in accordance with guidelines developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) (15-16), that has proven to be effective at distinguishing those who need emergency care at the ER from those who do not.

The system is much more than a phone, a nurse, and a computer, as it engages all of the participants in the medical care system in an integrated manner. We will describe it in detail below, but first let us note that in the system tests conducted to date, this approach permits the 80% of patients experiencing recurrent chest pain who do not require hospitalization to be distinguished from the 20% who do. This means that the entire population of patients experiencing cardiovascular symptoms can be triaged from home. Accordingly, low and moderate-risk patients avoid the inconvenience of an ER visit while high risk patients receive the undisputed benefits of ER and hospital care.

We have developed a system that provides better care for patients, greater control for physicians, and at considerably less cost. It effectively addresses the difficult convergence of economics, politics, demographics, and medicine mentioned at the beginning of this white paper,

The Care Management System

In 1998, investigators at the Mayo Clinic established that patients with unstable angina at moderate risk of death or nonfatal MI could be safely evaluated in an outpatient Chest Pain Unit (CPU) rather than in the Emergency Room (17). Experience has shown that patients reporting chest pain who are classified as having a low risk for death or nonfatal MI can be advised to undergo outpatient evaluation within 72 hours in lieu of an ER visit (15).

To date, no system is widely used that effectively applies these decision rules to the entire population of patients with suspected ACS while they are at home, but given that Americans now have an abundance of communication tools, including cell phones, computers, and the ubiquitous internet, we now have the means to correct this situation.

If patients with suspected ACS could promptly contact their physicians by telephone, they might be advised to make an office visit on the same day or in the near future instead of going to the ER.

The Care Management System (CMS) developed at Stanford University has shown conclusively that a telephone consultation or a visit to a same-day clinic could safely replace an ER visit in a high percentage of cases. The resulting benefits in terms of cost saved and enhanced quality of care are significant.

CMS is designed to reduce the personal and systemic barriers that prevent patients from initiating a prompt call for medical help. It provides an immediate, medically well-informed risk assessment of a patient's condition, and indicates appropriate treatment options within a triage risk model.

For those patients who are routed to the ER or a same-day clinic, it provides proactive coordination of care by preparing the medical staff for the patient's arrival. Finally, it enhances the continuity of care during the months following discharge from the ER or same-day clinic.

The CMS Process

From the patient's point of view, CMS begins with a baseline telephone instructional session conducted by a nurse care manager. This session is focused on training patients to recognize their own cardiovascular symptoms, and on encouraging strict adherence to necessary medications.

Patients also receive printed instructional materials and view an instructional DVD explaining how CMS operates. Family members and caregivers are strongly urged to participate in this learning process.

Patients are also instructed to initiate a simulation telephone contact with the nurse care manager during clinic hours in the two weeks following the baseline telephone contact. This simulation is designed to enhance the patient's capacity to master the most important element of the intervention – initiating a prompt telephone call for help.

To facilitate immediate telephone access to CMS, patients who own a cell phone are urged to carry it at all times, and are also are advised that emergency crews responding to 911 calls may require a land line connection with the caller.

Finally, the nurse care manager works closely with patients' physicians to ensure that patients are prescribed combination pharmacotherapy (aspirin, beta blockers, statins, ACE inhibitors) and nitroglycerin in accordance with ACC/AHA guidelines (6) and assists patients to achieve optimal doses of these medications.

The nurse care manager routinely follows up by telephone each month for the following three months, and quarterly thereafter, to make sure that each patient's medical status is stable.

During these contacts, the nurse care manager evaluates patients' symptoms, reviews their medications, and captures information about any clinic, ER visits, or rehospitalizations that occurred since the previous telephone contact. These data are then recorded electronically in the CMS system. The nurse care manager subsequently

contacts physicians, ERs, or hospitals to obtain copies of the latest electrocardiogram for scanning and uploading to the CMS clinical database.

Patients are encouraged to initiate telephone contact with CMS staff at any time to report symptoms of concern.

Patients are provided with a 1-800 telephone number that connects them to CMS. The nurse care manager and program cardiologist consult in person or by phone regarding the disposition of each patient initiating a symptom-related telephone contact with CMS. Both have immediate access to the patient's updated medical record, and the patient is an active participant in the decision-making process.

In every situation, patients always have the option to call 911 in the event of a perceived emergency.

Advice provided to patients by the CMS team is based on the patient's risk of death or nonfatal MI, as assessed by a standardized treatment algorithm created by the ACC and AHA (15-16) that is incorporated into the CMS decision support system. Additional algorithms developed by expert groups are also incorporated into the CMS database. These algorithms address not only ACS, but also conditions that simulate ACS, including aortic dissection and pericarditis, and those that accompany ACS, including stroke/transient ischemic attack and heart failure.

A decision support system incorporated into the CMS database provides additional assurance that patients' symptoms are systematically evaluated. When a patient calls, CMS staff ask a series of pertinent questions as prompted by the patient's symptoms. , Fewer than 5-8 minutes are required to establish a provisional diagnosis and a recommended disposition for each patient.

Patients classified as low risk are advised to remain at home, pending an immediate follow up telephone contact from CMS staff who have, in the meantime, consulted with their physician(s) by telephone to arrange for follow up and treatment. In the event that CMS staff are unable to contact the patient's physician within 10 minutes, they immediately call back to advise the patient to call 911 for transport to the ER.

Patients classified as moderate risk are scheduled for a same-day clinic evaluation by their cardiologist. The visit is arranged by the CMS nurse care manager, who provides clinic staff with updated medical data, including the most recently recorded ECG.

Patients classified as high risk are advised to call 911 for transport to the ER. The ER staff are apprised of the patient's imminent arrival, and are provided with updated medical data that foster more prompt and effective care (19-20).

The nurse care manager telephones the patient and the physicians caring for him or her as frequently as needed to assure that the patient's problems have been resolved. In addition, the nurse care manager calls all patients 24 hours after the initial telephone contact to reassess their current medical status and provides patients' physician(s) with a computer-generated Interval Status Report summarizing the care provided throughout the episode of illness.

In our pilot studies, CMS permitted prompt treatment of patients at moderate or high risk of death or nonfatal MI and provided greater convenience for the low-risk patients who were advised to remain at home, all without detriment to their safety

The Cardiologist

The cardiologist oversees the operation of CMS, providing quality control through ongoing real-time consultation with the nurse care manager. Cardiologists also consult by telephone on an as-needed basis with other physicians and healthcare providers to address issues arising during the patient's ongoing treatment. In conjunction with the nurse care manager, he or she creates periodic reports summarizing the clinical outcomes of populations of patients enrolled in CMS and modifies the clinical processes of CMS as needed.

The Nurse Care Manager

The nurse care manager's role is to coordinate the care provided under CMS. He or she represents CMS to patients, physicians and others involved in the patient's care. This individual acquires the patient's data at baseline and through subsequent telephone contact with patients and their physicians, updates the database application, and generates reports that apprise physicians of patients' current medical status.

He or she works closely with the CMS cardiologist to assure that any urgent issues in management presented by patients are addressed immediately, and that any changes in the patient's management are communicated promptly to the physician(s) caring for the patient. Finally, the nurse initiates routine follow up telephone contacts with patients to identify and address any unresolved issues. He or she reviews individual cases with the CMS cardiologist on an ongoing basis and modifies the clinical routines under CMS as needed.

Many patients who experience symptoms hesitate to call 911 for immediate transport the ER, but experience with CMS has shown that they seldom procrastinate in making a simple phone call to a nurse care manager for advice.

The CMS Computer System

The Decision Support System (DSS) incorporated into CMS provides a comprehensive informational framework for coordination of care, including:

- a data repository for storing patient-related data obtained at baseline and by telephone contact throughout follow up,
- computerized decision support for the CMS team's response to patient-initiated telephone contacts,
- a call manager program that schedules follow up telephone contacts with patients and their physicians,
- a report generator that provides summaries of the clinical status of individual patients, and
- large-scale data analytics to assess clinical status and clinical outcomes across the entire population of enrolled patients.

- CMS also provides two features not commonly found in most EMRs. First is a baseline status report, generated at the time that the patient enrolls into CMS, which comprehensively summarizes the patient's medical status.
- And second, periodic computer-generated Interval Status Reports that support prompt decision-making in the event of subsequent changes in patients' symptoms.

The role of the Decision Support System (DSS) in coordinating the care provided by CMS staff is shown in Figure 1. The DSS contains data collected from hospital medical records, clinic and ER visits and notes generated during telephone contacts between CMS staff and patients, and between CMS staff and physicians.

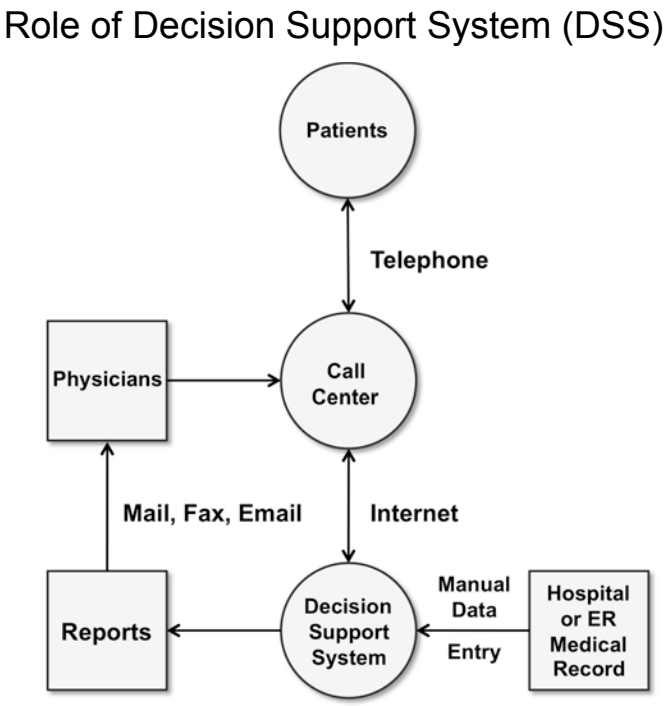

Figure 1

The CMS nurse care manager and cardiologist access the clinical database from their office-based computers or by cell phones with web access to the database. Access to the CMS website is password protected. The database will alert CMS staff through text messaging that there is patient activity to be reviewed. Alarms embedded in the database remind CMS staff to initiate follow-up contacts at 24 hours.

The provisional diagnoses generated by the DSS foster standardized and cost-effective care, because they are based on authoritative management guidelines (15-16). Whereas implementation of these guidelines is presently limited to ER settings, CMS permits telephone triage of patients the home.

Consequently, the triage point occurs much earlier after the onset of symptoms, as shown in Figure 2.

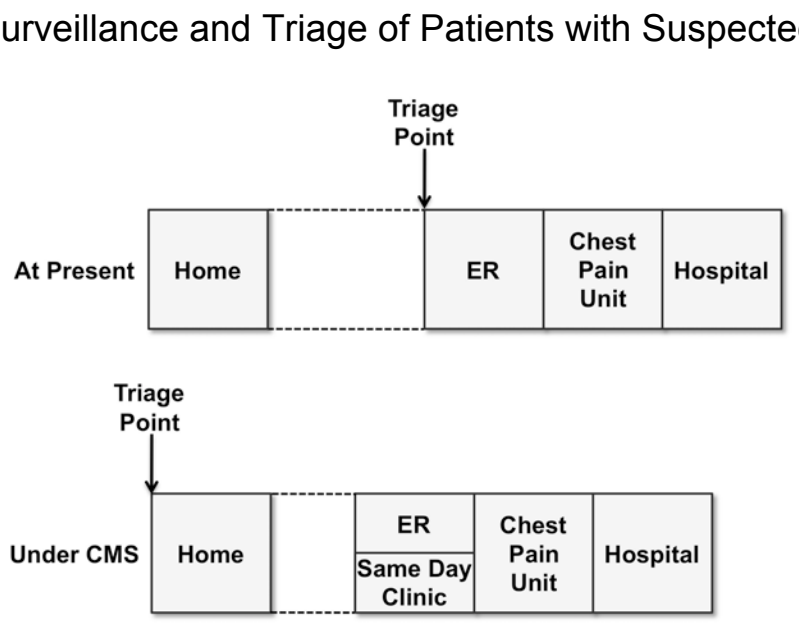

Figure 2

Comparison of triage point in present practice and under CMS.

ACS Diagnosis

ACC/AHA decision rules used to structure the decision making process used by CMS staff are shown in Figure 3.

Many telephone contacts initiated by patients enrolled in CMS will represent a stable pattern of angina pectoris or non-ischemic conditions. The differential diagnosis of conditions treated in the ER includes aortic dissection, chest wall pain, esophagitis, gallbladder attack, heart failure, panic attack, pericarditis, pneumonia, pulmonary edema, pulmonary infarction, seizure, stroke/TIA and syncope. These diagnoses and "chest pain not otherwise specified" represent the great majority of patients reporting chest pain at the ER (21-22).

Decision rules designed to identify these non-ischemic conditions are incorporated into the Inbound Call form used by the nurse care manager. This form structures the data needed to establish a provisional diagnosis of these conditions, each of which may simulate or accompany ACS. The form also provides a recommendation regarding the appropriate treatment for the patient.

Patients with a provisional diagnosis of a serious, progressive condition such as aortic dissection, gallbladder attack pericarditis, pneumonia, acute pulmonary edema, pulmonary infarction, seizure, stroke/TIA or syncope will be advised to call 911 for transport to the ER.

Patients with a provisional diagnosis of a benign condition such as esophagitis, chest wall pain, chronic heart failure, panic attack, dizziness or palpitation unaccompanied by syncope will be advised that CMS staff will telephone the patient's cardiologist or PCP to discuss options for treatment and will call them back promptly.

Each patient's risk status for subsequent ACS is established upon enrollment. This includes a history of one or more previous MI's and tests reflecting the degree of impairment of cardiac pumping capacity (left ventricular dysfunction) and the extent of limitation of coronary blood flow (myocardial ischemia).

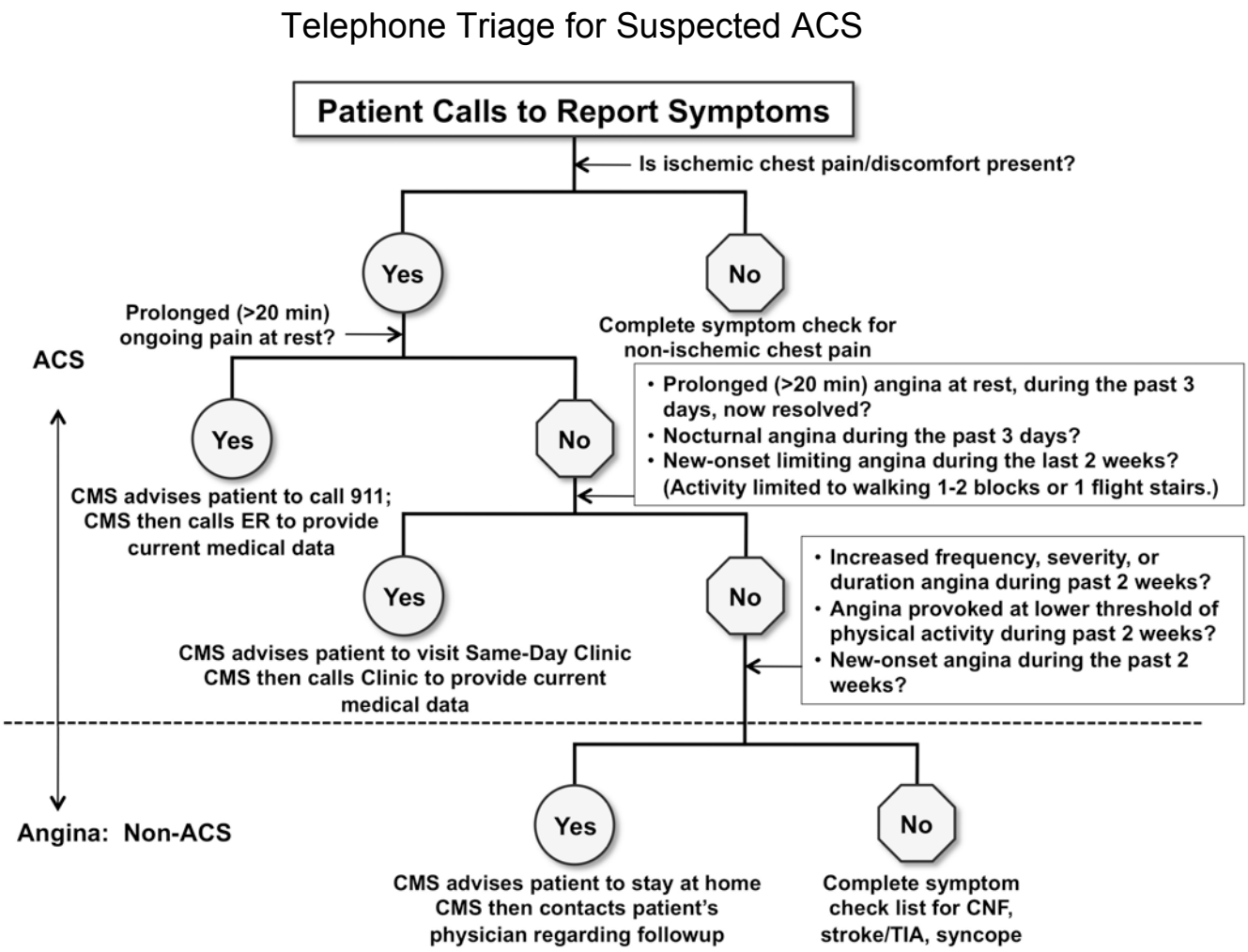

Figure 3

The algorithm poses a stepwise series of questions regarding the character, severity, location and persistence of chest pain and the factors that aggravate or ameliorate it. Responses to these questions permit stratification of patients into high, moderate and low risk groups.

Important features of the interval history since the patient's last contact with CMS staff include frequency and severity of chest pain and other cardiovascular symptoms, changes in the pattern and dosage of anti-ischemic medications, and the frequency of unscheduled medical contacts, including ER visits and hospitalizations prompted by new or worsening cardiovascular symptoms.

Based on the work of Allison et al. (23) and our pilot studies, no fewer than 25% of all patients undergoing ER evaluation for suspected ACS are expected to experience recurrent cardiovascular symptoms in the following 6 months. The expected outcomes of telephone triage shown in Figure 4 are based on a sample of 100 patients.

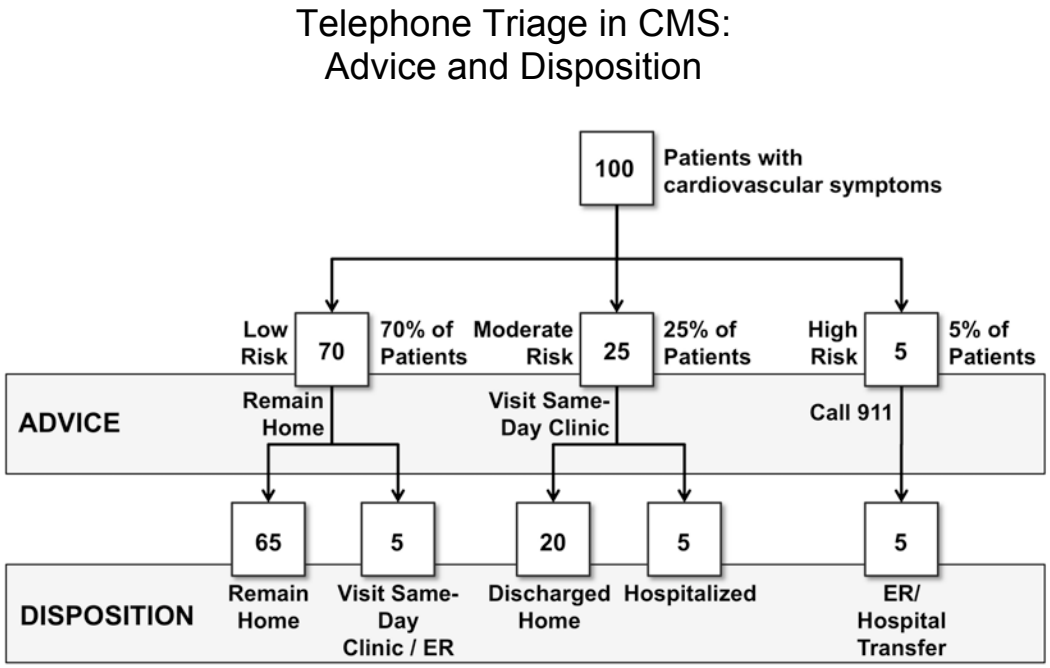

Figure 4

Among each 100 patients initiating telephone contact, approximately 70 are expected to be classified as low risk. These patients will continue to monitor their symptoms and adjust their anti-ischemic medications, if any, and remain at home, awaiting the Nurse Care Manager's immediate follow up call.

Approximately 25 patients calling to report cardiovascular symptoms are expected to be classified as moderate risk for death or nonfatal MI. They will be advised to visit a same-day cardiology clinic if they can arrive by 4:30 pm or call 911 for transport to the ER if this is not possible.

If the patient's symptoms have worsened since the initial telephone contact with CMS staff or the patient appears ill on presentation to the same-day cardiology clinic, the clinic staff immediately arranges for the patient to be transported by gurney to the ER. The patient's cardiologist maintains responsibility for the patient's care throughout the course of the patient's same-day clinic evaluation.

Immediately after the patient's arrival, the clinic staff records an ECG and the patient's cardiologist assesses the patient's clinical status and, if appropriate, orders

a point-of-service cardiac biomarker. Depending on the results of these tests, the cardiologist discharges the patient home or admits him or her to the hospital.

On the following day, the nurse care manager telephones the patient to determine his or her medical status, enters the relevant data into the database, and sends an interval status report to the patient's primary physician and/or cardiologist.

Except for the provision of expedited care, including prompt recording of an electrocardiogram and measurement of a biomarker, the functions of the clinic will remain unchanged. Among patients undergoing evaluation in the same-day cardiology clinic, 80% are expected to be discharged home and 20% are expected to be hospitalized.

Approximately 5 patients calling during clinic hours to report cardiovascular symptoms will be classified as high risk for death or nonfatal MI. They will be advised to call 911 for transport to the nearest ER.

In approximately 5 additional patients, not shown in the figure, cardiovascular symptoms will be severe and rapidly progressive, or symptoms and signs of stroke or TIA will be present. At the time of their enrollment in CMS, patients are instructed that if they experience these symptoms subsequently, they should call 911 for transport to the ER and then call CMS staff, who provide the ER staff with an updated Interval Status Report prior to their patient's arrival.

Operational Objectives of CMS

Preserving patients' safety.

To assure that patients reach CMS by phone at any time, overlapping telephone coverage is shared by 3 CMS staff, augmented by simultaneous email prompts generated by patient-initiated telephone contacts.

Physicians retain their present authority and autonomy. Because their physician(s) are involved in every patient care decision, no patient receives less care under CMS than at present. Patients advised by CMS staff to call 911 for transport to the ER or attend a same-day clinic visit will continue to see their physicians just as they do presently. The medical decision-making process is identical, whether patients enter the door marked "ER" or "Cardiology Clinic".

The only unique arrangement for care provided under CMS is the opportunity for physicians to consult with CMS staff by telephone regarding the management and follow up of low-risk patients who have been advised to remain at home. It is commonplace in clinical practice that physicians provide advice to patients reporting symptoms by telephone. CMS simply enhances the reliability of the process.

Features that enhance the safety of the CMS include the following:

1. Patients are provided with initial instruction on how to recognize and respond promptly to cardiovascular symptoms, which may lower their threshold to seek prompt help.

2. Patients are provided with immediate telephone access during clinic hours to healthcare professionals familiar with their care who are equipped with a database containing updated medical information.
3. Telephone triage decisions implemented by the CMS staff are based on the same management algorithms that presently guide ER care not only for ACS but for conditions that mimic or accompany ACS.
4. CMS staff help to coordinate the care provided by all of the patient's physicians, including not only the PCP and cardiologist who provide routine care, but cardiologists and ER physicians who provide care in the event of an emergency.
5. Routine telephone follow up provided by CMS staff helps to identify and address symptoms that patients might not otherwise report to their physicians and fosters patients' adherence to cardioprotective drug regimens that may attenuate symptoms of angina pectoris and lower the risk of subsequent ACS.

Building healthcare teams

The actions taken by the CMS healthcare team permit practicing cardiologists to direct the care of patients reporting a change in symptoms with minimal disruption of their customary clinical activities.

For patients judged by the CMS nurse care manager or cardiologist to be at moderate risk, triage is performed prior to patients' arrival in the same-day clinic. Accordingly, all that is required for the cardiologist to hospitalize patients or discharge them home from the clinic is an interpretation of an electrocardiogram and the result of a point-of-service cardiac biomarker ordered and reported by CMS staff.

Reevaluating healthcare reimbursement policies

In the future, healthcare reimbursement will be driven by the financial imperative to enhance the efficiency as well as the effectiveness of American healthcare. The elements of CMS contribute not only to potential enhancement in care delivery, but to documentation and evaluation of the processes and outcomes of the care.

One of the greatest barriers to establishing effective health care teams is the present fee-for-service basis of reimbursement, which perpetuates the present patchwork system of care for suspected ACS. There is presently no detailed strategy to direct the management of patients with CAD outside the ER and hospital setting. Healthcare teams composed of non-physicians as well as physicians are regarded by many experts as essential to the mission and reimbursement patterns associated with hospital-based care. However, healthcare teams are difficult to organize and support in the outpatient arena, where coordination of care is most needed. The viability of outpatient-based healthcare team is further limited by an ambiguous mission. In practical terms, physicians often perceive the participation of non-physicians in outpatient practice as a threat to their professional autonomy and fiscal well-being. In matters of staffing, the interests of physicians tend to dominate: even when a non-physician could provide a service equivalent to that of a physician, the tendency is for the physician to provide it. Studies of healthcare teams conducted in Europe and Israel have demonstrated equivalent clinical outcomes for

physicians and specially trained nurses working collaboratively within a care management setting (24-25).

As we have noted, fewer than 10% of patients presenting to the ER with chest pain ultimately demonstrate an acute MI within 72 hours; identifying these patients presently requires an ER visit in all cases and hospitalization in half the cases. This inefficient, costly approach could be replaced by an efficient, outcomes-based approach in which an advanced system of communication, implemented by a healthcare team, coordinated the care of such patients.

Anticipated Outcomes of CMS

The potential impact of CMS on clinical practice is expected to be significant, for the following reasons:

1. Healthcare that is coordinated is likely to prove more cost-effective than healthcare that is not. CMS integrates all the major elements essential to healthcare restructuring, including:
    - The central role of the EMR in all aspects of healthcare delivery,
    - The vital role of healthcare teams, and
    - Multiple communication channels, including the telephone and computer that ensure the continuity of care.
2. CMS presently addresses the healthcare needs of the 17 million Americans with established CAD. Moreover, with minor programmatic expansion it could address the needs of additional millions of individuals with complications of CAD, including heart failure and arrhythmias, and manifestations of atherosclerotic vascular disease in other vascular beds, including stroke and transient ischemic attacks. Finally, the features and functions of CMS extend beyond atherosclerotic disease to other illnesses such as cancer that require ongoing coordination of care across multiple delivery sites.
3. The magnitude of the potential economic benefits of using CMS to coordinate the care of patients with established coronary artery disease can be inferred from the present costs of caring for the 2.4 million Americans with previously established CAD who seek ER care for suspected ACS each year. The present charges to Medicare for the treatment of suspected ACS in patients treated in private hospitals are as high as $6,000 for each ER visit and $12,000 for the hospitalizations that follow in half of cases.

    Pilot studies conducted by our group in public hospitals have shown the potential to reduce these ER visits and hospitalizations by 50% or more. This translates into a gross reduction of charges for ER and hospital care for these 2.4 million patients from $29 billion to $14.5 billion. Under present reimbursement policies, the actual rate of reimbursement by Medicare for these charges is approximately 20%. The costs reimbursed by Medicare for ER and hospital care thus represent approximately $5.8 billion and $2.9 billion, respectively. The annual net cost savings are reduced by an amount equivalent to the investment costs of establishing and maintaining CMS. Assuming a rate of recurrent ER visits of 25% in the first 6 months following

hospitalization for ACS, CMS would achieve a return on investment (ROI) of $1.05. If the actual rate of recurrent ER visits in the first 6 months were actually 50%, CMS would achieve an ROI of at least $3.10 for each dollar spent to coordinate the care of these patients.

4. The deliverable elements of CMS have been thoroughly tested in pilot projects. The deliverables include:

   A structured operations manual for use by the healthcare team

   An education manual for patients and their families and

   The Decision Support System used to coordinate patient care and facilitate reporting on the process and outcomes of the care.

   Because the elements of CMS are highly portable, they can be readily adopted by organizations wishing to provide ongoing clinical surveillance and coordination of care to enrolled patients with established CAD.

5. The CMS represents a sound implementation of the Medical Home practice concept. By providing a single and consistent and point of contact between a patient and all aspects of cardiac care, the problems of fragmentation that the Medical Home concept addresses are realized.

Advantages of CMS

CMS affords advantages to healthcare providers, patients and the healthcare system as a whole as follows:

Advantages for physicians whose patients are enrolled in CMS

1. Greater control over the management of their patients, resulting from timely telephone contacts with CMS, augmented by comprehensive computer-generated reports and telephone contacts regarding the current status of any patient. Patients discharged following hospital treatment of ACS are presently scheduled weeks or months in advance for cardiology clinic follow up visits, but patients who are stable at the time of the scheduled visit have no compelling medical reason for the visit if their needs for continuing evaluation and reassurance could be met by alternative means, including telephone contact with their cardiologist.
2. Quicker response to patients who have become clinically unstable, who are not presently afforded the opportunity for an expedited visit because all the clinic slots have been previously scheduled for clinically stable patients.
3. Increased participation by cardiologists in their patients' care. In current practice, patients are frequently admitted to the ER without their cardiologists' knowledge, which limits the cardiologist's options in directing their ongoing care. CMS enables cardiologists to tailor the intensity of care to the needs of their patients without the necessity of an ER visit.
4. CMS staff provides practical assistance in acquiring data, scheduling visits and following up with patients and their physicians. This permits cardiologists to direct

the care of patients reporting cardiovascular symptoms with a minimum of disruption to their ongoing clinical activities.

5. Greater cost-effectiveness of the care provided to patients. Business analytics incorporated into the CMS database afford a strategic advantage to physician groups, permitting greater efficiency in their practice, including a reduction in the frequency of ER visits, inpatient discharges, total inpatient bed days and readmissions within 30 days.
6. Financial advantages for physicians. Arrangements for reimbursement of physicians increasingly incorporate gain-sharing, funded by savings generated by increased efficiencies and appropriate resource use (26). This permits physician groups to share in savings without increasing costs to the health plan.

Advantages for patients enrolled in CMS

1. The reassurance provided by immediate telephone access to CMS for consultation and advice. Shared decision-making incorporated into the telephone interactions between patients and CMS fosters trust in and cooperation with CMS staff.
2. Expedited care provided in same-day clinic and ER settings obviates long delays. Most patients enjoy the convenience of staying home.
3. Immediate access to administrative assistance from CMS staff for scheduling of follow up office visits, obtaining prescriptions, etc.
4. Cost-savings resulting from reduction in the frequency of ambulance transport to the ER and co-payments for ER care as well as fewer absences from work and ad hoc demands on family members.
5. Less disruption of daily routines by symptoms, reflecting enhanced adherence to anti-anginal medications.
6. The patient-centered care provided by CMS throughout the episode of illness permits CMS staff to address patients' and families' questions and concerns that often receive short shrift during office visits.

Advantages for the healthcare system as a whole

CMS fosters healthcare that is more accessible and potentially more cost effective than standard care.

1. The healthcare team and the advanced applications of HIT incorporated into CMS help to achieve the objectives for healthcare restructuring cited in the Institute of Medicine report, "Crossing the Quality Chasm" (27).

   These include the following:

   a. The efficiency of care is enhanced by, immediate, ongoing telephone assessment of patients' clinical status, which permits care to be tailored to patients' needs based on risk of death and nonfatal MI.

b. The timeliness of care is fostered by just-in-time scheduling of expedited cardiology clinic and ER visits,

c. The effectiveness of care provided in these venues is enhanced by the distribution of computer-generated reports of patients' current medical status, including their most recent electrocardiogram. This avoids duplication of effort and hastens care delivery in same-day clinic and ER settings.

2. Elimination of unnecessary ER visits for low risk patients, which reduces ER overcrowding. The ER has become the default medical care provider for many individuals unable to bear the financial and opportunity costs of standard clinical care (28-29). At a time when the availability of ERs, especially those operated by public hospitals, is diminishing nationwide, the increasing ranks of the uninsured pose a threat to the continued viability of ERs across the nation (28-29).

   In California alone, the number of hospitals maintaining ERs fell from 568 to 355 during the period 1990-2000. (29). CMS provides the following benefits to the emergency care system:

   1. The number of patients with non-urgent cardiac conditions permits low- and moderate-risk patients to be triaged to non-ED venues, thus alleviating ER overcrowding, delays in hospitalization from the ER and ambulance diversion from the ER (30).

   2. Patients with urgent cardiac conditions such as acute MI who are referred earlier in their clinical course may achieve greater benefits from hospital-based interventions (31). The ready availability of current medical information, including a copy of the most recently recorded electrocardiogram, hastens the provision of hospital-based angioplasty and thrombolysis for patients with acute ST-segment elevation myocardial infarction (STEMI).

   3. CMS encourages patients' use of emergency medical services (EMS) for transport to the ER, hastening provision of treatment for ACS. At present, only half of patients presenting to the ER for evaluation of chest pain arrived by ambulance (32).

   4. Immediately after patients are triaged by telephone to EMS, the nurse care manager or cardiologist telephones the ER staff to alert them that a patient will arrive imminently, faxes a copy of the patient's most recent interval status report from the electronic database and leaves the telephone number at which CMS staff can be reached for further discussion.

Summary:

The Six Pillars Of Healthcare Innovation

Present concerns about the future viability of Medicare have forged an unusual consensus that the system requires systemic change. The immediate priority in health care reform will likely focus on the expansion of health care benefits, yet without enhancements in the efficiency of health care delivery, expansion of benefits is likely to prove disappointing.

Initiatives such as CMS that focus on coordination of care among multiple healthcare providers and healthcare venues have heretofore functioned only at the periphery of the healthcare system. Now these systems must move into a phase of widespread adoption.

Six major factors will influence systemic change in the future.

1. Reimbursement. The fee-for-service model of reimbursement has stifled innovation not only by hospitals and health care providers, but also by technology providers and other potential innovators. Without a shift to a system of reimbursement that recognizes and rewards continuity of care and demonstrated healthcare quality, innovation will continue to lag.
2. Public Involvement. For most Americans, the healthcare system remains an enigma, lacking both transparency and responsiveness. At present the public is generally unfamiliar with innovations that could foster care that is not only more cost-effective but more accessible. Once the public understands the new options such as CMS that could become available through advanced web applications and new models of healthcare delivery, it will demand change.
3. Health information technology is a necessary but not sufficient aspect of systems change. However, innovations in publicly-available communications technology such as the iPhone and web-based database applications available to healthcare providers, will foster change in the future.
4. Medical expertise has not heretofore been operationalized in ways that foster widespread or standardized application. Medical expertise is often perceived as the exclusive province of physicians (a retail model of distribution) rather than a guide to the implementation of this expertise by non-physician healthcare providers as well (a wholesale model of distribution). Indeed, the medical knowledge distilled by expert groups into various management guidelines is operationalized by physicians in a distinctly non-uniform fashion. Accordingly, physician's familiarity with the patient's problems often eclipses the authoritativeness of the guidelines in matters of medical decision making.

The practical implementation of medical knowledge by physicians is also conditioned by non-scientific factors, including reimbursement. For example, physicians are better reimbursed for the application of their knowledge during an office visit than during a telephone or email contact. Accordingly, they prefer to apply their knowledge in an office setting.

Medical culture prizes problem solving, especially when the deductive method is in play. For most physicians, the satisfaction of diagnosing an obscure condition is often a highlight of a professional career. For many physicians, acknowledging the collective judgment of the experts who have compiled management guidelines is problematic.

5. The team approach to healthcare, widely recognized as essential to care in hospitals, especially in medical diagnostic laboratories and surgical practice, is not equally honored in the outpatient arena.

6. The predominant focus of healthcare delivery continues to be the hospital. Coordination of care across the home, ER, and hospital interface lies outside the mission of hospitals and their affiliated ERs. Coordination of care requires fungible medical expertise that can be implemented by members of healthcare teams that have access to patients' current medical information. The mission of such teams is to facilitate the delivery of healthcare services in a variety of settings, including the home.

Appendices

CMS Research Prototypes and Implementations

As a research prototype, CMS has demonstrated efficacy in coordinating the care of patients with established CAD. Transformation of CMS from a prototype to an operational system requires larger scale clinical trials, as well as changes in health care reimbursement policy that recognize and promote cost-effective care delivery. Adoption of systems like CMS will accelerate when the American public demands innovations that provide "concierge care for the rest of us."

The CMS has been tested in the following pilot implementations.

1. Palo Alto Veteran's Administration Hospital, 2006-2007

Number of patients enrolled: 30

Duration of trial: 6-month follow up

Summary of results: No ER visits were recommended by CMS staff to the 3 patients reporting cardiovascular symptoms by telephone. One patient called 911 directly and was hospitalized for emergency cardiac catheterization.

2. San Francisco General Hospital, 2007-2008

Number of patients enrolled: 60

Duration of trial: 4-month follow up

Summary of results: 8 patients initiated a telephone contact to report cardiovascular symptoms during clinic hours. None was advised to call 911. One underwent a same-day clinic visit followed by cardiac catheterization and one was hospitalized for non-cardiac symptoms and released the following day. The remaining 6 patients were advised to remain at home. None of the 8 patients underwent a subsequent ER visit or myocardial infarction. An additional 8 patients experiencing cardiovascular symptoms after-hours were hospitalized via the ER.

3. Montreal Heart Institute, 2008-present

Number of patients enrolled to date: 150

Duration of trial: 1-year follow up of 200 enrolled patients

Summary of results: In 2008, cardiologists at the Montreal Heart Institute adopted CMS as the "operating system" for their clinical practice because it permitted them to eliminate overcrowding of the ER by clinically low-risk patients, while also providing greater efficiency in the management of moderate- and high-risk patients. ER visits have been reduced by 50% without adverse clinical effects

About the Author

Robert F. DeBusk, MD is Professor of Cardiovascular Medicine at Stanford University School of Medicine. In 1974 he established and continues to direct the Stanford Cardiac Rehabilitation Program (SCRP). The Care Management System (CMS) described in this document was developed by members of SCRP. The mission of the SCRP is to develop and disseminate systems and tools for the coordination of care for patients with established coronary artery disease.

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For additional information, please visit our web site:

http://stanfordchroniccaresystem.com/index.html

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