



Effective Health Care Program

Outpatient Case Management for Adults With Medical Illness and Complex Care Needs

Executive Summary

Background

Chronic diseases are the leading cause of illness, disability, and death in the United States.¹ Providing medical care for chronic illness is often complex, as patients require multiple resources, treatments, and providers. One strategy for improving care for chronic conditions is to develop programs that improve care coordination and implement care plans.^{2,3,4} Case management (CM) is one such supplemental service, in which a person, usually a nurse or social worker, takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals.

CM tends to be more intensive in time and resources than other chronic illness management interventions, and it is important to evaluate its specific value. CM is often utilized when the coordination and integration of care is difficult for patients to accomplish on their own. CM usually involves high-intensity engagement with patients, and case managers often adopt a supervisory role in comprehensively attending to patients' complex needs.⁵ Conceptually, a case manager can be seen as an agent of the patient, taking a "whole-person" (rather than solely clinical or disease-focused)

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

approach to care, and serving as a bridge between the patient, the practice team, the health system, and community resources.



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

**Effective
Health Care**

The coordinating functions performed by a case manager include helping patients navigate health care systems, connecting them with community resources, orchestrating multiple facets of health care delivery, and assisting with administrative and logistical tasks. Case managers also can perform clinical functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. Such clinical functions are often the defining aspects of other chronic illness management interventions. In the context of chronic illness care, they are central to the role of a case manager, but a case manager also performs coordinating functions.

The evolution of CM models in health care and their expanding use in chronic illness management has led to the term “case management” being used to describe a wide variety of interventions. As a result, there is no consensus about the core components of CM. Moreover, the term “case management” is often used interchangeably with other forms of chronic illness management interventions such as “disease management” and “self-management support.”

Individual CM programs usually are customized for the clinical problems of the population being served. Thus, a CM program for homeless people with AIDS has a much different mix of activities than a program serving patients with dementia and their caregivers or one designed to improve the quality of diabetes care. Some CM interventions include primarily coordinating functions while others focus mainly on clinical activities. Other programs target patients with characteristics—limited social support or physical or mental disability—that make them particularly vulnerable to lack of care coordination, while others serve unselected populations with a given chronic illness. Case management interventions can be intensive, with multiple face-to-face interactions and home visits, while others may entail only infrequent telephone calls. In some programs, case managers operate independently, while in others, they work closely with a patient’s usual care provider or with a multidisciplinary team of health professionals. The variability of CM interventions is a comparative effectiveness issue that is addressed in this report. We examine a wide variety of CM approaches and define when and where CM leads to consistent effects on outcomes that are meaningful to patients and health care systems.

Objectives

As noted, the situations in which CM has been used are numerous and diverse. In recognition of the substantial heterogeneity of purposes, approaches, and populations

included within the broad category of CM, we limited the scope of this review in a number of ways. We aimed to define and identify a subset of CM models representing a sizable category of CM that is common and meaningful for patients and their caregivers. We also aimed to circumscribe the scope of included CM models to ensure that the review would be adequately focused and practical. Such an approach allows for a more complete understanding of the evidence regarding the included category of CM. We necessarily excluded certain types of CM. We limited the scope of this review to CM interventions for medical, as opposed to psychiatric, illness. CM is often used to improve the management of psychiatric illnesses such as depression, schizophrenia, or substance use disorders. CM in those contexts, however, is substantively different in its nature and objectives from CM for chronic medical illness. Although we did not include studies in which the goal of CM was primarily to improve psychiatric care, we did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness. Similarly, we included models of case management that integrate care for psychiatric disorders that are associated with significant medical comorbidities, such as dementia. Additionally, we restricted the review to CM programs having an ongoing and sustained relationship between the case manager and patient. Hence, despite promising evidence for certain models of short-term, intensive CM or models that focus on transitional care, we did not include such models in this review.^{6,7} We also limited the scope of this review to outpatient settings.

This report summarizes the existing evidence addressing the following Key Questions:

Key Question 1:

In adults with chronic medical illness and complex care needs, is case management effective in improving:

- a. *Patient-centered outcomes*, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?
- b. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?
- c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2:

Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3:

Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

The analytic framework (Figure A) depicts the key questions in the framework of the populations, intervention, and outcomes considered in the review.

Methods

Input From Stakeholders and Topic Refinement

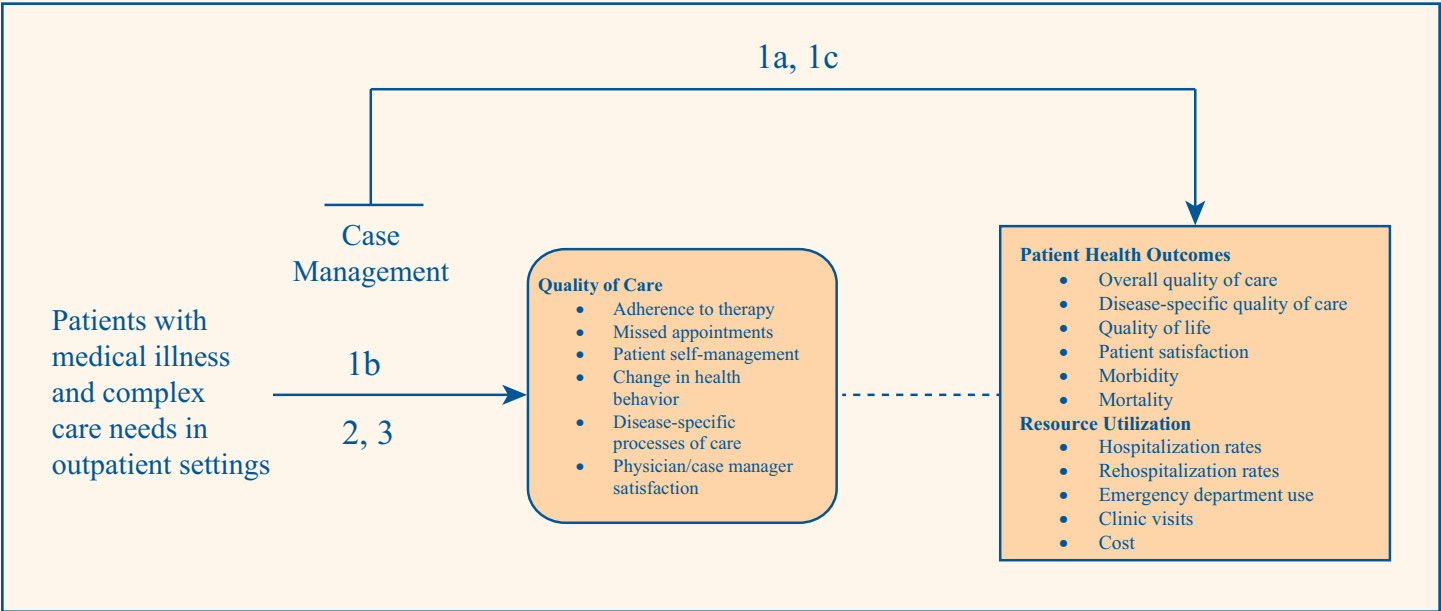
Input from stakeholders was received during several phases of the project. In a topic refinement phase, the scope of the project was refined with input from a panel of Key Informants including representatives of public organizations and societies with an interest in CM, individuals who perform CM research, experts on the chronic care model, and practicing case managers. The Key Questions for the report were then revised and

posted for public comment on the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care (EHC) Web site for 4 weeks. Public comments were received by the study team and were considered for additional refinements of the Key Questions. A Technical Expert Panel (TEP) helped refine Key Questions, identify important issues, and define parameters for the review of evidence. The TEP also reviewed the research protocol, which is posted on the AHRQ EHC Web site (effectivehealthcare.ahrq.gov). Statements of potential conflicts of interest for all participants, researchers, and authors were reviewed by AHRQ. The draft report was reviewed by an AHRQ Task Order Officer and an associate editor prior to peer review. Simultaneous with the peer review period, the draft report was posted on the AHRQ EHC Web site where it was available for 4 weeks for public comment. A disposition table detailing peer reviewer and public comments and the authors’ responses will be posted on the AHRQ EHC Web site 3 months after posting of the final report.

Data Sources and Selection

We worked with medical librarians who have extensive experience with conducting literature searches for comparative effectiveness reviews. We searched MEDLINE® (Ovid), CINAHL® (EBSCO), the Cochrane Central Register of Controlled Trials (Ovid EBM Reviews), the Cochrane Database of Systematic Reviews (Ovid EBM Reviews), and the Database of Abstracts of Reviews of Effects (Ovid EBM Reviews). We searched by broad level subject terms and keywords. The search

Figure A. Analytic framework



Note: Numbers refer to Key Questions.

was limited to English language materials and adult populations. The search covered the time period through August 2011. Gray literature searches included clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, and WHO Trial Registries). Additional studies were identified by reviewing the reference lists of published clinical trials and review articles that addressed CM.

We developed criteria for inclusion and exclusion of studies based on the Key Questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) as described below. The titles and abstracts for all citations were reviewed independently by two team members. Full-text articles were retrieved if one or both of the reviewers judged the citation to be possibly relevant. The full-text articles then were reviewed independently by two team members for inclusion/exclusion. Disagreements were adjudicated by a third team member.

Populations of Interest

This review focuses on adults with medical illness and complex care needs in outpatient settings. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs were defined broadly, and we included studies with case definitions based on health care resource utilization, patient health status, and/or multifactor assessments that included measures such as socioeconomic status or patient self-efficacy. The included studies sometimes addressed populations in which psychiatric problems, such as depression or dementia, were important comorbid conditions. Studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder were excluded.

Interventions

We define CM as a process in which a person (alone or in conjunction with a team) manages multiple aspects of a patient's care. Key components of CM include planning and assessment, coordination of services, patient education, and clinical monitoring. We excluded studies in which the case manager was a licensed independent practitioner, such as a primary care physician, a geriatrician, or a nurse practitioner. This is because such CM is part of the primary medical care provided to the patient rather than a separate clinical service.

Comparators

In most studies, CM is compared with usual care (i.e., care without a CM component). Usual care can be quite variable across studies, but in most cases the comparator was the same milieu of clinical services without a distinct CM component. When a study compared two or more different types of CM, then the comparator was the alternative type of CM. For clinical trials and other studies having a comparison group, we specifically examined the study's reports for information about contamination (provision of CM or other care coordination services to the control group).

Outcomes of Interest

The outcomes of interests are specified in the Key Questions listed above. The three categories of outcomes are patient-centered outcomes, quality of care outcomes, and resource utilization outcomes. These categories were derived from the set of outcomes specified in descriptions of CM programs in the literature. These programs addressed the needs of defined patient populations and have discrete clinical goals. These three categories reflect the categories of goals that usually are addressed in CM.

Comparative effectiveness reviews (CERs) commonly classify outcomes as either benefits or harms. The CM literature has generally not classified harms of CM. Thus, the outcomes listed above are not classified as either benefits or harms.

Timing

A level of longitudinal engagement with patients was a criterion for study inclusion. We excluded studies that provided CM for only short durations (30 days or less). This criterion excluded many studies that evaluated short-term posthospitalization programs (often termed "transitional care" programs). Such programs fall into a large category of inpatient discharge planning activities that are beyond the scope of this review.

Settings

We included only studies in the outpatient setting, including primary care, specialty care, and home care settings. No geographic limitations were applied.

Types of Studies

We included randomized trials and observational studies pertinent to the Key Questions. The observational studies

included studies using nonexperimental designs such as cohort, case-control and pre-post designs. Previously published systematic reviews were not included as part of the evidence base but were compared with the results of the current review.

Evidence Synthesis

Data were abstracted and used to assess applicability and quality of the study: study design; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, ethnicity, primary disease, comorbidities, complex care needs, and insurance carrier); CM intervention characteristics (including case manager professional identification and prior training); pre-intervention training for case managers; caseload and the nature of care provided by the intervention (e.g., patient education, coordination of services, medication monitoring, and adjustment); results for each outcome, focusing on the outcomes of interest (patient-centered, resource utilization, and process of care outcomes). All data abstracted from included studies were verified for accuracy and completeness by a second team member. Disagreements were adjudicated by the lead investigator.

We used predefined criteria to assess the potential for bias in individual controlled trials and observational studies adapted from methods proposed by Downs and Black⁸ (observational studies) and methods developed by the U.S. Preventive Services Task Force.^{9,10} Individual studies were rated as “good,” “fair,” or “poor.” Because of the broad range of models of CM, we grouped the studies by the types of program and the clinical problems that were chiefly addressed. For the majority of studies, these groupings were based on particular diagnoses, such as congestive heart failure (CHF), diabetes, or dementia, and studies of programs that addressed the needs of older adults with severe illness. We reviewed the findings of the studies for each of these categories and then assessed overall findings (across population groups), as related to the project’s Key Questions.

We performed a qualitative data synthesis because the heterogeneity in populations and interventions generally did not allow for quantitative synthesis.

The strength of evidence for each Key Question was initially assessed for the outcomes applicable to each patient category. Our approach is consistent with the methods described by Owens et al.¹¹ to evaluate the body of evidence for each outcome in each patient category. This approach uses the following categories:

- Quality (good, fair, poor)
- Consistency (consistent, inconsistent, unknown)
- Directness (direct or indirect)
- Precision (precise, imprecise)

Without formal pooled analyses, we were not able to assess the possibility of publication bias. The strength of evidence was assigned an overall grade of High, Moderate, Low, or Insufficient according to a four-level scale.¹¹

A defining characteristic of comparative effectiveness reviews is their intent to evaluate “the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under “real-world” conditions.¹² There is not currently an agreed-upon system or tool to evaluate applicability, so we describe applicability according to the PICOTS format. Specifically, since outcomes and interventions are often specific to patient populations and medical conditions, we detail results of case management according to patient populations. Additionally, factors about the intervention of CM itself may influence applicability. For example the intensity of the intervention may not be feasible across settings. Therefore, these factors are described within each section when possible.

Results

Overall, the multiple search sources yielded 5,645 citations, of which 1,201 full-text articles were retrieved and 153 articles were judged to be relevant (109 total studies). The majority were randomized trials. The studies were sorted by patient population and were assigned to the following categories:

- Older adults with one or more chronic diseases (20 studies/30 articles)
- Frail elderly (14 studies/17 articles)
- Dementia (15 studies/26 articles)
- Congestive heart failure (12 studies/12 articles)
- Diabetes mellitus (12 studies/24 articles)
- Cancer (6 studies/8 articles)
- Chronic infections (HIV or tuberculosis) (15 studies/17 articles)
- Other medical problems (15 studies/19 articles)

The specific outcomes reported in studies varied across the population groups, particularly for the patient-centered

outcomes (Key Question 1a). Thus, the applicability of conclusions drawn from the evidence syntheses often is specific to the individual patient populations. These population-specific conclusions are summarized in Table A below.

The sample sizes of the studies of CM were variable, but many of the studies included fairly small samples of patients. Thus, for most studies subgroup analyses were not possible. For Key Question 2, the population comparisons were usually based on indirect comparisons from separate studies.

Nearly all of the clinical trials of CM programs compared a single type of program with a usual care condition. There were very few trials that directly compared more than one model of CM. This limited the evidence available for Key Question 3. Another limitation was that many studies included incomplete information about the content of the CM that was delivered to patients.

Due to heterogeneity in the characteristics of CM interventions and the limitation of small sample sizes in many studies, the strength of evidence for the conclusions often is only low or moderate. This applies to statements about both positive effects and the lack of effect on outcomes. However, in some cases there were consistent findings in large clinical trials of uniform populations. In such cases, the evidence statements were assigned high strength of evidence ratings.

Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*?

Mortality

Patients provided CM did not experience lower mortality in general populations of patients with chronic illness, in the frail elderly, those with HIV infection, or in patients with specific diseases such as cancer, congestive heart failure, or dementia.

Quality of Life and Functional Status

CM interventions produced mixed results in terms of improving patients' quality of life (QOL) and functional status. In general, CM was frequently successful in improving aspects of functioning and QOL that were directly targeted by the interventions. For instance, CM was successful in improving caregiver stress among persons caring for patients with dementia and CHF-related QOL among patients with CHF. The measures used to

evaluate QOL and functional status varied across studies, and overall, the improvements in QOL and functional status achieved by CM were either small or of unclear clinical significance. CM was less successful in improving overall QOL and functioning, as indicated by global measures not specific to a particular condition.

Ability To Remain at Home

One measure of the clinical significance of improvements in functioning for elderly patients is the ability to remain at home and avoid nursing home placement. This outcome was often the primary objective of CM programs for patients with dementia. In most studies of the frail elderly and of patients with dementia, CM was not effective in maintaining patients' ability to live at home. Evidence from one study suggests that a high-intensity CM intervention sustained over a period of several years can produce a substantial delay in nursing home placement for patients with dementia.

Disease-Specific Health Outcomes

The effect of CM on disease-specific outcomes was inconsistent. In some studies, CM had a positive impact on specific symptoms, including pain and fatigue in patients with cancer and depressive symptoms among caregivers of patients with dementia. Notably, however, CM had an inconsistent impact on clinical outcomes among patients with diabetes, including glycohemoglobin levels, body weight, and lipids.

Patient Satisfaction With Care

CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Satisfaction was most substantially improved in the domain of coordination among health care providers.

Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*?

Disease-Specific Process Measures and Receipt of Recommended Services

CM was effective in increasing the receipt of recommended health care services when it was an explicit objective of the CM intervention. For instance, CM interventions designed to improve cancer therapy

adherence for patients with breast and lung cancer were successful in increasing the receipt of radiation treatment, as recommended in clinical guidelines. The effect of CM on guideline-recommended care in general, however, was less consistent. Studies showed only sporadic effects on elements of quality of care, such as receipt of appropriate medications for patients with CHF or diabetes, or receipt of appropriate preventive services for elderly patients.

Patient Self-Management

CM was effective in improving patient self-management behaviors, including dietary and medication adherence, for specific conditions such as CHF or tuberculosis, when patient education and self-management support were included within CM interventions.

Adherence

Few studies measured the frequency of missed appointments or other adherence measures as an outcome of CM interventions.

Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving resource utilization?

Hospitalization Rates

Although hospitalization rates were often included as an outcome, trials of CM generally did not demonstrate reductions in these rates.

Emergency Department Use

CM had a variable effect on emergency department (ED) use. Several studies found reduced ED use in patients receiving CM, but other studies found no effect.

Clinic Visits

Few studies measured the frequency of clinic visits as an outcome of CM interventions. Those that did generally found varying results, and no conclusions can be drawn about this outcome.

Overall Expenditures

Most studies examining the impact of CM on the overall cost of care showed no significant difference between groups of patients receiving CM and control groups. Although the cost of CM programs often was modest relative to overall costs among patients with high utilization, the effect of CM on reducing utilization was minimal.

Key Question 2: Does the effectiveness of case management differ according to *patient characteristics*?

Medical Conditions

Individual studies had inconsistent findings on whether CM interventions are more successful for patients with high disease burden. While it is possible that there is a mid-range of disease burden in which CM is most effective, the evidence base does not permit defining how to identify such patients.

Age

Most studies of CM included mainly elderly patients, making it difficult to determine impact of age on CM effectiveness.

Socioeconomic Status

Studies did not routinely report the effect of CM according to socioeconomic indicators among enrolled patients. Some studies explicitly targeted low-income or homeless populations. There was no apparent pattern to suggest an influence of patients' socioeconomic status on the effectiveness of CM.

Social Support

Few studies explicitly evaluated patients' level of social support. However, studies that targeted patients with limited social support did not tend to find better results.

Formally Assessed Health Risk

Some studies explicitly targeted patients considered to be at high risk of poor outcomes. The methods used to evaluate risk, however, varied substantially across studies. The studies have not defined a specific level of risk for which CM is most effective for improving outcomes.

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*?

Setting

Characteristics of the setting in which CM was implemented (e.g., integrated health system, home health agency, outpatient clinic) did not clearly influence the effectiveness of CM.

Case Manager Experience, Training, Skills

Studies did not consistently provide details about the experience, training, or skills of case managers. In most

studies the case managers were registered nurses, and some had specialized training in caring for patients with the conditions targeted by the CM intervention (e.g., diabetes, cancer). There was low strength of evidence indicating that pre-intervention training of nurses in providing CM for the targeted conditions, the use of protocols or scripts to guide clinical management, and collaboration between a case manager and a physician (or multidisciplinary team) specializing in the targeted clinical condition, resulted in more successful interventions.

Case Management Intensity, Duration, Integration With Other Care Providers

There was low strength of evidence that more intense CM interventions, as indicated by greater contact time, longer duration, and face-to-face (as opposed to only telephone) visits, produced better outcomes, including functional outcomes and lower hospitalization rates.

Case Manager Functions

Case managers typically performed multiple functions. These included but were not limited to assessment and planning, patient education, care coordination, and clinical monitoring. In general, emphasis on specific functions varied according to patients' conditions and the primary objectives of specific CM interventions. For example, interventions among patients with cancer typically focused on coordination and navigation, while interventions for patients with diabetes and CHF focused more on patient education (for self-management) and clinical monitoring. Most studies did not carefully measure the amount of effort case managers devoted to different functions, making it difficult to discern the degree to which emphasis on different case manager functions impacted CM effectiveness.

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>patient-centered outcomes</i> , including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?	Older adults with one or more chronic diseases	<i>Mortality.</i> CM programs that serve patients with one or more chronic diseases do not reduce overall mortality (9 studies).	High
Key Question 1a	Older adults with one or more chronic diseases	<i>Functional status.</i> CM programs that serve patients with one or more chronic diseases do not result in clinically important improvements in functional status (3 studies).	High
Key Question 1a	Frail elderly	<i>Mortality.</i> CM does not affect mortality in frail elders (5 studies).	Low
Key Question 1a	Frail elderly	<i>Nursing home admissions.</i> CM programs that serve frail elderly patients do not decrease nursing home admissions (2 studies).	Low
Key Question 1a	Dementia	<i>Mortality.</i> Patients with dementia who receive services from CM programs do not have lower mortality rates (12 studies).	High
Key Question 1a	Dementia	<i>Problematic behavioral symptoms.</i> CM programs that serve patients with dementia do not reduce problematic behavioral symptoms.	Moderate
Key Question 1a	Dementia	<i>Caregiver depression and strain (burden).</i> CM programs that serve patients with dementia do reduce depression and strain among caregivers (13 studies).	Moderate

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a	Dementia	<i>Time to nursing home placement.</i> CM programs that serve patients with dementia and have duration of no longer than 2 years do not confer clinically important delays in time to nursing home placement (9 studies).	Moderate
Key Question 1a	Congestive heart failure	<i>Mortality.</i> CM programs that serve adults with CHF do not reduce mortality (6 studies).	Low
Key Question 1a	Congestive heart failure	<i>Patient satisfaction.</i> CM programs that serve patients with CHF do increase patient satisfaction (3 studies).	Moderate
Key Question 1a	Congestive heart failure	<i>Quality of life.</i> CM programs that serve patients with CHF do improve CHF-related quality of life (6 studies).	Low
Key Question 1a	Diabetes mellitus	<i>Glucose management.</i> CM programs that serve adults with diabetes do improve glucose management (12 studies).	Moderate
Key Question 1a	Diabetes mellitus	<i>Lipids, BMI/weight.</i> CM programs that serve adults with diabetes do not improve measures of lipid management or BMI/weight. (8 studies).	Moderate
Key Question 1a	Diabetes mellitus	<i>Mortality.</i> CM programs that serve adults with diabetes do not reduce mortality (1 study).	Low
Key Question 1a	Diabetes mellitus	<i>Glucose control.</i> CM improves glucose control among adults with diabetes.	Low
Key Question 1a	Cancer	<i>Satisfaction with care.</i> CM programs that serve patients with cancer do improve satisfaction with care (4 studies).	Moderate
Key Question 1a	Cancer	<i>Cancer-related symptoms, functioning, quality of life, survival.</i> CM does improve selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall quality of life or survival (8 studies).	Low
Key Question 1a	HIV	<i>Mortality.</i> CM programs that serve adults with HIV infection do not improve survival (2 studies).	Low
Key Question 1b: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>quality of care</i> , as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?	Older adults with one or more chronic diseases	<i>Patient perception of care coordination.</i> CM programs that serve patients with one or more chronic diseases do increase patients' perceptions of the coordination of their care (2 studies).	High
Key Question 1b	Dementia	<i>Clinical guideline adherence.</i> CM programs that focus on clinical guideline measures for care of dementia do increase adherence to those measures (1 study).	Low

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1b	Congestive heart failure	<i>Self-management behaviors.</i> CM does increase patients' adherence to self-management behaviors recommended for patients with CHF (3 studies).	Moderate
Key Question 1b	Cancer	<i>Appropriate treatment.</i> CM programs that serve patients with cancer do increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment (2 studies).	Moderate
Key Question 1b	Tuberculosis	<i>Treatment success.</i> Short-term CM programs that emphasize medication adherence do improve rates of successful treatment for tuberculosis in vulnerable populations (4 studies).	Moderate
Key Question 1c: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>resource utilization</i> , including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?	Older adults with one or more chronic diseases	<i>Medicare expenditures.</i> CM programs that serve patients with one or more chronic diseases do not reduce Medicare expenditures (3 studies).	High
Key Question 1c	Older adults with one or more chronic diseases	<i>Hospitalization rates.</i> CM programs that serve patients with one or more chronic diseases do not reduce overall rates of hospitalization (17 studies).	Moderate
Key Question 1c	Frail elderly	<i>Hospitalization rates.</i> CM does not decrease acute hospitalizations in the frail elderly (11 studies).	Low
Key Question 1c	Dementia	<i>Health care expenditures.</i> CM does not change total health care expenditures for patients with dementia (6 studies).	Moderate
Key Question 1c	Diabetes	<i>Hospital readmission rates.</i> CM does not reduce hospitalization rates among adults with diabetes.	Low
Key Question 1c	Cancer	<i>Health care expenditures.</i> CM programs that serve patients with cancer do not affect overall health care utilization and cost of care (5 studies).	Low
Key Question 1c	Other medical problems	<i>Emergency department visits.</i> CM programs that serve populations that have chronic obstructive pulmonary disease (COPD) or are homeless do reduce emergency department visits (3 studies).	Low

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 2: Does the effectiveness of case management differ according to <i>patient characteristics</i> , including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?	Older adults with one or more chronic diseases	<i>Disease burden.</i> CM programs that serve patients with one or more chronic diseases are more effective for reducing hospitalization rates among patients with greater disease burden (2 studies).	Low
Key Question 3: Does the effectiveness of case management differ according to <i>intervention characteristics</i> , including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?	Older adults with one or more chronic diseases	<i>Personal contact.</i> CM programs that serve patients with one or more chronic diseases are more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians (4 studies).	Low
Key Question 3	Dementia	<i>Duration.</i> CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than 2 years are more effective for delaying nursing home placement than programs providing services for 2 years or less (1 study).	Low
Key Question 3	Congestive heart failure	<i>Integration with multidisciplinary team.</i> CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers.	Low
Key Question 3	Cancer	<i>Intensity, integration, training, protocols.</i> CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols (3 studies).	Low

BMI = body mass index; CHF = congestive heart failure; CM = case management; COPD = chronic obstructive pulmonary disease
 Note: This table does not include statements for which the evidence was insufficient to draw a conclusion.

Discussion

CM is a strategy for improving the delivery of clinical services to patients with complex needs. Based on the entire range of interventions described in the included studies, the types of patients who potentially could benefit from CM generally fell into four categories:

- Patients with progressive, life-threatening chronic diseases that can be improved with proper treatment, such as CHF or HIV infection.
- Patients with progressive, debilitating, and often irreversible diseases for which supportive care can enhance independence and QOL, such as dementia or multiple chronic diseases in the aged.
- Patients with progressive chronic diseases for which self-management can improve health and functioning, such as diabetes mellitus.
- Patients for whom serious social problems impair their ability to manage disease, such as the homeless.

For all of these clinical categories health care resources generally are available but may be inaccessible or poorly coordinated. Case managers can help surmount these problems, but the role of the case manager is complex. Depending on the organization and strategy of CM programs, the case manager can play distinctly different roles:

- A care provider who helps patients to improve their self-management skills and/or helps caregivers to be more effective in helping and supporting patients.
- A collaborative member of the care delivery team who promotes better communication with providers and advocates for implementation of care plans.
- A patient advocate who evaluates patient needs and works to surmount problems with access to clinical services.

There are multiple strategies for fulfilling these roles, and CM programs are consequently complex and often difficult to replicate. Organizationally, programs can be freestanding or imbedded in clinical settings (usually primary care or specialty practices). Case managers can interact with patients in their homes, in clinics, or by telephone. They can have outpatient caseloads of hundreds or only a few dozen, and they can follow prespecified protocols or develop personalized care plans based on patient assessments. Case managers can work independently or can function as a member of a CM team. The studies of CM use a variety of approaches to describe their programs, and full specification of the

programs' content often is not possible. Acknowledging this heterogeneity of study populations, interventions, and outcomes, we sought to discern the conditions under which CM was effective or ineffective.

There is a substantial evidence base about CM for complex chronic diseases. More than 50 randomized trials and a smaller number of good-quality nonexperimental studies have been conducted in a variety of patient populations. The total number of participants in these studies approaches 100,000. The majority of these studies have given good descriptions of the patient populations, making it possible to organize the evidence by population groups. The clinical trials have included both highly innovative and targeted programs and community-based programs that service broad population groups. In some cases, there has been enough similarity in patient populations that indirect comparisons of different types of programs can be made with moderate confidence.

The cumulative evidence about CM is sufficient to draw several conclusions, some of which pertain to the inability of CM programs (as they have been commonly deployed) to achieve some desired outcomes. Generally, the conclusions reached in this report pertain only to specific patient populations. Because CM programs generally are customized to the patient groups served, it usually is not possible to apply the results to other patient populations. In this review, we found that, on balance, CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The most positive findings are that CM improves the quality of care, particularly for patients with serious illnesses that require complex treatments (cancer and HIV). For a variety of medical conditions, CM improves self-management skills. CM also improves QOL in some populations (CHF and cancer) and tends to improve satisfaction with care. For the caregivers of patients with dementia, targeted CM programs improve levels of stress, burden, and depression.

We found a low strength of evidence that CM is effective in improving resource utilization for patients with CHF, COPD, or those with chronic homelessness. In most other cases, CM programs have not demonstrated cost savings. For patients who receive CM for multiple chronic diseases, there is a high strength of evidence that the programs do not reduce Medicare expenditures. While the effectiveness of CM may depend on selection of the appropriate target population, the published studies suggest that this type of careful case selection is difficult to implement. In the published studies, criteria for enrolling patients in CM programs were generally broad measures, such as levels

of overall health care utilization or hospitalization within a prior time period.

Because of the relatively low number of trials that compare different types of CM models, conclusions about the features of programs that are most effective can be made only with a low strength of evidence. The results of trials across different clinical conditions suggest that CM effectiveness was greater when the intervention was lengthy, high in patient contact, and included face-to-face (rather than telephone-only) interactions. This finding validates the premise that the relationship between case manager and patient is likely to be a key ingredient for successful CM interventions. CM also appears to be most effective when the case manager works closely with patients' usual care providers (usually primary care physicians) and/or collaborates with a physician (or multidisciplinary team of health care providers) with expertise in managing the targeted medical condition. This finding suggests that CM may be most effective when case managers are embedded within a collaborative, team-based intervention model. Finally, there also is some evidence that CM is successful in achieving outcomes when the intervention includes specific training modules and protocols that are tailored towards those outcomes. This suggests that the breadth and flexibility of CM may need to be complemented by focused efforts—including specific training, guidelines, and protocols—to achieve explicitly targeted outcomes.

Implications for Future Research

The existing evidence base includes a large number of randomized trials comparing CM with “usual care.” While the components of usual care were quite variable across studies, in some cases (particularly the Medicare Coordinated Care Demonstration [MCCD] trial)¹³ the studies had large sample sizes and overall good quality. Thus there is a relatively low yield in continuing to repeat such studies. Instead, future clinical research needs to address the gaps in the current evidence base. These gaps include:

- Lack of effective risk assessment tools for choosing candidates for CM. Some published trials¹⁴ have used existing tools, but no studies have compared tools or rigorously examined patient subgroups to learn which patients achieve the greatest benefits from CM. The factors included in better risk profiles could include:
 - Demographics including age, gender, and ethnicity
 - Living situation and ability to meet basic living needs

- Access to primary care and other health care services
 - Social support
 - Health care utilization profiles
 - Clinical risk factors for adverse outcomes.
- Lack of understanding of the length of time to continue CM. Nearly all trials have set seemingly arbitrary durations of the intervention (often 1 to 2 years). It is not known when the benefits of the intervention have been achieved. Some of the negative results may be due to the CM being too short. This is particularly important if developing an effective long-term relationship between the patient and case manager affects the program's success.
 - Imprecision about the intensity of CM. Existing trials have infrequently examined whether patient outcomes are influenced by the frequency of case manager contact, the length and content of the contacts, and the approach to followup of problems.

Other examples of CM elements that should be explicitly described in future research include:

- Training received by case managers
- Case manager experience
- Specific functions of case managers and the distribution of effort devoted to different activities
- Modes of contact (clinic visits, home visits, telephone calls)
- Average caseload
- Relationship to other health care providers
- Use of protocols, guidelines, and information technology

CM typically involves case managers providing both direct clinical support and coordination for patients, as well as education and empowerment to enable patients to better manage their own conditions and coordinate their own care. Better specification of intervention components and population characteristics would contribute to greater understanding of when interventions should emphasize direct support compared with patient education.

Many CM interventions employed more than one case manager, but few studies examined the effectiveness of CM delivered by different case managers. CM is a human intervention, and the effectiveness of CM may vary substantially according to the skills, experience, and personality of the person delivering the intervention.

Understanding how much variability there is from one case manager to another would provide valuable information about the degree to which CM can be standardized and the importance of choosing individuals to implement CM.

Because studies comparing CM with usual care have generally found only small differences in important outcomes, it is uncertain whether future research that compared CM with other interventions would be fruitful. Interventions that are less intensive or more narrowly focused may be effective for changing certain outcomes but are unlikely to show important differences from the results with CM as it was deployed in the previous studies.

Glossary

Case management (CM): A health care service in which a single person, working alone or in conjunction with a team, coordinates services and augments clinical care for patients with chronic illness.

References

1. Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington DC: The National Academies Press; 2001.
2. Boulton C, Kane RL, Pacala JT, et al. Innovative healthcare for chronically ill older persons: results of a national survey. *Am J Man Care*. 1999;5(9):1162-72. PMID: 10621082.
3. Kane RL. What Can Improve Chronic Disease Care? *J Am Geriatr Soc*. 2009;57(12):2338-45. PMID: 20121992.
4. McDonald KM, Sundaram V, Bravata DM, et al. Care Coordination. Vol 7 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, editors. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290-02-0017). AHRQ Publication No. 04(07)-0051-7. Agency for Healthcare Research and Quality: Rockville, MD; June 2007.
5. Krumholz HM, Currie PM, Riegel B, et al. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy Writing Group. *Circulation*. 2006 Sep 26;114(13):1432-45. PMID: 16952985.
6. Coleman EA, Parry C, Chalmers S, et al. The care transitions intervention: results of a randomized controlled trial. *Arch Intern Med*. 2006 Sep 25;166(17):1822-8.
7. Naylor MD. Transitional care for older adults: a cost-effective model. *LDI Issue Brief*. 2004;9(6):1-4. PMID: 15181894.
8. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health*. 1998 Jun;52(6):377-84. PMID: 9764259.
9. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task force: a review of the process. *Am J Prev Med*. 2001 Apr;20(3 Suppl):21-35.
10. U.S. Preventive Services Task force Procedure Manual. AHRQ Publication No. 08-05118-EF, July 2008. www.uspreventiveservicestaskforce.org/uspstf08/methods/procmmanual.htm.
11. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health Care Program. *J Clin Epidemiol*. 2010 May;63(5):513-23. PMID: 19595577.
12. Atkins D, Chang SM, Gartlehner G, Buckley DI, Whitlock EP, Berliner E, Matchar D. Assessing applicability when comparing medical interventions: AHRQ and the Effective Health Care Program. *J Clin Epidemiol*. 2011 Nov;64(11):1198-207. Epub 2011 Apr 3. PMID: 21463926.
13. Peikes D, Chen A, Schore J, et al. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries. *JAMA*. 2009 February 11, 2009;301(6):603-18. PMID: 19211468.
14. Boulton C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. *Arch Intern Med*. 2011 Mar 14;171(5):460-6. PMID: 21403043.

Full Report

This executive summary is part of the following document: Hickam DH, Weiss JW, Guise J-M, Buckley D, Motu'apuaka M, Graham E, Wasson N, Saha S. Outpatient Case Management for Adults With Medical Illness and Complex Care Needs. Comparative Effectiveness Review No. 99. (Prepared by the Oregon Evidence-based Practice Center under Contract No. 290-2007-10057-I.) AHRQ Publication No. 13-EHC031-EF. Rockville, MD: Agency for Healthcare Research and Quality; January 2013. www.effectivehealthcare.ahrq.gov.

