The Effectiveness of Disease and Case Management for People with Diabetes

A Systematic Review

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Overview: This report presents the results of a systematic review of the effectiveness and economic efficiency of disease management and case management for people with diabetes and forms the basis for recommendations by the Task Force on Community Preventive Services on the use of these two interventions. Evidence supports the effectiveness of disease management on glycemic control; on screening for diabetic retinopathy, foot lesions and peripheral neuropathy, and proteinuria; and on the monitoring of lipid concentrations. This evidence is applicable to adults with diabetes in managed care organizations and community clinics in the United States and Europe. Case management is effective in improving both glycemic control and provider monitoring of glycemic control. This evidence is applicable primarily in the U.S. managed care setting for adults with type 2 diabetes. Case management is effective both when delivered in conjunction with disease management and when delivered with one or more additional educational, reminder, or support interventions.

Medical Subject Headings (MeSH): community health services, diabetes mellitus, evidence-based medicine, preventive health services, public health practice, review literature (Am J Prev Med 2002;22(4S):15–38)

Introduction

Diabetes mellitus (diabetes) is a prevalent, costly condition that causes significant morbidity and mortality. In the United States, 15.7 million people (5.9% of the total population) have diabetes, of whom 5.4 million are undiagnosed.[1] In 1997 alone, 789,000 new cases were diagnosed.[1] Moreover, according to death certificate data, diabetes is the seventh leading cause of death in the United States.[1] Mortality is primarily related to heart disease: adults with diabetes have death rates from heart disease about 2 to 4 times higher than those without diabetes.[1] In addition, the risk of stroke is 2 to 4 times higher in people with diabetes. Diabetes is the leading cause of new cases of blindness in adults aged 20 to 74 years, and it is also the leading cause of end-stage renal disease, accounting for about 40% of new cases. Neuropathy is also a major problem, as 60% to 70% of people with diabetes have this condition, and more than half of lower limb amputations occur among people with diabetes. Finally, the rate of pregnancies resulting in death of the newborn is twice as high among women with diabetes than among those without this disorder.[1]

Consistent with its extraordinary effect on the health of Americans, the costs of diabetes to the U.S. healthcare system are enormous: total (direct and indirect) costs were estimated at $98 billion in 1997.[2] Selby et al.[3] calculated that per-person expenditures for members of a managed care organization with diabetes were 2.4 times higher than for those without diabetes. Thirty-eight percent of the total excess costs was spent on treating long-term complications, particularly coronary heart disease.

Traditionally, healthcare delivery involves individual providers reacting to patient-initiated complaints and visits. Care is frequently fragmented, disorganized, duplicative, and focused on managing established disease and complications. Providers practice what they have been taught and what their anecdotal experiences have

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led them to believe is effective. The goals are generally short term, such as pain control or avoidance of hospital admission. Management is provider-directed and focuses on pharmacologic and technologic interventions, with little attention to patient self-management behaviors or provider–patient interactions.[4]

Traditional methods of healthcare delivery do not adequately address the needs of individual people or populations with diabetes. For example, in a survey of the care received by patients of primary care providers, people with diabetes were receiving only 64% to 74% of the services recommended by the American Diabetes Association (ADA) Provider Recognition Program.[5] And in a chart audit covering 1 year in a health maintenance organization (HMO) setting, glycated hemoglobin (GHb)[a] values were documented for only 44% of people with diabetes (ADA recommends two to four measurements per year), and annual urine protein measurements were performed on only 48% of patients.[6]

Available evidence shows that improving care for people with diabetes results in cost savings for healthcare organizations. In a review of economic analyses of interventions for diabetes, eye care and preconception care were found to be cost saving, and preventing neuropathy in type 1[b] diabetes and improving glycemic control with either type 1 or type 2 diabetes were found to be clearly cost-effective.[7] Gilmer et al.[8] modeled cost savings at an HMO and found that every percentage point increase in hemoglobin A1c (HbA1c) above normal was associated with a significant increase in costs over the next 3 years. Testa et al.[9] noted that improved glycemic control was associated with short-term decreases in healthcare utilization, increased productivity, and enhanced quality of life. Wagner et al.[10] found that a sustained reduction in HbA1c was associated with cost savings among adults with diabetes within 1 to 2 years of improved glycemic control.

In the last decade, innovative interventions for healthcare delivery have emerged that show promise for improving care, outcomes, and costs for individuals and populations with diabetes. Disease and case management are two such new interventions. This review examines the extent and quality of the evidence of their effectiveness when applied to people with diabetes.

[a]GHb (including hemoglobin A1c [HbA1c]) describes a series of hemoglobin components formed from hemoglobin and glucose, and the blood level reflects glucose levels over the past 120 days (the life span of the red blood cell).

[b]Type 1 diabetes, previously called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes, accounts for 5% to 10% of all diagnosed cases of diabetes and is believed to have an autoimmune and genetic basis. Type 2 diabetes was previously called non–insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes. Risk factors for type 2 include obesity, family history, history of gestational diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity. (Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. National diabetes fact sheet. 1998. Available at: www.cdc.gov/diabetes/pubs/facts98.htm. Accessed January 10, 2002.)

The *Guide to Community Preventive Services*

The systematic reviews in this report represent the work of the independent, nonfederal Task Force on Community Preventive Services (the Task Force). The Task Force is developing the *Guide to Community Preventive Services* (the *Community Guide*) with the support of the U.S. Department of Health and Human Services (DHHS) and in collaboration with public and private partners. The Centers for Disease Control and Prevention (CDC) provides staff support to the Task Force to develop the *Community Guide*. A special supplement to the *American Journal of Preventive Medicine*, "Introducing the *Guide to Community Preventive Services*: Methods, First Recommendations and Expert Commentary," published in January 2000,[11] presents the background and the methods used to develop the *Community Guide*. Evidence reviews and recommendations have been published previously on vaccine-preventable diseases,[12–14] tobacco use prevention and control,[15–17] and motor vehicle occupant injury.[18,19]

The *Community Guide* addresses many of the diabetes-related objectives of *Healthy People 2010*, the prevention agenda for the United States.[20] Objectives 5-11 through 5-15 relate to improving screening for complications involving the kidney, retina, extremities, and the oral cavity and monitoring of glycemic control.[20] By implementing interventions shown to be effective, healthcare providers and administrators can help their organizations achieve these goals while using resources efficiently. This report, in combination with the accompanying recommendations,[21] provides information on interventions that can help communities and healthcare systems reach *Healthy People 2010* objectives.

Methods

The *Community Guide*'s methods for conducting systematic reviews and linking evidence to effectiveness are described elsewhere.[22,23] In brief, for each *Community Guide* topic, a systematic review development team representing diverse disciplines, backgrounds, and work settings conducts a review by

- developing an approach to identifying, organizing, grouping, and selecting interventions for review;
- developing an analytic framework depicting interrelationships between interventions, populations, and outcomes;
- systematically searching for and retrieving evidence;
- assessing and summarizing the quality and strength of the body of evidence of effectiveness;
- translating evidence of effectiveness into recommendations;
- summarizing data about applicability, economic and other effects, and barriers to implementation; and
- identifying and summarizing research gaps.

The diabetes systematic review development team (see author list) generated a comprehensive list of strategies and created a priority list of interventions for review based on the (1) importance of the intervention in decreasing morbidity and mortality and in improving quality of life for people with

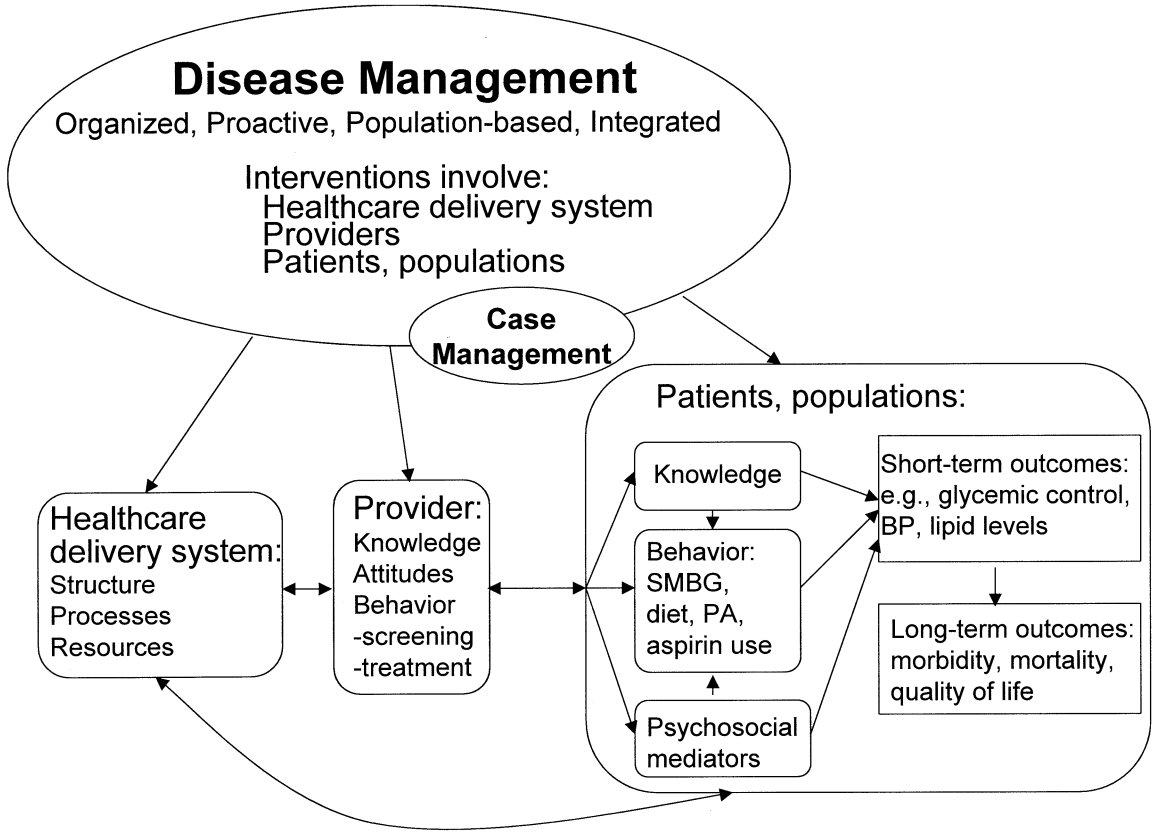

Figure 1. Analytic framework for disease and case management. Ovals denote interventions, rectangles with rounded corners denote short-term outcomes, and rectangles with squared corners denote long-term outcomes.
BP, blood pressure; PA, physical activity; SMBG, self-monitoring of blood glucose.

diabetes, (2) potential cost-effectiveness of the intervention, (3) uncertainty about the effectiveness of the intervention, and (4) potential feasibility of implementing the intervention in routine public health practice. Two priority areas were selected for review. The systematic review on the effectiveness of diabetes self-management education interventions in community settings is found in the accompanying article.[24] In this review we focus on two healthcare system interventions: disease management and case management.

The analytic framework for disease and case management interventions (Figure 1) illustrates our conceptual approach and depicts the relationships between interventions and provider and patient outcomes. The multifactorial nature of disease management is demonstrated by listing the subelements under the main elements of healthcare delivery system, providers, patients, and populations. Case management can be implemented along with disease management, as a single intervention, or with other interventions. It is, therefore, depicted as overlapping with disease management in Figure 1.

Outcomes for disease and case management also involve the healthcare system, provider, and patient or population (Table 1). Evidence for all outcomes listed was examined in these reviews, but the recommendations of the Task Force[21] were based on a subset of the outcomes thought to be most related to health and quality of life (those outcomes are in bold in Table 1). The healthcare system's structure, processes, and resources affect the knowledge, attitudes, and behaviors of providers, particularly with respect to screening for complications and prevention and treatment practices. Provider monitoring and subsequent appropriate management of GHb, blood pressure, and lipid levels can be associated with improved outcomes, as these physiologic measures are related to health outcomes[25–29], and effective treatments and prevention strategies are available.[29–32] Annual screening for retinopathy, nephropathy, and foot lesions and peripheral neuropathy, followed by appropriate management for people identified with abnormalities, is associated with improved health outcomes in people with diabetes.[30,33–37]

Disease and case management can affect patient knowledge[38] and psychosocial mediators such as self-efficacy,[39] social support,[40] and health beliefs,[40,41] which, in turn, predict self-care behaviors. Patient self-care behaviors (e.g., self-monitoring of blood glucose) and lifestyle correlate with short-term outcomes (glycemic control, blood pressure, lipid concentrations, renal function, lesions of the feet, and diabetic retinopathy),[25,37,42–48] which, in turn, affect long-term health (microvascular and macrovascular disease), quality of life, and mortality.[25–28,31,49]

The *Community Guide* focuses on interventions in community settings, interventions involving populations, and healthcare system approaches to care. Our consultants (see Acknowledgments) judged disease and case management to be important healthcare system-level interventions for people with diabetes. Our review did not examine evidence of the effectiveness of clinical care interventions focused on the individual patient: recommendations on clinical care can be

Table 1. Outcomes reviewed for disease and case management interventions in diabetes

Intermediate (process) outcomes		
Patient	Provider	Healthcare system
Patient knowledge	Provider participation	Health insurance
		Coverage, adequacy
Patient skills	Provider satisfaction	
Problem-solving skills		Provision of services
Self-monitoring blood glucose	Provider productivity	Regular source of care
Medication administration (including insulin)	Number of patients seen	Regular visits
		Availability of patient education
Psychosocial outcomes	**Screening and monitoring**	
Self-efficacy	**Blood pressure**	Health care utilization
Health beliefs	**Glycemic control**	Number of admissions
Mood	**Lipid levels**	Number of out-patient visits
Attitude	**Retinopathy**	Length of stay
Coping skills	**Peripheral neuropathy**	
Self-assessed health status	**Microalbuminuria**	Public health services
Locus of control	**Weight**	Availability
Perceived barriers to adherence		Quality
	Provider treatment	
Patient satisfaction with care	**Glycemic control**	
	Cardiovascular disease	
	Hypertension	
	Nephropathy	
	Neuropathy	
	Retinopathy	
	Vaccination: pneumococcal, influenza	
	Use of ACE inhibitors	
	Use of aspirin	

Short-term outcomes	Long-term outcomes	
Patient	Patient	Healthcare system
Glycemic control	**Macrovascular complications**	Economic outcomes
Glycated hemoglobin	**Peripheral vascular disease**	Outpatient utilization
Fasting blood glucose	**Coronary heart disease**	Hospitalization rates
	Cerebrovascular disease	Cost
Physiologic outcomes		Cost-effectiveness/benefit
Weight	**Microvascular complications**	
Lipid levels	**Decreased vision**	
Foot lesions	**Peripheral neuropathy**	
Blood pressure	**Renal disease**	
Microalbuminuria	**Foot ulcers**	
Retinopathy	**Amputations**	
	Periodontal disease	
Lifestyle		
Physical activity	**Mortality**	
Diet		
Smoking	**Quality of life**	
Substance abuse	**Disability/function**	
Mental health	**Pregnancy-related outcomes**	
Depression	**Neonatal morbidity and mortality**	
Anxiety	**Maternal morbidity**	
Work-related		
Work days lost		
Restricted duty days		

Outcomes in bold are those on which the Task Force based its recommendations.
ACE, angiotensin-converting enzyme; CVD, cardiovascular disease.

obtained from the ADA[29] and the U.S. Preventive Services Task Force provides screening recommendations.[50]

Data Sources

The scientific literature was searched through December 2000 by using the MEDLINE database of the National Library of Medicine (started in 1966), the Educational Resources Information Center database (ERIC, 1966), the Cumulative Index to Nursing and Allied Health database (CINAHL, 1982), and Healthstar (1975). The medical subject headings (MeSH) searched were *diabetes*, *case management*, and *disease management*, including all subheadings. Text word searches

were performed on multiple additional terms, including care model, shared care, primary health care, medical specialties, primary, or specialist. Abstracts were not included because they generally had insufficient information to assess the validity of the study using *Community Guide* criteria.[22] Dissertations were also excluded, because the available abstracts contained insufficient information for evaluation and the full text was frequently unavailable. Titles of articles and abstracts extracted by the search were reviewed for relevance, and if potentially relevant the full-text article was retrieved. We also reviewed the reference lists of included articles, and our consultants provided additional relevant citations.

Study Selection

To be included in the review, studies had to (1) be primary investigations of interventions selected for evaluation; (2) be conducted in Established Market Economies[c]; (3) provide information on one or more outcomes of interest preselected by the team (Table 1); and (4) meet minimum quality standards.[22] All types of comparative study designs were included, including studies with concurrent or before-and-after comparison groups.

Data Abstraction and Synthesis

Community Guide rules of evidence characterize effectiveness as strong, sufficient, or insufficient on the basis of the number of available studies, the suitability of study designs for evaluating effectiveness, the quality of execution, the consistency of the results, and effect sizes.[22] Each study that met the inclusion criteria was evaluated by using a standardized abstraction form[51] and assessed for suitability of its study design and threats to internal validity, as described previously.[22] Studies were characterized as having good, fair, or limited quality of execution on the basis of the number of threats to validity;[22] only those with good or fair execution were included. A summary effect measure (i.e., the difference between the intervention and comparison group) was calculated for outcomes of interest. Absolute differences were used for outcomes with consistent measurement scales (e.g., HbA1c and blood pressure) and relative differences for outcomes with variable scales or weights of measurement (e.g., quality of life). Interquartile ranges are presented as an index of variability when seven or more studies were available in the body of evidence; otherwise ranges are shown.

Summarizing Other Effects and Barriers

The *Community Guide* systematic review of disease and case management in diabetes routinely sought information on other effects (i.e., positive and negative health or nonhealth "side effects") and barriers to implementation (if there was evidence of effectiveness); these effects were evaluated by the systematic review development team and mentioned if they were considered important.

[c]Established Market Economies as defined by the World Bank are Andorra, Australia, Austria, Belgium, Bermuda, Canada, Channel Islands, Denmark, Faeroe Islands, Finland, France, Germany, Gibraltar, Greece, Greenland, Holy See, Iceland, Ireland, Isle of Man, Italy, Japan, Liechtenstein, Luxembourg, Monaco, the Netherlands, New Zealand, Norway, Portugal, San Marino, Spain, St. Pierre and Miquelon, Sweden, Switzerland, the United Kingdom, and the United States.

Economic Evaluations

Methods for the economic evaluations in the *Community Guide* were published in 2000.[23] Reviews of studies reporting economic evaluations were performed only if the intervention was found to be effective.

Summarizing Applicability

The body of evidence used to assess effectiveness was also used to assess applicability. The systematic review development team and the Task Force drew conclusions about the applicability of the available literature to various populations and settings after examining data on patient and intervention characteristics, settings, follow-up periods, methods of participant recruitment, and participation rates.

Summarizing Research Gaps

Systematic reviews in the *Community Guide* identify existing information on which to base public health decisions about implementing interventions. An important additional benefit of these reviews is the identification of areas in which information is lacking or of poor quality. Where evidence of the effectiveness of an intervention was sufficient or strong, remaining questions about effectiveness, applicability, other effects, economic consequences, and barriers to implementation are presented. In contrast, where the evidence of effectiveness of an intervention was insufficient, only research questions relating to effectiveness and other effects are presented. Applicability issues are also included if they affected the assessment of effectiveness. The team decided it would be premature to identify research gaps in economic evaluations or barriers before effectiveness was demonstrated.

Reviews of Evidence

Disease Management

Disease management has played a prominent role in innovative systems of clinical care over the past two decades. The earliest application of a disease-focused intervention involved prescription drugs,[52] and the first use of the term *disease management* appears to have been in the late 1980s at the Mayo Clinic.[53] In the mid-1990s the term emerged in the general medical literature, and by 1999 approximately 200 companies offered disease management services.[54] The initial focus of disease management was cost control, but, more recently, quality as well as economic efficiency have driven disease management interventions. These interventions are used in several clinical care areas, primarily for costly, chronic diseases or conditions such as heart failure,[55,56] arthritis,[57] and depression.[58,59]

The development of disease management has spawned a variety of definitions and related terms. We define disease management as an organized, proactive, multicomponent approach to healthcare delivery that involves all members of a population with a specific disease entity such as diabetes. Care is focused on and integrated across (1) the entire spectrum of the disease and its complications, (2) the prevention of comorbid

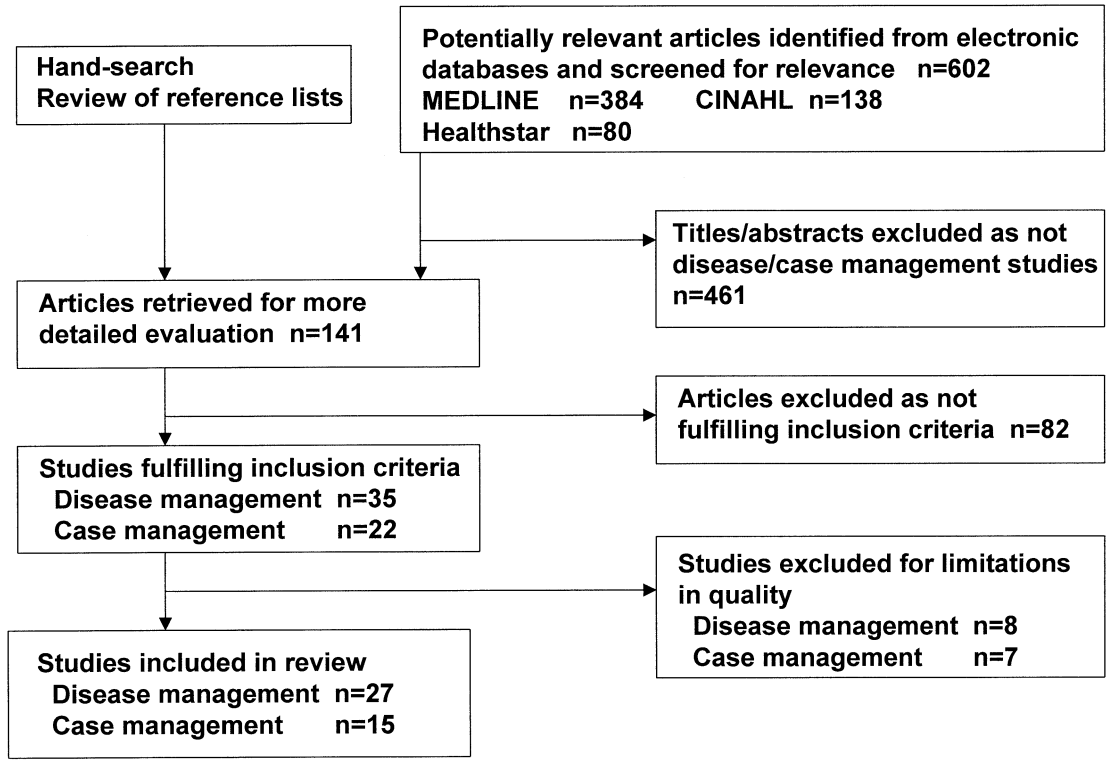

Figure 2. Systematic review flow diagram.
n, number of studies; CINAHL, Cumulative Index to Nursing Allied Health.

conditions, and (3) the relevant aspects of the delivery system. The goal is to improve short- and long-term health or economic outcomes or both in the entire population with the disease. The essential components of disease management are (1) the identification of the population with diabetes or a subset with specific characteristics (e.g., cardiovascular disease risk factors), (2) guidelines or performance standards for care, (3) management of identified people, and (4) information systems for tracking and monitoring. Additional interventions can be incorporated that focus on the patient or population (e.g., diabetes self-management education [DSME]), the provider (e.g., reminders or continuing education), or the healthcare system or practice (e.g., practice redesign in which "planned improvements" are made in "the organization of practice to better meet the needs of the chronically ill"[60]).

Effectiveness. Our search identified 35 studies (in 36 reports) examining interventions that met our definition of disease management (Figure 2).[61–96] The most common reasons that studies did not meet our definition were that they did not use some form of practice guidelines or that the entire target population was not identified, monitored, and managed.[25,97–123] Of the 35 studies, eight were not included because of multiple limitations in execution, usually inadequate descriptive information of the study population or intervention characteristics, or inadequate statistical analyses.[88–95] Among the 27 remaining studies, design suitability[22] was greatest in nine, moderate in three, and least suitable in 15. Details of the 27 qualifying studies are provided on the *Community Guide* website (www.thecommunityguide.org).

The 27 studies provide evidence of effectiveness for several patient and provider outcomes (Table 2). Effectiveness of disease management interventions on GHb levels is shown in Figure 3 and on rates of provider monitoring in Figure 4. GHb improved in 18 of 19 studies, with a median net change of −0.5% (interquartile range, −1.35% to −0.1%). Strong evidence existed for improvement in the percentage of providers performing annual monitoring of GHb and for retinopathy screening. Sufficient evidence was present of improvement in screening by providers for foot lesions or peripheral neuropathy, lipid concentrations, and proteinuria (Figure 4). Evidence was insufficient to determine the effectiveness of disease management on other important patient outcomes, including weight and body mass index, blood pressure, and lipid concentrations, as few studies examined these outcomes and the reported results were inconsistent.

Economic. Two economic studies were included in this review. The first study, conducted in Scotland, reported the average cost for adult patients of an integrated care disease management intervention versus traditional hospital clinic care.[65] Integrated care patients were

Table 2. Effects of disease and case management interventions in diabetes.

Intervention	Intervention description	Provider monitoring and screening	Patient outcomes
Disease management (n=27)	Disease management in the clinical setting is an organized, proactive, multicomponent approach to healthcare delivery, that involves populations with diabetes. Care is focused on and integrated across the entire spectrum of the disease and its complications, the prevention of comorbid conditions, and the relevant aspects of the delivery system. Median follow-up for studies examining GHb: 18 months	**GHb** (n=15)+15.6% (interquartile range, +4% to +39%)[63,65–67,70,71,77,78,81–87] **Lipid concentrations** (n=9) +24% (interquartile range, +21% to +26%)[67,70,75,77,81,82,85–87] **Dilated eye exams** (n=15) +9% (interquartile range, +3% to +20%)[63,65,71,72,75–77,79–85,87] **Foot exams** (n=9) +26.5% (interquartile range, +10.9% to +54%)[65,67,71,75,76,79,81,85,87] **Proteinuria** (n=7) +9.7% (interquartile range, 0 to +44%)[61,70,75,79,82,83,87]	**Intermediate outcomes** **Knowledge** (n=1) improved in type 2 diabetes, deteriorated in type 1 (p>0.05)[65] **Self-monitoring of blood glucose** (n=1) improved (p<0.0001)[68] **Self-efficacy** (n=1) improved (p>0.05)[68] **Patient satisfaction** (n=2) improved[68,71] **Healthcare utilization** Inpatient utilization (n=5) −31% (−82.3% to +11.4%)[68,70,71,85,87] Number of visits (n=4) −5.6% (−12.9% to +25.8%)[66,71,78,96] % patients with annual exam (n=3) +7.7% (+2.7% to +45.0%)[79,82,84] **Physiologic outcomes** **GHb** (%) (n=19) −0.5% (interquartile range, −1.35% to −0.1%)[62–69,71,73,74,78–81,83,85,86,96] **Weight** (kg) (n=3) +0.2 (−2.0 to +2.8)[79,83,96] **Body mass index** (kg/m^2) (n=4) +0.45 (−0.9 to +1.5)[64,65,69,73] **Blood pressure** (mmHg) (n=6) SBP +0.9 (−10.0 to +3.1); DBP −1.6 (−4.0 to +0.1)[64,65,69,70,87,96] **Lipid concentrations** (mg/dL) (n=4)[64,86,87,96] Total cholesterol (n=2) −4.7[96] and −12.0[64] LDL (n=2) −4.3[86] and +4.2[96] **Quality of life** (n=1) improved (p=0.025)[67]

(continued on next page)

Table 2. Effects of disease and case management interventions in diabetes (continued)

Intervention	Intervention description	Provider monitoring and screening	Patient outcomes
Case management (n=15)	Case management is "a set of activities whereby the needs of populations of patients at risk for excessive resource utilization, poor outcomes, or poor coordination of services are identified and addressed through improved planning, coordination, and provision of care."[126] Median follow-up for studies examining GHb: 12.5 months	**GHb** improved where case management was combined with disease management (n=5) +33% (interquartile range, +13% to +42%)[66,67,70,77,85] **Proteinuria** (n=3) +44%,[70] +63%,[79] and odds ratio 1.65[61] **Dilated eye exams** (n=4) +35% (+4% to +76%)[67,77,79,85] **Foot exams** (n=2) +54%[79] and +84%[67] **Lipid testing** (n=4) +30% (+24 to +44%)[67,70,77,85]	**Self-efficacy** (n=2) improved (p=0.01)[137] and (p=0.26)[68] **Patient satisfaction with diabetes care** (n=1) improved (p=0.003)[68] **Self-monitoring of blood glucose** (n=1) improved (p<0.0001)[68] **Healthcare utilization** Inpatient utilization (n=4) median relative change −18% (−82% to −18%)[68–70,85] Annual visits (n=2) increase in one study (p>0.05),[96] decrease in another[66] (no statistics) **Physiologic outcomes** **GHb** improved where case management was combined with disease management (n=11) −0.5% (interquartile range, −0.65% to −0.46%)[62,66–68,73,79,85,96,135–137] and improved where case management was implemented without disease management (n=3) −0.4% (−0.6% to −0.16%)[135–137] **Lipid concentrations** (mg/dL) (n = 3) Total cholesterol (n=2) −4.7[96] and 0[67] LDL (n=1) +4.2[96] **Body mass index** (kg/m^2) (n=1) +0.3[73] **Weight** (kg) (n=4) 0.0 (−4.5 to +16.8)[79,96,135,138] **Blood pressure** (mmHg) (n=2) SBP −20.5[138] and −4.2[96] DBP −6.1[138] and −2.3[96] **Quality of life** (n=2) improved in both studies (p=0.07),[137] (p=0.025)[67]

Results presented are median effect sizes (range) unless otherwise specified. The results presented for provider monitoring and screening are the annual rates of provider performance of the tests indicated, expressed as a percentage.

DBP, diastolic blood pressure; GHb, glycated hemoglobin; n, number of studies in the evidence set; NS, not significant; SBP, systolic blood pressure; LDL, low-density lipoprotein.

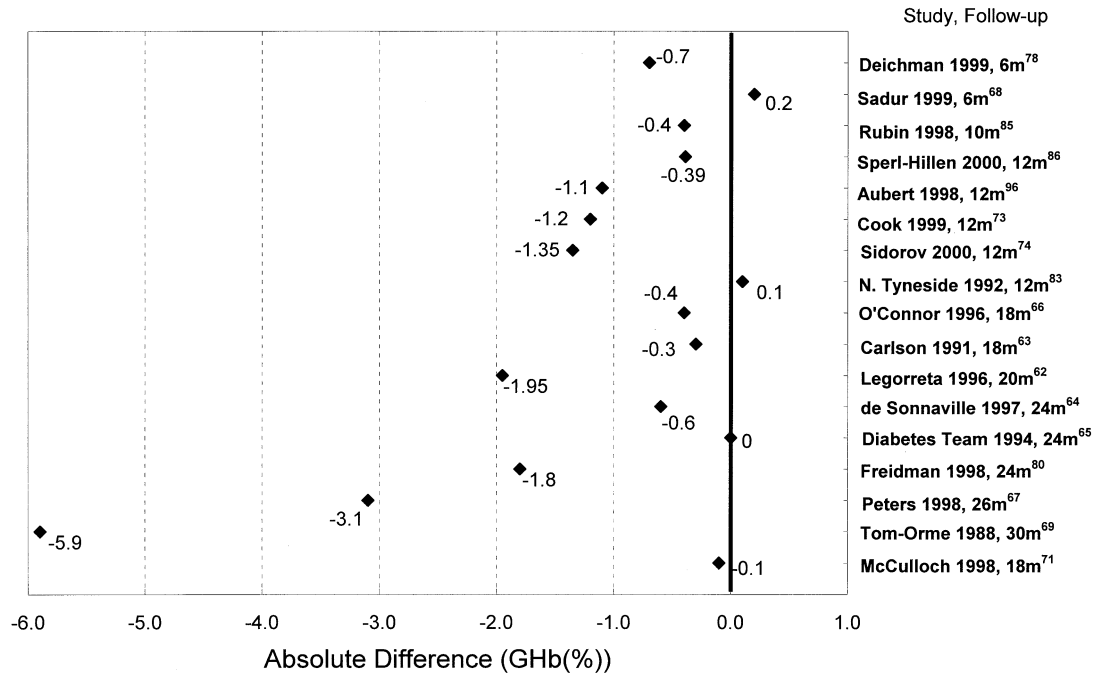

Figure 3. Effect of disease management on glycated hemoglobin. The study's first author and the follow-up interval from end of the intervention are shown on the y-axis. The absolute difference between the intervention and comparison group (post minus pre value) is shown on the x-axis. Median effect, −0.50%; interquartile range, −1.35% to −0.10%.
GHb, glycated hemoglobin; m, months.

seen in a general practice every 3 or 4 months and in the hospital clinic annually. General practitioners and patients received consultation reminders, patient records were consistently updated, and practices received care guidelines. Traditional care patients were seen at the clinic every 4 months and received appointment reminders. Costs included those associated with general practice and clinic visits (staff, administrative, overhead, and supply costs). The annual average adjusted costs were $143 to $185 for integrated care and $101 for traditional care, resulting in a higher annual average cost for the intervention of $42 to $84, adjusted to the *Community Guide* reference case.[23] After 2 years no significant difference was seen between the two groups for GHb, body mass index, creatinine, or blood pressure. The integrated care patients, however, had higher annual rates compared with the traditional care group for routine diabetes care visits (5.3 versus 4.8) and screening and monitoring of GHb (4.5 versus 1.3), blood pressure (4.2 versus 1.2), and visual acuity (2.6 versus 0.7). This study was classified as good, based on the quality assessment criteria used in the *Community Guide*.[23]

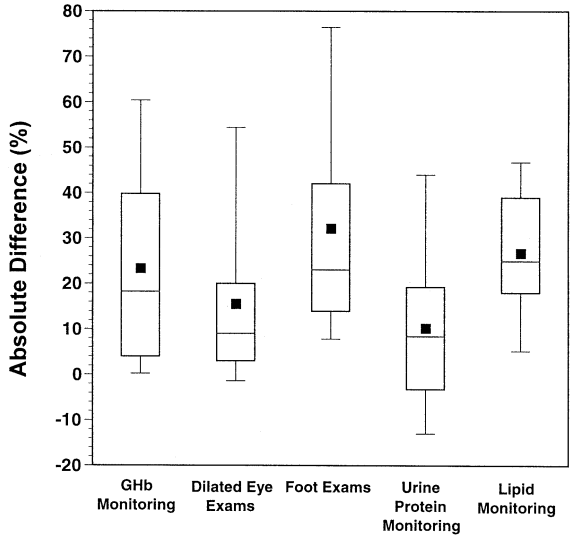

Figure 4. Effect of disease management on provider monitoring rates. The y-axis represents absolute change in provider monitoring rates (percentage of providers performing the test or screening in the last year) for each of the interventions on the x-axis. The box plot indicates the median, interquartile range, and range; the mean is denoted by a filled square.

The second study was a cost–benefit analysis of preconception plus prenatal care versus prenatal care only for women with established diabetes.[124] Preconception care involved close interaction between the patient and an interdisciplinary healthcare team (primary care and specialist physicians, nurse educator, dietitian, and social worker), intensive evaluation, follow-up, testing, and monitoring to optimize glycemic control and reduce adverse maternal and infant outcomes. The analysis modeled the program's costs and benefits, or savings, from reduced adverse maternal and neonatal outcomes. Program costs included per-

sonnel, laboratory and other tests, supplies, outreach, delivery, and time of the patient and a significant other. Costs for maternal and neonatal adverse outcomes were for hospital, physician, and subsequent neonatal care. Costs attributable to future lost productivity of mother and child were not included. The preconception care intervention's adjusted cost saving (net benefit) of $2702 per enrollee was the difference between estimated prenatal care only and the preconception and prenatal care intervention costs (program costs plus maternal and neonatal adverse outcome costs). The savings resulted largely from preventing the most expensive adverse events—congenital anomalies. The incremental benefit–cost ratio of 1.86 was the adverse outcome cost savings of the preconception plus prenatal care intervention versus the prenatal-only program divided by the difference in program costs. This ratio represents the savings for each additional dollar invested in the preconception and prenatal care program versus the prenatal care-only program. No effect size was determined, as this was a modeling study relying on secondary data. This study was classified as good, based on the quality assessment criteria used in the *Community Guide*.[23]

Applicability. These interventions were examined predominantly in two settings, community clinics[62–64,67,78,79,82,83,87] and managed care organizations, and thus conclusions about their effectiveness apply specifically to these settings. The managed care organizations included network or primary care-based models[61,77,86,96] and staff or group model HMOs.[66,68,70,72,74,80,81,84,85] Other settings (academic centers,[73,76] a hospital clinic,[65] and the Indian Health Service[69,75]) were examined but did not provide sufficient data to determine the effectiveness of disease management in those settings. The organizational components of community clinics and managed care delivery systems can differ from those in other delivery systems, limiting how applicable the interventions are in other types of delivery systems. However, findings in HMOs may be applicable to other organized, inclusive systems, such as the Indian Health Service.

Studies generally involved the entire population of providers in a facility, although in some studies the researchers selected specific providers to participate,[72,78,84] or the providers volunteered.[64,81,87] Researcher- or self-selected providers may have more of a commitment to change or have greater skills in systems change, the use of practice guidelines, or team approaches to care. Studies were conducted predominantly in urban centers in the United States[62,66–70,72–78,80,84–86,96,125] and Europe.[63–65,79,81–83,87]

The body of evidence on disease management examined either adults with type 2 diabetes or populations with mixed type 1 and 2 (predominantly type 2). Although type 1 patients were not examined exclusively in any study, these results likely apply to adults with type 1 disease. Despite important differences in characteristics between people with type 1 and type 2 diabetes, including age of onset, incidence of ketoacidosis, exogenous insulin dependence, and use of oral hypoglycemic drugs, the goals of treatment and general management guidelines are identical. Thus, effective methods of population management are likely to be similar for adults with type 1 and type 2 diabetes. Effectiveness can differ between children or adolescents and adults, however, as parents likely serve as intermediaries between the healthcare system and the child. No studies examined children with diabetes. No data were available on gestational diabetes (gestational diabetes develops in 2% to 3% of all pregnant women and disappears with delivery[1]), but disease management interventions likely apply to that population. Disease management has been studied in minority and racially mixed populations,[61,62,67,68,73,75,96] but it remains unclear how cultural characteristics can affect outcomes: access to these interventions might also differ between minority and Caucasian populations.

In summary, evidence for the effectiveness of disease management is applicable to adults with diabetes in managed care organizations and community clinics in the United States and Europe.

Case Management

Case management is an important intervention for people at high risk for adverse outcomes and excessive healthcare utilization.[126] It usually involves the assignment of authority to a professional (the case manager) who is not the provider of direct health care but who oversees and is responsible for coordinating and implementing care. In interventions involving diabetes, the case manager is generally a nonphysician, most commonly a nurse.

Case management was first used in nursing and social work as early as the 1850s,[127] and the terminology has evolved. The term *care management* is often used instead, and the American Geriatrics Society prefers this term to others.[128] The effectiveness of case management has been examined in a number of diseases, conditions, and situations other than diabetes: psychiatric disorders,[129] chronic congestive heart failure,[130] geriatric care,[131] and care initiated at the time of hospital discharge.[132,133]

Case management has five essential features: (1) identification of eligible patients, (2) assessment, (3) development of an individual care plan, (4) implementation of the care plan, and (5) monitoring of outcomes. Patients are generally identified because of high risk for excessive resource utilization, poor outcomes, or poor coordination of services. All people with diabetes might be targeted, but more commonly a subset with specific disease risk factors (e.g., coexisting

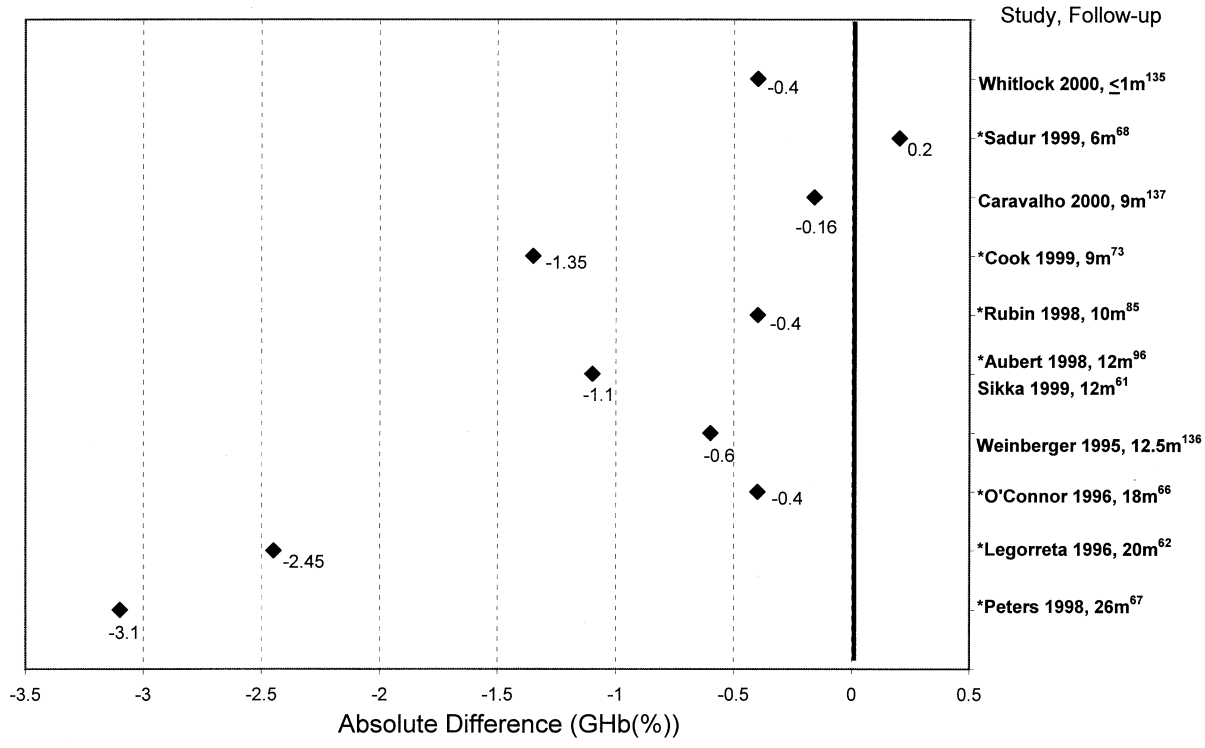

Figure 5. Effect of case management on glycated hemoglobin. The study's first author and the follow-up interval from end of the intervention are shown on the y-axis. An asterisk (*) indicates a study in which the intervention included disease management in addition to case management. The absolute difference between the intervention and comparison group (post value minus pre value) is shown on the x-axis. Median effect, −0.53%; interquartile range, −0.65% to −0.46%.
GHb, glycated hemoglobin; m, months.

cardiovascular disease or poor glycemic control) or high utilization (e.g., as determined by visits or costs) is targeted. After the population for case management has been identified, each individual patient's needs are comprehensively assessed, and an individual care plan is developed and implemented. Monitoring of the individual patient or population can involve process (e.g., patient satisfaction, service utilization), health, quality of life, or economic outcomes (e.g., cost, hospital admissions).

Case management interventions are often incorporated into multicomponent interventions, making it difficult to assess the effectiveness of case management itself. As Wagner[134] pointed out, these interventions can be "more than a case manager" and can be implemented in healthcare systems that encompass a more responsive system of care for the chronically ill along with other population-based interventions. Interventions that can be combined with case management include self-management education, home visits, telephone call outreach, telemedicine, and patient reminders.

Effectiveness. We identified 24 studies (in 27 reports) that examined the effectiveness of diabetes case management.[61,62,66–68,70,73,77,79,85,89,93,96,101,135–147] Seven studies were excluded because of multiple limitations in quality, usually inadequate descriptive information of the study population and intervention characteristics, or inadequate statistical analyses,[93,101,139–143] and two[146,147] were excluded for lack of relevant outcomes. Among the 15 qualifying studies, design suitability was greatest for 8, moderate for 1, and least suitable for 6. Details of the studies are found in Appendix A and at the website (www.thecommunityguide.org). The 15 studies provided data on numerous provider and patient outcomes (Table 2). Effectiveness of case management interventions on GHb is shown in Figure 5. Improvement in GHb was similar when case management was delivered in addition to disease management and when it was not. When case management was delivered with disease management, evidence was sufficient of its effect on provider monitoring of GHb. When examined without disease management, or in combination with disease management, evidence was insufficient of the effect of case management on lipid concentrations, weight or body mass index, and blood pressure, as studies were few, with inconsistent results. Quality of life improved in two studies.[67,137]

Economic. No studies were found that met the requirements for inclusion in a *Community Guide* review.[23]

Applicability. Except for one study in the United Kingdom,[79] all studies were performed in the United States. Settings were primarily managed care organiza-

tions,[61,66,68,70,77,85,96,137] although an academic center,[73] community clinics,[62,67,79,138,145] a U.S. military clinic,[135] and a U.S. veterans hospital[69,136] were included as well. In most studies the entire eligible population of providers at a clinic or in a healthcare organization was recruited to participate, but in three studies the researcher selected a subset of providers.[137,138,144]

Study populations were predominantly mixed by gender and race, and they were mainly adults with type 2 diabetes. One study[137] was of children with type 1 diabetes (mean age, 9.8 years). In numerous studies demographic information was missing, including age and type of diabetes.

Case management was implemented along with disease management in many of the studies.[61,62,66,68,73,77,79,85,89,96,145] In other studies additional interventions were used, including DSME,[136,137] telemedicine support,[135] insulin-adjustment algorithms,[137] group support,[137] visit reminders,[136] and hospital discharge assessment and follow-up.[69] It was not possible to determine the isolated effect of case management in these studies.

In summary, the evidence for the effectiveness of case management is applicable primarily in the U.S. managed care setting for adults with type 2 diabetes. The intervention is effective both when delivered in conjunction with disease management and when delivered with one or more educational, reminder, or support interventions.

Other Issues Related to Disease and Case Management

Other positive or negative effects. In addition to the positive effects of disease and case management discussed above, the Task Force identified an additional potential benefit in that the organized and evidence-based approach to care in diabetes can be extended to other diseases and healthcare needs in an organization. The same kind of infrastructure that supports diabetes disease and case management interventions, including information systems, practice guidelines, and support staff training and resources, could be used for the care of people with cardiovascular disease, mental health disorders, or chronic pain or for the delivery of preventive services (e.g., immunization of adults and children by using registries and reminder/recall systems). To our knowledge, however, this potential benefit has not yet been evaluated in the literature.

Barriers to implementation. The systematic review development team identified potential barriers at the level of the organization, the provider or support staff, or the patient when implementing disease and case management interventions, although these were not evaluated in this body of literature. Barriers at the organizational level include a deficiency of organizational leadership to support these interventions and the unavailability of financial resources necessary for implementation and maintenance. Furthermore, the organization may not have practice guidelines or the necessary skills and resources to develop guidelines, which can be perceived as a barrier. (Several practice guidelines are publicly available, such as the guidelines published annually by the ADA.[148])

For providers practicing in the traditional mode of reactive care, the switch to proactive, organized management requires the redesign of much of their practice and approach to patient care: appointment and follow-up scheduling; allocation of clinic time to review registries and practice guidelines; delineation of the roles of support staff and providers; the delegation of care traditionally performed by physicians to other professionals, such as nurses; team organization; and the use of planned visits and patient reminders.[60,149,150] Providers can find disease management time-consuming, particularly initially, and they can be inexperienced or uncomfortable with information systems. Barriers for using practice guidelines, described elsewhere,[151] include lack of awareness of or familiarity with them, disagreement with the guidelines, lack of confidence that patient outcomes can be improved, inability to overcome the inertia of previous practice, and external barriers such as inconvenience and insufficient time. In addition, little or no reimbursement may be available for delivering patient reminders and other proactive care strategies. Identifying patients to participate in these interventions may also be difficult. Patients can be identified, however, from provider and staff memory, hospital discharge summaries, claims data,[152,153] visit encounter forms, laboratory test results, patient-initiated visits, or pharmacy activity. Patient barriers include difficulties in maintaining healthy lifestyles and the complexity of self-management required for diabetes management.[154]

Research Issues for Disease and Case Management Interventions in Diabetes

Even though disease and case management were found effective in the managed care setting for improving glycemic control and provider monitoring of certain important outcomes, several important research gaps were identified in this review. One of the most pressing needs is to better define effective interventions. Disease management has multiple component interventions. To make optimal use of resources, however, only the interventions that contribute most to positive outcomes should be implemented, and these interventions need to be defined. Case management interventions are usually delivered with other interventions, and the effectiveness of these other interventions also needs to be defined. Are case management interventions delivered with disease management more effective than case

management delivered as a single intervention? Are there specific additional interventions that augment the effectiveness of disease and case management, such as DSME? Additional research questions relating to case management include identifying the optimal intensity (frequency and duration) of patient contact and determining whether professionals other than nurses (e.g., social workers or pharmacists) could function as case managers.

How best to integrate disease and case management interventions into existing healthcare systems also needs to be addressed. What are the strengths and limitations of delivering these interventions as part of primary care or specialty care, or might they best be delivered by contracted organizations and provider networks that are separate from the patient's healthcare delivery system (i.e., the carve-out model)?[155]

Although the existing effectiveness literature examines many important outcomes, research is needed to determine the effect of disease and case management on long-term health and quality of life outcomes, including cardiovascular disease events, renal failure, visual impairment, amputations, and mortality. Further work is also needed to determine the effect of case management on blood pressure, weight, lipid concentrations, and provider screening rates for retinopathy, peripheral neuropathy, and microalbuminuria. In addition, provider and patient satisfaction with these interventions needs much more attention from researchers.

As discussed earlier, the applicability of these data is somewhat limited, leaving numerous important questions unanswered. For example, are disease and case management effective in settings other than HMOs and community clinics, such as academic clinics and independent private practices? Do these interventions work better in some types of delivery systems than others? Are they effective for adolescents with diabetes? How do the cultural, educational, and socioeconomic characteristics of a population affect outcomes? What are the key barriers that providers perceive for disease and case management? How would it be best to obviate them? Do patients perceive any barriers to these interventions?

Numerous deficiencies in the methodologies of these studies were identified. Often there was inadequate descriptive information; studies need to include adequate demographic information (at a minimum, age, gender, race or ethnicity, and type of diabetes), a description of the delivery system infrastructure (automated information systems, prior use of guidelines, resource support, management [medical and nonmedical] commitment and support), and details of the intervention (components, frequency and duration of patient contact, who delivered the intervention, whether and which clinical practice guidelines were used, and degree and type of interface with primary care). In addition, more studies are needed with a concurrent comparison group to control for secular trends in healthcare delivery and patient practices. Finally, studies are needed in which a broad range of providers is recruited.

Conclusions

According to *Community Guide* rules of evidence,[22] strong evidence exists that disease management interventions are effective in improving glycemic control in people with diabetes and in improving provider monitoring of GHb and screening for diabetic retinopathy. There is sufficient evidence that disease management is effective in improving provider screening for foot lesions and peripheral neuropathy, screening of urine for protein, and monitoring of lipid concentrations. For case management, evidence is strong of its effectiveness in improving glycemic control. When case management is delivered along with disease management, evidence is sufficient that it is effective in improving provider monitoring of GHb. Deficiencies in methodology of the existing literature were identified, and research gaps noted, particularly in the areas of effectiveness of specific components of these interventions, effects on long-term health and quality of life outcomes, and application to diverse populations and settings.

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Appendix A: Summary Evidence Table
Case Management

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Aubert RE, et al.,[1] 1998 United States Randomized trial Greatest suitability Good quality	F/U: 12 months n=138 Limitations: 28% attrition	Type 2 (87.4%) 53y 60% female 77% white	I: Nurse case management intervention with diabetes education guidelines, diet and exercise reinforcement, and systematic treatment adjustments C: Usual care plus blood glucose meters and strips, and encouragement to enroll in diabetes education classes	(p-value represents between-group differences) Hemoglobin A1c (%): Absolute change: –1.1 Relative change: –12.2% ($p < 0.001$) Fasting blood glucose (mg/dL): Absolute change: –33.8 Relative change: –17.3% ($p = 0.003$) Systolic blood pressure (mmHg): Absolute change: –4.2 Relative change: NR ($p > 0.05$) Diastolic blood pressure (mmHg): Absolute change: –2.3 Relative change: –2.9% ($p > 0.05$) Weight (kg): Absolute change: +0.2 Relative change: NR ($p > 0.05$) Cholesterol (mg/dL): Absolute change: –4.7 Relative change: –2.1% ($p > 0.05$) Triglycerides: (mg/dL): Absolute change: –31.2 Relative change: –16.2% ($p > 0.05$) LDL (mg/dL): Absolute change: +4.2 Relative change: +3.2% ($p > 0.05$) Mean number visits in last 1y: Absolute change: +0.2 Relative change: NR ($p > 0.2$)

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Caravalho JY, et al.,[2] 2000 United States Before-and-after Least suitable Fair quality	F/U: 12 months n=56 Limitations: No description of group support or educational interventions; no control for differential exposure to intervention in newly diagnosed vs not newly diagnosed	Type 1 9.8y 55% female 66% white	Diabetes education and group support for parents and children, telephone visits (daily for 1 year if newly diagnosed)	Quality of life score (%): Relative change: +3.8% (p = 0.07, within) Self-efficacy score (%): Relative change: +5.6% (p = 0.01, within) Hemoglobin A1c (%): Absolute change: –0.2 Relative change: –1.7% (p = 0.73, within)
Chicoye L, et al.,[3] 1998 United States Before-and-after Least suitable Fair quality	F/U: 12 months n=5100 Limitations: No demographic information; duration, frequency, time frame, and who delivered the intervention unclear; no reporting of statistical tests	NR NR NR NR	DSME, patient reminders, registry, provider education; delivered by team: RN, pharmacist, certified diabetes educator, primary care physician	% patients who received the following exam or testing: Hemoglobin A1c: Absolute change: +13.0 Relative change: +29.6% (p < 0.01, within) Eye exam: Absolute change: +4.0 Relative change: +15.4% (p < 0.01, within) Lipid testing: Absolute change: +34.0 Relative change: +58.6% (p < 0.01, within)
Cook CB, et al.,[4] 1999 United States Before-and-after Least suitable Good quality	F/U: 6 months & 12 months n=698 Limitations: How physician feedback occurred not described	Type 2 57y 66% female 93% African American	DSME, medication adjustment according to step-care algorithm, registry, quality improvement; delivered by team for average of 8.6 visits over 12 months	Hemoglobin A1c (%) (6-month follow-up): Absolute change: –1.5 Relative change: –16.3% (p = 0.0025, within) Hemoglobin A1c (%) (12-month follow-up): Absolute change: –1.2 Relative change: –12.9% (p = 0.0025, within) Body mass index (kg/m^2) (12-month follow-up): Absolute change: +0.3 Relative change: +0.94% (p = 0.0025, within)

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Foulkes A, et al.,[5] 1989 United Kingdom Before-and-after Least suitable Fair quality	F/U: 2y n=213 Limitations: Limited demographic information; statistical methods not reported; no analysis of non-completers	Type 2 (72%) NR NR NR	Reorganized care: annual exams, case surveillance, standardized evaluation, self-management training; delivered by general practitioner and nurse, one exam per year	% patients who received at least 1 annual exam: Absolute change: +31.0 Relative change: +44.9% ($p < 0.05$, within) Weight (kg): Absolute change: –2.0 Relative change: –2.5% ($p > 0.05$, within) Fasting blood glucose (mmol/dL): Absolute change: –0.5 Relative change: –5.4% ($p > 0.05$, within) % patients who received the following screenings at baseline and follow-up: Urine protein: Absolute change: +63.0 Relative change: +394.0% (p NR) Dilated retinal exam: Absolute change: +53.0 Relative change: +196.0% (p NR) Foot exam: Absolute change: +54.0 Relative change: +200.0% (p NR)
Humphry J, et al.,[6] 1997 United States (Hawaii) Before-and-after Least suitable Fair quality	F/U: average 2.9y n=94 Limitations: Type of diabetes NR; use of a sub-sample in results; no statistical analyses; potential confounding by a cointervention	NR Newborn to >60y 75% female 100% Native Hawaiian	Diabetes management, centered on community healthcare workers as case managers, assistance in medication adjustment and DSME; delivered by team of community health workers, doctor, nurse, educator, and nutritionist, average of 63 encounters	% patients with weight loss of at least 10 lbs: Absolute change: +37.0 Relative change: NR % patients with decreased systolic blood pressure: Absolute change: +20.5 Relative change: NR % patients with decreased diastolic blood pressure: Absolute change: +6.1 Relative change: NR

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Legorreta AP, et al.,[7] 1996 United States Cohort study with comparison group Greatest suitability Good quality	F/U: 28m n=380 Limitations: Controls selected by researchers	Type 2 (85%) 61y 49.8% female 46% white	I: (Site A & B) Case management, tracking, physician education, patient reminders, provider guidelines, database registry, telephone call follow-up as needed; delivered by team (MD, RN, PA, endocrinologist, dietitian, ophthalmologist, podiatrist), every 3 months for 28 months C: Usual care	Glycated hemoglobin (%) (all within groups) Site A: Absolute change: –2.8 Relative change: –32.1% (p = 0.0001) Site B: Absolute change: –1.1 Relative change: –10.3% (p = 0.0028) % patients with LDL >160 (mg/dL): Site A: Absolute change: –55.0 Relative change: –25.8% (p = 0.008) Site B: Absolute change: –26.0 Relative change: –14.3% (p = 0.004)
O'Connor PJ, et al.,[8] 1996 United States Cohort study with comparison group Greatest suitability Fair quality	F/U: up to 18 months n=239 Limitations: No demographics of study population; no data on number of diabetes-related visits; attrition 26% for intervention, 45% for controls; no baseline comparison of demographic data	NR NR NR NR	I: Continuous quality improvement process, patient registries, educational outreach for DSME, screening, and monitoring of complications; primary care focused; delivered up to 18 months C: Usual care	% patients with at least 1 hemoglobin A1c at follow-up: Absolute change: –7.0 Relative change: –11.5% (statistics NR) Mean number of visits in last 1y: Absolute change: –0.3 Relative change: –5.6% (statistics NR) Mean hemoglobin A1c (%): Absolute change: –0.4 Relative change: –4.8% (p < 0.001, between)

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Peters AL, et al.,[9] 1998 United States Cohort study with comparison group Greatest suitability Fair quality	F/U: 2.3 years n=164 Limitations: No cluster analysis; covariates unclear; unequal groups at baseline	Type 2 (94%) 55.6y 51% female 40% white	I: Clinical guidelines, registries, RN care, patient reminders, DSME; delivered by an RN, quarterly for 2.3 years C: DSME, weekly for 4 weeks	% patients with monitoring in last 12 months (no statistics): Hemoglobin A1c: Absolute change: +60.0 Lipids: Absolute change: +44.0 Foot exams: Absolute change: +84.0 Ophthalmology referrals: Absolute change: +76.0 Hemoglobin A1c (%): Absolute change: –3.1 Relative change: –26.1% ($p < 0.05$, between) Cholesterol: No significant change Proteinuria: No significant change Blood pressure: No significant change Quality of life: Relative change: +4.7% ($p = 0.025$, between)

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Rubin RJ, et al.,[10] 1998 United States Before-and-after Least suitable Fair quality	F/U: variable: 6–14 months n = ~7000 Limitations: No demographics of study population; no statistical testing	NR NR NR NR	Carve-out model: multidisciplinary team, profile providers and hospitals, physician education, medical leadership panel with managed care organization, electronic tracking system, stratified by severity of diabetes; delivered by RN and case manager for 6–14 months	% patients with at least 1 exam in last 1y (no statistics): Glycated hemoglobin: Absolute change: +42.0 Relative change: +123.5% Eye exam: Absolute change: +17.0 Relative change: +73.9% Foot exam : Absolute change: +23.0 Relative change: +1150.0% Cholesterol: Absolute change: +24.0 Relative change: +61.5% Hospital admissions per 1,000 member diabetic years: Absolute change: –43.0 Relative change: –18.0% Bed days per 1,000 member diabetic years: Absolute change: –289.0 Relative change: –21.6% Hemoglobin A1c (%): Absolute change: –0.4 Relative change: –4.5%

Appendix continued

Author, Year *Location* *Study Design* *Suitability* *Study Quality*	*Follow-up Interval* *n* *Limitations*	*Demographics:* *Type of Diabetes* *Mean Age* *Sex* *Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Sadur CN, et al.,[11] 1999 United States Randomized trial Greatest suitability Fair quality	F/U: 6,12, and 18 months n=185 Limitations: 32% attrition; some control patients received the intervention	Type 2 (78%) 56y 43% female 75% white	I: DSME and cluster group visits; delivered by RN diabetes educator, with support from endocrinologist C: Usual care	Hemoglobin A1c (%) (6 month follow-up) Absolute change: –1.1 Relative change: –11.4% ($p < 0.001$,within) 12-month follow-up: Self-monitoring of blood glucose (number of times daily): Absolute change: +1.1 Relative change: +67.5% ($p < 0.0001$, between) Frequency of self-exam of feet: Absolute change: +1.3 Relative change: +25.8% ($p = 0.23$, between) Exercise (minutes per week): Absolute change: +13.0 Relative change: +15.4% ($p = 0.5$, between) 18-month follow-up: Hospitalizations per 1000 person-months Absolute change: –13.5 Relative change: –82.3% ($p = 0.04$, between)
Sikka R, et al.,[12] 1999 United States Randomized trial Greatest suitability Good quality	F/U: 12 months n=138 Limitations: 28% attrition rate with no comparison to completers	Type 2 (88%) 53.8y 59% female 76% white	I: Practice guidelines (urine screening and glycemic control), RN case management, registry; by RN or certified diabetes educator C: Usual care	Urine protein/microalbumin testing: OR: +1.7 ($p = 0.033$, between)
Weinberger M, et al.,[13] 1996 United States Randomized trial Greatest suitability Good quality	F/U: 6 months n=751 Limitations: Type of diabetes not reported	NR 63y 99% male 65% white	I: Before discharge: RN assessment, assigned PCP and scheduled for a visit; after discharge: 2 day follow-up phone call from RN, 1 week follow-up with primary care physician C: Usual care	% patients readmitted to hospital in 6 months: Absolute change: –0.9 (no statistics) Relative change: NR

Appendix continued

Author, Year Location Study Design Suitability Study Quality	*Follow-up Interval n Limitations*	*Demographics: Type of Diabetes Mean Age Sex Race/Ethnicity*	*Intervention*	*Results: Summary Effect Measures, p-value, within or between groups*
Weinberger M, et al.,[14] 1995 United States Randomized trial Greatest suitability Good quality	F/U: 14 months n=275 Limitations: None	Type 2 63y 100% female 59% white	I: Telephone calls by RN at least monthly to review regimens and signs/symptoms, facilitate compliance, and help reduce barriers to compliance and primary care; average 13 contacts per patient per year C: Usual care	Hemoglobin A1c (%): Absolute change: –0.6 Relative change: –5.6% (p = 0.046, between) Fasting blood glucose (mg/dL): Absolute change: –18.3 Relative change: –10.0% (p = 0.011)
Whitlock WL, et al., [15] 2000 United States Randomized trial Greatest suitability Good quality	F/U: ≤1 month from end of I n=28 Limitations: Use of recommended educational classes by controls not reported	Type 2 63y 64% female NR	I: Home telemedicine by nurse case manager and PCPs C: Usual care	Hemoglobin A1c (%): Absolute change: –0.4 Relative change: –4.2 % (p<0.05, within) Mean weight (lbs): Absolute change: –10.0 Relative change: –4.6% (p<0.05, within)

C, control group; DSME, diabetes self-management education; F/U, follow-up from end of baseline; I, intervention group; LDL, low density lipoprotein; m, months; n, sample size; NR, not reported; OR, odds ratio; PA, physician's assistant; PCP, primary care provider; y, year(s).

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