



CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Douglas Holtz-Eakin, Director

October 13, 2004

Honorable Don Nickles
Chairman
Committee on the Budget
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

In response to inquiries by you and your staff about whether disease management programs can reduce the overall cost of health care and how such programs might apply to Medicare, the Congressional Budget Office (CBO) has prepared the attached analysis. It examines peer-reviewed studies of disease management programs for specific conditions—congestive heart failure, coronary artery disease, and diabetes (selected in part because they are highly prevalent among Medicare beneficiaries)—and broader reviews of the relevant literature published in major medical journals.

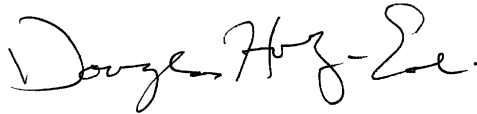
According to CBO's analysis, there is insufficient evidence to conclude that disease management programs can generally reduce overall health spending. It is important to note that such programs could be worthwhile even if they did not reduce costs, but CBO's analysis focused on the question of whether those programs could pay for themselves. The proposition that decreased use of acute care services might offset the costs of the screening, monitoring, and educational services in disease management programs is clearly appealing, but, unfortunately, much of the literature on those programs does not directly address health care costs. Instead, the focus is often on the processes of care or on intermediate measures of health, from which an overall impact on spending cannot reasonably be inferred. The few studies that report cost savings do so for controlled settings and generally fail to account for all health care costs, including the cost of the intervention itself. Furthermore, if disease management programs were applied to broader populations, the reported savings might not be attainable, and the programs could even raise costs. So while a few studies indicate that disease management programs could be designed to reduce overall health costs for select groups of patients (at least in the short term), little research directly addresses the issues that would arise in applying disease management to the older and sicker Medicare population.

CBO will continue to monitor this research as new information becomes available—in particular, the results of disease management demonstration projects now being developed by the Centers for Medicare and Medicaid Services.

Honorable Don Nickles
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I hope that you find this analysis useful. If you have questions or would like to discuss the analysis, please contact me at 226-2700 or Julie Lee at 226-2666.

Sincerely,

A handwritten signature in black ink that reads "Douglas Holtz-Eakin". The signature is written in a cursive style with a large initial "D" and a long horizontal stroke.

Douglas Holtz-Eakin
Director

Attachment

cc: Honorable Kent Conrad
Ranking Member, Senate Budget Committee

Honorable Jim Nussle
Chairman, House Budget Committee

Honorable John M. Spratt, Jr.
Ranking Member, House Budget Committee

Attachment

Attachment

An Analysis of the Literature on Disease Management Programs

October 13, 2004

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Introduction

Over the past decade, many health plans and organizations have begun to offer a new model of care for chronically ill patients—disease management—in an attempt both to improve the quality of care that enrollees receive and to slow the growth of their health care costs. Through a combination of enhanced screening, monitoring, and education; the coordination of care among providers and settings; and the use of best medical practices, disease management seeks to identify chronic conditions more quickly, treat them more effectively, and thereby slow the progression of those diseases. The presumption is that better care today will mean better health and, perhaps, less expensive care tomorrow.

Improving health outcomes and mitigating health care costs do not necessarily go hand in hand, and disease management programs may be a worthwhile investment even if they do not reduce overall health care spending. However, the debate about the value of disease management has encompassed both arguments. Proponents often claim that disease management programs not only improve quality but also pay for themselves by decreasing the use of acute care services enough to offset the costs of the additional screening, monitoring, and educational services. Given the Congressional Budget Office's (CBO's) focus on budgetary effects, the agency's analysis has centered on the questions of whether those programs have been effective in reducing health care costs and how such programs might apply to Medicare.

On the basis of its examination of peer-reviewed studies of disease management programs for congestive heart failure (CHF), coronary artery disease (CAD), and diabetes and the conclusions reached by other reviews of the relevant literature published in major medical journals, CBO finds that to date there is insufficient evidence to conclude that disease management programs can generally reduce the overall cost of health care services.

Estimating cost savings requires determining what disease management services themselves cost and whether they reduce the cost of other health services, but substantial uncertainties exist on both counts. All in all, the evidence on cost savings is limited. Most studies do not directly address costs. Instead, they report improvements in processes of care or in intermediate measures of health, from which an overall impact on spending cannot reasonably be inferred. The few studies reporting cost savings generally do not account for all health care costs, including the cost of the intervention itself.

Furthermore, those savings were achieved in controlled and limited settings, but if disease management programs were applied to broader populations, such savings might not be attainable and the programs could even raise costs. Thus, while there is evidence that disease management programs could be designed to reduce overall health costs for select groups of patients, little research exists that

directly addresses the issues that would arise in applying disease management to the older and sicker Medicare population.

Background

What Is Disease Management?

The term “disease management” covers a range of activities that attempts to address several perceived shortcomings of current medical practice. First, chronic conditions often go untreated or are poorly controlled until more serious and acute complications arise. Second, as reported by the Institute of Medicine, a large gap often exists between evidence-based treatment guidelines (what medical research has shown to be the most effective protocols for treating specific diseases) and current practice. Third, patients often receive care for a disease from many different physicians or providers and frequently are called upon to monitor, coordinate, or carry out their own treatment plan—with limited ability to do so.

Disease management programs vary widely in the specific techniques and tools that they use, but they share several common components that are designed to address those shortcomings. One component is to educate patients about their disease and how they can better manage it. The goal is to encourage patients to use medication properly, to understand and monitor their symptoms more effectively, and possibly to change their behavior. A second component is to actively monitor patients’ clinical symptoms and treatment plans, following evidence-based guidelines. A third component is to coordinate care for the disease among all providers, including physicians, hospitals, laboratories, and pharmacies. A disease management program can provide feedback on individual patients and support to physicians about patients’ status between office visits as well as up-to-date information on best practices for particular patients. Although disease management is sometimes used as a catchall that addresses any and all limitations of fee-for-service care, it does not encompass general coordination of care or basic preventive services, such as flu shots.

Until recently, care management techniques differentiated between two general approaches: disease management, which targeted individuals diagnosed with specific conditions, such as diabetes or congestive heart failure, and case management, which focused on high-risk patients with complex combinations of medical conditions and which was often triggered by an acute event such as hospital admission. The former often involved applying standardized techniques in a systematic way, while the latter was seen to require a treatment plan tailored to each patient’s unique circumstances. The distinction between the two approaches has blurred, however, as disease management firms have adopted broader and more-comprehensive approaches. Disease management programs are

rapidly expanding services and now typically assume responsibility for coordinating care for the range of chronic conditions that a patient may have.¹

Disease management programs differ greatly in their approaches to identifying and serving enrollees. One approach is to consider a health plan's entire population for the intervention in an effort to discover undiagnosed cases or to at least identify individuals whose conditions cannot be spotted accurately using their claims history. That approach minimizes the chances of missing beneficiaries who might gain from the intervention but also could incur substantial costs for serving individuals whose conditions might have remained stable or been well managed without the intervention. Another approach is to use predictive modeling to identify which enrollees are most likely to benefit from the intervention or to incur high medical costs in the future. That approach limits the number of enrollees served, thus reducing the cost of providing the services, but its success depends on the accuracy of the predictions. Yet another approach is to wait for an initial acute episode such as a hospitalization before beginning intensive management. That approach targets the intervention most narrowly, but because the disease may have progressed, the intervention may cost more per enrollee to implement, and some substantial health costs have already been incurred.

How Does Disease Management Work?

To illustrate how a typical disease management program might work, consider a program for treating diabetes, a disease characterized by a lack of control of blood sugar. Patients with diabetes need to monitor their blood sugar frequently and may take synthetic insulin or use other medications to help control their blood sugar levels. So patients have a large role in providing their own care, but many have difficulty doing so properly. The consequences of poor control can be serious, as diabetes can have a number of long-term complications, including damage to blood vessels and peripheral nerves, which can result in blindness, loss of kidney function, stroke, or amputation.

Initially, a disease management program would aim to improve "process outcomes," for example, to increase the number of enrollees who received a set of exams recommended by the American Diabetes Association: regular blood pressure screening; annual foot and eye exams; annual lab tests for kidney function; annual tests for cholesterol levels; and at least biannual lab tests for hemoglobin A1c, or HbA1c, a measure of the control of blood sugar levels over the previous two to four months. In addition, since diabetes is associated with an increased risk of heart disease and stroke, taking steps to help diabetics control

1. See the appendix for the Disease Management Association of America's definition of disease management.

their blood pressure and cholesterol and counseling them to quit smoking are also critical process outcomes.

If those process outcomes succeeded in preventing the onset of complications, the impact of the disease management program would be reflected in measures of health outcomes, such as the rates of amputations, heart attacks, and death. Because those health outcomes typically do not occur for many years after the onset of diabetes, they are not commonly measured in typical short-term studies of disease management. Instead, studies of the effectiveness of disease management programs often use measures of process outcomes (such as the monitoring of blood pressure and the regular screening of HbA1c levels) and measures of intermediate outcomes (such as improvement in blood pressure and HbA1c levels) as indicators of improvement in health.

Health outcomes affect both the quality of life and the utilization of health care. The quality of life is difficult to measure but seeks to encompass both physical and emotional well-being and has particular importance in cost-effectiveness analyses—which often report costs per “quality-adjusted life year” to capture changes in quality as well as in years of life. Health care utilization, such as hospital admissions and emergency department visits, reflects the number of acute episodes experienced by patients. A complete economic analysis would take into account the costs of those acute services and expenditures for other types of care that might substitute for hospital-based care. (See Figure 1.)

The Evidence on Cost Savings

Overall, the evidence on cost savings from disease management is quite limited. Moreover, many available studies that address the effect of disease management programs on health care expenditures have methodological limitations. As one reviewer of the literature on disease management has noted, the “lack of a consistent analytic framework has made comparisons of reported results impossible and has rendered many reports unreliable. The field particularly needs measurement standards for evaluating economic results.”²

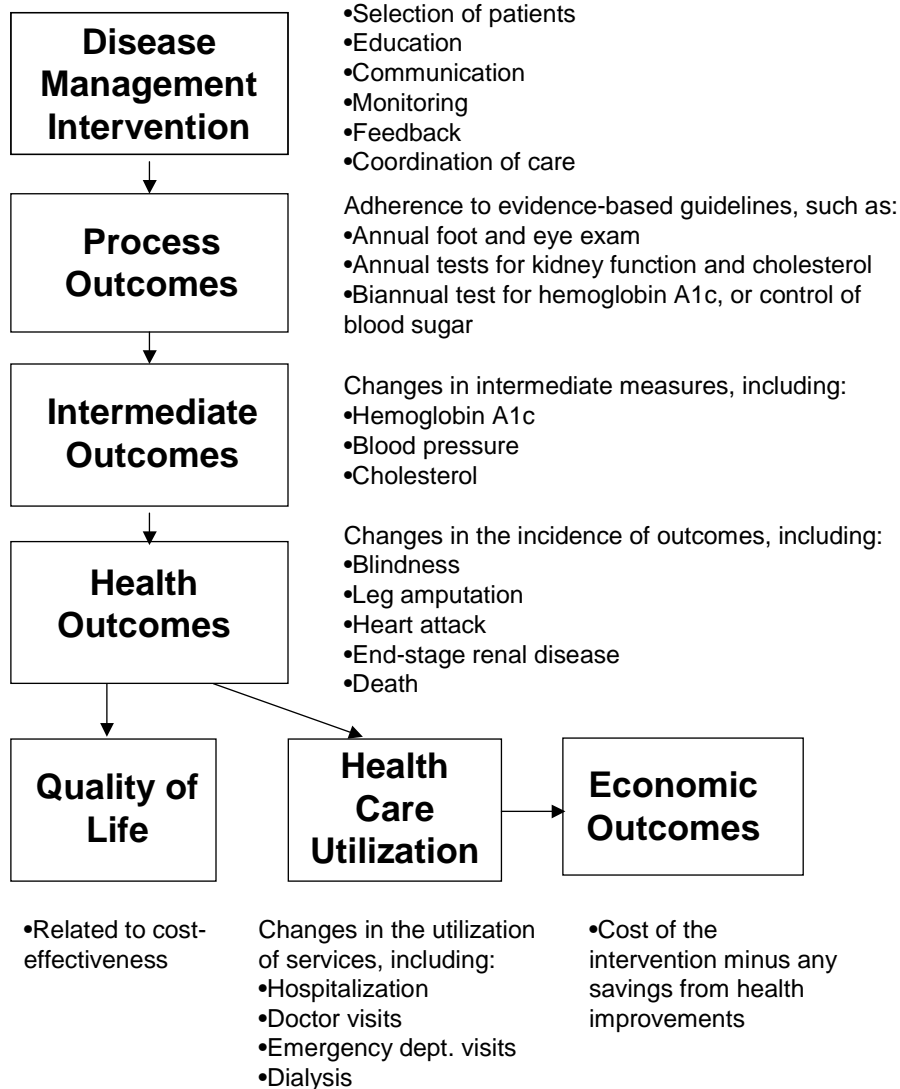
Methodological Issues

The proposition for disease management programs is that better care translates into improved health and, perhaps, to lower-cost care in the future. But because the programs directly influence only processes of care, causal links to health

2. Victor Villagra, “Strategies to Control Costs and Quality: A Focus on Outcomes Research for Disease Management,” *Medical Care*, vol. 42, no. 4 (2004), pp. III-24-III-30.

Figure 1.

The Path by Which a Disease Management Program for Diabetes Could Lead to Better Health Outcomes and Lower Health Costs



Source: Congressional Budget Office.

outcomes or to economic outcomes may be uncertain or could take several years to become evident.

By contrast, process outcomes are more readily available and are simply easier to measure than health or economic outcomes. They consist of well-defined, discrete items that can be checked off or counted. As a result, most studies tend to focus on processes of care and, perhaps, intermediate outcomes, and far fewer studies

have explored the effects on ultimate health outcomes or on the use of health services. For example, according to a review in the *American Journal of Preventive Medicine*, of 27 studies of disease management programs involving diabetes, all 27 analyzed process outcomes. Nineteen of the studies reported changes in the patients' HbA1c levels, and 10 examined other intermediate outcomes such as blood pressure and cholesterol levels. However, only two of the studies that were reviewed examined the impact on costs.³ Such a lack of investigation of the effects of disease management on health and economic outcomes is an important limitation of the existing literature.

Among the studies that sought to address costs, many did not account for all costs. But to measure the true effect of a disease management program on health spending, capturing all costs is necessary.

- First, the calculation must include the administrative costs of the program itself, including the cost of identifying the target population, enrolling patients, and providing intervention services. As discussed above, those costs can vary considerably depending on the strategy used to identify enrollees and the type of services provided.
- Second, all forms of health care spending related to the disease must be captured. The calculation must extend beyond tracking a decrease in hospital admissions and emergency department visits and capture any changes in the number of physician visits and tests or other outpatient services (including drugs) used to treat the condition. The calculation must also include cases of the disease that are newly diagnosed because of the program, which could also add to costs, at least in the short run.
- Third, unintended consequences of the intervention must also be taken into account. Errors in the process used to identify individuals for the program are inevitable, and the costs resulting from treating such “false positives” need to be included. If additional treatment and invasive testing lead to complications and side-effects, the costs of treating those should be included. The disease management program could even uncover and treat other health conditions that would not have been treated in the absence of the program, which could increase or decrease costs. The total cost of the program would depend on the balance of all such changes in the utilization of health care.

3. Susan L. Norris and others, “The Effectiveness of Disease and Case Management for People with Diabetes: A Systematic Review,” *American Journal of Preventive Medicine*, vol. 22, no. 4 (2002), pp. 15-38. The review also included 15 case management studies, but none of them examined economic outcomes.

Another important consideration is the comparability of patients who received the disease management intervention with those patients who did not. If the two comparison groups were equal in every aspect except the enrollment in the disease management program, then any observed differences in health, costs, or other measures could be attributed to the program. Such comparability is the objective of randomized clinical trials, in which individuals are randomly assigned to either an intervention group or a control group. Because of randomization, risk factors and other characteristics that would affect outcomes should be divided evenly between the two groups.

The analytical or methodological frameworks used in some studies are not as successful as randomization in “balancing out” all of the factors affecting outcomes between the intervention and reference groups. The imbalance could confound the disease management program’s impact with the effects of those other factors. Some of those confounding factors include the following.⁴

- **Selection Bias.** This problem can arise if the disease management program served only enrollees who wished to participate. Their costs could be lower than those for a reference group of nonparticipants simply because participants are more likely to be healthy or to take a more active role in managing their own care.
- **Regression to the Mean.** The evaluation design used in many studies depends upon comparing medical costs after a disease management program has been implemented with benchmark costs for the same population in the prior year. However, if study participants were chosen on the basis of having particularly high costs in a previous period or on the basis of an event commonly associated with high costs, their costs would be expected to fall regardless of whether or not they participated in a disease management program (following a statistical phenomenon known as regression to the mean).⁵ As a result, such studies are likely to overestimate the effectiveness of the treatment.
- **Other Confounding Factors.** Where the comparison is between enrollees before and after the program, an additional confounding factor is any overall improvements in treating the disease—such as new technologies or drugs—that may have arisen over the time period. Without controlling for such factors, studies that observed lower expenditures after the program

4. For a more detailed discussion, see Thomas W. Wilson, “Evaluating ROI in State Disease Management Programs,” *State Coverage Initiatives*, vol. 4, no. 5 (November 2003), pp. 1-5.

5. For example, only about 44 percent of the top quartile of spenders in Medicare’s fee-for-service program in 1997 remained in the top quartile in 1998.

than before would attribute the savings to the program's intervention—when those lower expenditures may instead have resulted from general improvements in technology or treatment regimens for all patients with that medical condition, whether receiving disease management or not. More generally, determining what the costs for the treatment group would have been had they not gotten the intervention is difficult in the absence of a randomly assigned control group.

Over and above such methodological limitations, interpreting the studies' results and extrapolating from them are difficult. Because studies are often designed for high-risk patients who are likely to benefit from disease management, participating patients are prescreened for various factors, including severity of the disease and comorbidities.⁶ As a result, the studies' findings may not be replicated apart from very specific research conditions or generalizable to a broader group of patients. Moreover, the effects of disease management may take years to become evident in health outcomes and in the utilization of health care services. Therefore, studies based on a relatively short follow-up period of one or two years may miss long-term benefits or costs.

CBO's Analysis

CBO reviewed the literature on the effectiveness of disease management programs for three diseases—congestive heart failure, coronary artery disease, and diabetes mellitus—which were selected because they are highly prevalent among Medicare beneficiaries and because the literature includes evidence of improved outcomes. CBO limited its review to published studies in peer-reviewed journals.⁷

Overall, the results of those studies are mixed and do not provide a firm basis for concluding that disease management programs generally reduce total costs. While there are cases of clinical and economic improvements by specific disease management programs for particular groups of patients, whether those results could be achieved for broader populations of patients is unclear.

Congestive Heart Failure. CHF is a disease in which the heart is unable to pump blood efficiently through the body. It can result from narrowed arteries supplying blood to the heart muscle (coronary artery disease), valvular heart disease, and other problems leading to cardiac muscle dysfunction. People suffering from CHF

6. In randomized studies, participants are typically assigned randomly to the intervention and control groups after the screening stage.

7. Relying on expert opinion, CBO reviewed widely cited studies, overarching reviews of the literature, and published studies that had a control group and an adequate number of patients in the sample. CBO was cognizant of the phenomenon known as publication bias, wherein studies with statistically significant results are more likely to be published than studies finding no significant effects. The complete list of the studies that CBO examined is included at the end of this document.

may become short of breath and have reduced tolerance for exercise. Many patients with CHF can be treated, but some patients with sufficiently advanced disease may become functionally impaired. CHF often results in hospitalization, when patients accumulate excess fluid in their lungs. The typical treatment during the admission includes reducing the volume of fluid, thereby relieving chest “congestion” and improving the efficiency of the heart’s pumping.

Many studies included in CBO’s review of the literature report a reduction in readmissions to the hospital and the length of hospital stays. A typical study was based on 100 to 300 patients who were randomly assigned to the intervention and control groups following a specific event, such as hospitalization with CHF. The disease management interventions varied widely, ranging from home visits by cardiac nurses to telephone calls by case managers, from involving a clinical pharmacist to increasing access to primary care. Not surprisingly, studies’ results depend on the particular program, but which activities within a program were responsible for the reported reduction in readmissions is unclear. Because most of the studies had relatively short follow-up periods of three to six months, they do not reveal the longer-term effects of the interventions. If the interventions were merely postponing readmissions or shifting costs to nonhospital services, then any reported savings would not accurately measure the program’s overall effect.

About half of the articles reviewed by CBO addressed costs and suggested a reduction in them. According to one study reporting savings, the rate of readmission within 90 days of discharge from the hospital was 28.9 percent for the intervention group compared with 42.1 percent for the control group.⁸ Similarly, the total number of hospital days was 35.7 percent lower for the intervention group. The overall cost of care was an average of \$153 (about 9 percent) lower per patient per month.⁹ The savings of about 33 percent from the lower readmission rate were offset by increased spending on the intervention and other medical care.

However, the applicability of those savings to a more general setting is limited by who was included in the study. Of the total of 1,306 patients who met the criteria for CHF, only 282 (or 22 percent) were included. The rest were excluded for various reasons, including physicians’ refusal to participate, the presence of dementia in patients, or their discharge to a long-term care facility. As the authors

8. Michael W. Rich and others, “A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure,” *New England Journal of Medicine*, vol. 333, no. 18 (November 2, 1995), pp. 1190-1195.

9. The overall cost of medical care during the 90-day follow-up period included the mean cost of readmission for all patients in each group and the average cost for nonhospital medical services and caregivers and, in the treatment group, for the intervention. All costs were reported in 1994 dollars.

noted, “the study was designed for high-risk patients during the high-risk period.” Therefore, the reported savings might not be achievable for a different group of CHF patients. For instance, some studies suggest that the reduction in readmissions and costs might be limited to patients with severe CHF. According to one study, total costs of patients with mild CHF in the intervention group were actually 288 percent higher at six months.¹⁰ For such patients, disease management programs might increase their access to care and their utilization of services, thus increasing health care costs.

Coronary Artery Disease. CAD, also known as coronary heart disease and ischemic heart disease, occurs when coronary arteries become hardened and narrowed. It develops gradually, as plaque accumulates on the inner walls or lining of the arteries and reduces the blood flow and oxygen supply to the heart. Many CAD patients suffer from chest pain. Untreated, CAD usually progresses and may lead to a heart attack, cardiac arrest, or congestive heart failure.

Most studies of disease management programs for CAD report some improvements in coronary risk factors. For example, one study of heart attack patients at Kaiser Permanente Medical Centers reports higher smoking cessation rates, lower cholesterol levels, and higher functional capacity (based on a treadmill exercise test) for the intervention group.¹¹ In the long term, however, the programs do not seem to lower total mortality. For example, one study reports no statistically significant difference in the total mortality rate during the 15-year follow-up period.¹² In general, a review of 12 studies on disease management programs for CAD concludes that while those programs can improve processes of care, reduce admissions to the hospital, and enhance patients’ functional status, their “impact on survival and recurrent infarctions, their cost-effectiveness, and the optimal mix of components remain uncertain.”¹³

10. Barbara Riegel and others, “Which Patients with Heart Failure Respond Best to Multidisciplinary Disease Management?” *Journal of Cardiac Failure*, vol. 6, no. 4 (December 2000), pp. 290-299. Mild CHF was defined as Class I in the New York Heart Association’s classification.

11. Robert F. DeBusk and others, “A Case-Management System for Coronary Risk Factor Modification After Acute Myocardial Infarction,” *Annals of Internal Medicine*, vol. 120, no. 9 (May 1,1994), pp. 721-729.

12. Helena Hämäläinen and others, “Reduction in Sudden Deaths and Coronary Mortality in Myocardial Infarction Patients After Rehabilitation: 15-Year Follow-up Study,” *European Heart Journal*, vol. 16 (1995), pp. 1839-1844. For the intervention group, the 15-year coronary mortality was lower, but cancer mortality was higher.

13. Finlay A. McAlister and others, “Randomised Trials of Secondary Prevention Programmes in Coronary Heart Disease: Systematic Review,” *British Medical Journal*, vol. 323 (2001), pp. 957-962.

As with CHF, a few studies suggest that intervention programs for patients with CAD can reduce costs in the short term. Again, however, the results apply to a select group of patients. According to one such study, the readmission rate within 24 weeks of discharge from the hospital was 20.3 percent for the intervention group and 37.1 percent for the control group, with imputed reimbursements for acute health services during the 24-week period of \$3,630 and \$6,661 per patient, respectively.¹⁴

The study targeted specifically those elderly patients who were at high risk for poor outcomes after discharge from the hospital because they had such liabilities as an inadequate support system and multiple health problems. Of the 1,296 eligible patients, only 28 percent enrolled in the study; 43 percent refused, and 29 percent were discharged before screening. Therefore, the observed reduction in rehospitalization applies only to the particular group of patients that was targeted and self-selected as likely to benefit from the intervention. For a broader population of CAD patients, the above findings might not apply.¹⁵

Diabetes. As discussed above, diabetes is a disease characterized by a lack of control of blood sugar. Although inadequate control of blood sugar levels can cause acute clinical problems and require hospitalization, in general, the most common health consequences of diabetes are chronic rather than acute. Therefore, disease management programs for diabetic patients are best evaluated for savings over the long term.

There is strong evidence that disease management interventions for diabetes reduce patients' HbA1c levels and increase their compliance in getting recommended examinations and screening (such as foot and eye examinations). However, there is not comparable evidence to conclude that disease management programs achieve other medical management targets (such as lowering weight, blood pressure, and cholesterol levels) or improve health outcomes (such as reducing rates of blindness or kidney failure).

A few studies have reported that programs for diabetes can save money in the

14. Mary D. Naylor and others, "Comprehensive Discharge Planning and Home Follow-up of Hospitalized Elders: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 281, no. 7 (February 17, 1999), pp. 613-620. The reported costs were calculated from standardized Medicare reimbursements for acute services and did not include additional costs for medications, assistive services, and other supplies. Cost savings for the intervention group were driven by the lower total DRG (diagnostic-related group) reimbursements from fewer hospital readmissions.

15. Identifying subgroups of CAD patients more likely to benefit from disease management (for example, patients who are likely to become hospitalized because they do not take their medications properly) and therefore more likely to result in cost savings probably requires additional screening, at extra expense.

short run, but the results do not appear robust to use in general. One widely cited study reports lower costs and utilization for patients enrolled in a disease management program at an HMO (health maintenance organization): \$395 per member per month in average paid claims for patients in the program compared with \$502 for other patients.¹⁶ The results from this study have limitations, including possible selection bias from optional enrollment and the limited applicability of the HMO setting. Also, the reported savings did not include the cost of the disease management program.¹⁷

According to another often cited study, there were savings between \$685 and \$950 per patient per year for a group of patients with improved HbA1c levels.¹⁸ The study compared patients who had their HbA1c levels decrease at least 1 percentage point during the first year of the study and remain at that point for an additional year (15 percent of the study sample) and patients who did not. But patients who saw improvements in their HbA1c levels probably differed from patients who did not in many other ways that would affect their health costs, so the reported results may have little to do with the effects of disease management.

Other Studies

Studies reviewing the effectiveness of disease management programs in general echo the lack of conclusive evidence on cost savings. In a recent study in the *American Journal of Medicine*, Joshua J. Ofman and his colleagues reviewed 102 studies published between 1987 and 2001 that met their criteria of rigor.¹⁹ They

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16. Jaan Sidorov and others, "Does Diabetes Disease Management Save Money and Improve Outcomes?" *Diabetes Care*, vol. 25, no. 4 (April 2002), pp. 684-689. See also Robert J. Rubin, Kimberly A. Dietrich, and Anne D. Hawk, "Clinical and Economic Impact of Implementing a Comprehensive Diabetes Management Program in Managed Care," *Journal of Clinical Endocrinology and Metabolism*, vol. 83, no. 8 (1998), pp. 2635-2642. In an analysis of several managed care plans, Rubin and his colleagues reported \$362 per member per month in average paid claims after the program compared with \$406 before the program, excluding the cost of the program itself.
 17. The authors estimate that the allocated cost of the diabetes program was less than the savings from fewer claims, about \$1.8 million compared with \$4 million.
 18. Edward H. Wagner and others, "Effect of Improved Glycemic Control on Health Care Costs and Utilization," *Journal of the American Medical Association*, vol. 285, no. 2 (January 10, 2001), pp. 182-189. Cost savings were statistically significant only for patients in the improved group with the highest baseline HbA1c levels (10 percent or higher).
 19. Joshua J. Ofman and others, "Does Disease Management Improve Clinical and Economic Outcomes in Patients with Chronic Diseases? A Systematic Review," *American Journal of Medicine*, vol. 117 (2004), pp. 182-192. The authors identified 16,917 titles and selected 102 studies that "used a systematic approach to care and evaluated patients with chronic disease, reported objective measurements of the processes or outcomes of care, and employed acceptable experimental or quasi-experimental study designs as defined by the Cochrane Effective Practice and Organization of Care Group."

found that disease management programs improved many different processes and outcomes of care, but they also reached the following conclusions:

“There is widespread belief that disease management may reduce health care costs for patients with chronic diseases. However, relatively few studies evaluated the effect of disease management on health care utilization or costs. Although a few programs showed some reductions, these findings were often modest and inconsistent. Both a smaller number and percentage of studies showed reductions in costs than improvements in quality of care that were due to disease management. Moreover, if the costs for program development and implementation were considered (few articles reported such costs), the economic ‘return on investment’ of these programs would be questionable. Thus, although disease management may improve the quality of care for patients with chronic disease, long-term studies may be required to show the economic benefit and financial return on investment.”

Other reviews of the literature have reached similar conclusions.²⁰ Thus, the prevailing evidence appears to be that while disease management programs improve adherence to practice care guidelines and lead to better control of the disease, their net effects on health costs are not clear.

Disease Management and Medicare

Policymakers are interested in disease management partly because they hope it will generate savings for federal health programs such as Medicare. Medicare’s fee-for-service program does not pay explicitly for disease management services today, and the potential for savings may seem greater because chronic conditions are more prevalent among the elderly and disabled. But translating the results of successful studies into savings for Medicare is not straightforward. First, there are questions about whether those results could be replicated over an extended period for elderly people who have several chronic conditions at the same time and are being cared for in a fee-for-service system. Second, even if disease management programs could reduce the total cost of providing care to the elderly and disabled, it is unclear whether Medicare’s existing payment systems would capture those savings or what the costs of the interventions needed to achieve them would be.

20. For example, see Rachel Christensen, “Disease Management Programs,” *Employee Benefit Research Institute Notes*, vol. 23, no. 8 (2002), pp. 1-5; Ashley Short, Glen Mays, and Jessica Mittler, “Disease Management: A Leap of Faith to Lower-Cost, Higher-Quality Health Care,” Center for Studying Health System Change Issue Brief No. 69 (2003), pp.1-4; and Statement of Mark E. Miller, Director, Medicare Payment Advisory Commission, “Disease Management in Traditional Medicare,” before the Senate Committee on Aging (November 4, 2003).

Limitations of the Available Evidence

Relatively little research exists that directly addresses the issues that would arise in applying disease management to the older and sicker Medicare population. The presence of multiple chronic conditions—a much more common phenomenon among the elderly—actually presents an additional difficulty because the standards of care that disease management programs are supposed to apply are less clear in that case. Moreover, to the extent that physicians' cooperation is a necessary component of adopting best medical practices, studies conducted in a managed care setting with a limited network of providers may not be applicable to Medicare's fee-for-service system, which covers nearly 90 percent of the enrollees. And interventions that depend on timely notification of an acute event like a hospitalization would present additional challenges for Medicare.

Another important difference between Medicare and private health plans is the different duration of the average member's enrollment. Enrollees in employer-sponsored health insurance often switch plans, encouraging a focus on short-term costs and savings. In contrast, beneficiaries remain in Medicare for many years, typically until death. While that time frame could allow any longer-term savings from disease management to accrue and could even encompass resulting improvements in life expectancy, those savings could be offset by additional spending on other medical conditions that enrollees developed over the remainder of their lifetime. If a disease management program merely changed the timing of significant expenditures—for example, postponing rather than preventing the need for a heart or kidney transplant—then the impact on spending associated with that specific disease could be modest; in turn, that outcome would increase the likelihood that new spending on other conditions would cancel out savings for the managed disease. Moreover, Medicare beneficiaries accrue a substantial portion of their lifetime program costs in the year that they die, costs that probably would be incurred one way or another. Indeed, if beneficiaries ended up dying from diseases that are more expensive to treat (such as cancer), the total cost for the program could actually increase.

It may also be the case that some savings from disease management are already incorporated into the "baseline" projections of Medicare spending under current law. For example, if disease management programs for Medicare intended to achieve savings by improving physicians' compliance with evidence-based treatment guidelines, then much of those savings might already have been captured—since physicians who treat Medicare patients also treat younger patients, including ones in private-sector disease management programs, and tend to use the same treatment protocols for both groups. At the same time, the home health and skilled nursing benefits available under Medicare could already be providing some of the active monitoring and educational services envisioned by proponents of disease management.

To address some of the limitations in the data on the effectiveness of disease management for Medicare, the Centers for Medicare and Medicaid Services (CMS) has been conducting various demonstration and pilot programs in both the fee-for-service and private plan systems.²¹ Several of the more recent projects will randomly assign eligible beneficiaries to treatment and control groups and then follow them for several years. Unfortunately, that design also means that results will not be available for some time.

CMS's latest demonstration, for which the agency is currently reviewing applications, is the program for "Voluntary Chronic Care Improvement Under Traditional Fee-for-Service," called for by section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. That new program, although not explicitly limited to disease management, is modeled after disease management programs—and one question it seeks to answer is whether savings from disease management can even be measured. Large in scale and scope, the demonstration is being designed to test programs in about 10 areas of the country (which in the aggregate must encompass at least 10 percent of the fee-for-service population).²²

Unfortunately, the only results that are currently available are for the Medicare Case Management Demonstration that was begun in 1993. An evaluation of that demonstration, citing in part a lack of physicians' cooperation, concluded that case management techniques alone did not yield savings or even improvements in health outcomes.

Obstacles to Savings in Medicare

Whether disease management programs could reduce Medicare spending would depend in part on the costs of implementing such programs and on the method of reimbursement. Typically, private health plans pay for disease management services on a per-enrollee, per-month basis. For Medicare, defining what services would be provided in exchange for the payment and setting a fee that was reasonable and commensurate with the cost of providing those services could be challenging. One difficulty would stem from the substantial variation that is now (understandably) observed in intervention strategies for different diseases and

21. For a discussion of CMS's projects, see Sandra M. Foote, "Population-Based Disease Management Under Fee-for-Service Medicare," *Health Affairs* (2003), pp. W3-342-W3-356, available at www.healthaffairs.org.

22. See Centers for Medicare and Medicaid Services, "Medicare Program: Voluntary Chronic Care Improvement Under Traditional Fee-for-Service Medicare," *Federal Register*, vol. 69, no. 79 (2004), pp. 22065-22079; Sandra M. Foote, "Chronic Care Improvement in Medicare FFS: Cosmetic or Transforming?" Health Insurance Reform Project Research Brief No. 13 (May 20, 2004), pp. 1-13; and Nora Super, "Medicare's Chronic Care Improvement Pilot Program: What Is Its Potential?" National Health Policy Forum Issue Brief No. 797 (2004), pp. 1-20.

among programs. As an alternative to payments for bundled services, Medicare could instead define various activities that disease management firms would undertake and establish a separate price for each activity (which is the way Medicare has often paid for other types of care in its fee-for-service program). Trade-offs would arise with either payment mechanism, though, as per capita payments create incentives to reduce the level of services provided while fee-for-service reimbursement systems generate incentives to provide excessive care. And regardless of the payment mechanism, total spending on disease management would depend significantly on how eligibility was determined; as discussed above, different targeting strategies have substantially different implications for the total cost of the intervention.

In addition or as an alternative, the payment rate for disease management services could be varied on the basis of some financial performance measures. For example, per capita administrative payments could be adjusted to reflect a disease management firm's success in reducing the overall health costs of its enrollees—though measurement issues could arise (as discussed above) in determining what costs would have been in the absence of the intervention. Although such an approach will be tested in Medicare's most recent demonstration, it could become particularly difficult to determine costs for a reference group once such a program was moved from testing to full-scale implementation.

Under a different approach, payments to disease management firms could reflect the full cost of the health services that their enrollees used—that is, the firms could receive a capitation payment to cover not just their administrative costs but all health services, and thus would bear insurance risk for those costs. A version of that approach is being tested in another of CMS's demonstrations, but much depends on how the level of the capitation payment is set; in the extreme, it could be difficult to distinguish that approach from the existing payment system for private health plans in Medicare (now known as Medicare Advantage).

Unless disease management firms did have to bear insurance risk for all of the covered benefits that their enrollees received, policymakers would need to consider how Medicare's current payment systems for medical services would affect the extent and nature of the cost savings that disease management programs could achieve. In some cases, the effect on Medicare spending would be complex:

- If disease management cut providers' costs of delivering Medicare services, that would not automatically yield savings for the program because of Medicare's payment structure. For example, if the length of hospitalizations or costs for treating a given condition during a hospital stay decreased, all of those savings would accrue to the hospital sector

because Medicare pays a fixed fee for each admission. In those cases, further legislation to reduce provider payment rates would be needed for Medicare to capture some of the resulting savings.

- Conversely, if disease management programs led to an increase in the use of physician services and associated lab and diagnostic tests, Medicare's payment system for physicians could prevent an increase in overall costs. Under Medicare's "sustainable growth rate" (SGR) payment system, the initial costs from more services would be offset by reductions in the rates for payments to physicians, and there would be no long-term impact on Medicare spending. In effect, physicians as a group would bear the increased costs instead of the Medicare program.²³

23. That scenario would be avoided if the legislation establishing disease management programs or separate legislation led CMS to increase the target payment levels under the SGR system to accommodate the increase in physician services. But Medicare spending would increase above the levels set in current law. If, instead, disease management programs reduced costs for visits to the doctor, and the SGR targets were not adjusted accordingly, the payment rates to doctors would increase, and Medicare would fail to capture those savings. (This discussion reflects an assumption that payments for the disease management programs would not themselves be included in the spending that is subject to the SGR targets.)

Appendix: The Disease Management Association of America's Definition of Disease Management

“Disease management is a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health. Disease management components include:

- Population identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models to include physician and support-service providers;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliances/surveillance);
- Process and outcomes measurement, evaluation, and management; and
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).

Full-service disease management programs must include all six components. Programs consisting of fewer components are disease management support services.”

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