Comparative Effectiveness Review
Number 246

Management of High-Need, High-Cost Patients: A "Best Fit" Framework Synthesis, Realist Review, and Systematic Review

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The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new healthcare technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see https://effectivehealthcare.ahrq.gov/about/epc/evidence-synthesis.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the website (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Management of High-Need, High-Cost Patients: A "Best Fit" Framework Synthesis, Realist Review, and Systematic Review

Structured Abstract

Background. In the United States, patients referred to as high-need, high-cost (HNHC) constitute a very small percentage of the patient population but account for a disproportionally high level of healthcare use and cost. Payers, health systems, and providers would like to improve the quality of care and health outcomes for HNHC patients and reduce their costly use of potentially preventable or modifiable healthcare services, including emergency department (ED) and hospital visits.

Methods. We assessed evidence of criteria that identify HNHC patients (best fit framework synthesis); developed program theories on the relationship among contexts, mechanisms, and outcomes of interventions intended to change HNHC patient behaviors (realist review); and assessed the effectiveness of interventions (systematic review). We searched databases, gray literature, and other sources for evidence available from January 1, 2000, to March 4, 2021. We included quantitative and qualitative studies of HNHC patients (high healthcare use or cost) age 18 and over who received intervention services in a variety of settings.

Results. We included 110 studies (117 articles). Consistent with our best fit framework, characteristics associated with HNHC include patient chronic clinical conditions, behavioral health factors including depression and substance use disorder, and social risk factors including homelessness and poverty. We also identified prior healthcare use and race as important predictors. We found limited evidence of approaches for distinguishing potentially preventable or modifiable high use from all high use. To understand how and why interventions work, we developed three program theories in our realist review that explain (1) targeting HNHC patients, (2) engaging HNHC patients, and (3) engaging care providers in these interventions. Theories identify the need for individualizing and tailoring services for HNHC patients and the importance of building trusting relationships. For our systematic review, we categorized evidence based on primary setting. We found that ED-, primary care–, and home-based care models result in reduced use of healthcare services (moderate to low strength of evidence [SOE]); ED, ambulatory intensive caring unit, and primary care-based models result in reduced costs (low SOE); and system-level transformation and telephonic/mail models do not result in changes in use or costs (low SOE).

Conclusions. Patient characteristics can be used to identify patients who are potentially HNHC. Evidence focusing specifically on potentially preventable or modifiable high use was limited. Based on our program theories, we conclude that individualized and tailored patient engagement and resources to support care providers are critical to the success of interventions. Although we found evidence of intervention effectiveness in relation to cost and use, the studies identified in this review reported little information for determining why individual programs work, for whom, and when.

Contents

Tables

Figures

Appendixes

Evidence Summary

Main Points

- Data from claims and health records can identify characteristics associated with being high-need, high-cost (HNHC) patients but are limited in selecting specific patients who are most appropriate for care management interventions.
- Much work remains in distinguishing preventable and modifiable high healthcare use from high use more generally.
- Identifying and targeting HNHC patients for interventions to change their healthcare use requires capturing their medical and social complexities. Building and maintaining trusting, caring relationships between HNHC patients and care providers underpins successful patient interventions. Both patients and care providers require support and practical resources to foster an effective relationship.
- We found moderate to low strength of evidence (SOE) that emergency department (ED)–based, primary care–based, and home-based care models are associated with reduced use of healthcare services; low SOE that ED, ambulatory intensive caring unit (aICU), and primary care models are associated with reduced costs; and low SOE that system-level transformation and telephonic/mail models are not associated with use or cost differences.

Background and Purpose

In the United States, payers, health systems, and providers focus on the HNHC patient population because they account for a disproportionally high level of healthcare utilization and cost, even though they constitute a small percentage of the patient population. Payers, particularly Medicare and Medicaid, are moving from fee-for-service payment arrangements to alternative payment models. Financial success of these models can depend, in large part, on their effectiveness in addressing care for HNHC patients.

Poor control of chronic clinical conditions, particularly when coupled with functional limitations, mental health conditions, and social risk factors, can result in potentially preventable or modifiable overreliance on the ED and hospital. Interventions for HNHC patients aim to improve their quality of care and health outcomes while reducing their healthcare use and cost. The goal of this review is to provide actionable evidence to help identify HNHC patients and determine the causal mechanisms and effectiveness of complex interventions that intend to improve HNHC patient and healthcare system outcomes.

Methods

We used review approaches best suited to assess the evidence for our Key Questions (KQs). To determine how to identify HNHC patients (KQ 1), we used the best-fit framework synthesis approach to consider our findings in relation to a National Academy of Medicine (NAM) taxonomy. To examine the causal mechanisms and contexts of interventions leading to reductions in healthcare use and cost (KQ 2), we used realist review methodology. Finally, to synthesize the evidence of the effectiveness of interventions targeting HNHC patients (KQ 3), we used systematic review methodology. We searched multiple databases and the gray literature using publication dates from January 1, 2000, to March 4, 2021. We included quantitative and qualitative studies of adult HNHC patients (high healthcare use or cost) in the United States. We describe our methods in the full report.

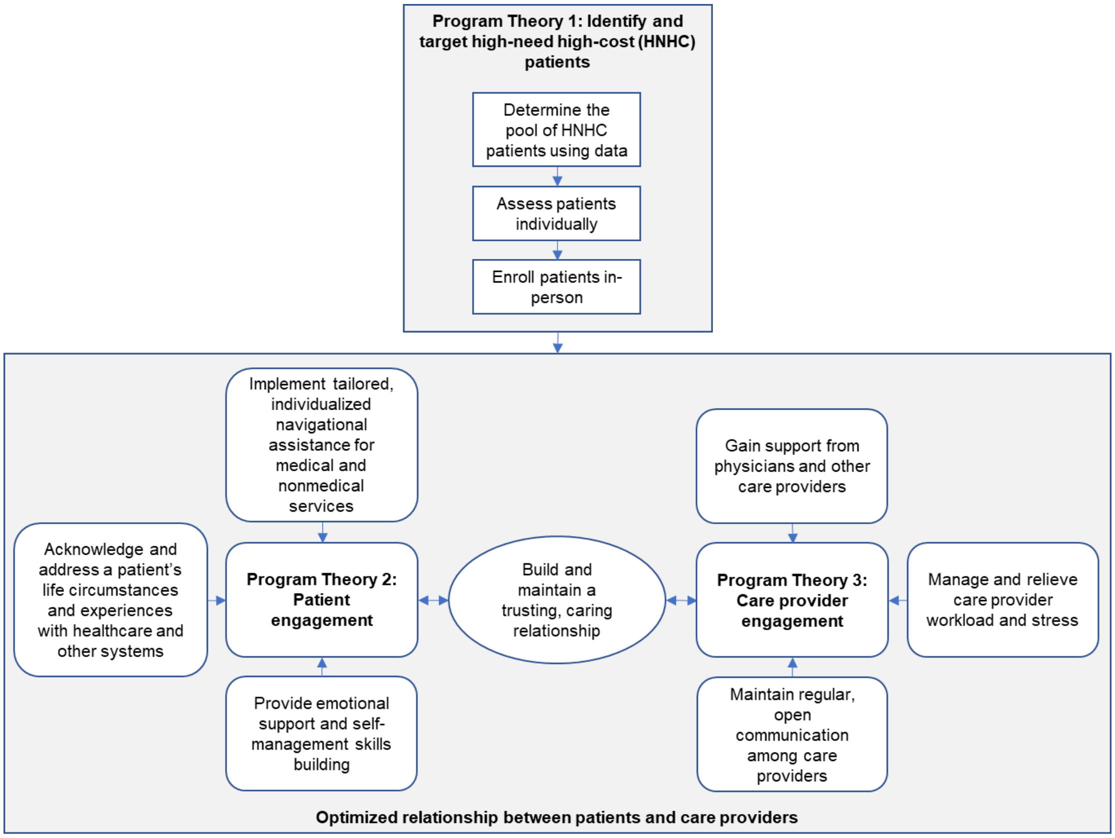
Results

We included 110 studies (117 articles) in our review. KQ 1 includes 60 studies (61 articles). KQ 2 includes 48 studies (51 articles; 14 articles were also evidence for KQ 1 and 27 articles for KQ 3). KQ 3 includes 40 studies (46 articles).

KQ 1: Criteria that can be used to identify or predict HNHC patients. Consistent with the NAM taxonomy, we found that chronic conditions, whether measured individually or through an algorithm, rating scale, or counts, were associated with being an HNHC patient, as were behavioral health risk factors, including depression and substance use disorder, and social risk factors, including homelessness and poverty. We also identified prior high use and race as consistent predictors of being an HNHC patient. Few studies sought to differentiate high use of care that is potentially preventable from all high use.

KQ 2: Contexts, mechanisms, and outcomes of interventions that reduce preventable or modifiable healthcare use among HNHC patients. We developed three realist program theories. Figure A presents a framework showing their relationship. Program Theory 1 explains that the pathway for identifying HNHC patients for inclusion in interventions requires capturing a combination of their prior use of and experience accessing healthcare services, chronic disease(s), nonmedical barriers to care, clinician judgment, and willingness to participate. Program Theory 2 explains that once HNHC patients are enrolled, engaging them in interventions requires building a trusting relationship between the patient and care providers. Tailored, individualized assistance for medical and nonmedical needs, emotional support, and self-management education empower patients to participate in their own care. Program Theory 3 explains that care provider engagement is facilitated by targeted outreach, adequate staffing support with shared values, and regular and open communication.

Figure A. Framework of optimizing interventions for HNHC patients



KQ 3: Effectiveness and harms of interventions for HNHC patients in reducing potentially preventable or modifiable healthcare use and costs and improving health outcomes. All but one study compared interventions with usual care. We categorized the evidence based on the primary setting of the intervention (system level, telephonic/mail, community, ED, aICU, primary care, and home based). Findings were limited.

In relation to changes in utilization, ED-based models resulted in a reduction in all-cause ED visits (moderate SOE), while telephonic/mail models achieved no difference in all-cause ED visits (low SOE) or ambulatory care sensitive condition ED visits (low SOE). ED- and primary care–based models resulted in a reduction in all-cause inpatient admissions (low SOE), while telephonic/mail models resulted in no difference (low SOE). Home-based care models resulted in lower ambulatory care sensitive condition inpatient admissions (low SOE). Primary care visits increased among ED model participants, a favorable outcome because it supports the goal of shifting care from the ED to a more appropriate source of care (low SOE).

In relation to total costs, aICU and primary care–based models were associated with reductions (both low SOE), while system-level transformation models and telephone/mail models resulted in no difference (low SOE). ED models were also associated with lower ED costs (low SOE) but no change in inpatient costs (low SOE).

Telephonic/mail models, home-based care models, and community-based models found no difference in mortality (low SOE for all 3 models).

Studies identified virtually no harms and reported few health and patient-reported outcomes and no social risk outcomes. The evidence was insufficient to draw conclusions for these outcomes.

Limitations

Each of the three methodological approaches brings unique strengths and weaknesses to our findings. A constraint to identifying patient characteristics associated with being HNHC is a limited methodology for distinguishing high use that is modifiable. As a result, the effect of patient and health system factors were generally evaluated only in relation to all high use. For the realist review, our analysis depended primarily on the studies included in the systematic review. Many of these studies contained minimal information about the implementation of the interventions at the clinic level, limiting our ability to more fully construct our program theories. For the systematic review, while effectiveness studies reported changes in cost and use, we found virtually no patient-reported or process outcomes, further limiting our ability to understand why some interventions were successful while others were less so.

Implications and Conclusions

A central dilemma facing interventions intended to reduce the healthcare use and cost of HNHC patients is how to reliably identify the patient population and to do so before a future period of preventable or modifiable high use. Using patient characteristics available in electronic patient data is a first step, but identification of good candidates for HNHC patient interventions is improved through individualized participant selection. Similarly, interventions themselves need to be individualized to address the complex needs of HNHC patients. Although we found some evidence of overall intervention effectiveness in relation to use and cost, the studies identified in this review provide little information for determining why individual programs work, for whom, within different contexts.

Chapter 1. Introduction

Background

In the United States, the patient population referred to as high-need, high-cost (HNHC) is often the focus of healthcare payers, health systems, and providers. Although no single definition of HNHC exists, it is generally understood that these patients constitute a very small percentage of the population but account for a disproportionally high level of healthcare use and cost.[1-5] Payers in the United States, particularly Medicare and Medicaid, are increasingly requiring health systems, coordinated care organizations, and healthcare providers to progress from payment through fee-for-service arrangements toward alternative payment models that include financial risk.[6-9] Participants in alternative payment models, particularly those that include financial risk, acknowledge that their success in these models depends, in large part, on their effectiveness in addressing the care and costs for HNHC patients.[10, 11]

Payers and health systems would like to accomplish two goals in relation to HNHC patients: (1) reduce their healthcare use and ensuing costs that are potentially preventable or modifiable, which is often overuse of acute care in an emergency department (ED) or multiple hospital inpatient admissions resulting from poor control of medical conditions,[12-16] and (2) improve their quality of care and health outcomes.[14-16] Despite strong motivation to address how to more appropriately provide healthcare for HNHC patients, challenges and controversies complicate approaches to both identifying these patients and determining the mechanisms of complex interventions that can affect their healthcare use, cost, and quality of care.

The Decisional Dilemma: Identifying and Addressing High Utilization and Cost Appropriately

A key challenge for practitioners (which we define as healthcare providers, payers, and health systems), as well as researchers, is that there is no consensus on a definition of HNHC patients, those high-need patients for whom high costs or use are potentially preventable or modifiable. The most common approach is to define the HNHC population as the patients with the highest healthcare use or costs during a historical time period, but no consensus has been reached on the appropriate duration of the time period and the number and types of services.[12, 13] Also, focusing on use and cost alone can obscure detecting future high-need patients. Many high-cost patients use this level of care for a relatively short period of time, and it is the appropriate choice for treating their condition (e.g., certain types of cancer or orthopedic surgery patients).[17] A second approach is to identify HNHC patients based on diagnoses, such as individuals with multiple co-occurring chronic conditions.[18, 19] Relying chiefly on a diagnostic criterion, however, ignores that not all high-need patients have high costs that are preventable or modifiable. A large percentage of high-need patients use care appropriately, even if it may be costly (i.e., needed healthcare is received through ongoing relationships with primary care and specialist providers). Often, factors co-occurring with physical diagnoses, including functional limitations, mental health conditions, substance use, and social risk factors, are important drivers of high healthcare use and cost.[20] Overall, HNHC patients are those patients with chronic conditions for whom reducing use of high-cost healthcare services in favor of other types of care is theorized to result in better care and better outcomes. For the purposes of this review, we focus on studies of patients with high healthcare costs or use. Within this larger group of studies, we will highlight analyses that more directly identify patients whose use of healthcare services would be considered inappropriate and is potentially preventable or modifiable.

Description of the HNHC Patient Population

A common approach to describing the magnitude of the HNHC patient population nationally is in relation to the concentration of healthcare costs or use disproportionately attributed to a specific percentage of the population. National data from the Agency for Healthcare Research and Quality (AHRQ)–sponsored Medical Expenditure Panel Survey reports that, in 2016, patients ranked in the top 5 percent by their healthcare expenditures accounted for 50 percent of total healthcare expenditures.[21] Among these top 5 percent of spenders, 42 percent were 65 years of age or older. Persons in the top 5 percent of spending were more likely to have at least one inpatient stay during the year with inpatient stays accounting for 40 percent of their healthcare expenditures.[21] The Pew Charitable Trust found that the top 5 percent of Medicaid patients nationally use 60 percent of Medicaid funding.[22] In relation to ED use, AHRQ's Healthcare Cost and Utilization Project data reported that among Medicare beneficiaries 65 years of age or older, approximately 5 percent of the population accounted for 16 percent of ED visits and 14 percent of ED charges.[23] Among Medicare beneficiaries younger than 65 years, 6 percent accounted for 26 percent of ED visits and 24 percent of ED charges. Further, a systematic review on frequent ED use across payers found that, across studies, approximately 5 to 8 percent of patients visiting the ED were frequent users, with this small group accounting for 21 to 28 percent of all ED visits.[24]

The HNHC patient population can be further characterized in relation to the prevalence of multiple chronic conditions. According to the Center for Health Care Strategies (CHCS), 80 percent of high-cost Medicaid beneficiaries have three or more chronic conditions.[25] CHCS further found that among Medicaid-only beneficiaries with a disability, each additional chronic condition was associated with an average increase in costs of $8,400/year. Among Medicaid-only beneficiaries, the most common diagnostic pairs of diseases among the highest cost patients are cardiovascular-pulmonary (30%), cardiovascular-gastrointestinal (25%), cardiovascular-central nervous system (25%), central nervous system-pulmonary (24%), and pulmonary-gastrointestinal (24%).[25] Based on Centers for Medicare & Medicaid Services administrative data from 2011, the burden of multiple (≥2) chronic conditions among Medicare beneficiaries is high, accounting for over two-thirds of the fee-for-service population, while those with six or more conditions account for 14 percent of the population.[26]

What Is Known From Other Systematic Reviews

The present work builds on and extends earlier systematic reviews. We identified three reviews focusing on characteristics associated with being HNHC patient and eight reviews of interventions for these patients.

The three reviews of studies of HNHC patient characteristics identified their populations differently. One focused on high-cost patients,[27] the second on frequent ED users,[28] and a third on ED users whose visits were identified as primary care sensitive, preventable, inappropriate, or unnecessary.[29]All three reviews elucidated factors associated with being HNHC, organized according to Andersen's model of predisposing, enabling, and need characteristics.[30] The study of high-cost patients found that having multiple chronic conditions, mental illness, and advancing age were all associated with higher healthcare costs.[27] Patient income had a variable effect. Frequent ED users were more likely to have a fair or poor self-perception of their health coupled with mental health and substance abuse concerns.[31] Characteristics associated with high primary care–sensitive ED use included being female, being black, and having Medicaid coverage.[29]

The present review modified the approach used in these reviews in several ways. The Wammes et al. review of high-cost patients included studies from multiple countries, while we limit our work to the United States, so that our findings are generalizable to the United States' healthcare coverage and delivery systems.[27] We add to the literature on characteristics associated with high healthcare use by separately examining high inpatient or outpatient use, as well as high ED use. We also include studies of chronic disease subgroups. Finally, while the earlier reviews organized their findings using the Anderson chronic disease framework, we group characteristics associated with being HNHC patients using the typology developed by the National Academy of Medicine.[20]

Multiple reviews have synthesized the literature on interventions that are hoping to change the utilization patterns, decrease costs, and improve clinical outcomes among HNHC patients. One review by Raven and colleagues (2016) examined studies of interventions, implemented in the United States, intended to reduce ED visits.[32] They found that case management reduced ED use and increasing ED copayments had mixed results. We identified six other reviews focusing on ED use.[12, 13, 33-37] Of these, five were not limited to studies conducted in the United States so the findings would not necessarily be applicable to the U.S. healthcare system.[12, 13, 33, 34, 36] A sixth review of ED interventions was limited to studies conducted in the United Sates but allowed the weaker pre-post designs that did not control for confounding.[37] Similarly, a review of interventions to address frequent hospitalization[38] and one of intensive outpatient care programs[39] also included pre-post designs.

Some of the limitations of earlier reviews of intervention studies are addressed in the present review. In prior work, the institutional settings in which studies were conducted were often not adequately described.[12] Also, information about social determinants of health, including socioeconomic status, behavioral health status, housing stability, and racial/ethnic demographics, was often missing. When systematic reviews included important social variables, analysis was limited to one or two factors. For example, several key systematic reviews (e.g., Soril et al.,[13] Edwards et al.,[15] and Baker et al.[14]) contain scant detail regarding social risk factors of health and the settings within which interventions occurred.

Attempts to synthesize the literature on interventions for HNHC patients are challenged by the absence of a consensus in the field of a unifying classification schema or taxonomy organizing key dimensions of these complex interventions into meaningful distinctions for grouping and separately considering their components.[40] Intervention classification in recent systematic reviews regarding high utilizers differed significantly. One systematic review stratified interventions by home based, clinic based, and primary care augmentation.[15] Another categorized interventions into case management, individual care plans, and information sharing.[13] Baker et al.[14] stratified interventions by population type: adults (1) with two or more chronic diseases, (2) with one chronic disease and depression, and (3) identified at risk for high healthcare utilization.

Intervention Strategies

Complex interventions designed to target HNHC patients have been developed at multiple organizational/system levels. The following strategies are ways of organizing the delivery of healthcare that are theorized as the context for influencing and improving both care delivery and costs for HNHC patients. We stratified the universe of interventions in terms of "levels" of intervention. Recognizing that these strata are interconnected, they are intended to specifically name the organizational actor that is the potential intervention implementer.

Payer-Level Interventions

Payers are invested in reducing healthcare costs and inappropriate use by HNHC patients. Various alternative models of health services delivery can support HNHC patient interventions. For example, accountable care organizations (ACOs) align financial incentives and health outcome accountability to promote care coordination among a large group of healthcare providers across the care continuum (ambulatory outpatient, acute care, post-acute care, and home health settings). ACOs use a variety of strategies to accomplish these goals. They support care coordination by increasing physicians' access to a uniform source of complete information about patients' health service use and health status. Techniques such as population segmentation and risk stratification can be used to focus resources on HNHC patient populations. Together, these enhancements can increase coordination among healthcare settings, particularly during transitions between settings in episodes of care.

One example of a payer-driven model is home-based primary care. This model moves the delivery of the majority of primary care from an ambulatory office-based setting to a patient's residence.[41] Intended to be a comprehensive care delivery model, this model typically involves a team-based approach and combines home-based care for medical needs with intensive management and care coordination. Home-based care programs serve a patient population that has a high probability of being HNHC because participants commonly have complex chronic conditions, functional limitations, and physical restrictions in accessing traditional office-based care. Home-based primary care may benefit HNHC patients if such approaches can better address patients' specific needs, values, and preferences.

Health System– and Provider-Level Interventions

Many complex healthcare interventions are organized at the health system and provider levels. Health system–level interventions are often designed to support changes at the patient population level by promoting a culture that furthers program goals and organizes intervention activities across participants.[42] Rather than focusing on individual patients, system-level participants are generally clinics or practices, which in turn are often expected to implement provider- and patient-level interventions. Provider-level interventions target care providers to change how they treat patients. Examples of provider-level interventions include the distribution of evidence-based guidelines and protocols, provider education and training, and provider feedback reports.

At the health system and provider levels, data are often used to report healthcare service use that may indicate that a patient is HNHC and needs additional services. One example is ED alerts. ED alerts inform clinicians that a patient has received care in the ED, which can help them identify patients whose patterns of care might be considered HNHC and in need of additional support services. Another strategic use of data to identify HNHC patients is "hotspotting." This strategy uses data to identify individuals whose high costs are outliers, understand the problem, dedicate resources, and design effective interventions.[43] Hotspotting interventions typically include multidisciplinary, coordinated care that treats the whole patient, including the nonmedical and social determinants that affect health, such as housing, mental health, substance abuse, and emotional support. The underlying idea is that intensive and highly individualized care addressing the unique needs of an HNHC patient, including social determinants of health, will improve clinical outcomes and reduce health expenditures beyond the cost of the high-intensity, highly individualized hotspotting intervention.[44]

Cross-Sector Interventions

Although not traditionally considered in the domain of healthcare, supportive services addressing social risk factors can affect the success or failure of complex interventions for HNHC patients. Interventions that focus on cross-sector issues intend to bridge the gap between engaging healthcare professionals who deliver direct care and addressing individual patients' nonmedical needs. A variety of roles, such as care managers, social workers, community health workers, patient navigators, and peer-to-peer networks, can directly provide or connect patients with needed support services.

Support services are intended to address patient barriers related to resource limitations, health literacy, and treatment adherence, thereby improving patient outcomes. Relatedly, staff providing supportive services can assist with social risk factors that have been identified as predisposing factors limiting access to care. Predisposing factors may include low income, poor education, poor nutrition, homelessness, and lack of transportation. For example, stable housing could improve patients' ability to interact consistently with their healthcare providers and social support systems, which, in turn, could increase adherence to their treatment plan.[40]

Complex Interventions for HNHC Patients

Intervention strategies that target HNHC patients encompass the approaches discussed above. We grouped interventions for HNHC patients, using the scheme proposed by Bodenheimer to group care management programs, into seven categories based on the primary setting in which the intervention is delivered (with several modifications).[45] We included system-level transformation models that affect a larger population of patients, but we only report findings for those patients who are HNHC. We did not include hospital discharge models because they are outside the scope of this review. Most of the interventions designed to target the complex needs of HNHC patients are themselves complex and are often a hybrid of various models, so some may not neatly fit into one of these seven categories.

- **System-level transformation model**: Clinics, practices, and other organizations modify how care is delivered to all patients.
- **Telephonic/mail model**: Care is delivered remotely by telephone or mail.
- **Community-based model**: Care provider meets with the patient wherever the patient is located.
- **ED-based model**: Patients are recruited and receive care in the ED.
- **aICU (ambulatory intensive caring unit) model**: Care is received in a separate high-risk clinic or through a high-risk team within a primary care clinic.
- **Primary care model**: Care is embedded in one or more primary care practices.
- **Home-based care model**: Care is delivered in the patient's home.

Clinical and Policy Context

As discussed above, an important health policy context for this review is payers in the U.S. healthcare system incentivizing complex healthcare systems and their providers to move toward new structures of care, such as ACOs. At the same time, they are increasingly requiring or creating incentives for these healthcare systems to accept payment models that include financial risk.[6-9] Healthcare systems participating in these payment models acknowledge that addressing the utilization and costs of HNHC patients is critical to their success in meeting their performance and financial goals.[10, 11]

Key to meeting policy goals is equipping health systems, individual providers, and patients with clinical supports. Issues in changing health systems' and providers' delivery of care include leadership support, changes in workflow, provider and staff skills development, adequate infrastructure, and staffing. Barriers for patients may include insufficient understanding, affordability, acceptability, and accessibility.

Purpose and Scope of the Review

This review has three main objectives, all with the shared purpose of identifying actionable evidence to support informed decisions concerning care for HNHC patients. The intended audience of the review reflects the broad range of stakeholders who are concerned about care in this population, including clinicians, healthcare systems, payers, and policymakers at the local, State, and national levels. Our first objective is to summarize the evidence related to identifying HNHC patient populations. The second is to develop and refine causal theories explaining why particular interventions, in various circumstances, are more likely to be successful in changing potentially preventable or modifiable healthcare use among HNHC patients. Our third objective is to review the evidence supporting the overall effectiveness of interventions for HNHC patients.

Interventions to address the needs of HNHC patients are frequently complex. Often, we have a limited understanding of the role that individual components of these interventions (such as care management) independently or synergistically contribute to the intervention's outcomes. Sources of complexity can include characteristics of the intervention itself (e.g., multiple components) or of its causal pathway (e.g., multiple mediators or moderators, feedback loops, synergies between components, multiple outcomes, or interaction between the intervention and context).[46] For the purpose of this review, we explored the nature of interactions between the interventions and the setting and investigated the underlying causal mechanisms that may explain the outcomes of the intervention, considering differences in the patient population, intervention setting, and provider context.

Report Organization

Chapter 2 of the report presents the three Key Questions (KQs) that guide the review, the approaches used to address the KQs, and an overview of the methods used to conduct the review. Chapter 3 presents the findings for the KQs; this chapter presents an overview of the literature yield across the KQs and then presents detailed findings by KQ. Finally, Chapter 4 summarizes our findings and discusses the implications of the findings for clinical practice, education, research, and policy.

We provide additional details of our approach to conducting the review in Appendix A and additional supporting details on our results in Appendix B. Appendix references are shown in Appendix C.

Chapter 2. Methods

Below we list the Key Questions (KQs), illustrate the analytic framework, and describe the approaches used in this review. We also briefly outline the study selection criteria, data sources and searches, data extraction and risk of rigor/bias, data synthesis and analysis, and grading of the strength of the body of evidence. Additional details can be found in the methods appendix (Appendix A).

Key Questions

The review addresses the following three KQs.

KQ 1. What criteria identify or predict that patients will be high-need, high-cost (HNHC)?

  a. How do criteria incorporate patient clinical characteristics?
  b. How do criteria incorporate patient demographic, behavioral health, and social risk factors?
  c. How do criteria incorporate types, amount, duration, and patterns of healthcare use?
  d. Do criteria differ when HNHC is identified at the population, payer, healthcare system, and provider levels?
  e. How can potentially preventable or modifiable high use of healthcare be differentiated from necessary and appropriate high use?

KQ 2. What are the mechanisms that lead to reductions in potentially preventable or modifiable healthcare use, and result in improved health outcomes and cost savings in interventions serving HNHC patients?

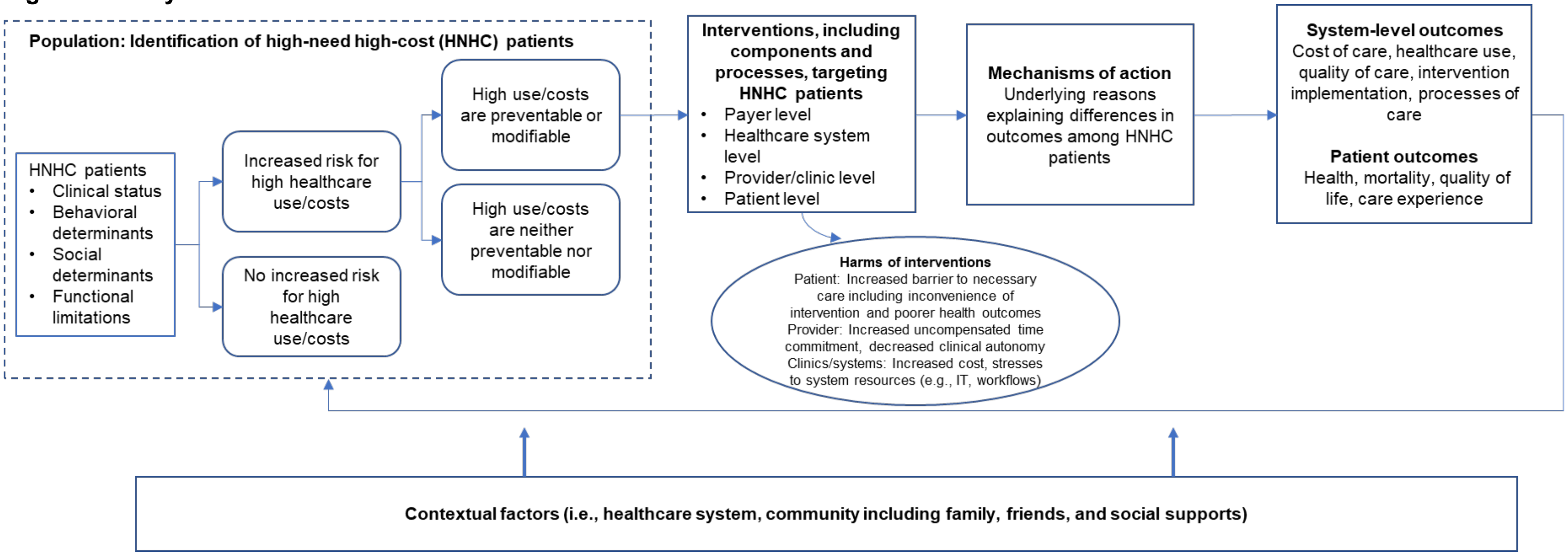
  a. What are the important contexts, such as the characteristics of HNHC patients, the broader healthcare delivery system, and the community, that affect whether mechanisms facilitate the desired outcomes?

KQ 3. Overall, what is the effectiveness and what are the harms of interventions for HNHC patients in reducing potentially preventable or modifiable healthcare use and costs and in improving health outcomes?

Analytic Framework

The framework in Figure 1 illustrates the relationships across the KQs, including the target population, interventions, contexts, mechanisms, and outcomes.

Figure 1. Analytic framework



HNHC = high-need, high-cost; IT = information technology; KQ = Key Question.

Review Approach

We used three methodologies to conduct our review, tailoring our approach for each KQ. We used a "best fit" framework synthesis approach for KQ 1,[47, 48] a realist review approach for KQ 2,[49] and a systematic review methodology for KQ 3.[50]

The topic of this report was developed by the Agency for Healthcare Research and Quality (AHRQ) in consultation with the Oregon Health Evidence Review Commission. We conferred with a six-member Key Informant (KI) stakeholder panel to help ensure that the review team understood the most up-to-date policy perspectives and activities in the field and could focus the review so that it would be relevant across potential end users. The KIs provided insights that were useful in designing the project's taxonomy for grouping characteristics of HNHC patients and appreciating important intervention features to inform the review. The review team also was advised by a Technical Expert Panel (TEP) who further commented on the approach being used in the review. The TEP included individuals with expertise in the different review methodologies being used.

To answer KQ 1, we used a "best fit" framework synthesis as an a priori framework to sort evidence into themes across included studies to achieve our aim of describing the HNHC patient population.[47, 48] Consistent with this approach, we began from an identified framework that we used to sort evidence into themes across included studies (i.e., the distinguishing characteristics and reasons why some patients are HNHC). During our review of the evidence, we used an iterative process to consider new themes that were not captured in the initial framework. In the end, we present a summary of the data and syntheses of the evidence and our conclusions within a framework corresponding to our final conceptual model.

The realist review approach we used to answer KQ 2 is intended to facilitate developing program theories explaining and describing how complex HNHC patient interventions work, for whom, and in what particular contexts and settings, as supported by evidence from qualitative and quantitative studies.[51] We used this approach to unpack and understand the causal processes for achieving outcomes within complex interventions. To explain these causal processes, we developed, refined, and tested context-mechanism-outcome (CMO) configurations. CMOs are the building blocks for developing program theories that explain the underlying (often unseen and intangible) causal mechanisms that underpin interventions.[52] Realist review findings can provide support for theories for why outcomes may differ because of interpersonal relationships and subtle contextual conditions.

To answer KQ 3, we used a systematic review approach to synthesize and assess the evidence on the impact of interventions for HNHC patients on specific outcomes of interest. The systematic review followed AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (available at https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview). Our reporting is in accordance with the Preferred Items for Reporting in Systematic Reviews and Meta-Analyses.[50]

Discussions with our KI and TEP panels contributed to the development of potential mechanisms for our KQ 2 realist review. In keeping with realist review methods, for KQ 2 we refined the scope of the realist review as we uncovered evidence and focused the depth and breadth of the review.[53]

The final protocol is posted on the Effective Health Care website at https://effectivehealthcare.ahrq.gov/products/high-utilizers-health-care/protocol. The PROSPERO registration is CRD42020161179.

Study Selection

Eligible studies met the following inclusion criteria: (1) included noninstitutionalized adults, 18 years of age or older, (2) analyzed an eligible outcome (e.g., healthcare use, cost, patient health management behaviors, clinical outcomes, and satisfaction with care; physicians' and health professionals' satisfaction with clinical practice; patient and health professional harms), (3) measured outcomes after at least 6 months, (4) were conducted in the United States, and (5) published in English.

Studies included for each KQ met additional criteria specific to the KQ.

For KQ 1, eligible studies included quantitative and qualitative designs. We required that all quantitative cohort and cross-sectional studies of exposures control for potential confounding (i.e., univariate results were not included). We also included latent class and cluster analysis designs.

Eligible KQ 2 studies were any design, quantitative or qualitative, considered to be of sufficient rigor (i.e., the method used to generate the particular piece of data was considered by the review team to be credible [plausible] and trustworthy).[54] Furthermore, studies needed to provide information on HNHC interventions that was relevant for adding to theory and explanation of CMO configurations.[55]

Eligible KQ 3 studies were randomized controlled trials (RCTs), cluster randomized trials, cohort studies, case-control studies, and quasi-experimental designs. Included studies needed to compare results for intervention participants with a comparison group in any other intervention or treatment as usual.

Intervention studies included as evidence for KQ 2 and KQ 3 were conducted in any outpatient healthcare delivery settings, including ambulatory care, emergency department, the community, and the home. KQ 2 and KQ3 interventions included, but were not limited to, alternative delivery models, system- or practice-level interventions, patient supportive services (e.g., community health workers, patient navigators), and social determinants of health–related interventions (e.g., transportation, health literacy, housing, and caregiver support). We excluded studies conducted solely in an inpatient setting that supported discharge planning because previous reviews are available about these interventions. However, we included studies that identified patients in the inpatient setting when intervention services were mostly provided after discharge.

For all KQs, we included studies that involved HNHC patients with 6 or more months of high healthcare cost or use. Among studies included for KQ 2 and KQ 3, we sought to also identify the subgroup of studies that met a more stringent criterion—HNHC patients with 6 or more months of high healthcare cost or use AND either two or more chronic physical health conditions or a combination of one or more chronic physical health conditions and one or more behavioral health conditions. For KQs 2 and 3, we sought to understand what, if any, differences were observed in intervention components, context, and effectiveness. Across all studies, we accepted the authors' definitions of HNHC that otherwise met our other inclusion criteria (e.g., length of time, conducted in the United States). In most studies, high use or cost was measured without directly evaluating whether individual episodes of care were potentially preventable or modifiable.

Appendix A lists detailed inclusion and exclusion criteria, organized by a PICOTS (population, intervention, comparator, outcome, timing, setting, and study design) framework.

Data Sources and Searches

We conducted focused searches of MEDLINE® via PubMed®, the Cochrane Clinical Trials Central Register, CINAHL®, Embase®, PsycINFO®, Web of Science, Academic Search Premier, and Scopus from January 1, 2000, to March 4, 2021. We also conducted targeted searches for grey literature on the Centers for Medicare & Medicaid Services website, the Commonwealth Fund website, and SIREN Evidence Library, among others. We posted a *Federal Register* notice on December 16, 2019 and requested supplemental evidence and data on January 16, 2020. Additional information on the data sources and searches is provided in Appendix A. We updated the literature search on March 4, 2021, during the public posting period of the draft report.

Data Extraction and Risk-of-Bias/Risk-of-Rigor Assessments

For each included study for KQ 1 and KQ 3, one investigator extracted information specifically selected to address each KQ into an evidence table. This included information about design, population, intervention, and outcomes. A second investigator reviewed the information for completeness and accuracy.

KQ 2 data extraction was guided by uncovering information that explained the cause for a particular outcome under the influence of one or more contexts. Data were abstracted into NVivo software using a coding framework grounded in our initial program theory of CMOs. One investigator extracted relevant excerpts from the studies, and a second investigator audited the extractions. Coding of all included studies using the coding framework proceeded as both an inductive and deductive process; that is, we continued to identify and add to the coding framework as we proceeded with data extraction.

For KQ 1, we did not assess the risk of bias of included studies. The studies we included to answer KQ 1 were mostly quantitative observational studies of exposures (multivariate predictive or cross-sectional designs), and fewer were cluster analyses or qualitative studies. No validated tool is available for evaluating the risk of bias of cross-sectional or cluster analysis studies (the majority of our included studies).[56]

In relation to the rigor of quantitative studies included to answer KQ 1, we limited our review to multivariate designs that controlled for potential confounding. Predictive studies are multivariate analyses where the outcome (use or cost) is measured in a later period than the independent variables included to “predict” the outcome. In cross-sectional studies, all data are obtained during the same period. Cluster analysis, and the associated technique latent class analysis, are statistical methods for identifying “hidden” or unobservable class membership (groupings) among subjects using observed variables.[57]

We appraised the rigor of qualitative studies included to answer KQ 1 (methodological strength and limitations) as recommended in the Cochrane Handbook.[58] We conducted the assessment using the Critical Appraisal Skills Programme tool.[59] Included quantitative and qualitative studies were determined to have clear aims and research questions.

For KQ 2, we used RAMESES (Realist And Meta-narrative Evidence Syntheses: Evolving Standards) project standards to guide our judgments in quality appraisal tasks.[53, 54, 60, 61] Data were appraised based on relevance, trustworthiness, plausibility of the argument underlying the theory, and rigor. We did not formally assess methodological rigor (risk of bias) because all relevant information in a document may be used to build and refine the program theories, including the discussion.[60] However, we globally assessed the quality of the included documents to determine whether the data were trustworthy and credible. Studies were considered sufficiently rigorous (trustworthy and credible) based on two senior team members' assessment that the study followed its specified methodology and was credible.

For KQ 3 studies, the criteria set forth by AHRQ's *Methods Guide for Comparative Effectiveness Reviews* guided our assessment of methodological risk of bias.[50] Two independent investigators assessed the risk of bias of each study, using predefined criteria established in the Cochrane Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I)[62] tool for observational studies and the Cochrane RCT[63] tool for RCTs. We rated outcomes as low, some concerns, high, or unclear risk of bias for each study in KQ 3.

Data Synthesis and Analysis

Describing the HNHC patient population (KQ 1). The a priori framework we used to initially structure the best-fit framework synthesis is the taxonomy developed by the National Academy of Medicine (NAM) in their report *Effective Care for High-Need Patients: Opportunities for Improving Outcomes, Value, and Health* as our a priori framework.[20] This taxonomy groups HNHC patients first based on their clinical and functional characteristics. Among the six patient groups presented in the taxonomy, four met the inclusion criteria for this review: nonelderly disabled, multiple chronic conditions, major complex chronic conditions, and frail elderly. NAM's other two categories—children with complex needs and individuals with advancing illness/end-of-life care—are outside the scope of the review because interventions for these two groups have significantly different intervention goals and pathways for delivering care. Within these clinical and functional groups, the taxonomy proposed additional, cross-patient group assessments based on behavioral health factors and social risk factors that are believed to influence how individuals use healthcare and increase the risk of receiving fragmented care. Behavioral health factors included serious mental illness, substance use disorder, cognitive decline, and chronic toxic stress. Social risk factors included low socioeconomic status, low health literacy, social isolation, community deprivation, and housing insecurity. Based on the evidence from our included studies, we considered whether the NAM taxonomy was the best fit for the evidence or if modifications would be useful.

Understanding interventions for HNHC patients (KQ 2). We used a realist review approach to gain a greater understanding of the complex payment and delivery models, social interventions, and health programs used to address healthcare utilization among HNHC patients. Consistent with this approach, our goal was to explain what works (or fails), for whom, under what circumstances, and why.[52] We sought to identify, elucidate, and refine the various underlying theories that could explain the approach of different complex interventions, explore implementation chains, assess intermediate outcomes, and examine modifications or adaptations applied in various circumstances.[52]

Once all papers were coded at the conceptual level, one investigator sorted excerpts across studies by concepts and developed initial, partial CMO configurations. A second investigator reviewed the CMOs for agreement with their own interpretation. The team then examined the CMOs alongside the developing program theories and iteratively reworked the CMOs as more data were added and the program theories were refined.

Review of the evidence supporting the effectiveness of interventions for HNHC patients (KQ 3). To further support the goal of producing actionable information, we used traditional Evidence-based Practice Center (EPC) Program systematic review methods to synthesize the evidence of the overall effectiveness of the interventions on cost, utilization, clinical and functional, and social risk outcomes. We categorized the evidence based on the primary setting of the intervention (system-level transformation, telephonic, community, emergency department, ambulatory intensive caring unit, primary care, and home based), generally following the framework proposed by Bodenheimer to group care management interventions.[45]

Several studies included as evidence for KQ 3 assessed multiple cohorts or conducted multiple analyses. Some interventions were assessed in relation to two separate and distinct HNHC patient cohorts who received the same treatment.[64-68] Other interventions looked at outcomes for HNHC patients, distinct from a more general patient population; some patients might have been included in multiple cohorts constructed for separate studies.[69, 70, 71] Still other interventions conducted multiple analyses on different subsets of their HNHC patient population to answer different research questions.[72] We refer to each of these cohorts, populations, and analyses as "samples," and each sample is considered as evidence from a separate study.

Because of the diversity of intervention designs and outcomes, we generally used a narrative synthesis approach to report most of our findings. We conducted a quantitative synthesis of results by calculating a pooled estimate when three or more samples with the same study design had similar treatment and comparison groups and reported an estimate of the same outcome measure within a setting. Pooled estimates were not calculated if samples were potentially overlapping. We used Stata® 16 (StataCorp, College Station, TX) to calculate effect sizes and associated 95 percent confidence intervals.

Grading the Strength of the Body of Evidence

We graded the strength of evidence for KQ 3 outcomes based on guidance established for the EPC Program.[73] Developed to grade the overall strength of a body of evidence, this approach incorporates five key domains: risk of bias (includes study design and aggregate quality), consistency, directness, precision of the evidence, and reporting bias. This approach requires looking beyond statistical significance alone. It requires considering whether studies are consistent and of high quality and outcomes are direct and clinically relevant. It emphasizes the adequacy of the sample size to rule out spurious associations and results.

The domains listed above are reflected in an overall rating regarding the strength of the evidence of high, moderate, low, or insufficient. Two reviewers assessed each domain for each key outcome with differences resolved by consensus.

- A high rating indicates high confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- A moderate rating indicates moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate.
- A low rating indicates low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.
- An insufficient rating indicates that the evidence does not permit estimation of an effect because the evidence is limited to a single study, or multiple domain ratings indicate weakness in the evidence base (i.e., the evidence base may comprise studies with limitations; be inconsistent, indirect, or imprecise; or be biased in reporting). When high risk-of-bias studies are likely to alter the judgment, we offer a strength-of-evidence grade that relies on the better quality evidence. When the signals from the evidence base are conflicting and we cannot attribute the differences to risk of bias alone, we assign the grade as insufficient.

Evidence bases consisting of RCTs begin with an overall rating of high; downgrading any domain (study limitations, precision, consistency, directness, and reporting bias) results in lower ratings. Evidence bases consisting of observational studies begin with a rating of low. They may be downgraded for the domains listed above. They may also be upgraded on three domains: dose-response association, plausible confounding that would decrease the observed effect, and strength of association (magnitude of effect). Often our strength-of-evidence grades that were higher than insufficient included a combination of RCT and observational evidence. For some outcomes, we have graded the evidence as a finding of no difference between the intervention and comparison groups. In these cases, we concluded that the effect estimate and corresponding confidence interval are within the boundaries of a minimally important difference.[74]

Based on EPC Program guidance, the evaluation of reporting bias is limited to RCTs. Because many of the RCTs we included in the review reported null findings, we concluded that reporting bias is not a particular concern in this body of evidence.

Chapter 3. Results

In this chapter, we present the yield from literature searches first, followed by a brief description of the characteristics of included studies. The remainder of the chapter presents results organized by Key Question (KQ). Within each KQ section, we first present key points followed by detailed results. The detailed results for KQ 1 use a best fit synthesis approach to organize and synthesize evidence from studies that examine patient healthcare use, chronic conditions, and other risk factors that were used to identify or predict who will be a high-need, high-cost (HNHC) patient. The detailed results for KQ 2 present results from a realist review from which we developed three program theories related to interventions for HNHC patients: recruiting patients, engaging patients, and engaging clinicians. The detailed results for KQ 3 present evidence on the effectiveness of outcomes from interventions for HNHC patients.

In this chapter, we separately present our evidence and findings for each of the KQs.

Details on results of literature searches, included studies, excluded studies, and results for all outcomes can be found in the Appendix B, Results.

Literature Searches and Study Characteristics

The electronic search, grey literature, and reference mining identified 2,923 citations. After title and abstract screening, 873 studies were retrieved for full-text review. A total of 110 studies (117 articles) met our eligibility criteria and were included in the analyses.

Description of Included Evidence

The evidence includes a mix of study designs to answer the different KQs (Table 1).

Table 1. Key characteristics of included studies

Study Characteristics	Categories	Total # of Unique Studies (Articles)	# KQ 1 Studies (Articles)	# KQ 2 Studies (Articles)	# KQ 3 Studies (Articles)
Total		110 (117)	60 (61)	48 (51)	40 (46)
Study design	RCT	19 (20)	0 (0)	15 (16)	19 (20)
	Intervention study: observational with comparison	23 (28)	0 (0)	13 (15)	21 (26)
	Exposure study: cluster analysis	10 (10)	11 (11)[a]	1 (1)	0 (0)
	Exposure study: multivariate cross-sectional	33 (33)	33 (33)	0 (0)	0 (0)
	Exposure study: multivariate predictive	11 (12)	11 (12)[a]	5 (5)	0 (0)
	Qualitative study: various designs	14 (14)	6 (6)	14 (14)	0 (0)
Healthcare coverage of study participants	Medicaid only	14 (17)	8 (9)	6 (8)	5 (7)[b]
	Medicare only or dual Medicare/ Medicaid	35 (37)	17 (17)	16 (16)	17 (19)
	Commercial only	9 (9)	9 (9)	1 (1)	0 (0)

Study Characteristics	Categories	Total # of Unique Studies (Articles)	# KQ 1 Studies (Articles)	# KQ 2 Studies (Articles)	# KQ 3 Studies (Articles)
Healthcare coverage of study participants (continued)	Mixed coverage across participants	39 (40)	26 (26)	18 (19)	5 (6)
	Uninsured	3 (4)	0 (0)	2 (2)	3 (4)
	Unknown	10 (10)	0 (0)	5 (5)	10 (10)

[a] One study included two types of analyses and is, therefore, counted twice; predictive and cluster.[75]

[b] One companion article was the evaluation report for multiple studies; this article was a companion article for two studies.

KQ = Key Question; RCT = randomized controlled trial.

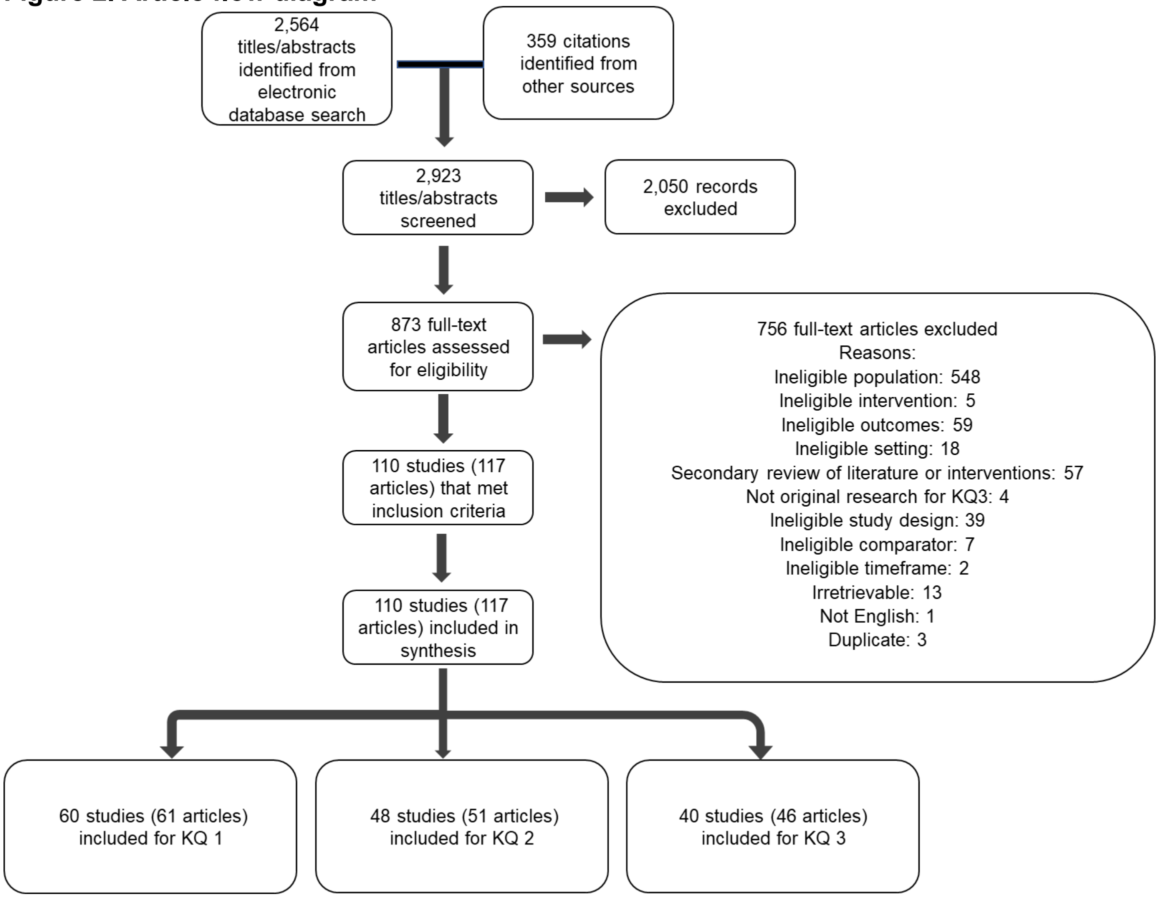
For KQ 1, we identified 60 studies reported in 61 articles, including 11 multivariate predictive studies,[75-86] 33 multivariate cross-sectional studies,[87-119] 10 cluster analysis studies,[120-129] and six qualitative studies.[130-135]

For KQ 2, we identified 48 studies (51 articles).[20, 44, 64-69, 72, 76, 79, 80, 82, 85, 124, 130-165] Of these, 13 studies were also used to answer KQ 1 (14 articles), 25 studies were also used to answer KQ 3 (27 articles), and 10 studies were unique to KQ 2 (10 articles).[20, 137, 145, 147, 148, 150, 155-157, 164, 165]

For KQ 3, we identified 40 studies, including 19 randomized controlled trials (RCTs) and 21 observational studies (46 articles). Five RCTs were assessed as having low risk of bias, and 14 RCTs (15 articles) were assessed as having some concerns for bias,[44, 64-68, 138, 141, 144, 150, 152, 159-163, 166-169] No observational studies were assessed as having low risk of bias, 13 observational studies (17 articles) were assessed as having some concerns for bias, and 8 observational studies (9 articles) were assessed as having high risk of bias.[69-72, 139, 140, 142, 146, 149, 151, 153, 154, 158, 170-182]

Figure 2 (also shown as Figure B-1) presents the flow of articles considered for inclusion at the title/abstract and full-text stages of review and those ultimately included in our syntheses.

Figure 2. Article flow diagram

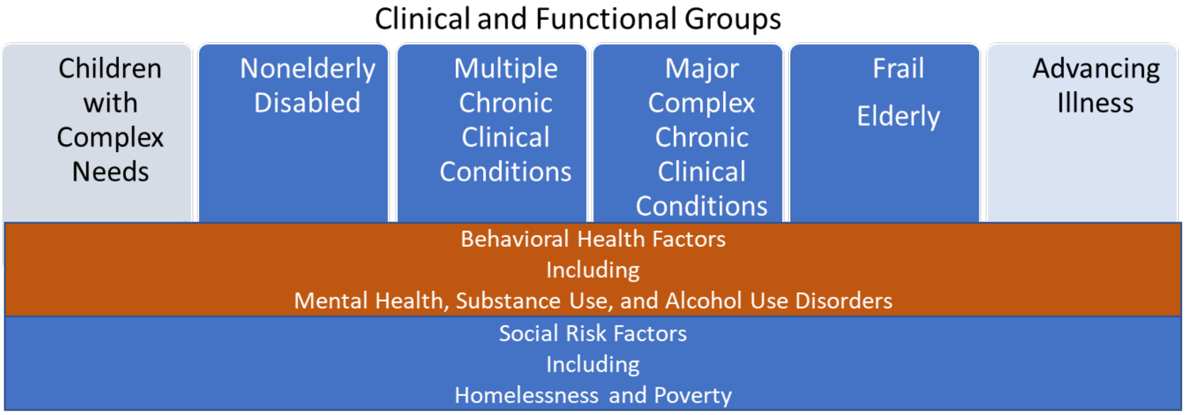


Note: The sum of the number of studies per KQ exceeds the total number of studies because some studies were applicable to multiple KQs.
KQ = Key Question.

KQ 1. What criteria identify or predict that patients will be HNHC?

We used a "best fit" framework synthesis approach to consider our findings in relation to an existing framework.[47, 48] (Chapter 2 includes a description of the best fit framework methodological approach to study synthesis.) In keeping with this approach, we reviewed included studies to determine if the key HNHC patient characteristics identified in studies echoed themes in the taxonomy developed by the National Academy of Medicine (NAM) in their report *Effective Care for High-Need Patients: Opportunities for Improving Outcomes, Value, and Health*.[20] Figure 3 depicts the NAM taxonomy, which groups HNHC patients first based on their clinical and functional characteristics. The taxonomy further conceptualizes behavioral health and social risk factors as affecting healthcare utilization across clinical and functional groups. A goal of the taxonomy was to identify smaller homogeneous subgroups for targeting interventions.[20] Based on the evidence from our included studies, we used an iterative process to consider whether the NAM taxonomy is the best fit for the evidence or if modifications would be useful.

Figure 3. Best fit framework synthesis: National Academy of Medicine High-Need, High-Cost patient characteristic taxonomy



Source: Adapted and reproduced with permission from the National Academy of Sciences (*Effective Care for High-Need Patients: Opportunities for Improving Outcomes, Value, and Health*)[20] and from Abrams (*Matching Patients to Tailored Care Models: A Strategy to Enhance Care, Improve Outcomes, and Curb Costs*).[183]

Our review encompassed four of the six NAM taxonomy clinical and functional groups: nonelderly disabled, multiple chronic clinical conditions, major complex chronic clinical condition, and frail elderly. We did not consider children with complex needs because our review was limited to adults. Our scope also did not include the advancing illness group because the characteristics and goals of care management, the focus of this review, differ from those of interventions that focus on end-of-life care.

In the NAM taxonomy, the multiple chronic and major complex chronic clinical condition groups differ by the type, number, and combination of conditions. The multiple chronic clinical condition group is defined as having only one complex chronic condition and/or between one and five noncomplex chronic conditions.[20] The major complex chronic clinical condition group is defined as having two or more complex chronic conditions or at least six noncomplex chronic conditions. Examples of complex chronic clinical conditions include acute myocardial infarction, ischemic heart disease, chronic kidney disease, congestive heart failure, dementia, diabetes, chronic lung disease, and stroke. Examples of chronic clinical conditions considered noncomplex include arthritis, immune disorders, cancer, inflammatory bowel disease, osteoporosis, hypertension, and thyroid disease.

Included Evidence

We identified 60 studies (reported in 61 articles) that examined characteristics of noninstitutionalized HNHC patients, 18 years of age and older (Table 2). We considered HNHC as having 6 months or more of potentially preventable or modifiable high healthcare use or cost. Studies differed in their definition of HNHC patients. Almost always, HNHC was defined solely as a measure of high use, whether in relation to emergency department (ED) visits (N=31), inpatient visits (N=12), or a mix of types of visits (N=7). Less often, HNHC was measured in relation to high cost (N=14). In each study, authors uniquely established criteria that they determined represented inappropriately high use or cost and examined the patient (and sometimes the healthcare system) characteristics significantly related to meeting these criteria. Only a few studies sought to more directly define and measure high-use episodes or costs that were potentially preventable or modifiable.

Table 2. Number of studies by population level and criteria used to define HNHC patients

Level	ED Visits	IP Visits	All Utilization	Cost
Population based	Cross-sectional: 8[92, 93, 95, 100-104]	-	Cross-sectional: 1[114] Qualitative: 1[133]	Cross-sectional: 1[118]
Payer: Medicaid[a]	Predictive: 2[79, 81] Cross-sectional: 2[105, 107] Cluster: 1[120]	Predictive: 2[84, 85]	-	Predictive: 2[76, 78, 82]
Payer: Medicare[a]	Predictive: 1[80] Cross-sectional: 1[108]	Predictive: 1[88] Cross-sectional: 1[108]	Cluster: 1[126]	Predictive: 1[86] Cross-sectional: 1[119] Cluster: 2[127, 128]
Health plans, including managed care and accountable care organizations[b,c,d]	Cross-sectional: 1[113]	Cross-sectional: 2[111, 113]	-	Predictive: 1[75] Cross-sectional: 3[115-117] Cluster: 2[75, 122]
Veterans Health Administration	Cross-sectional: 1[88]	Predictive: 1[83] Cluster: 2[124, 125]	Cross-sectional: 1[77] Cluster: 1[123]	-
Health system or multiple facilities[b]	Cross-sectional: 3[87, 91, 113]	-	Cluster: 1[129] Qualitative: 1[135]	-
Single facility[b]	Cross-sectional: 9[89-91, 94, 96-99, 106] Cluster: 1[121] Qualitative: 2[131, 132]	Cross-sectional: 2[109, 110] Qualitative: 1[134]	Cross-sectional: 1[112]	Qualitative: 1[130]

[a] Medicaid or Medicare populations are counted with the payer, even if the analysis was limited to single or multiple facilities.
[b] Study population included multiple payers.
[c] One study separately analyzed HNHC in relation to ED and IP visit patient outcomes.[113]
[d] One study included both a cross-sectional and cluster analysis.[75]
- Denotes no studies.

ED = emergency department; HNHC = high-need, high-cost; IP = inpatient.

The evidence included to answer KQ 1 fell into four broad groups of methodological approaches. We present characteristics for each included study in separate tables by analysis type: predictive (Table 3), cross-sectional (Table 4), cluster (Table 5), and qualitative (Table 6). For cross-sectional (Table 4) and predictive studies (Table 3), we also present outcomes and categories of predictors included in multivariate models. For cluster analyses (Table 5), we also present clusters identified in the analysis. For qualitative studies (Table 6), we also present the main findings.

We structured the presentation of our results to separately answer each of our KQ 1 subquestions and correspond to the NAM taxonomy:

- KQ 1a: Patient clinical conditions (corresponding to the NAM clinical and functional groups)
- KQ 1b: Patient demographic, behavioral health, and social risk factors (encompassing the NAM behavioral health and social risk factors)
- KQ 1c: Types, amount, duration, and patterns of use
- KQ 1d: Differences by payer, healthcare system, and provider level
- KQ 1e: Identifying potentially preventable and modifiable use

Although most studies included patients across clinical and behavioral health conditions, nine studies focused on subgroups of HNHC patients. Subgroups included those with specific chronic clinical conditions associated with high healthcare use (i.e., asthma,[95] chronic obstructive pulmonary disease [COPD],[93] acute heart failure syndrome,[92] migraine headache,[102] or mental health conditions).[85, 87, 90] Another subgroup study was limited to disabled Medicaid beneficiaries.[85] The ninth subgroup study separately analyzed Medicare beneficiaries younger than 65 years of age and those 65 years of age and older.[108]

Predictive Studies

Predictive analysis is deemed to be the most rigorous design, among available analytic approaches, because it is better able to establish causation (i.e., the use or cost outcome occurred after the diagnosis and other characteristics of interest). All predictive studies used regression analysis suited to the functional form of the outcome (e.g., logistic, Poisson) and the intent of the analysis (e.g., stepwise, lasso linear) to identify predictors of HNHC patient healthcare use or cost in a subsequent period, while controlling for potential confounding variables. Predictive analyses examined the association between HNHC patients' characteristics and/or behavior during an index time period, typically a year, and their healthcare use or cost in a future time period, ranging from 6 months or longer, most often 1 year. We identified 11 predictive studies, reported in 12 articles (Table 3).

Table 3. Predictive studies with evidence for KQ 1 (N=11)

Author, N	HNHC Outcome Measured During the Followup Period[a]	Study Population	Clinical Health Conditions	Demographic Character-istics	High-Impact Behavioral Character-istics	High-Impact Social Risk Character-istics	Provider and Health System Character-istics
Billings et al., 2013 N=212,259[81]	ED visits (3+, 5+, 8+, 10+)	Medicaid: Frequent ED users in NYC, 2007	Number of chronic conditions, diagnosis, CCI rating scale	Age, gender, race	MI, SUD	Not measured	Utilization over prior 3 years
Colligan et al., 2016 N=5,400,237[80]	ED visits (4+)	Medicare: national 20% sample, 2009-2010	Diagnoses, HCC score	Age, gender, race	MI	Not measured	Medicaid, Prior year: level of ED use, continuity of care index
Kanzaria, 2017 (N=173,273)[79]	ED visits (4+), persistent over 2, 3, 6, and 11 years	California nonelderly adults, 2005-2015; ED visits 4+ in 2005, 2005-2015	Not measured	Age, race	Anxiety disorder, Depression, SMI, SUD, AUD	Urbanicity, poverty	Insurance type, level of ED use in the base year
Billing et al., 2007 (N=98,000)[85]	Inpatient readmissions (1+)	NYC, Medicaid enrollees, disabled and SMI subgroups, 2000-2004	Diagnosis	Age, race, gender	SMI, MI, SUD	Zip code	Prior utilization

Author, N	HNHC Outcome Measured During the Followup Period[a]	Study Population	Clinical Health Conditions	Demographic Characteristics	High-Impact Behavioral Characteristics	High-Impact Social Risk Characteristics	Provider and Health System Characteristics
Chang et al., 2019 (N=258,759)[83]	Risk of 90-day inpatient readmission (persistently high, intermittently high, or initially high)	VA population in top 5% risk of inpatient admission, based on CAN score, 2012-2014	Diagnoses	Age, race, gender	MI, SUD	Zip code change, urban	Prior utilization
Raven, 2008 (N=36,457)[84]	Inpatient admissions (1+ readmission)	Medicaid patients at 1 NYC public hospital users, 2001-2006	Chronic condition, self-rated health status	Not measured	MI, SUD	Homelessness, Social Isolation	Prior utilization
Meek, 2000 (N=4,210)[77]	All utilization (6+ encounters in 6 months)	Midwest, commercial managed care enrollees, 6 primary care visits in past year, 1997	Self-reported health rating scale	Age, race, gender	MI	Not measured	Prior utilization
Yang et al., 2017, 2019 (N= between 464,572 and 535,422 in each of the years)[76, 82]	Cost higher than expected, after risk adjustment	Texas Medicaid beneficiaries, 2011-2014	Disease diagnoses	Age, race, gender, disabled status	Not measured	County of residence	Prior utilization, fee-for-service or MCO
Yang et al., 2018 (N=1,734,896)[78]	Cost (top 10% expenditures)	Texas Medicaid beneficiaries, 2011-2014	Disease diagnoses	Age, race, gender, disabled status	Not measured	Not measured	Prior utilization
Bayliss et al., 2016[b] (N=6,047)[75]	Cost (top 25%, total costs)	Kaiser Permanente Colorado, newly enrolled ACA members, 2014; completed the Brief Health Questionnaire	Number of chronic conditions, condition that interferes with daily activity, self-reported health	Age, gender	Depression	Financial constraints	Prior insurance coverage, type of coverage, prior ED and IP use, prescription medications
Keeney, 2020 (N=3,093,211)[86]	Cost (top 10% of expenditures)	Fee-for-service Medicare beneficiaries, 2013-2016	Multimorbidity, medical complexity	Age, gender, race	Not measured	Not measured	Persistence of high-need status, Medicaid dual eligible

[a] The outcome is measured in the next 12-month period unless otherwise specified.

[b] This study also included a cluster analysis.

ACA = Affordable Care Act; AUD = alcohol use disorder; CAN = Care Assessment Need model; CCI = Charlson Comorbidity Index; ED = emergency department; HCC = hierarchical condition categories; HNHC = high-need, high-cost; IP = inpatient; KQ = Key Question; MCO = managed care organization; MI = mental illness; N = number; NYC = New York City; SMI = serious mental illness; SUD = substance use disorder; VA = Veterans Health Administration.

Predictive Tools and Modeling

Some of the predictive studies developed, tested, or refined tools or modeling techniques to predict future use or cost. These studies reported on the overall performance of the tool or modeling technique and did not always separately report on the individual patient characteristics that were included in the prediction.

Among these, Billings and colleagues developed and tested an algorithm to identify disabled Medicaid beneficiaries at high risk of rehospitalization and high costs within 12 months of an index hospitalization.[85] Raven and colleagues assessed the accuracy of Billings and colleagues' algorithm to identify Medicaid patients at high risk of subsequent rehospitalization within 12 months, based on their diagnoses and prior service use.[84] In both studies, the algorithm calculated a rehospitalization positive predictive value (PPV) of 0.67 among individuals with a risk score greater than 50 (on a scale ranging from 0-100). Billings and colleagues also developed an algorithm to predict future high ED use among Medicaid beneficiaries, based on prior use and medical and behavioral health conditions.[81] The PPV for this algorithm was 0.663.

Chang and colleagues tested a previously validated algorithm, the Care Assessment Needs (CAN) score, for predicting the persistence of risk of rehospitalization in the Veterans Health Administration (VA) system for a period of 24 months. The analysis examined predictors significantly associated with being persistently high risk, as measured by the CAN score.[83]

Yang and colleagues assessed several methodological approaches to examining analytic model residuals to identify HNHC patients who have higher than expected healthcare expenditures from year to year with the goal of distinguishing potentially preventable from nonpreventable healthcare use.[76, 82] Yang and colleagues also used Medicaid claims data to examine different analytic approaches to using machine learning models to accommodate a large number of interaction terms and recurrent neural networks to process sequential events and predict future costs.[78] Major findings from Yang and colleagues' analyses are reported in relation to answering KQ 1e.

Several studies examined the role of patient self-reported information in predicting future high cost and use. Meek and colleagues tested a patient self-reported health perception assessment tool for predicting future use of all services (PPV=0.67).[77] Bayliss and colleagues examined the effectiveness of the Brief Health Questionnaire, a 10-question needs assessment, coupled with demographic information, in predicting future high cost, measured as being in the top 25 percent in the subsequent 6 to 12 months.[75] The authors considered the approach to be "moderately predictive" in identifying patients who would be high cost (c-statistic=0.75).

Cross-Sectional Studies

Cross-sectional studies (N=33) seek to identify HNHC patients by analyzing the association between patient characteristics and high utilization or cost *in a single time period*. All studies used a regression model suited to the functional form of the outcome (e.g., logistic, multinomial, Poisson) and attempted to control for potential confounding variables. Table 4 presents characteristics for each of the cross-sectional studies.

Table 4. Cross-sectional studies with evidence for KQ 1 (N=33)

Study Citation Sample Size	HNHC Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
Chang, 2014 (N=863)[87]	ED visits (4+ over 12 months or 3+ over 2 months)	Patients with MI conditions, ED use across 4 hospitals in the Boston area, 2008-2009	Diagnoses	Age, gender	MI, SUD, AUD	Homelessness	Prior utilization
Doran et al., 2013 (N=5,531,379)[88]	ED visits (1, 2-4, 5-10, 11-25, >25)	VA population in 2010	Diagnoses, CSI	Gender, Age	Depression, SMI, MI, SUD, AUD	Homelessness, income	Outpatient clinic visits
Behr et al., 2016 (N=1,443)[89]	ED visits (2+, 3+, 4+, 5+)	Urban Level 1 trauma center ED patients, triaged ESI 4-5 (least urgent), data period NR	Patient perception of seriousness of need	Gender, race	MI, SUD	Employment, consulted with family member prior to visit	Insurance type, patient report of prior utilization, service quality
Buhumaid et al., 2015 (N=569)[90]	ED visits (4+)	Patients with MI dx and ED use in DC academic hospital, 2009	1 or more chronic conditions	Age, gender, race	SUD, AUD	Homelessness	Insurance type
Thakarar et al., 2015 (N=412)[91]	ED visits (2+)	ED patients enrolled in homelessness program with 1+ OP visit to Boston safety net hospital, 2011-2013	Diagnoses rating scale	Age, gender, race	MI, SUD	Housing status	Utilization
Hasegawa et al., 2014 (N=294,678)[92]	ED visits (3+ for AHFS)	CA and FL ED patients with AHFS, 2010-2011	Selected diagnoses	Age, gender, race	Depression, SUD	Area income	Insurance type
Hasegawa et al., 2014 (N=1,890)[93]	ED visits (3+ for acute exacerbation of COPD)	CA and FL ED patients with acute exacerbation of COPD, 2010-2011	Selected diagnoses	Age, gender, race	Depression, SMI, SUD	Area income	Insurance type
Doran et al., 2014 (N=965)[94]	ED visits (3+)	ED patients with low acuity complaints, NYC ED, 2007-2008	Chief complaint, overall health	Age, gender, race	Not measured	Education, employment	Self-reported access and quality of care
Hasegawa et al., 2014 (N=965)[95]	ED visits for asthma (3+)	Patients with asthma at 48 EDs across 23 states, 2011-2012	Not measured	Age, gender, race	Not measured	Area income	Insurance type
Liu, 2013 (N=965)[96]	ED visits (3+)	ED patients, one urban ED, 2007-2008	Overall health	Age, gender, race	MI, SUD, AUD	Employment,	Prior utilization, access, cost, quality of care

Study Citation Sample Size	HNHC Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
Milbrett, 2009 (N=201)[97]	ED visits (continuous measure)	Midwestern hospital ED patients with 6+ visits, 2005-2006	Diagnoses	Gender, race	SMI	Employment status, marital status	Insurance type, have PCP
Ruger, 2004 (N=71,941 visits)[98]	ED visits (2, 3-5, 6-20, >20)	Urban, academic hospital ED patients, 2001	ED Triage Acuity Level, DRG severity level	Age, gender	Not measured	Not measured	Insurance type
Mandelberg, 2000 (N=348,858 visits)[99]	ED visits (5+)	Urban, academic hospital ED patients, 1993-1998	Not measured	Age, gender, race	Not measured	Homelessness	Insurance type
Vinton, 2014 (N=157,818)[100]	ED visits (4+, 10+)	National Health Interview Survey, 2004-2009	Diagnoses, rating scale	Age, gender, race	MI, AUD	Employment, income	Insurance type, prior ED and outpatient use
Hunt, 2006 (N=59,725)[101]	ED visits (4+)	Community Tracking Study Household Survey, 2000-2001	Rating scale	Race	MI	Income	Insurance type, prior ED and outpatient use, relationship with physician
Friedman, 2009 (N=59,725)[102]	ED visits (4+)	Nationally representative survey of migraine sufferers, 2004	Headache disability score	Age	Depression	Income	Insured status, medication use, provider type, prior ED use for other conditions
Zuckerman, 2004 (N=89,626)[103]	ED visits (3+)	Urban Institute’s National Survey of America’s Families, 1997 and 1999	Rating scale, disability status	Race	Not measured	Income	Insurance type, Access to care, outpatient use
Castillo, 2018 (N=71,449)[104]	ED visits (6+)	ED patients in CA, age 65+, 2014	Pain, Injury, CCI	Age, gender, race	Psychiatric, SUD	Not measured	Admitted/transferred
Kanzaria, 2019 (N=20,661)[105]	ED visits (4-7)	Medicaid ED patients, nonaged, San Francisco MCO Health network, 2013-2015	Selected comorbidities, disabled	Age, gender, race	Alcohol use, drug use disorders, psychoses, depression	Homelessness, jail	Not measured
Ali, (N=474)[106]	ED visits (3+)	Medicaid ED patients receiving care at an ED in Washington, DC, 2015-2016	Physical illness score	Age, gender	MI, SUD	Homelessness	Not measured

Study Citation Sample Size	HNHC Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
Kalyani, (N=54,981)[107]	ED visits (2+)	Medicaid enrollees in PA with MI, 2007-2012	Elixhauser comorbidity index	Age, gender, race	Multiple MI conditions, Substance use	Not measured	Medicaid eligibility type, prior PCP and BH use
Surbhi, 2020 (N=1,092)[108]	ED visits, inpatient admissions for ACSCs over 6- month period	Medicare beneficiaries Memphis, TN, one or more ACSCs, Inpatient admissions (3+) or (Inpatient admissions 2+ and 2+ ED visits in 6 months), 2011-2013	ACSC conditions (hypertension, type 2 diabetes, congestive heart failure, coronary artery disease, COPD, asthma, CCI	Age, gender, race	MI,	Dual eligible	Medication nonadherence, unique medication, prescribers, office visits
Bell, 2017 (N=494)[109]	Inpatient admissions (3+)	Atlanta, GA large safety-net hospital ED patients, 2011-2013	Number of chronic conditions	Age, gender, race	MI, SUD, AUD	Homelessness, income	Insurance type
Porter, 2019 (N=2,621)[110]	Inpatient readmissions (3+)	Southeast academic medical center inpatients, 2014-2016	Number of chronic conditions, rating scale	Age, race, gender	MI, SUD	Not measured	Insurance status
Emechebe, 2019 (N=19,817)[111]	Inpatient readmissions by 180 days (1+)	Medicaid managed care and Medicare Advantage patients insured by WellCare Health Plan, 2013-2017	CCI	Age, race, gender	Alcohol abuse, anxiety, depression, SMI	Financial assistance, other social needs assistance, food, housing, transportation	Type of insurance
Rohrer, 2008 (N=698)[112]	All outpatient utilization (27+ visits)	Family medicine practice, 2005-2006	Rating scale	Age, gender	Not measured	Not measured	Not measured
Blumenthal 2017 (N=2,639)[113]	Top 5%: ED visits, acute hospitalizations	Partners Healthcare ACO members (12 practices), 2014-2015	Self-report rating scale, CCI	Age, race, gender	MI	Not measured	Not measured
Reichard 2015 (N=53,586)[114]	All utilization (≥75th percentile in 2 years)	Weighted sample of working age adults, 2006-2008	Number of chronic conditions, disability status	Not measured	Not measured	Not measured	Insurance status, utilization
Walker et al., 2003 (N=1,963)[115]	Costs: total, inpatient and ED	Female Puget Sound HMO members, 1996-1997	Not measured	Age, race	PTSD, other MI	Not measured	Not measured

Study Citation Sample Size	HNHC Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
Robinson et al., 2016 (N=1,921)[116]	Cost (top 10% total costs)	Commercial health plan enrollees in 14 geographically diverse U.S. plans with depression, 2011, 2009-2010	Diagnosis, rating scale	Age, gender	MI, SUD, AUD	Employment	All commercially insured
Sterling et al., 2018 (N=378)[117]	Cost (top 20% over 2 years)	Kaiser Permanente Northern California members with chronic conditions or stable disability, 2009-2011	Not measured	Age, gender	MI	Income	Not measured
Berkowitz et al., 2018 (N=11,781)[118]	Cost (top 10%, top 5%, top 2%)	Adults, National Health Interview Survey 2011, MEPS 2012-2013	Not measured	Age, gender, race	Not measured	Food insecure, education, income, urban residence, region	Health insurance
Figueroa, 2019 (N=5,507,218)[119]	Cost (top 10% of expenditures)	Medicare beneficiary 20% sample, 2012-2014	Chronic conditions	Age, gender, race	Depression	Income, region	Has Part D, Medicaid dual eligible, high cost in earlier year

[a] The outcome in the next 12-month period unless otherwise specified.

ACO = accountable care organization; ACSC = ambulatory care sensitive condition; AHFS = acute heart failure syndrome; AUD = alcohol use disorder; BH = behavioral health; CA = California; CCI = Charlson Comorbidity Index; COPD = chronic obstructive pulmonary disease; CSI = Charlson severity index; DC = District of Columbia; DRG = diagnosis-related group; dx = diagnosis; ED = emergency department; ESI = Emergency Severity Index; FL = Florida; GA = Georgia; HMO = health maintenance organization; HNHC = high-need, high-cost; KQ = Key Question; MCO = managed care organization; MEPS=Medical Expenditure Panel Survey; MI = mental illness; N = number; NR = not reported; NYC = New York City; OP = outpatient; PA = Pennsylvania; PCP = primary care physician; PTSD = post-traumatic stress disorder; SMI = serious mental illness; SUD = substance use disorder; TN = Tennessee; U.S. = United States; VA = Veterans Health Administration.

Unlike the predictive analyses, cross-sectional studies cover the same time period for the outcome and independent variables. Because of this, it is often difficult to establish if time-varying patient characteristics, such as diagnoses or insurance type, were present at the start of the study period. This prevented inferences of temporal associations (e.g., presence of diagnoses predicts future high-need or high-cost utilization). Cross-sectional studies are also generally unable to provide insights about the persistence of patients being HNHC over time. For these reasons, we present predictive and cross-sectional results separately.

Cluster Analyses

We identified 12 cluster analyses examining combinations of characteristics of HNHC patients (Table 5). Cluster analysis and the associated technique latent class analysis are statistical methods for identifying “hidden” or unobservable class membership (groupings) among subjects using observed variables.[57] These analyses separate groups of HNHC patients based on combinations of both modifiable and nonmodifiable characteristics, including healthcare utilization patterns, disease groups, demographic characteristics, and level of functioning. The analyses are considered particularly useful for identifying homogeneous subgroups of HNHC patients to include in interventions. In the text, we use the term “cluster analysis” to denote all forms of analysis designed to identify unobservable groupings (e.g., latent class, item response, structural equation modeling). See Table 5 for the specific analytic approach to clustering that was used in each study.

Table 5. Cluster analysis studies with evidence for KQ 1 (N=12)

Study Citation Sample Size	Analytic Approach	Population	Clusters: Number and Types	Cluster Results
Yang, 2018 (N=1,734,896)[120]	Latent class analysis	Texas Medicaid beneficiaries with 12 or more ED visits in 4 years, 2011-2014	3 clusters based on timing of intervals between ED visits	• Cluster 1 (peak at 64-128 days between visits): younger adult patients with asthma or vulnerable to respiratory infections with 2 to 3 months between ED visits • Cluster 2 (peak at 4-16 days between visits): mentally or chronically ill with 1 to 2 weeks between ED visits • Cluster 3 (peak not specified): Pregnant women with ED visit frequency between that of Clusters 1 and 2
Birmingham, 2020 (N=5731)[121]	Latent class analysis	One Midwestern hospital-based ED patients with 4+ visits, 2015	4 groups of ED frequent users	• Cluster 1: short-term: tend to stop within a year • Cluster 2: heart-related conditions • Cluster 3: long-term: highest proportion of Medicaid and Medicare <65 groups • Minor care: all had visits with musculoskeletal discharge diagnoses
Bayliss et al., 2016 (N= 1,512)[75]	Cluster analysis	Kaiser Permanente Colorado, newly enrolled ACA members, top 25% total costs, 2014	8 clusters based on self-reported functioning, health status, and healthcare utilization	Clusters that authors considered actionable: • Fair/poor health, requiring prescription medications, with financial constraints, a positive depression screen, and high hospital utilization in the prior year • Low morbidity and low prior utilization, but moderate prescription medication needs • Good health, but lacking health insurance in the preceding year so needing preventive care • Low morbidity and high ED use
Newcomer, 2011 (N=15,480)[122]	Latent class analysis	Kaiser Permanente Colorado members, top 20% total costs in both of 2 years, 2+ chronic conditions, 2006-2007	10 clusters based on chronic conditions, including BH dx	• Frail elderly • Kidney disease with diabetes and obesity • Diabetes with obesity and MH conditions • Cardiac disease and obesity • MH conditions and obesity in younger adults • Cancer with obesity and MH conditions • COPD with obesity and MH conditions • Chronic pain with MH conditions • Abdominal and orthopedic surgeries with obesity • Gastrointestinal bleeding with obesity and MH conditions

Study Citation Sample Size	Analytic Approach	Population	Clusters: Number and Types	Cluster Results
Szymkowiak et al., 2017 (N=16,912)[123]	Latent class analysis	VA homeless veterans with ≥ 1 hospital admission and/or ≥ 2 ED visits, during any of 8 quarters, 2014-2015	7 clusters based on healthcare utilization	• Medical inpatients: 24% • ED only medical: 24% • ED only MH/SU: 13% • MH inpatient only: 13% • SU inpatient only: 10% • MH inpatient + ED: 8% • SU inpatient + ED: 7%
Wong et al., 2018 (N=7,289)[124]	Latent class analysis	VA hospital inpatients during 1-week period, top 5% for risk of future hospitalization, based on CAN score, November 2012	2 clusters based on risk of rehospitalization over a two-year period	Baseline characteristics explained 23% of variation in group assignment Moderately high risk (65% of patients) • Greater decline in risk of hospitalization over time Persistently high risk (35% of patients) • Higher rates of healthcare use, particularly number of hospitalizations • Higher rates of nearly all comorbidities, including COPD and heart failure • Higher rates of alcohol abuse and SUD
Prenovost, 2018 (N=68,400)[125]	Item response theory	VA CAN score in top 10%; predicted risk of hospitalization ≥ 25%, 2014	6 clusters based on chronic conditions, including BH	• Substance abuse and additional complexity because of depression, anxiety, liver disease, and chronic hepatitis • Complex MH: depression most frequent dx, often increased complexity with diabetes and hypertension • Complex diabetes: comorbid dx associated with complexity: hypertension, diabetes, renal failure, and depression, with depression an important marker of complexity • Liver disease or chronic hepatitis: intermediate complexity related to hypertension or diabetes • Cancer and cardiovascular disease: hypertension most common comorbid dx, followed by CAD and CHF • Cancer and MH dx: depression most frequent BH dx
Hyer, 2020 (N=19,522)[126]	Cluster analysis	Medicare beneficiaries, age 65+, underwent a total hip or total knee arthroplasty, highest median pre-operative expenditure, 2012-2016	5 clusters,	• Annual preoperative expenditures lowest and relatively low preoperative utilization • Preoperative expenditures a little higher than cluster 1. Costs largely driven by medical/surgical supplies and surgical care before hip or knee surgical admission • Female (63%), median preoperative health expenditures $3,500 more than cluster 2, lowest number of preoperative inpatient encounters, highest pharmacy charges • Median preoperative health expenditures similar to cluster 3, highest medical/surgical supply charges • Highest comorbidity burden; highest annual preoperative expenditures, high pharmacy charges, lab services, diagnostic radiology services

Study Citation Sample Size	Analytic Approach	Population	Clusters: Number and Types	Cluster Results
Lee, 2016 (N=14,855)[127]	Cluster analysis	Medicare fee-for-service Cleveland Clinic health system patients, top 10% of costs, 2012	5 clusters	• Ambulatory care: primarily outpatient care, cancer and chemotherapy most common conditions • Surgical: median 2 IP surgeries vs. none • Critically ill: higher odds of heart failure and cardiac arrhythmia and arrest and the highest median • inpatient costs • Frequent care: median of 2 IP, 3 ED, and 29 outpatient visits. Common: MH, SUD, and COPD/asthma • Mixed utilization: median of 1 admission, 1 ED visit, and 23 outpatient visits
Powers, 2018 (N=6154)[128]	Cluster analysis	Members of a Medicare Advantage plan, top 10% of costs, 2013-2015	10 clusters	• Acute exacerbations of chronic disease (mixed) • End-stage renal disease • Recurrent gastrointestinal bleed • Orthopedic trauma • Vascular disease • Surgical infections and other complications • Cirrhosis with hepatitis C • ESRD with increased medical and behavioral comorbidity • Cancer with high-cost imaging and radiation therapy • Neurologic disorders
Grant, 2020 (N=104,869)[129]	Latent class analysis	Kaiser Permanente of Northern California members with high utilization (high likelihood of hospitalization and/or 2 ED visits), 2017-2019	7 clusters based on clinical profiles	• Highest acuity: highest utilization (both inpatient and outpatient) with most comorbid conditions • Older patients with CVD • Frail elderly: highest 1-year mortality and most frailty-related needs • Chronic pain management: high outpatient use and medical needs complicated by MH needs • Active cancer treatment: intensive oncologic therapy with associated medical and pain management issues • Psychiatric illness: severe mental illness complicated by low income, social needs, and pain management • Less clinically engaged: prevalent comorbidities but fewer Visits

ACA = Affordable Care Act; BH = behavioral health; CAD = coronary artery disease; CAN = Care Assessment Needs; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; dx = diagnosis; ED = emergency department; ESRD = end-stage renal disease; IP = inpatient; KQ = Key Question; MH = mental health; N = number; SU = substance use; SUD = substance use disorder; VA = Veterans Health Administration.

Qualitative Studies

We identified six qualitative articles for answering KQ 1 (Table 6). The studies relied on chart review and interviews with patients, providers, administrators, and stakeholders. They largely discuss high-impact patient clinical and demographic characteristics, as well as behavioral health and social risk factors associated with high utilization. The studies included personal experience and informed opinions characterizing HNHC patient and health system mismatch that may be relevant for developing successful care management strategies.[130, 134]

Table 6. Qualitative studies with evidence for KQ 1 (N=6)

Study Citation Sample Size	Definition of HNHC[a] Patient Population/ Setting	Analytic Approach	Main Findings
Ganguli, 2017[130] (N= 5)	Patients selected from among 50 who had the highest total costs Academic medical center	Mixed methods: patient/caregiver interviews, analysis of claims data, and chart review	Patients with complex medical issues, physical disability, frailty, and BH use seemed to have increased healthcare costs Patient socioeconomic status, social network, activation, and trust in clinicians and the health system appeared to affect costs, with patient activation and trust appearing to mediate costs
Hardy et al., 2018[131] (N=260)	5+ ED visits among patients enrolled in primary care clinic Large primary care safety net clinic in North Carolina	Mixed methods: analysis of electronic health record data matched with encounter data; chart review of 10 highest ED users for top 3 complaints	HNHC patients' chief presenting complaints were similar to other patients but most had a greater number (4+ complaints) that were associated with chronic conditions, often confounded by BH concerns and treatment nonadherence HNHC patients had more ED visits for the same types of complaints and visits occurred more closely together in clusters
Birmingham et al., 2017[132] (N= 100)	4+ ED visits Patients meeting high ED use criteria at an urban, level 1 trauma center	Structured interviews with patients	The primary reason for ED use was emergent health concerns, although many would prefer after-hours alternatives. A majority thought that it would be helpful having a nurse providing one-on-one help managing their care Barriers to care included forgetting to schedule regular health checkups and having difficulty taking time away from daily responsibilities for necessary medical care
Hasselman et al., 2013[133] (N=14 Summit participants)	Programs included a variety of definitions: common characteristics included high ED use, inpatient admissions, readmissions, and poly-pharmacy Medicaid	Expert panel testimony at "Super utilizer summit"; panel members included representatives from HNHC patient intervention programs, states, CMS, health plans, and other stakeholders	The panel identified strategies for targeting HNHC patient subgroups that are most likely to be affected by complex care management • Use multiple data sources to ID HNHC patients to avoid inaccuracies, including real-time notification of inpatient admissions, patient assessments, EHRs, conversations with caregivers • Assess social determinants of health • Predictive modeling can be an alternative to waiting for delays in availability of claims data • The HNHC patient population is heterogeneous; cluster analysis can be used to ID subgroups • ID exclusions, including pregnancy, oncology, surgery for acute conditions, age 80 and older with dementia • HNHC patient identification is an iterative process

Study Citation Sample Size	Definition of HNHC[a] Patient Population/ Setting	Analytic Approach	Main Findings
Chan et al., 2019[134] (N=15 clinic staff)	1+ inpatient admissions in the prior 6 months, with multiple medical or MH conditions or poor engagement in care FQHC in Portland, Oregon	Semi-structured interviews with staff participating in an intervention for HNHC homeless patients	HNHC patient complexities are driven mainly by nonmedical factors including poverty, homelessness, low health literacy, MH, and substance use disorders Patient-health system mismatch arises from patient's social circumstances limiting access to services, BH issues interfering with care engagement, and lack of health system flexibility to address the mismatch, such as availability of longer visits
Das et al. 2019[135] (N=56; 11 health system leaders; 21 physicians; 21 patients and 3 caregivers)	1 chronic condition and either 3+ ED visits or 2+ inpatient admissions 5 health systems in 3 cities: New York City; Gainesville, Florida; and Chicago, Illinois	Interviews with health system leaders and focus groups of HNHC patients, caregivers, and physicians	Key themes identified as drivers of preventable high healthcare utilization: Unmet BH needs: inadequate access to MH and substance use disorder treatment, poor patient followup to care due to depression, and state MH involuntary treatment laws not able to address root causes of disorders Social determinants of health: inadequate health literacy, unstable housing, lack of adequate social support, and financial burdens of co-pays for care and medications Challenges accessing the healthcare delivery system: lack of transportation, long wait times for outpatient appointments, unable to find doctors who take Medicaid, and administrative pressure for physicians to keep outpatient visits short

[a] HNHC definition includes utilization over a 12-month period unless otherwise stated.

BH = behavioral health; CMS = Centers for Medicare & Medicaid Services; dx = diagnosis; ED = emergency department; EHR = electronic health record; FQHC = Federally Qualified Health Center; HNHC = high-need, high-cost; ID = identify; KQ = Key Question; MH = mental health; N = number.

Study Outcomes

We found wide variation across studies in the definition of high healthcare use or cost that was used as the outcome in regression analyses across predictive and cross-sectional exposure studies and used to define the HNHC patient population in cluster analyses. Table 7 presents the criteria used across predictive, cross-sectional and cluster analysis studies.

The largest group of studies (N=29) considered HNHC is in relation to ED visits.[79-81, 87-104, 108, 120, 131, 132] No standard or consensus definition for frequent or persistent ED use currently exists, as several studies noted, resulting in the number of ED visits varying across studies. Some studies included multiple analyses with different cutoffs, with the exploratory goal of identifying how differences in the definition for high ED use affected which characteristics would be significantly associated with the outcome. The number of ED visits categorized as HNHC ranged from two or more ED visits in a 12-month time period in four studies[89, 91, 98, 107] to over 25 visits in a 12-month time period in one study on the VA population.[88]The median number of ED visits categorized as HNHC was four or more visits.

Table 7. Definitions of HNHC patient healthcare use or cost across studies

Study Population	Analysis Type	2+ ED Visits	3+ ED Visits	4+ ED Visits	5+ ED Visits	6+ ED Visits	>6 ED Visits	Multiple Measures	2+ IP Admission	All Utilization in Top Decile (≥75th)	Top 10% in Cost	Top 20% in Cost	Top 25% in Cost	Cost Ratios
Medicaid	Predictive	-	2[81]	-	1[81]	-	-	1[81]	2[84, 85]	-	2[76, 78, 82]	-	-	-
	Cross-sectional	1[107]	-	1[105]	-	-	-	-	-	-	-	-	-	-
Medicare	Predictive	-	-	1[80]	-	-	-	-	-	-	3[86, 127, 128]	-	-	-
	Cross-sectional	1[108]	-	-	-	-	-	-	1[108]	-	1[119]	-	-	-
	Cluster analysis	-	-	-	-	-	-	-	-	-	1[126]	-	-	-
VA	Predictive	-	-	-	-	-	-	-	1[83]	-	-	-	-	-
	Cross-sectional	1[a][88]	-	-	1[b][88]	-	1[88]	1[88]	-	1[123]	-	-	-	-
Hospital/ health system	Predictive	-	-	1[87]	-	-	-	-	-	-	-	-	-	-
	Cross-sectional	2[89, 91, 95, 98]	5[89, 92-95]	4[89, 90, 95, 96, 106]	3[89, 95, 96, 99]	1[87]	2[95-98]	4[89, 95, 96, 98]	2[109, 110]	2[112, 113]	-	-	-	-
	Cluster analysis	-	-	1[121]	-	-	-	-	-	1[129]	-	-	-	-
Commercial (including HMO)	Predictive	-	-	-	-	-	-	-	-	1[77]	-	-	1[75]	-
	Cross-sectional	-	-	-	-	-	-	-	-	-	1[116]	1[117]	-	1[115]
Population based	Predictive	-	-	1[79]	-	-	-	-	-	-	-	-	-	-
	Cross-sectional	-	-	3[100-102]	1[104]	-	-	1[100, 101]	-	1[114]	1[118]	-	-	-

[a] The outcome is 2-4 visits.
[b] The outcome is 5-10 visits.
- Denotes no studies.

ED = emergency department; HMO = health maintenance organization; HNHC = high-need, high-cost; IP = inpatient; VA = Veterans Health Administration.

Eleven studies considered HNHC in relation to inpatient admissions.[83-85, 108-111, 124, 125, 134, 135] Criteria ranged from two or more admissions in nine studies[83-85, 108, 111, 124, 125, 134, 135] to three or more admissions in two studies.[109, 110]

More global measures that considered more than one type of healthcare utilization were included in six studies.[18, 113-115, 173, 184] These measures included all healthcare utilization,[77, 112, 114] all outpatient utilization,[18] or a combination of ED use and inpatient utilization.[108, 113]

Lastly, high cost was considered in 10 studies reported in 11 articles.[75, 76, 78, 82, 86, 115-119] High cost was typically defined as inclusion in the top 10 percent of total expenditures; however, two studies defined high cost as the top 20 and 25 percent of expenditures,[75, 117] and one study defined high cost as higher than expected expenditures after risk adjustment.[76, 82]

KQ 1a. How do criteria incorporate patient clinical characteristics?

Key Points

- Eleven of 13 studies that assessed the role of specific complex chronic conditions (i.e., congestive heart failure, COPD, cardiovascular disease, dementia, and diabetes) found positive associations with high-use outcomes, including ED visits, inpatient admissions, total healthcare visits, and total cost.
- We found virtually no data on the association between combinations of two or more specific chronic conditions and high use or cost. However, both studies that used predictive and cross-sectional designs found a positive association between high use or cost and having a greater number of comorbid conditions. Many individually measured chronic conditions had an independent effect on high use or cost.
- Several rating scales or assessments, including the Charlson Comorbidity Index (CCI), the hierarchical condition category (HCC), and the CAN score, predicted high use. The HCC and CAN are population specific to Medicare beneficiaries and VA patients, respectively. The CAN score was also effective in identifying latent clusters among VA HNHC patients.
- Higher scores on patient self-assessment tools, such as the global health score, were associated with high use. The evidence was limited to cross-sectional studies.

Results of Studies

We present our findings describing chronic clinical conditions associated with high use or cost, separately by predictive, cross-sectional and cluster analysis study design, in Tables 8 through 12. The clinical conditions are presented in three ways: specific diagnoses, number of conditions, and rating scales assessing condition severity. Additional study detail is included in Appendix Tables B-1 and B-2.

Table 8. Number and results of studies examining the association between chronic clinical conditions and high ED use

Diagnosis, Health Condition, or Rating Scale	Predictive Studies	Cross-Sectional Studies
Diagnosis: Arthritis	1[a,b,80]	2[a,b,99, 100]
Diagnosis: Asthma	-	1[97]
Diagnosis: Cerebrovascular disease[d]	-	1[a,b,100]
Diagnosis: Congestive heart failure[d]	1[a,b,80]	3[a,b,88, 93, 105]
Diagnosis: COPD[d]	1[a,b,80]	4[a,b,88, 92, 99, 105]
Diagnosis: Cardiovascular disease[d]	-	2[a,b,93, 100]
Diagnosis: Dementia[d]	1[a,b,80]	-
Diagnosis: Diabetes[d]	1[a,b,80]	4[a,b,92, 93, 100, 105]
Diagnosis: Heart disease[d]	-	1[87]
Diagnosis: Hepatitis C	-	1[a,b,91]
Diagnosis: Hepatobiliary disease	-	1[a,b,87]
Diagnosis: HIV	-	1[91]; 1[a,b,105]
Diagnosis: Hypertension	1[a,b,80]	1[100]
Diagnosis: Obesity	-	1[e,93]
Diagnosis: Pancreatic disease	-	1[87]
Diagnosis: Renal disease	1[80]	3[a,b,88, 92, 99]
Diagnosis: Seizure	-	1[a,b,99]
Diagnosis: Sickle cell	-	1[a,b,99]
Diagnosis: Vascular disease[d]	-	1[87]
Health Condition: # of Conditions	-	-
Rating Scale: Charlson Comorbidity Index	1[a,b,81]	3[a,b,88, 104, 108]; 1[91]
Rating Scale: Poorer global health rating		5[a,b,100, 101, 103, 106, 113]
Rating Scale: Hierarchic categorical condition score	1[a,b,80]	-
Rating Scale: DRG Severity Index	-	1[a,b,98]
Rating Scale: Elixhauser index	-	1[a,b,107]
Rating Scale: MIDAS disability score	-	1[a,b,102]

Note: When the relationship in a study was not statistically significant, the direction of effect is not shown.

[a] Denotes positive association

[b] Denotes if the association, positive or negative, is statistically significant.

[-] Denotes no studies.

[d] Denotes complex chronic clinical conditions as defined by NAM. Psychiatric disease is presented separately under findings for KQ 1b.

[e] Denotes negative association.

DRG = diagnosis-related group; ED = emergency department; HIV = human immunodeficiency virus; KQ = Key Question; MIDAS = Migraine Disability Assessment; NAM = National Academy of Medicine.

Table 9. Number and results of studies examining the association between chronic clinical conditions and high number of inpatient visits

Diagnosis, Health Condition, or Rating Scale	Predictive Studies	Cross-Sectional Studies
Diagnosis: Arthritis	1[a,b,83]	-
Diagnosis: Chronic kidney disease[d]	1[a,b,83]	-
Diagnosis: Congestive heart failure[d]	1[a,b,83]	-
Diagnosis: Cardiovascular disease[d]	1[a,b,83]	-
Diagnosis: Diabetes[d]	1[a,b,83]	-
Diagnosis: Hypertension	1[a,b,83]	-
Health Condition: # of Conditions	-	2[a,b,109, 110]
Rating Scale: Charlson Comorbidity Index–based rating	-	2[a,b,108, 110]
Rating Scale: Global self-report health rating	-	1[a,b,113]

Note: When the relationship in a study was not statistically significant, the direction of effect is not shown.
[a] Denotes positive association.
[b] Denotes if the association, positive or negative, is statistically significant.
- Denotes no studies.
[d] Denotes complex chronic conditions as defined by NAM. Psychiatric disease is presented separately under findings for KQ 1b.

KQ = Key Question; NAM = National Academy of Medicine.

Table 10. Number and results of studies examining the association between chronic clinical conditions and high healthcare use, based on all visits

Diagnosis, Health Condition, or Rating Scale	Predictive Studies	Cross-Sectional Studies
Diagnosis: COPD[a]	1[b,c,77]	-
Diagnosis: Diabetes[a]	1[b,c,77]	-
Diagnosis: Hypertension	1[77]	-
Health Condition: # of Conditions	-	1[b,114]
Rating Scale: Charlson Cormorbidity Index	-	1[b,c,112]
Rating Scale: Other rating scale	-	1[b,c,114]

Note: when the relationship in a study was not statistically significant, the direction of effect is not shown.
[a] Denotes complex chronic conditions as defined by NAM. Psychiatric disease is presented separately under findings for KQ 1b.
[b] Denotes positive association.
[c] Denotes if the association, positive or negative, is statistically significant.
- Denotes no studies.

COPD = chronic obstructive pulmonary disease; KQ = Key Question; NAM = National Academy of Medicine.

Table 11. Number and results of studies examining the association between chronic clinical conditions and high cost of care

Diagnosis, Health Condition, or Rating Scale	Predictive Studies	Cross-Sectional Studies
Diagnosis: Cerebrovascular disease[a]	-	1[116]; 1[b,b119]
Diagnosis: Cardiovascular disease[a]	-	2[b,b116, 119]
Diagnosis: Diabetes[a]	-	1[c,c116]; 1[b,b119]
Diagnosis: Hypertension	-	-
Diagnosis: Pulmonary circulation disorder	-	1[b,b119]
Health Condition: # of Conditions	1[b,75]	1[b,b114]
Rating Scale: Charlson Cormorbidity Index–based rating	-	1[b,b116]
Rating Scale: Global health rating	1[b,b75]	1[116]

Note: when the relationship in a study was not statistically significant, the direction of effect is not shown.

[a] Denotes complex chronic conditions as defined by NAM. Psychiatric disease is presented separately under findings for KQ 1b.

[b] Denotes statistically significant positive association.

[c] Denotes statistically significant negative association.

- Denotes no studies.

KQ = Key Question; NAM = National Academy of Medicine.

Table 12. Number of studies that identify chronic clinical conditions as characteristics defining high-utilization/high-cost clusters

Diagnosis, Health Condition, or Rating Scale	Number of Studies, Citations
Diagnosis: Cerebrovascular disease[a]	1[122, 128]
Diagnosis: Chronic kidney disease[a]	1[122]
Diagnosis: Congestive heart failure[a]	2[124, 125, 127]
Diagnosis: COPD[a]	2[122, 124, 127]
Diagnosis: Cardiovascular disease[a]	3[122, 125, 129]
Diagnosis: Dementia[a]	1[122]
Diagnosis: Diabetes[a]	2[122, 125]
Diagnosis: Heart disease[a]	2[121, 122]
Diagnosis: Hepatitis	1[125]
Diagnosis: Hepatobiliary disease	1[125]
Diagnosis: Hypertension	2[124, 125]
Diagnosis: Musculoskeletal	1[121]
Diagnosis: Obesity	1[122]
Diagnosis: Renal disease	3[124, 125, 128]
Rating Scale: Global health rating	1[75]

[a] Denotes complex chronic conditions as defined by NAM. Psychiatric disease is presented separately under findings for KQ 1b.

COPD = chronic obstructive pulmonary disease; KQ = Key Question; NAM = National Academy of Medicine.

Specific Diagnoses

Diagnoses and counts of chronic clinical conditions included in studies were based on International Statistical Classification of Diseases and Related Health Problems (ICD)-9 or ICD-10 codes and identified in electronic health records, claims data, or state or facility databases. Specific conditions included both complex chronic and noncomplex chronic conditions, consistent with those identified though the NAM framework.[185] Studies often assessed the independent effect of more than one condition but rarely assessed combinations of specific conditions, making a direct comparison with the NAM framework difficult.

Across predictive and cross-sectional studies, five complex chronic conditions (congestive heart failure, COPD, cardiovascular disease, dementia, or diabetes) consistently had a positive significant association with high-utilization outcomes, including ED visits,[80, 88, 92, 93, 99, 100, 105] inpatient admissions,[83] and total healthcare visits[77] as well as high cost.[119] Consistent with these findings, heart-related conditions were identified as a defining characteristic in two cluster analyses.[121, 129]

Four studies focused on patients with a specific chronic clinical condition: heart failure,[92] COPD,[93] acute asthma,[95] and severe headache.[102] The studies of heart failure and COPD patients found that having both health failure and COPD significantly increased the odds of high ED use. Diabetes also increased the odds of high ED use.

Among a Medicaid population, the correlation between being in the top 10 percent1 of expenditures, after 6 and 12 months, was similar in specific disease cohorts (diabetes, COPD, hypertension, and asthma) as in the more general population.[78]

Two studies of patients with mental health diagnoses did not consistently find a significant association between specific chronic conditions and high use or cost.[87, 116] In one study, high ED use was associated with hepatobiliary disease but not other measured complex chronic conditions, such as heart disease or kidney disease.[87] In the other study, high healthcare costs among patients with depression were not associated with having cerebrovascular disease or diabetes but were related to having cardiovascular disease and obesity.[116]

Chronic pain was not a focus in the NAM framework. However, we found that it was associated with being HNHC in three[88, 104, 116] of four exposure studies.[97] Chronic pain was also identified as a group in two cluster analyses[122, 129] and as a defining characteristic in one qualitative study.[133]

Number of Chronic Conditions

Having a greater number of chronic conditions was found to be positively associated with being HNHC in two predictive studies[75, 114] and three cross-sectional studies.[88, 109, 110] Similarly, one qualitative study of high ED use found that both HNHC patients and less frequent users generally had complaints related to chronic conditions.[131] However, HNHC patients had a greater number of complaints.[131]

One of the cross-sectional studies, conducted by Reichard and colleagues, explored the association of the number of chronic conditions and disability with high overall utilization and cost (Table 7).[114] They found that although the number of chronic conditions was positively related to high utilization and high cost, the resulting groups had diverse healthcare needs. Their model estimate was improved by also taking disability into account. The authors concluded that the best model includes functional disability and service utilization over the preceding year, in addition to the number of chronic conditions.

Functional Limitations and Frailty

Similar to the Reichard et al. study, Bayliss and colleagues tested a predictive model of characteristics associated with patients being in the top 25 percent for healthcare costs in the succeeding 6 to 12 months. They showed that Kaiser member self-report of having conditions that interfere with daily activities was a significant predictor of future high cost.[75] Cluster analyses, using Kaiser member data in this and a second study, similarly found that chronic conditions that interfere with activities of daily living[75] and being frail elderly[129] were distinct clinical profiles. A qualitative study of five high-cost patients further supported that physical disability and frailty contribute to higher costs.[130]

Rating Scales

Many analyses included rating scales or assessments, conducted by a clinician, provided through patient self-report, or developed through secondary data. Specific assessments included the CCI, the HCC, the CAN score, the diagnosis-related group (DRG) Severity Index, health needs assessment (HNA), the Migraine Disability Assessment (MIDAS) questionnaire, and global health scores. Three predictive studies[75, 80, 81] and 11 cross-sectional studies[88, 100-104, 110, 112-114, 116] included an assessment tool or rating scale to characterize HNHC patients.

The CCI rating scale was used most often across studies. The CCI is a comorbidity summary measure that has been widely used in the healthcare literature.[186, 187] CCI encompasses 19 medical conditions that are weighted to reach a total score ranging from 0 to 37, based on the relative risk of death within 12 months associated with the condition. To account for the effects of increasing age, one point is added to the CCI score for each decade of life over the age of 50.[188] The CCI, as well as its adaptations, such as the Quan-Charlson, have been validated in multiple studies.[189, 190]

A higher CCI score was found to be associated with HNHC across studies. One predictive study, conducted in a New York City Medicaid population, reported a positive association between a higher CCI and high ED use.[81] Cross-sectional studies reported positive associations between higher CCI scores and high ED use in two studies:[88, 104] high total healthcare visits in one study[112] and cost in one study.[116] These associations were found across diverse patient populations: veterans, seniors, patients served by hospitals in the state of Florida, and commercial health maintenance organization (HMO) members.

The HCC score is a risk adjustment approach created by the Centers for Medicare & Medicaid Services (CMS) to calculate risk scores for Medicare to reimburse managed care plans. HCC scores are designed to represent the expected medical costs of a Medicare beneficiary in the coming year. HCC scores cluster ICD codes into 79 categories.[191] One predictive study by Colligan and colleagues found HCC score to be positively related to future frequent ED use in a Medicare population, controlling for other patient characteristics.[80]

The CAN score is a tool developed by the VA to identify patients who are the highest risk of rehospitalization or mortality within a specific time period, such as 90 days or 1 year. The score estimates a patient’s risk based on demographic characteristics, comorbid conditions, and healthcare use.[192]

The CAN score was used to identify clusters of HNHC patients in four studies of patients served by the VA (Table 4).[83, 123-125] One study, using the CAN score, identified seven clusters among homeless veterans. The groups differentiated patients based on whether high use was related to inpatient or ED services or both, mental health problems, and substance use disorder (SUD) diagnosis.[123] In another study, the VA sought to identify unique clusters of HNHC patients that could be used to develop tailored care management strategies for clinically distinct groups and avoid applying “one-size-fits” all strategies. Using the CAN score, six distinct groups of HNHC patients were revealed, based on comorbid physical and mental health diagnoses, including substance use comorbid with liver disease and hepatitis, complex diabetes comorbid with renal failure and depression, and liver disease comorbid with hypertension or diabetes.[125] The analysis showed that the groups differed by demographic characteristics and use patterns, which underscored how each group was unique. Another study used CAN scores to determine if it were possible to identify clusters of high-risk patients based on risk scores trajectories.[124] Using patient scores over a 2-year period, researchers identified two subgroups of patients: one subgroup with patients exhibiting higher mean hospitalization probabilities that remained persistently high over time and another subgroup with patients exhibiting lower mean hospitalization probabilities and a more pronounced decline in hospitalization risk over time. The CAN score was used in another study of VA patients to examine the tool's ability to identify patterns of risk status over time.[83] This study found that among the high-risk population the majority of patients did not remain persistently high-risk during 2 years of followup. Instead, they found 29 percent of VA patients were persistently high risk after 1 year, and 14 percent remained persistently high risk after 2 years. Almost half (42%) were classified as persistently low risk by the end of the study.

The DRG Severity Index ranges from 0 to 4, least to most severe. Based on medical records, it categorizes illness severity based on principal medical diagnosis, comorbidities, and procedures.[98] A cross-sectional study in one ED found that a higher DRG Severity Index was generally related to a higher number of ED visits when comparing one to two but not when comparing 20 or more visits to one.[98]

The self-reported global health score refers to a single-item health measure in which patients use a Likert scale to rate their current health status from excellent to poor. It is a popular mechanism for assessing health because it is easy to use. The rating scale has been extensively studied and has been shown to be a good predictor of disability and mortality from many diseases.[193-195] One predictive study and five cross-sectional studies included a measure of self-reported health.[75, 100, 101, 103, 113, 116] Among these, three studies found a significant positive relationship between self-reported poor health and high ED utilization.[100, 101, 103] A fourth study examined the feasibility of using a self-reported physical health measure to assess the risk for high healthcare utilization. The study determined that poorer self-reported physical health, measured during routine healthcare visits, was associated with significantly higher rates of hospitalization but not ED visits.[113] Poorer self-reported health was significantly related to higher future costs,[75] but was it was not significantly associated with cost in a cross-sectional study that also controlled for CCI score and specific chronic disease diagnoses.[116]

The MIDAS disability score is based on a brief, self-administered questionnaire designed to quantify headache-related disability over a 3-month period and measures disability in terms of days missed at work and reduced productivity in work and nonwork activities. The MIDAS score has been shown to have moderate reliability in predicting the need for medical care.[196] A 2004 population-based survey from the American Migraine Prevalence and Prevention Study found a positive association between the MIDAS disability score and frequent ED use.[102]

KQ 1b. How do criteria incorporate patient demographic, behavioral health, and social risk factors?

To answer KQ 1b, we synthesized the evidence on patient demographic characteristics, behavioral health, and social risk factors associated with being HNHC. Tables 13 and 14 present an overview of our findings by outcome and study design. We discuss each of these characteristics in separate sections below. Additional detail concerning these factors can be found in Tables B-9 and B-10 in Appendix B.

Table 13. Number of multivariate studies examining demographic characteristics associated with high healthcare use or cost among HNHC patients, by direction and significance of effect

Outcome	Study Design	Male Versus Female	Black Versus White	Hispanic Versus White	Native American Versus White	Asian Versus White	Combined Minority Versus White
ED visits	Predictive	-	1[a,80] 1[79]	1[a,80] 1[b,79]	1[a,80]	1[b,80]	-
	Cross-sectional	7[a,88, 92, 93, 95, 97, 104, 105] 4[b,89, 100, 106, 107] 5[87, 90, 91, 99, 108]	9[a,89, 90, 92, 99, 100, 103-105] 2[107, 108]	2[a,92, 104] 3[b,93, 99, 100] 2[103, 105]	1[a,99]	4[b,99, 100, 104, 105] 1[103]	1[b,97] 1[91]
IP admissions	Predictive	1[a,83]	1[b,108]	1[a,83]	-	-	-
	Cross-sectional	-	-	-	-	-	-
All utilization	Predictive	1[b,77]	-	-	-	-	-
	Cross-sectional	1[112]	-	-	-	-	-
Cost	Predictive	1[b,75]	-	-	-	-	-
	Cross-sectional	1[a,119] 2[116, 118]	1[a,119]	1[a,119]	-	-	-

[a] Denotes positive direction, all significant meaning positively associated with higher utilization or cost.
[b] Denotes negative direction, all significant meaning negatively associated with lower utilization or cost.
If no superscript letter, then denotes nonsignificant.
- Denotes no studies.

ED = emergency department; HNHC = high-need, high-cost; IP = inpatient; vs. = versus.

Table 14. Number of multivariate studies examining behavioral health and social risk factors associated with high healthcare use or cost among HNHC patients by direction and significance of effect

Outcome	Study Design	Depression	SMI	Other/ Unspecified Mental Health Conditions	SUD	AUD	Homeless	Employed	Low Income or Poverty
ED visits	Predictive	1[a,79]	1[79]	2[a,79, 80]	1[a,79]	1[a,79]	-	-	1[a,102] 1[79]
	Cross-sectional	4[a,88, 92, 93, 105] 1[102]	4[a,88, 93, 105, 197] 1[97]	8[a,88, 89, 96, 100, 101, 104, 107, 108] 3[91, 106, 113]	9[a,87-89, 92, 93, 96, 104, 105, 107] 3[90, 91, 106]	5[a,88, 90, 96, 99, 105] 3[87, 91, 100]	4[a,87, 88, 90, 99] 1[91]	3[b,89, 97, 100,]	7[a,92, 93, 100, 101, 103, 108, 119] 2[95, 108]
IP admissions	Predictive	-	1[a,85]	1[a,83]	-	-	1[b,83]	-	-
	Cross-sectional	-	-	2 [108, 113]	1[a,109]	1[109]	1[a,109]	-	1[108] 2[108, 109]
All utilization	Predictive	-	-	1[77]	-	-	-	-	-
	Cross-sectional	-	-	-	-	-	-	-	-
Cost	Predictive	-	-	-	-	-	-	-	-
	Cross-sectional	1[a,198] 1[117]	-	3[a,115-117]	1[a,116]	-	-	1[b,116]	1[118]

[a] Denotes positive direction, all significant meaning positively associated with higher utilization or cost.
[b] Denotes negative direction, all significant meaning, negatively associated with lower utilization or cost.
If no superscript letter, then denotes nonsignificant.
- Denotes no studies

Findings for Kanzaria[79] are presented at the 1-year followup only for consistency with other evidence. The study also presented findings at 2-, 5-, and 10-year followups.
Findings for Meek[77] are based on self-report and are mixed.

AUD = alcohol use disorder; ED = emergency department; HNHC = high-need, high-cost; IP = inpatient; SMI = serious mental illness; SUD = substance use disorder.

Demographic Risk Factors

Key Points

- Older age was generally associated with measures of HNHC. The exception is the nonaged disabled Medicare patients where measures of HNHC, particularly ED use, were higher in the younger group.
- The association between gender and measures of HNHC was mixed.
- The association between race and ethnicity with healthcare use varied by group. In comparison with white race, black race was associated with higher ED use, Asian race was associated with lower ED and inpatient use, and the results for Hispanic ethnicity were mixed.

Results of Studies

Demographic characteristics, including age, gender, and race, were included in almost all studies. In some analyses, they were used solely as control variables in multivariate models and findings were not presented.

Age

Virtually all predictive and cross-sectional articles included age in modeling characteristics to identify HNHC patients. No cluster analysis included age as an indicator for creating clusters, and no qualitative studies discussed age as a factor contributing to HNHC. Because of differences in the age range across studies and categories used to depict age in analyses, we did not identify one metric that would be helpful in sorting our findings into a table. Therefore, we do not report findings by age in Table 12.

Older age was commonly associated with higher healthcare use and cost, compared with younger age, across predictive and cross-sectional studies. An exception is one study of high inpatient use that found the opposite relationship.[110] Patients who were 60 years of age and older, originally admitted to one family medicine inpatient service, had lower odds of a “high frequency readmission” (3 or more inpatient readmissions in a given year) compared with younger patients.[110] The family medicine inpatient service consisted of a team of interns, residents, and pharmacy students supervised by an attending physician. The role of the team was to promote greater continuity between outpatient primary care providers and the hospital medicine team. Because the finding of this study was counterintuitive, the authors theorized that these physicians might not be as alert to the possibility of readmission among younger patients and may not probe to ensure that this high-risk portion of the nonaged population has appropriate aftercare supports.

Consistent with the NAM framework, in Medicare population studies, the effect of age also followed a different pattern. Based on a national sample, Colligan and colleagues found that, compared with beneficiaries 65 to 74 years of age, the probability of frequent future ED use was higher among nonaged disabled Medicare beneficiaries.[80] Beneficiaries 18 to 34 years old had the largest relative risk of future frequent ED use (relative risk ratio = 3.1 [3.0 to 3.2])—even higher than other younger than 65 age groups. The significant effect of age was observed in this study after controlling for the potential confounder of disability as the reason for Medicare entitlement (the reason those younger than 65 years would qualify for Medicare). Consistent with these findings, in one cluster analysis of frequent ED users, a defining characteristic of one identified group was having Medicare coverage because of nonaged disability.[121]

Being a nonelderly disabled Medicare beneficiary was also related to being persistently high cost. One study found this group to be more likely to be high cost each year in a 3-year period rather than transition in and out of cost periods, compared with older beneficiaries.[119]

Another study of Medicare beneficiaries examined ambulatory care sensitive conditions (ACSC)-related ED and inpatient visits, separately among the elderly and younger disabled populations, to see whether the factors driving high use were the same or differed between the groups.[108] In both groups, a greater number of ED visits was related to medication nonadherence, a higher CCI score, and having a mental health condition. Only in the younger group were ED visits positively related to the number of unique prescribers, and only in the elderly group were they positively related to the number of office visits. Similarly, a greater number of inpatient admissions was related to medication nonadherence and a higher CCI score in both groups but related to only dual eligibility in the older group.

Gender

Gender was a covariate in virtually all multivariate models. In a number of analyses, gender was included in the model to control for potential confounding, and the independent effect of the variable was not reported. Overall, we found no discernible pattern of differences by gender across studies.

Race/Ethnicity

Racial groups and/or Hispanic ethnicity (compared with white race) were commonly included variables in analyses (20 predictive and cross-sectional studies) (Table 12). Race was not a characteristic of note in cluster or qualitative analyses.

The interpretation of race/ethnicity in findings is complicated by possible mediating factors. Considerations such as poverty and access to care have been known to have a complex relationship with race, particularly black race. As a result, in some cases, race may be a proxy for some other patient characteristics, rather than an additional risk factor.[199-201] A recent study found that algorithms that predict future costs and use the data to qualify individuals for HNHC patient interventions may underestimate the needs of black patients.[202] Black patients have been found to use fewer services than white patients, relative to their illness severity. Because of this, predictions and access to interventions based on just being in the highest cost group can be racially biased. The study also found that black patients tend to generate different types of service costs, including lower rates of surgical inpatient services and higher rates of ED services.

The effect of black relative to white race was measured in relation to high ED use and inpatient use. We generally found black race to be associated with a greater probability of high ED use, including two predictive[79, 80] and nine cross-sectional studies.[89, 90, 92, 99, 100, 103-105, 203] Black race was related to lower inpatient use in two studies.[83, 204]

Differences between Asian race or Hispanic ethnicity and white race were measured in fewer studies. Asian race was associated with a lower probability of high ED use and inpatient episodes.[80, 104, 105] The relationship between Hispanic ethnicity and high use was mixed.

In relation to high cost, among Medicare beneficiaries, black race or Hispanic ethnicity was positively associated with being persistently high cost over a 3-year period, controlling for chronic conditions and poverty.[119]

Behavioral Health Risk Factors

Key Points

- Mental health concerns, such as depression or mental health disorders that occur along with a physical health diagnosis, are indicators of high use and high cost and often defining characteristics in patient clusters. The results for serious mental illness (SMI) are mixed.
- SUD is consistently associated with high use and high cost.
- Results for the association between alcohol use disorder (AUD) and high use are mixed.

Results of Studies

Twenty-six studies examined the association between behavioral health conditions (mental health concerns, SUDs, and/or AUDs) and being a HNHC patient (Table 13). Mental health concerns were further delineated as depression, SMI, and other mental health disorders.

Mental Health Conditions

The independent effect of depression on being a HNHC patient was measured in relation to ED use and high cost. Depression was significantly associated with high ED use (1 predictive study after 2 years[79] and 4 cross-sectional studies).[88, 92, 93, 105] Depression was also related to high cost (1 predictive study among a commercial HMO population[75] and 1 cross-sectional study).[119] A qualitative study described depression as being associated with seeking inappropriate hospital care and difficulty advocating for less aggressive medical care.[130]

The findings for diagnoses reflective of SMI were nuanced in one predictive analysis that examined patterns in high ED use over time. Schizophrenia was significantly negatively associated with persistent high ED use (compared with nonpersistent high use) at the 3- and 6-year followups but not by 11 years.[79] Instead, persistent high ED use after 11 years was associated with having an anxiety disorder or having attempted suicide or intentionally self-inflicted injury.

Similarly, four cross-sectional studies revealed a positive association between SMI and high ED use.[88, 93, 105, 107] Among these, the relationship was found among patients with COPD[93] and among patients with a broader range of psychiatric conditions.[107] In the psychiatric population, having multiple psychiatric conditions was also a significant predictor.[107]

Five cluster analysis studies included behavioral health characteristics.[122, 123, 125, 129, 205] Generally, a measure of poor mental health functioning or mental health diagnoses stood out as a characteristic among clusters. In one analysis, severe mental illness, coupled with low income, social needs, and pain management, was identified as one HNHC patient clinical profile.[129]

Qualitative studies support the quantitative findings of association between SMI and high healthcare use. One such study clarified that unmet behavioral health needs and poorly managed SMI, not just the presence of SMI, were significant drivers of preventable high levels of healthcare use among HNHC patients.[135] Several other qualitative studies concluded that patient-system mismatch, not patient diagnosis alone, contributed to high utilization.[130, 134] High utilization can result from patients' "behavioral issues interfering with care engagement, and lack of health system flexibility to address these barriers"[134, p. 497] in primary care, partially due to the limited time allowed to spend with each patient. "When you're looking at your work list and there are 30 people and you know you'll only get to 20 that day and when there's someone who keeps paging you and demanding your attention and you know there won't be any impact or reward, it's really hard to put your time there."[130, p. 209]

Other measures of mental health disorders were global mental health assessments obtained by clinicians or through self-report. The identification of a mental health disorder through one of these assessments was associated with high ED use in two predictive studies[79, 80] and six cross-sectional studies.[87-89, 96, 101, 104] It was also a predictor of future high inpatient utilization.[83, 85]

Three cross-sectional studies found a positive association between other mental health conditions and high healthcare cost.[115-117] In one of these studies, HMO members with high symptom severity related to post-traumatic stress disorder (PTSD) were estimated to have healthcare costs twice those of patients without PTSD in adjusted analyses.[115] Another study of HMO members revealed that being in the highest cost group significantly increased with the presence of any psychiatric diagnosis or adverse childhood experience (defined as physical, sexual, or emotional abuse; physical or emotional neglect; having a substance-abusing or mentally ill parent; having an incarcerated parent; or witnessing domestic violence).[117] One qualitative study supported these findings, noting the association of childhood trauma with high use of healthcare. Based on the experience of defining HNHC patient clusters, a healthcare program noted that although identified clusters were largely heterogeneous the prevalence of childhood trauma was a "common thread" across the groupings.[133]

In two studies of patients with psychiatric diagnoses, high ED use was positively associated with having Medicare coverage and homelessness.[87, 90] The effect of other characteristics, such as SUD, AUD, and Medicaid coverage, were inconsistent across the two studies.

Substance and Alcohol Use Disorders

SUDs were associated with high use: a predictor of both future high ED utilization[79] and inpatient admission.[85] Similarly, in cross-sectional studies, SUD was associated with high ED use;[87-89, 92, 93, 96, 104, 105, 107] inpatient admissions;[109] and, among patients with depression, total costs (odds ratio [OR] =5.4).[83]

Results from studies examining comorbid AUDs and high ED utilization were mixed. One predictive study showed a positive association between AUD and persistent high ED use.[79] Five cross-sectional studies showed a positive association,[88, 90, 96, 99, 105] while three did not find a relationship.[87, 91, 100]

Social Risk Factors

Key Points

- Studies conducted in hospitals and health systems, including the VA, found homelessness to be associated with high ED utilization.
- Studies conducted in hospitals and health systems and population-based survey data did not find a clear relationship between employment status and high healthcare utilization.
- The role of poverty, as defined by either an individual's low income or neighborhood poverty rate, is unclear.

Results of Studies

Twenty-seven predictive or cross-sectional studies evaluated social risk factors (i.e., homelessness, unemployment, poverty/low income, and education) (Table 7).[79, 83, 87-93, 95, 97, 99-103, 105, 106, 109, 111, 116-119, 125, 203, 204]

Predictive studies' results were mixed regarding the association between both homelessness or low income and being a HNHC patient.[79, 83, 87, 204] Five cross-sectional studies found a positive association between homelessness and high ED utilization.[87, 88, 90, 99, 105] Patient self-identified need for housing support was significantly related to higher inpatient use in one study.[111]

Among 11 cross-sectional studies that examined the relationship between poverty and high utilization, seven studies found that low income or poverty was related to high utilization of healthcare,[92, 93, 100-103, 119] and four studies indicated no significant association.[95, 109, 118] However, the measure of poverty in several of the studies did not capture individual patient income, but instead, the neighborhood poverty rate, while also controlling for type of insurance.[79, 92, 93, 95, 109]

One study attempted to tease out the independent effect of food insecurity, separate from the more commonly measured risk factors of low income and education.[118] Based on data from a national sample of adults, self-reported food insecurity was significantly related to an increased odds of being in the top 10 percent of expenditures (adjusted odds ratio [AOR]=1.73), while income level and education were not. Access to care, as indicated by having health insurance coverage, was also a significant predictor in the model.

KQ 1c. How do criteria incorporate types, amount, duration, and patterns of healthcare use?

Key Points

- We identified 12 studies that included baseline healthcare use or cost to measure high healthcare use or cost in a future period. Five of the studies included baseline healthcare use or cost as components of algorithms developed to predict the risk of future behavior. Commonly, these algorithms did not report on the independent effect of prior cost or use on outcomes, limiting our available evidence to predict or explain the role of this characteristic separate from others.
- Prior ED visits are a strong predictor of future use. A higher number of prior ED visits is associated with greater odds of ED use in a subsequent period.
- We identified more limited evidence linking a positive association between multiple years of being high cost and predicting high cost in a subsequent period.

Results of Studies

Each of the 12 predictive studies that modeled future high healthcare use or cost included cost or use measures at baseline as covariates in regression models. Although most of the studies reported the independent effect of earlier use or cost, five of the studies developed algorithms that incorporated measures of prior healthcare use but only reported on the algorithm's overall performance in effectively predicting high use and cost outcomes.[76, 78, 82-85] Because of this, we cannot report on the unique contribution of earlier cost or use in some of the studies. (Each of the algorithms is described earlier in the chapter.)

In contrast, and more commonly, all other predictive studies separately measured and reported prior healthcare use in regression models. Across three studies predicting high ED use in a future period, baseline ED use was a large and consistent predictor.[79-81] One study of Medicare beneficiaries found that both frequent (4+) and infrequent (1-4) prior ED visits were the largest predictors of future high ED use.[80] The magnitude of effect of being a frequent user at baseline (rate ratio [RR]=35.2) dwarfed the effect of being an infrequent user (RR=4.2). Similarly, one study of the CA nonaged population found the odds of high ED use in a future period (4+ visits) to be positively related to a larger number of ED visits in the base year; ranging from 5 to 7 visits (AOR = 1.6) to 18+ visits (AOR = 6.07).[79]

Consistent with predictive analyses, high ED use was associated with prior use based on self-report data from the National Health Interview Survey, the Community Tracking Study Household Survey, the American Migraine Prevalence and Prevention Study, and the National Survey of American Families.[100-103] In the National Health Interview Survey, high ED use was associated with the ED being identified as the usual source of care (AOR=7.09) and in the migraine study with the ED being a frequent source of care for other ailments (AOR=42.0). In the three nationally representative surveys, high ED use was associated with having a larger number of outpatient visits in the past year; in one study: AOR=5.5 for four to nine visits,[100] in a second study: AOR=3.02 for five or more visits,[101] and in a third: AOR=5.29 for three or more visits.[103]

Among Medicaid frequent ED users (12 or more visits over 4 years), three clusters were identified, based on timing between visits and common diagnoses.[120] The most frequent visiting pattern (peak at 4 to 166 days between visits) consisted of more individuals who were chronically physically or mentally ill.

Three studies predicted future inpatient use among patients with one or more admissions during a baseline period. All of the studies that examined inpatient use tested algorithms and did not separately report on the role of earlier use.[83-85] One cluster analysis of VA patients at the highest risk for rehospitalization based on their CAN score found that the cluster of individuals at persistently high risk had a higher rate of healthcare use, particularly inpatient visits, coupled with a higher rate of comorbidities, SUD, and AUD.[124]

Four other studies examined characteristics associated with being high cost in a future time period. One study examined Medicare enrollees high cost in 2016 (top 10%) in relation to their pattern of high-need status from 2013-2015. High need was defined by multimorbidity, medical complexity, frailty, functional limitations that require assistance, and receipt of acute or post-acute care services.[86] Compared with never being high need during 2013-2015, the adjusted odds of being high cost in 2016 was positively related to being high need in the earlier period: persistently high need (AOR=11.7), transiently high need (AOR=5.1), and newly high need in 2015 (AOR=5.8). A second study of newly insured Kaiser members found that a positive predictor of high cost was prior year ED use (OR=1.8).[75] The other two studies reported the predictive success of algorithms.[76, 78, 82]

Only one study predicted future use in relation to all encounters (6 or more) including inpatient, outpatient, labs, and pharmacy, for example.[77] In an analysis primarily focused on the role of patient self-reported health perceptions, the researchers found that prior hospitalizations and physician visits were positively related to future encounters.

Five cluster analyses grouped patients who were identified as being in the highest percentile of total costs.[75, 122, 126-128] Two of the studies based clusters on prior utilization: in one based on type and frequency/pattern of use[127] and in another based on type of use and condition.[75]

KQ 1d. Do criteria differ when HNHC is identified at the population, payer, healthcare system, and provider levels?

Key Points

- Analyses across payers revealed that prior high healthcare use and behavioral health diagnoses are predictive of high ED across populations (levels) of analysis. Specifically, prior high healthcare use was predictive of high ED use among Medicaid, Medicare, VA, hospital/health systems, and population-based studies. Behavioral health diagnoses were predictive of high ED use among Medicare, VA, and hospital/health system populations.
- Among multipayer and population-based studies, having Medicare and Medicaid insurance coverage was predictive of high healthcare use.

Results of Studies

We compared the criteria used to define HNHC and significant population characteristics or predictors in studies by the level of analysis (i.e., population, payer, healthcare system, or provider). Table 7 provides a summary of outcomes by study population level.

The largest group of the identified studies, 22 of the 60 reviewed, were conducted by single hospitals, multiple hospitals located in specific geographic areas such as states or counties, or health systems.[87, 89-91, 94, 96-99, 106, 109, 110, 112, 113, 121, 129-132, 134, 135] This was followed by 11 population-based studies;[92, 93, 95, 100-104, 114, 118, 133] 10 studies focusing on the Medicaid population;[76, 78, 79, 81, 82, 84, 85, 105, 107, 120] nine studies of health plan enrollees, including managed care and accountable care organizations (ACOs);[75, 111, 113, 115-117, 122] seven studies of the Medicare population;[80, 86, 108, 119, 126-128] and six studies focusing on patients who use the VA healthcare system.[77, 83, 88, 123-125]

We found that two factors, prior high healthcare utilization and behavioral health diagnoses, were predictive of high future healthcare use and cost across all payers. Specifically, prior high healthcare use was predictive of high ED and inpatient (IP) utilization among Medicaid, Medicare, VA, hospitals/health systems, and population-based studies. Studies involving Medicaid beneficiaries showed that prior high primary care use predicted high future ED visits and prior hospitalization predicted high future IP use.[81, 84] Two studies of state Medicaid populations, published in three articles, found prior high healthcare use of any kind predicted future high cost.[76, 78, 82] One study focusing on the Medicare population found that frequent ED use in 1 year (4 or more visits compared with no visits) was the strongest predictor of ED use in the subsequent year (RR=35.2).[80]

Of note, one population-based predictive study found that persistent frequent ED use at 3-, 6, and 11-year intervals in a State-level population was predicted by the intensity of ED use at baseline across the time interval, controlling for other factors.[79] Population-based cross-sectional studies supported the findings regarding prior utilization. One study found a positive association between heavy use of other outpatient care with frequent ED use.[101] Another cross-sectional population-based study found that having had three or more outpatient visits but perceiving that one has unmet medical needs was associated with high ED use.[103] A population-based study of individuals with debilitating headaches found that, after controlling for disease severity, frequent ED use was associated with lower income and prior utilization of the ED for reasons other than headache.[102]

A predictive population-based study supported prior utilization, defined as at least one ED visit, at least one inpatient admission, or at least 10 health professional office visits during the past 12 months, as a predictor of high inpatient hospital care.[206] The study found that prior healthcare utilization yielded the single largest incremental gain in predictive performance of an inpatient utilization predictive model. They also found that the predictive ability of the model was improved by adding health conditions and health-related quality of life to prior use.[206]

Behavioral health diagnoses were predictive of high healthcare utilization and cost among Medicare, VA, and hospital/health system populations. One study of Medicare beneficiaries in Memphis, TN, found a strong association between a mental health condition and ED visits and inpatient stays for ambulatory care sensitive conditions.[108] Another study of Medicare beneficiaries that analyzed a 20 percent national sample, using 2012-2014 data, found an association between a diagnosis of depression and having high healthcare expenditures.[119] The impact of behavioral health diagnoses on high utilization and cost predominated in studies of the VA population. Two of the VA studies focused on behavioral health and social risk factors as drivers of HNHC patient outcomes. One cross-sectional study of ED utilization found that the factors most strongly associated with multiple distinct levels of ED use, including 1, 2 to 4, 5 to 10, 11 to 25, and greater than 25 ED visits per year, were a diagnosis of schizophrenia, homelessness, and opioid prescriptions.[88] Persistent risk of inpatient utilization was predicted by number of mental health visits. The study found a negative relationship between persistent inpatient utilization and homelessness but included a caveat that the finding could have been mediated by specialized services for the homeless provided in the area.[83] Additionally, three of the publications conducted in the VA medical system were cluster analyses, designed to better identify unique subpopulations that would lend themselves to more efficient and effective care management strategies to reduce high utilization and high costs.[123-125] Each of these studies identified behavioral health conditions as a defining component of clusters of HNHC patients. Two cross-sectional health system studies found an association between behavioral health conditions, defined as illicit drug use or a mental health condition[91] or a poor global mental health scale score.[113]

Among multipayer and population-based studies, having Medicare and Medicaid insurance coverage was found to be predictive of high healthcare utilization. Five multipayer cross-sectional studies evaluated multiple aspects associated with high ED utilization and found an association between Medicaid and/or Medicare coverage and high ED utilization.[89, 90, 93, 95, 99] An additional cross-sectional study focused on frequent ED use among a cohort of ED users with a primary psychiatric complaint. Significant predictors of ED use included Medicare coverage, along with a positive screen for cocaine use, homelessness, personality disorder, and hepatobiliary disease.[87]

Several population-based studies evaluated the association of public insurance with high ED utilization. One predictive study found that persistent frequent ED utilization was positively associated with having public health insurance (Medicaid or Medicare) compared with commercial insurance.[79] Cross-sectional studies also supported the findings regarding insurance status. Two studies found a positive association between having public insurance, as opposed to private insurance, and frequent ED use.[101, 103]

Despite the prevalence of chronic disease and disability among the elderly population, we found few studies focused solely on Medicare beneficiaries.[80, 86, 108, 119, 126-128] Predictors of frequent ED among the Medicare population included younger age, chronic medical or mental health conditions, HCC score, dual enrollment in Medicaid, and five or more physician visits.

KQ 1e. How can potentially preventable or modifiable high use of healthcare be differentiated from necessary and appropriate high use?

Key Points

- One study, reported in two publications, sought to directly differentiate between potentially preventable use of healthcare and high use. The study reported an alternative mechanism for identifying individuals at risk for potentially preventable healthcare use that relied on examination of higher than expected expenditures (high residuals based on regression analysis). The study found patient high residuals to be generally consistent across at least two time periods.
- Two studies examined patients who used the ED for nonemergent care. However, neither study was able to identify differences between frequent and less frequent users.
- All other studies examined high use or cost. No quantitative studies sought to distinguish individual visits or costs that might have been preventable or modifiable from total visits or costs.

Results

Generally, studies set thresholds for identifying HNHC patients based on being high users (e.g., 4 or more outpatient visits in 12 months or top decile of all-cause total costs).[116] Uniquely, a Yang et al. study, reported in two publications, sought to differentiate potentially preventable use of healthcare from other high use. The analysis was conducted using 4 years of Medicaid data from Texas.[76, 82] The study compared two modeling approaches: linear regression and gradient boosting machine tree-based models. High utilizers were defined as those with higher than expected costs (identified through high residuals), after adjusting for diagnoses, demographics (age, sex, race, and disability status), county of residence, and whether enrolled in a fee-for-service or managed care organization (MCO) plan. Residuals were used to define an empirical threshold for identifying higher than expected utilizers to "formally discriminate the point at which the right long tail of residuals consistently deviates from the normal distribution."[82, p. 5] The study then examined correlations in excessive utilization over time to determine if the model could predict persistent patterns. It found consistent temporal patterns of high use between 2 consecutive years, HNHC patients in the top 5 percent in 1 year ranked at approximately 75 percent in residuals' percentile in the following year, compared with other patients, who on average had a rank of 50 percent. The temporal association decreased with time.

Yang et al. compared the results from their modeling with results using the 3M™ Potentially Preventable Events software. The 3M software is considered an approach to identifying future potentially preventable inpatient readmission and ED visits. However, the 3M software is proprietary, so the authors of this study were seeking an alternative using readily available data and analytic approach. They found that there were moderate positive correlations between 3M potentially preventable readmission events and the residuals approach to identifying high utilizers, ranging from 0.26 to 0.30. Similarly, the correlation between 3M potentially preventable ED visits and the residual approach ranged from 0.25 to 0.34. A limitation of this study, cited by Yang et al., is that some patient-level characteristics that could add to the precision of the modeling were unavailable, such as disease severity and social risk factors, because the study relied on claims data.

Three cross-sectional studies concerned patient population whose ED use may be preventable or modifiable, at least in part. The studies focused on patients receiving care at an ED who were assigned an Emergency Severity Index score of 4 or 5 at one visit, a classification of least urgent/nonemergent.[94, 98] Across the studies, the authors did not evaluate the severity score of these patients' earlier ED visits. Therefore, we cannot conclude that the characteristics they found associated with high use across all ED visits can be extrapolated to apply to patients who only have ED use that would be considered preventable or modifiable. Still, two studies found that least urgent/nonemergent ED care was associated with a greater number of visits.[98] The third study[94] surveyed patients to understand their reasons for using the ED. They found that high- and low-use groups did not significantly differ in their reasons (i.e., need, convenience, access, costs, and quality), controlling for potential confounding. One qualitative study found that although high-ED-use patients primarily reported using the ED for emergent concerns, they would prefer after-hours alternatives and more help managing their care.[132]

Several cross-sectional studies examined preventable ED visits. One cross-sectional analysis in a dissertation measured variables associated with a continuous measure of preventable ED visits. An ED visit was defined as primary care treatable if the evaluation and management code on the claim was not listed under the ED Indicator Procedure List.[106] Significant characteristics associated with a larger number of preventable ED visits included being homeless, poorer social support, and having both SUD and mental illness diagnoses. Having a regular source of care and the level of continuity of care were not associated with the outcome. As discussed in greater detail in the age-related results, a cross-sectional study of HNHC Medicare patients examined predictors of ACSC ED and inpatient visits and found that medication nonadherence was a predictor for greater use for both types of care.[108]

One cross-sectional study sought to distinguish characteristics associated with persistent high cost (every year during a 3-year period) from transient high cost (1 or 2 years during the same period) in the Medicare population.[119] Significant predictors were specific chronic conditions, depression, higher income, being younger than 65 years of age, being black or Hispanic, and being eligible for Medicare because of end-stage renal disease (ESRD). The increased odds from ESRD dwarfed all other characteristics (OR=26.5).

KQ 2. What are the mechanisms that lead to reductions in potentially preventable or modifiable healthcare use and result in improved health outcomes and cost savings in interventions serving HNHC patients?

Key Points

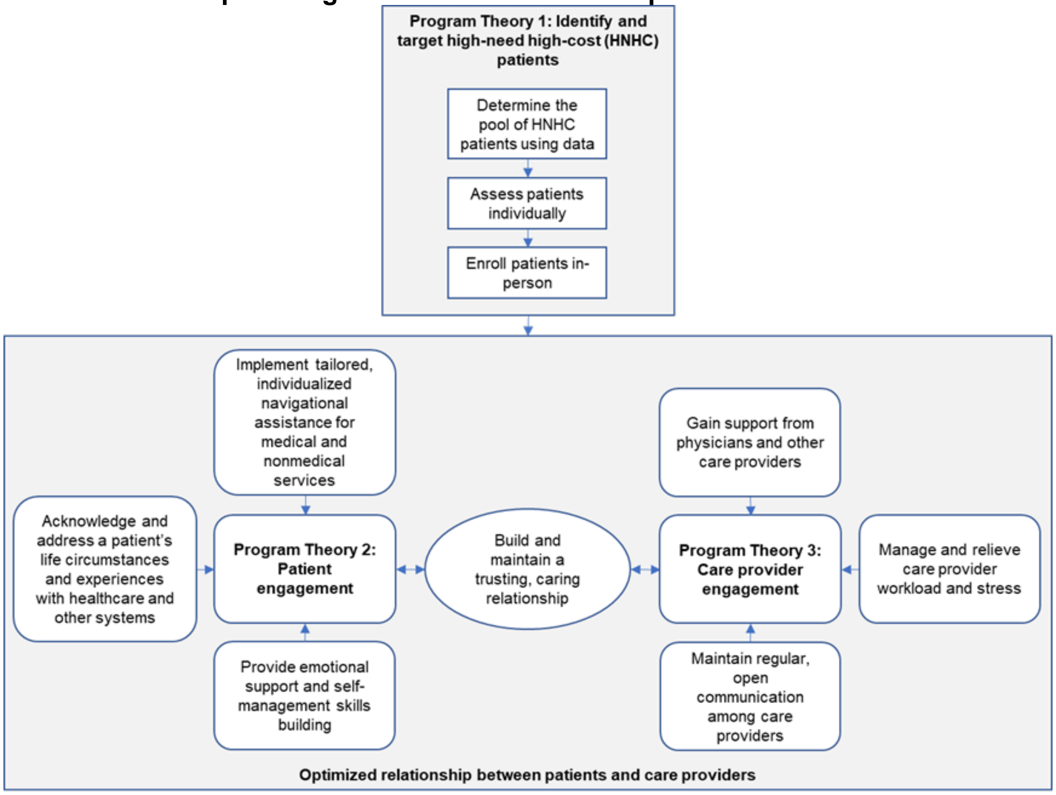
- Using 48 studies (51 articles), we developed three program theories to explain the context-mechanism-outcome (CMO) relationships concerning HNHC patient recruitment and patient and provider engagement in HNHC patient interventions.
- **Program Theory 1.** Identifying and targeting HNHC patients for interventions intended to reduce potentially preventable or modifiable healthcare use and costs require capturing their complexity, based on consideration of a combination of factors. A patient's prior use of healthcare services, chronic diseases, nonmedical barriers to accessing care, experience with the healthcare system, clinician judgment, and willingness to participate in an intervention may all contribute.

- **Program Theory 2.** Trusting relationships are the basis for engaging patients in care management, particularly patients with complex medical, social, and behavioral needs, such as HNHC patients. Establishing trust is crucial to an intervention's ability to empower patients to manage their chronic conditions and overall health and to engage with intervention staff and other care providers.
- **Program Theory 3**. Obtaining healthcare provider buy-in and building structures and processes to give them support for their efforts are crucial components for engaging care providers in interventions for HNHC patients. Engagement of care providers helps improve intervention performance and outcomes because providers affect the successful implementation of the intervention through their actions and inactions.

In total, 48 studies (51 articles) were included in the realist review. Of the 51 articles, 14 were also used as evidence in KQ 1, and 27 articles were used as evidence in KQ 3. These studies were used to develop CMO configurations related to the implementation of interventions for HNHC patients. These CMOs were then used to iteratively refine three realist program theories (our model of how and under what conditions an intervention is expected to work).

Program Theory 1 concerns the pathway for identifying and targeting individuals for HNHC patient interventions. Once patients are enrolled in interventions, building and maintaining trusting and caring relationships between patients and care providers can help interventions succeed. We set out key considerations for engaging HNHC patients (Program Theory 2) and for engaging care providers (Program Theory 3) so that each has the necessary emotional support and practical resources to develop and maintain an effective ongoing relationship. Figure 4 presents a framework showing the relationship between the three program theories.

Figure 4. Framework of optimizing interventions for HNHC patients



Program Theories

Program Theory 1: Identifying and Targeting HNHC Patients for Inclusion in Interventions

A necessary initial step in the pathway to effecting change in HNHC patients' use of potentially preventable or modifiable healthcare—and related costs—is for interventions to identify which patients are likely to be HNHC in a future period. Determining the optimal combination of characteristics has been described as "a delicate balance."[20] Basing identification of high-need patients exclusively on cost algorithms will miss many people; alternatively, if the focus is exclusively on chronic conditions, a large number of people may be identified whose chronic conditions are under control.[20] In addition, social risk factors can increase nonmedical barriers to accessing care.[20] Appendix Table B-11 presents the detailed CMO configurations that underpin this program theory.

Determining HNHC Patients Using Data

As a first step to specifying the patient population from which to select intervention participants, claims and other sources of electronic health data can be used to identify individuals with current high healthcare use and costs and disease complexity. Current healthcare use and cost data are often included in models predicting future high healthcare use and cost.[76, 79, 80, 82, 85, 124, 136-138, 159] However, while these data are generally considered necessary, they are not sufficient for identifying the population. The data on prior cost or use have been described as being limited to providing "broad brush information" because no algorithm or predictive model specification has been found that is able to reliably predict future high use across patients with chronic disease[66, 133, 137] (see also KQ 1 findings). One barrier to developing accurate projections is "regression to the mean" (a patient with high cost and use in a baseline period using closer to the average level of service and costs in the followup period).[64, 65, 85, 138]

The accuracy of data-based healthcare use and cost projections can be facilitated by refining current period specifications in some specific ways: (1) limiting data to healthcare use that would be the focus of an HNHC patient intervention, that is, care that is potentially preventable or modifiable (i.e., excluding services such as chemotherapy for cancer treatment, orthopedic surgery, and HIV treatment);[139] (2) including data across care settings and payers to capture the continuum of care;[135, 137, 139, 160] (3) focusing on use of services in "real time,"[67, 133, 139, 159, 161] particularly, if possible, while a patient is still hospitalized, to identify the urgent need for an intervention;[65, 85] and, when considering ED visits, (4) focusing on visits that occur in clusters (more than one visit during a relatively short period of time), even if the presenting complaints are not categorically different from those of lower utilizers (those who would not be considered HNHC patients), because a cluster pattern has been found to be associated with HNHC patient ED service use.[131, 162]

In addition to providing information on individuals' levels of healthcare costs and use, claims data and other electronic health data can be used to identify individuals with complex chronic disease. Indicators include whether the patient has multiple chronic conditions;[64] functional limitations;[20] and high scores on measures of clinical risk severity, such as the Chronic Condition Indicator,[64, 66-68, 140, 141, 159] concurrent HCC,[67] and the Predictive Risk Intelligence SysteM (PRISM).[163]

The accuracy of identifying HNHC patients can be improved by also identifying behavioral health diagnoses. Behavioral health diagnoses include mental health diagnoses (ranging from depression and anxiety to serious mental illness) and substance use disorder diagnoses. Behavioral health diagnoses comorbid with chronic medical conditions are associated with higher ED use and poorer disease management.[68, 85, 133, 135, 142] However, determining the correct pattern of healthcare claims to use to identify the HNHC patient population can be obfuscated by the co-occurrence of multiple complex medical conditions and social risk factors.[131] For example, among HNHC patients with mental illness or substance abuse in addition to medical conditions, fewer visits may be associated with the mental illness or substance abuse condition than expected.[131] Partnering and sharing data with public health agencies and community-based organizations may also help identify hard-to-reach patients with multiple challenges.[164]

Assessing Patients Individually

HNHC patients' self-assessments of characteristics about themselves, which are not generally available through electronic clinical data, can be obtained during an enrollment decision process. This information can be used to further refine predictions of future modifiable high-cost care and use. An example of one tool is the Medicare Health Risk Assessment, which captures a patient's self-assessment of health status, psychosocial risks, depression, behavioral risks, pain, activities of daily living, and instrumental activities of daily living.[143, 144] Other simple assessments that can be administered directly to patients to assess their risk include determining whether they are only somewhat or not very confident that they can manage and control most of their health problems; have had moderate or severe pain during the past 4 weeks; have been bothered extremely or quite a bit during the past 4 weeks by emotional problems, such as anxiety, irritability, depression, or sadness; believe that the medications they are receiving may be causing illness or side effects; and have been prescribed more than five medications.[141] The Patient Activation Measure can identify "less activated" patients who are less able to effectively manage their conditions and therefore have a greater likelihood of needing care management services.[155] Low health literacy scores are associated with poorer patient activation.[135]

HNHC patients may also face healthcare system–related barriers that negatively affect their ability to self-manage their health and that may not be identifiable through claims data or self-assessment tools. HNHC patients' reliance on the ED system is related to negative prior experiences with the traditional service delivery system not being designed for patients with complex healthcare needs.[134, 135] Resulting specific barriers to changing their behavior include distrust for providers and the larger healthcare system;[130, 140, 145] the time and expense of getting to a primary care provider's office, particularly if multiple visits and public transportation are required;[135] providers not accepting their insurance;[135] the cost of care being expensive;[135] long wait times to see a primary care provider; care after hours not being available;[135] and the belief that better quality of care is available in the ED than with the primary care provider/clinic.[132] Among HNHC patients who are homeless or who have unstable housing, greater ED use is also associated with the ED providing shelter and respite.[135]

Enrolling Patients in Person

The intake assessment can be used to facilitate the decision to enroll and the strategy to engage an HNHC patient by determining the patient's willingness to participate in the program, be monitored and contacted, and comply with therapy and the intervention.[139, 140, 145-148] The HNHC patient's current provider's judgment can add to the identification and selection of patients who are appropriate for the intervention.[146, 148] Notably, socioeconomically disadvantaged or marginalized HNHC patients may appear less willing to engage in the program because of distrust of the healthcare system and symptoms of their conditions (and/or substance use).[148] To prevent further marginalization or exclusion, more subtle indicators or extended periods of outreach and trust-building may be necessary to accurately gauge a patient's willingness to participate.[148, 149] Indicators among marginalized populations of their willingness to participate can be as subtle as returning or answering phone calls from the care team or showing up for an initial appointment.[148] Community health workers can help the care team understand the challenges and needs of these patients.[145] Excluding the patients who are more difficult to engage may reinforce and exacerbate disparities.[148]

Successful enrollment of HNHC patients who might otherwise be excluded in an intervention is facilitated by two logistical considerations: (1) conducting the enrollment in person is more successful than by telephone[65] and (2) when an intervention seeks to include participants who have been recently hospitalized, conducting the enrollment process before inpatient discharge can increase participation because many patients live in difficult social circumstances and locating them after discharge to initiate an intervention can be challenging.[44, 85, 142]

Program Theory 2: Engaging HNHC Patients in Interventions To Improve Their Management of Their Chronic Conditions

HNHC patients commonly have a long history of personal and health system barriers that have kept them from receiving appropriate care. Patients can be engaged in care management interventions that can help them change their health behaviors if care providers can gain patients' trust and if intervention programs are individualized to meet each patient's unique combination of medical and psychiatric diagnoses and social risk factors. Appendix Table B-12 presents the detailed CMO configurations and supporting data that underpin this program theory.

Addressing Patients' Life Circumstances and Prior Experiences

After successfully enrolling HNHC patients into an intervention intended to change their use of healthcare services, intervention care providers need to focus on building relationships with patients that will facilitate behavior change. HNHC patients often come to interventions that are primarily intended to help them manage their chronic diseases with a complex history of personal, social, and medical issues. Personal and current life circumstances can inhibit HNHC patients' ability to benefit from the interventions. A diverse set of life challenges may include mental illnesses, substance abuse, emotional or physical traumas that may stem from early life, extreme poverty, and low literacy.[44, 68, 85, 135, 140, 145, 156]

Many personal challenges may also be compounded by system-level barriers that cause further distrust and marginalization among HNHC patients. System-level barriers pervade all levels of healthcare with issues ranging from the lack of systemic support or safety net (e.g., lack of Medicaid insurance or housing) to cultural and communication barriers that arise from the lack of cultural competency and inadequate translation services.[135, 140, 145, 151, 161, 163] These barriers often prevent HNHC patients from identifying, asking for, and receiving needed social and medical services.

In addition to inhibiting their ability to enroll in interventions, HNHC patients' history of negative experiences and attitudes toward the healthcare system and providers also contribute to their not accepting and seeking all of the help and care they need.[135, 140, 151, 156] Patients may have experienced disrespect by providers as a result of sex-, race-, or socioeconomic-based discrimination or feel uncared about, disengaged from maintaining self-care, or a lack of self-worth or deservingness of services.[145, 156] These past experiences may lead to further difficult interactions with the healthcare system, distrust and avoidance of specific providers or settings, and a lower likelihood of engaging with their treatment. Patients may see themselves as outsiders, as someone who would "never want to conform to the rules."[140, 145, 151, 156]

Building Relationships With Care Providers

Critical to engaging HNHC patients in an intervention, improving disease self-management skills, and addressing a negative history with the healthcare system, patients need to trust the individuals providing the intervention services.[140] Care team members with roles such as care or case managers, community navigators, and social workers are often tasked with being the primary person to build a trusting relationship with participating HNHC patients.[67-69, 149, 151] Initially, providing basic help can support initial steps in establishing a trusting relationship. This type of help can range from basic life needs such as arranging transportation to helping with other medical and nonmedical needs, such as modifying cooking practices to improve diet and organizing medications.[140-142, 145, 149, 156-158, 165]

Patients value care managers who make them feel listened to and who are easy to talk to, who can explain things in lay terms, and who can be a conduit to other members of the care team.[69] HNHC patients report feeling more supported, confident, and motivated in their efforts to change when they have more frequent and longer visits with a care manager and, relatedly, have a greater opportunity to discuss both their clinical and psychosocial needs and receive feedback more often, especially after taking small steps on their own.[134, 140, 151, 156, 157]

Patients are reassured knowing they have a care team to support them in managing their health and welfare.[68, 134, 140, 150, 156] Actively involving patients in decision making can help build their self-confidence, and a caring and emotionally supportive care team and support group can provide HNHC patients with the motivation to improve their health behaviors.[135, 151, 156] One key marker of program success occurs when a patient who is frightened or in a crisis calls a trusted member of their care team, receives and can access the reassurance they need to avoid an unnecessary hospital or ED visit, and is able to wait to receive care at an outpatient appointment.[67, 140, 151, 156]

Providing Individualized Care for Medical and Nonmedical Services

Given the HNHC patient population's heterogeneity and challenging life circumstances, patients can better respond to interventions that are individualized and tailored, offer access to nonmedical services, are flexible in how or when services are provided, and consider that psychosocial needs may initially take precedence over medical services and treatment. Allowing interventions to specifically address each patient's needs and circumstances empowers providers to work with patients and their families to develop targeted interventions that reflect the patient's diverse needs.[134, 139, 140, 142, 145, 160, 162, 170] Interventions may need to resolve nonmedical needs and facilitate access to services addressing these needs because these issues may drive patients' perceived ability to cope with and benefit from healthcare interventions.[68, 85, 134, 140, 142, 160] High co-occurrence of mental illnesses, substance abuse, and housing instability among HNHC patients suggests that interventions targeting HNHC patients need to address these issues concurrently or before managing health.[85, 134]

Interventions may teach patients how to connect to medical and nonmedical services to address their personal and system-level barriers and build their self-confidence.[44, 85, 141, 142, 151, 157, 158, 161] Patients also enhance their self-efficacy by learning how to navigate these services for themselves. Because the burden of coexisting chronic diseases is heterogeneous and periods of time of decompensation differ, the necessary length of time in interventions differs, and interventions end when a patient "graduates" or demonstrates the interventions objective (e.g., self-management behavior.[140, 145]

Recognizing Barriers to Patient Change

Even after establishing successful relationships between members of the care team and HNHC patients, an intervention may not lead to reductions in potentially preventable or modifiable hospital admissions or ED visits, at least in the short term.[150] Some patients may continue to prefer to visit the ED, despite being provided with alternatives, because they believe that the ED is the best place to receive care or because the ED does not require a copay.[72, 151] For HNHC patient interventions, patient-centered success may need to be evaluated in relation to incremental goals, such as changes in self-care behaviors, interactions with the clinic, and relationships with providers, rather than achieving healthcare utilization or cost goals.[44, 134, 150] However, gradual improvements in patients' experiences with their care providers may lead to long-term benefits in health behaviors and clinical outcomes.[150]

Program Theory 3: Supporting Care Providers Participating in Interventions To Improve HNHC Patients' Management of Their Chronic Conditions

Interventions for complex HNHC patients are themselves complex, changing the process of delivering care, often with multiple components that require coordination among a multidisciplinary set of care providers, to offer an individualized array of services to each HNHC patient. Intervention care providers often include physicians and nurses, with additional services provided through such roles as care or case managers, social workers, community health workers, care coordinators, administrative support, nutritionists, and mental health and addiction specialists.[44, 64, 65, 68, 141, 142, 150-153] Obtaining care providers' buy-in and building structures and processes to support their efforts help improve intervention performance and outcomes, because care providers affect the success of the intervention through both their actions and inactions. Appendix Table B-13 presents the detailed CMO configurations and supporting data that underpin this program theory.

Gaining Support From Physicians and Other Care Providers

Initially, support from organizational leaders and physician champions of the HNHC patient intervention can help smooth the path for implementing new processes into a care setting.[65, 68] Buy-in for the intervention is crucial across all care providers, and leadership support should be used to help attain staff support.[68] For example, organizational leadership involvement in coordinating the introduction of new care processes and new care team members, across the healthcare system, encourages existing care providers to accept new resources and approaches.[68]

When implementing interventions, health systems' use of targeted outreach to physicians supports securing their engagement, a necessary component for program success.[65, 68, 138] Garnering initial physician support and participation in an intervention is facilitated by outreach to physicians directly by a medical director[68] or nurse[138] or indirectly through practice staff and practice administrators by a nurse.[138] Outreach is more likely to be effective when it is practice specific, tailored, and face-to-face.[68, 138] Physicians' support for an HNHC patient intervention is increased if they believe the intervention will benefit their patients' care.[66, 68, 138] Giving physicians themselves a role in targeting the patients they identify as those most likely to benefit from the intervention can add to gaining physician support.[66] Recruiting physician champions can also facilitate support among fellow physicians,[65] as well as others among the practice staff.[68] Gaining buy-in from other practice staff, such as practice nurses, is similarly facilitated through face-to-face conversations about how the intervention goals and processes will supplement existing services.[68]

After initial physician support is obtained, it needs to be maintained and supported. A sufficient number of patients within a practice need to be participating in the intervention to justify the up-front work and cost to the practice.[65, 66] Designing an intervention that acknowledges the additional time needed to care for HNHC patients can be used to encourage physicians' continued support.[65, 68, 135, 146, 165] These designs may range from healthcare system–wide modifications such as providing higher reimbursements for sicker patients or using a capitation payment model that pays providers a set monthly amount per patient to other financial incentives such as physician enrollment incentives or counting of HNHC patients as more than one non-HNHC patient on physician panels.

Managing and Relieving Care Provider Workload and Stress

Acknowledging and managing care provider workload and stress are vital for sustaining interventions for HNHC patients. Interventions that provide medical and support services to HNHC patients can lead to provider stress and feelings of being overwhelmed. Ultimately, these feelings can result in turnover among physicians, care managers, and other care providers.[69, 154] The increase in stress can be explained by the increase in workload and responsibilities that many providers experience when participating in HNHC patient interventions[154] and by the emotional toll of working among sicker and frailer patients.[68]

To address the added workload and responsibilities, successful interventions change their organization of care and make additional resources available to practices and care providers to ensure they have the confidence and skills they need. This support may include training, supporting dedicated time to implement new processes, creating new positions, and hiring new support staff for care providers.[68, 69, 135, 145, 154] HNHC patient interventions often organize providers into care teams to both deliver more coordinated HNHC patient care and provide mutual support for each other.[68, 69, 72, 134, 140, 154] As members of a care team, physicians can focus their efforts on providing high-quality patient clinical care, while additional care providers, like care or case managers and social workers, do many of the supportive tasks (e.g., building trust, managing medication, referring community resources).[68, 69, 145, 159, 161, 162, 165] Other staff, such as community health workers, may add additional, nonclinical peer perspectives and insights into the needs and challenges faced by HNHC patients that the more traditional, health system–focused care team members may not have considered previously.[145, 159] As the care team gains experience with the workload and responsibilities of care managers and social workers, tasks that do not require their expertise (e.g., appointment reminders) may be delegated to other staff members, like administrative assistants.[145] Care provider caseloads can also be reassessed after initial implementation. The care team will be better able to judge the necessary and sustainable levels of support and services provided to patients of different levels of need and modify the protocol to support fewer services for patients with less need.[69]

Finally, team members may gain emotional and technical support through peer counseling across offices and healthcare systems.[68, 69, 154] Providing regular opportunities for care team members to talk to other providers facing similar challenges helps them cope with their frustrations in caring for HNHC patients and receive mutual support and assistance.[154] For example, a care manager network across health systems gives care managers opportunities to share best practices and provide emotional support for each other.[68, 69]

Maintaining Communication Across Care Providers

Regular, open communication among care team members supports the complexity of treating HNHC patients by fostering the development of cohesive coordinated care teams with shared values and commitments.[72, 134] Tools to ensure regular communication among all care team members include regular newsletters, email feedback, intervention websites, and care team meetings.[65, 68, 154]

Regular, multidisciplinary team meetings are an important forum for care teams to provide or exchange information on performance and care delivery and may be conducted at multiple organizational levels.[72] Organization-wide meetings may be used to discuss broader performance and intervention goals and implications. Practice-level meetings may be used to discuss practice-specific issues, including individual physician performance, protocol development, and trainings.[68, 72, 161] At the care team level, meetings or huddles that include all care team members provide the opportunity to openly discuss specific patient cases and develop care plans.[68, 72, 145, 154, 161, 165] These open discussions foster a supportive environment for discussing positive and negative elements of patient care approaches[68] and performance on quality metrics, outcomes, and other performance goals.[72] Physicians also receive practical, constructive feedback on approaches to care during care team meetings.[72, 154] To maximize the benefits of care team meetings, physicians and other care providers need sufficient time to attend the meetings and to act on patient care plans.[154]

Placing care team members in the same physical location also facilitates communication by making it easier for team members to discuss patient concerns and coordinate patient care.[72] Being co-located in the same practice, having spaces designed to encourage face-to-face conversations, or, even better, sitting next to each other allow all team members to be heard, thus fostering strong working relationships, good team communication, and ultimately improvements in the coordination of patient care.[66, 72, 134, 165] When introducing new positions such as care managers or care coordinators, having these individuals embedded in practices and be physically part of the care team is particularly valuable because it encourages physicians and other existing practice staff to use their services.[66, 68, 69] Strong team communication and coordination related to patients' needs can ultimately help teams achieve long-term intervention goals (e.g., avoiding unnecessary readmissions, inpatient admissions, and ED visits).[72] Conversely, care teams find it challenging to effectively and efficiently communicate with all of an HNHC patient's providers when they receive part of their care from providers with whom communication processes have not been established, such as when providers are located in other healthcare systems.[66, 138]

KQ 3. Overall, what is the effectiveness and what are the harms of interventions for HNHC patients in reducing potentially preventable or modifiable healthcare use and costs and in improving health outcomes?

For KQ 3, we organized our findings by seven intervention model types, based on the principal setting: system-level transformation, telephonic/mail, community, ED, ambulatory intensive caring unit (aICU), primary care, and home based. For each model type, we present an overview of our findings followed by detailed results. The detailed results describe the included studies and then present outcomes by the following categories: utilization outcomes, cost outcomes, clinical and functional outcomes, and social risk outcomes.

Within each outcomes section, we present strength-of-evidence findings for outcomes graded as moderate or low. (We found no high strength-of-evidence bodies of evidence.) Summary tables in Appendix B present greater detail on study characteristics, including risk-of-bias assessments, intervention components, and outcomes.

Literature Searches, Study Characteristics, and Overview of Findings

Among the 40 studies included in KQ 3 (see the beginning of the chapter for a breakdown of the studies by design and risk of bias), 47 samples were included in the analysis. As described in the Methods section, six studies included multiple cohorts, populations, or analyses. We considered each comparison between an intervention and comparison group to be a “sample.” Each sample is included as evidence from a separate study.

Our inclusion criteria require patients to have had high healthcare cost or use. In almost half of the study samples, researchers also required patients to have at least one chronic condition (Table 15). More than half of the samples had more than 1,000 patients. The number of intervention sites varied across studies, ranging from one site (38% of samples) to six or more sites (34% of samples).

Table 15. Key characteristics for KQ 3 included samples (N=47)

Study Characteristics	Categories	Number of Samples	Percentage of Samples
Risk-of-bias assessment by study design	RCT: Low risk-of-bias studies	6	13%
	RCT: Some concerns for risk-of-bias studies	18	38%
	Observational: Some concerns for risk-of-bias studies	16	34%
	Observational: High risk-of-bias studies	7	15%
Participant eligibility	High use only	22	47%
	High cost only	2	4%
	High use and any chronic condition	12	26%
	High cost and any chronic condition	11	23%
Participant age range	<65 only	3	6%
	65+ only	16	34%
	All adults	25	53%
	Not reported	3	6%
Participant race	Majority white (>50%)	6	13%
	Majority nonwhite (>50%)	17	36%
	Not reported	24	51%

Study Characteristics	Categories	Number of Samples	Percentage of Samples
Participant high-risk conditions	Majority with mental health diagnosis (>50%)[a]	4	9%
	Majority with substance abuse (>50%)[b]	3	6%
	Majority with COPD diagnosis (>50%)	1	2%
	Majority with heart disease diagnosis (>50%)[c]	3	6%
	Majority with social risk (>50%)[d]	1	2%
Participant insurance status	Medicare only or dual Medicare/Medicaid	25	53%
	Medicaid only	5	11%
	Mixed across participants	4	9%
	Uninsured or Medicaid	4	9%
	Unknown	9	19%
Sample size	<100	6	13%
	100 to <1,000	13	28%
	1,000 to <9,999	16	34%
	≥10,000	12	26%
Comparison group	Usual care	46	98%
	Received education materials and an incentive	1	2%
Number of study sites	1	18	38%
	2 to 5	12	26%
	6+	16	34%
	Not reported	1	2%

[a] Mental health diagnoses include schizophrenia and other psychotic disorders, bipolar disorder, and major depression.

[b] Substance abuse includes alcohol and drug abuse.

[c] Heart disease diagnoses include coronary artery/vascular disease, congestive heart failure, stroke/myocardial infarction, and cardiac arrest.

[d] Social risk factors include homelessness, low income, low education, and social isolation.

COPD = chronic obstructive pulmonary disease; KQ = Key Question; RCT = randomized controlled trial.

Table 16 provides a summary of our strength-of-evidence decisions by outcomes by intervention model type. (Appendix Table B-14 is a more detailed listing with over 100 unique outcomes, by intervention model type). Among the 30 outcomes reported by two or more samples within a model type, we found favorable findings (moderate to low strength of evidence) in relation to changes in utilization and cost from ED, aICU, primary care, and home-based care models. Outcomes were graded as low for no difference in effect if at least several large RCT samples reported no difference between the intervention and treatment groups. Much of the evidence was graded as insufficient. Generally, these results across studies were inconsistent or imprecise, and meaningful conclusions cannot be drawn with the current evidence.

Table 16. Summary of strength of evidence for HNHC patients by intervention model type for outcomes reported in more than one sample

Outcome Group	Outcome Measure (Subgroup)	System Level	Tele-phonic/ Mail	Com-munity Based	ED Based	aICU	Primary Care	Home Based
Utilization outcomes	ED visits, all-cause	I	L-ND	I	M-F	-	I	I
	ED visits, ACSC	-	L-ND	-	-	-	I	I
	Inpatient admissions, all-cause	I	L-ND	I	L-F	-	I	I
	Inpatient admissions, any	-	I	-	-	-	L-F	I
	Inpatient admissions, ACSC	-	L-ND	-	-	-	I	L-F
	Inpatient admissions, any ACSC	-	I	-	-	-	I	L-F
	Inpatient days	-	-	I	-	-	I	-
	Outpatient visits	-	-	-	I	-	I	-
	Primary care visits	-	-	-	L-F[a]	-	I	-
	180-day readmission, count	-	-	I	-	-	-	-
Cost outcomes	Total costs	L-ND	L-ND	I	-	L-F	L-F	I
	Inpatient costs	-	-	I	L-ND[a]	-	-	-
	ED costs	-	-	I	L-F	-	-	-
	Hospital costs of care	-	-	-	I	-	-	-
	Outpatient costs	-	-	-	I[a]	-	-	-
	Total costs (high-cost, high-risk HNHC patients)	-	-	-	-	-	-	I
	Total costs (high-cost HNHC patients)	-	-	-	-	-	-	I
Clinical and functional outcomes	Mortality rate	-	L-ND	L-ND	-	I	I	L-ND
	Influenza vaccine	-	I	-	-	-	L-U	L-F
	Progression to ESRD	-	I	-	-	-	-	-
	Progression to ESRD (CKD patients)	-	I	-	-	-	-	-
	Graft or fistula prior to hemodialysis (CKD patients)	-	I	-	-	-	-	-
	Graft or fistula prior to hemodialysis (ESRD patients)	-	I	-	-	-	-	-
	HbA1c test (diabetes patients)	-	I	-	-	-	I	I
	LDL test (diabetes patients)	-	I	-	-	-	I	I
	LDL test (IVD patients)	-	I	-	-	-	I	I
	Eye exam (diabetes patients)	-	I	-	-	-	-	-

Outcome Group	Outcome Measure (Subgroup)	System Level	Tele-phonic/ Mail	Com-munity Based	ED Based	aICU	Primary Care	Home Based
Clinical and functional outcomes (continued)	Nephrology/nephropathy test (diabetes patients)	-	I	-	-	-	-	-
	Lipid test (IVD patients)	-	I	-	-	-	-	-
	Oxygen saturation test (COPD patients)	-	-	-	-	-	-	I

I: Insufficient, two or more samples reporting on the outcome within the model type; L-F: Low strength of evidence for favorable findings for the outcome; L-ND: Low strength of evidence for no difference for the outcome; L-U: Low strength of evidence for unfavorable findings for the outcome; -: No eligible evidence; M-F: Moderate strength of evidence for favorable findings for the outcome.

[a] Shumway et al.[167] specified the outpatient and inpatient costs as medical outpatient costs and medical hospital costs.

ACSC = ambulatory care sensitive conditions; aICU = ambulatory intensive caring unit; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; ED = emergency department; ESRD = end-stage renal disease; HbA1c = hemoglobin A1c; HNHC = high-need, high-cost; IVD = ischemic vascular disease; LDL = low-density lipoprotein.

Notably, no social risk outcomes (i.e., variables in the social services domain that may affect care delivery)[20] and a limited number of clinical and functional outcomes were reported in two or more samples within a model type. Therefore, evidence for these outcomes was often either not available or rated as insufficient strength of evidence.

Findings by Model Type

System-Level Transformation Models

Overview

- Four observational studies, including five samples, each rated some concerns for risk of bias, reported on system-level transformation models.
- We found no difference in total costs among system-level transformation models (-\$5.41 [95% confidence interval (CI), -38.28 to 49.10]; 5 observational samples, I^2=44.6%), based on evidence from all five observational samples (low strength of evidence for no difference between interventions and usual care).
- We found insufficient evidence to judge all utilization and clinical and functional outcomes.

Detailed Results

Four studies, including five samples, reported on system-level transformation models compared with usual care (Appendix Table B-15).[69-72, 181, 182] This set of models consisted of interventions that were designed, funded, and overseen by CMS. They were designed to be relevant to the delivery of care to all of the practice's or clinic's patient population. The models tested whether organizations were able to implement a diverse set of changes to alter how they deliver care and whether those changes affected the cost and quality of care their patients received. All four studies were observational designs and were rated as some concerns for risk of bias.

One study, the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice initiative, aimed to help FQHCs obtain patient-centered medical home (PCMH) status.[71] PCMH status would signify that the FQHC provides continuous, comprehensive, coordinated, and patient-centered medical care. In this study, 503 FQHC intervention sites were compared with 827 comparator FQHC sites at the end of 3 years.[71]

The second study focused on one component of CMS's Independence at Home (IAH) demonstration. IAH supported the provision of team-based primary care in the homes of chronically ill and functionally limited fee-for-service (FFS) Medicare enrollees by providing financial incentives to home-based primary care practices.[72, 181] The IAH evaluation conducted two analyses using different study populations. The first analysis (included in this section) assessed the 5-year average annual effect of the IAH payment incentive to home-based primary care practices on cost and utilization outcomes. IAH practices earned a payment incentive if Medicare expenditures for their IAH patients were below a spending target and the practice met quality standards.[72] The IAH incentive payment analysis compared all IAH-eligible patients in IAH practices, including those who received home-based care before the demonstration began, with IAH-eligible patients from the same geographic area who did not receive care at IAH practices and did not ever receive home-based primary care.[72] The second analysis assessed the effect of home-based primary care patient services (discussed in the Home-Based Care Models section).[72]

The other two system-level models, the Comprehensive Primary Care (CPC) initiative and the Comprehensive Primary Care Plus (CPC+) initiative, were multipayer models that aimed to reform care delivery and payment in primary care practices. CPC's goal was to improve primary care delivery by offering care management fees and shared savings to primary care practices to support improvements across five care delivery functions: access, chronic and preventive care, care management, patient and caregiver engagement, and care coordination.[69] The CPC study compared 4-year outcome differences between 497 intervention practices with 908 matched comparison practices.

CPC+ built on the CPC model and required primary care practices to make more advanced care delivery changes and to target more complex patients.[70, 182] In the first 2 (of 5) years of CPC+, primary care practices focused on improving the quality of care they provided to patients, including setting up processes and staff for care management and for screening and addressing unmet behavioral health and social service needs; improving coordination with hospitals, EDs, and specialists; and improving timely followup with patients after an ED or hospital visit. The CPC+ study included two samples consisting of practices located across 18 geographical regions. The first sample compared 1,373 CPC+ practices with 5,243 matched comparison practices. A second sample compared 1,515 CPC+ practices with 3,784 comparison practices. Compared with the first CPC+ sample, the second sample of practices was required to make more advanced care delivery changes to support their complex patients. The practices in the second sample received more financial payments to support their changes.

Intervention Characteristics

Across the four interventions, CMS provided organizations with different levels of financial and learning support and data feedback (Appendix Table B-16). FQHCs transforming to PCMH status received a quarterly care management payment of $18 for each eligible Medicare patient to support delivery of patient-centered care; technical assistance from the National Committee for Quality Assurance (NCQA); and feedback reports on their achievement toward NCQA PCMH status, utilization, and expenditure measures.[71]

Similar to the FQHC intervention, CPC and CPC+ provided financial support to practices, including care management fees to assist in practice reforms.[69, 70] CPC also offered shared savings to practices to reward cost savings, and CPC+ also offered prospective performance-based payments. Financial support was provided by Medicare and other payers including Medicaid and various commercial payers. CPC and CPC+ intervention practices received technical assistance, data feedback, and learning support (e.g., group learning activities and individualized coaching).[69, 70] Compared with CPC, CPC+ practices had more requirements related to care delivery, such as developing care plans, following up with patients after ED or hospital discharge, and implementing enhanced health information technology functionalities to support care delivery requirements.[70]

The IAH model differed from the other transformation models in that it used an incentive payment to motivate IAH practices to implement a variety of strategies to improve care and reduce unnecessary costs.[72] The incentive payment was proportional to the difference between the practices' targeted and actual spending and performance on quality measures.

FQHC, CPC, and CPC+ noted variation across sites in the uptake of intervention components, including learning support,[69] technical assistance, and data feedback reports.[71] For the FQHC intervention, the study authors noted that isolating an intervention effect was difficult because comparison sites had access to many of the same resources to support efforts toward achieving PCMH status. These resources included technical assistance and funding from the Health Resources and Services Administration, state Medicaid programs, and private MCOs,[71] including support for tracking quality and providing feedback to physicians. In IAH, practices developed and tested their own strategies to identify effective processes to improve their quality of care; some practices provided performance feedback to their providers.[72]

While the interventions across the four studies included all patients, we present the findings specific to the HNHC patient subgroup. The FQHC study reported on two samples of intervention patients that met our HNHC inclusion criteria. One sample was patients whose number of ED visits was in the 90th percentile, and the second was patients whose number of FQHC visits was in the 90th percentile. Both samples were compared with patients with visits below the 90th percentile of the same metric in comparison sites.[71] The two FQHC samples may include overlapping patients. Because of this concern, we report on just one of the patient populations, the ED patients with high use. We selected the ED patient analysis because a selection criterion based on ED use was more like the criteria used by other studies. All IAH participants were HNHC patients. Medicare patients were included in the IAH payment incentive analysis if they had two or more chronic conditions, two or more difficulties in performing activities of daily living that require human assistance, and a hospitalization and use of acute or subacute rehabilitation services in the previous 12 months.[72] CPC reported on one HNHC patient sample, defined as two or more hospitalizations in the past 2 years, with at least 2 of 13 chronic conditions. CPC+ reported on two HNHC patient samples based on the two samples of practices; both samples were defined as one or more hospitalizations in the past year, with at least 2 of 12 frequently occurring chronic conditions.[70]

Intervention Outcomes

Utilization Outcomes

Utilization outcomes were available for the IAH and FQHC interventions only. In relation to ED visits, the IAH incentive payment intervention group experienced a favorable, significantly greater decrease in ED visits than its comparison group while the FQHC sample did not experience an effect (Appendix Table B-17). Because of mixed findings, we rated ED visits as insufficient strength of evidence (Table 17; full strength-of-evidence domain decisions can be found in Appendix Table B-18). Neither of the interventions found a significant difference from the comparison group in the number of inpatient admissions, and this outcome was also graded as insufficient strength of evidence.[71, 72]

Cost Outcomes

All four studies found no differences in changes in total costs among the five samples of HNHC patients (Appendix Tables B-19 and B-20).[69-72, 181, 182] The pooled effect size showed no difference in annual total cost between the groups (mean difference, -\$5.41 [95% CI, -38.28 to 49.10]; 5 observational samples, I^2=44.6%) (Appendix Figure B-2). Because total costs were observed to not be less across all five samples, we rated this outcome as low strength of evidence for no difference (Table 17). Notably, CPC+ Sample 2 intervention group found an unfavorable, significantly greater increase in total costs than its comparison group. However, study authors suggested interpreting this finding with caution because many subgroup analyses were performed and this significant difference may have occurred because of chance.[182] The

Table 17. Summary of findings for system-level transformation models versus usual-care outcomes

Outcome	Population	# Samples/Design (n M)	Findings[b]	Strength of Evidence
ED visits, all cause	HNHC patients	2 OBS[71, 72] (N=NR[a])	1 OBS sample had favorable findings and 1 OBS sample found no difference	Insufficient
Inpatient admissions, all cause	HNHC patients	2 OBS[71, 72] (N=NR[a])	2 of 2 OBS samples found no difference	Insufficient
Total cost	HNHC patients	5 OBS[69-72] (N=NR[a])	4 of 5 OBS samples found no difference; 1 of 5 OBS samples had unfavorable findings MA pooled mean difference: -\$5.41 (95% CI, -38.28 to 49.10); 5 observational samples, I^2=44.6%	Low (No difference)

[a] The FQHC,[71] CPC,[69] and CPC+[70] studies did not report sample sizes for their HNHC patient populations; the total sample size for FQHC was 730,353, 1,730,958 for CPC, 5,163,969 for CPC+ Sample 1, and 4,804,265 for CPC+ Sample 2. The sample size was 42,132 for the IAH study.[72]

[b] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

CPC = Comprehensive Primary Care; CPC+ = Comprehensive Primary Care Plus; ED=emergency department; FQHC = Federally Qualified Health Center; HNHC = high need, high cost; IAH = Independence at Home; MA = meta-analysis; N = number; NR = not reported; OBS = observational study.

authors also hypothesized that total costs may have increased for HNHC patients because increased care management led to identification of additional health problems and subsequent service use.

Clinical and Functional Outcomes

In relation to clinical and functional outcomes, differences in mortality rate were reported only in the IAH incentive payment sample and were found to be not significant.[72] The FQHC sample was the only other study to report any clinical and functional outcomes, and no differences were observed for receipt of hemoglobin A1c (HbA1c) tests, low-density lipoprotein (LDL) tests, eye exams, nephropathy tests, and lipid checks, among diabetic and ischemic vascular disease (IVD) patients (Appendix Tables B-21 and B-22).[71]

Social Risk Outcomes

No social risk outcomes were reported among the system-level transformation studies.

Telephonic/Mail Models

Overview

- Five RCTs and one observational study reported on telephonic/mail models. Telephonic/mail models were interventions where services were primarily provided remotely (telephonically or by mail) by a health plan. Three of the RCTs randomized two samples, an original sample and a refresh sample, so a total of nine samples were included in the evidence.

- The evidence on telephonic/mail models comes from studies with moderate study limitations.
- Based on evidence from four RCT samples (N=20,693), we found no difference in the number of ED visits (RR, 1.01 [95% CI, 0.94 to 1.08]; I^2=0%); ACSC ED visits (RR, 0.99; 95% CI, 0.88 to 1.10; I^2=0%), inpatient admissions (RR, 0.99 [95% CI, 0.92 to 1.06]; I^2=0%), and ACSC inpatient admissions (RR, 0.95 [95% CI, 0.85 to 1.06]; I^2=0%) (low strength of evidence for no difference).
- We found that change in total healthcare cost was not improved by the interventions, based on evidence from seven RCT samples (mean difference, -$8.52 [95% CI, -130.02 to 112.98]; 7 RCT samples; N=25,000; I^2=22.4%) (low strength of evidence for no difference).
- We found no difference in the mortality rate (mean difference, 0.34 [95% CI, -1.06 to 1.74]; I^2=0%), based on evidence from four RCT samples (N=20,693) (low strength of evidence for no difference).
- The evidence is insufficient to judge other utilization, cost, and clinical and functional outcomes.

Detailed Results

Six studies, analyzing nine samples, reported on telephonic/mail models (Appendix Tables B-23 and B-24).[64-66, 138, 144, 172] A telephonic/mail model is an intervention where most services are provided remotely, either telephonically or by mail. These interventions were generally operated by a health plan.

Intervention Characteristics

Five of the six studies (reporting on 8 samples) were RCTs.[64-66, 138, 144] All five RCTs were rated as some concerns for risk of bias. The one included observational study was rated some concerns for risk of bias.[172]

In one RCT, Kaiser Permanente of Ohio provided the HNHC patient intervention group with Healthtrac, a health promotion program. Healthtrac mailed health education materials and questionnaires to members and returned a personalized letter and feedback with recommendations and actions to reduce the risks identified in the letter.[144] The HNHC patient comparison group received baseline education materials and incentives but did not receive personalized followup materials.[144] Eligible Kaiser Permanente members had 11 or more outpatient visits in the past 2 years and a diagnosis of one of three target conditions (arthritis, hypertension, diabetes).[144]

The other four RCTs were separate programs implemented as part of the Medicare Care Management for High Cost Beneficiaries (CMHCB) demonstration.[64-66, 138] The CMHCB programs were multifaceted interventions that tested a pay-for-performance contracting model and provided new care management or coordination for high-cost or complex Medicare FFS patients. Through the pay-for-performance model, CMHCB programs received a negotiated monthly management fee for each of their intervention group members and a share of any Medicare savings achieved among the intervention group. Programs administered patient assessments to help them create services tailored to an individual patient’s needs. CMHCB compared intervention-group patients with those receiving usual care. Usual-care patients were not contacted.

One CMHCB RCT, Texas Senior Trails (TST), provided multidisciplinary care management to help multimorbid patients coordinate health and social services.[138] In TST, nurse care managers provided services most often in writing or by telephone. Twenty percent of participants received in-person services. The program emphasized sharing information with patients' physicians.[138]

The second CMHCB RCT, the Health Buddy Consortium program, was a care management program for heart failure, diabetes, and COPD patients.[66] The intervention provided patients with a Health Buddy device, a home monitoring device set to 1 of 13 disease-specific programs, that allowed nurse care managers to monitor and communicate with patients daily. Alternatively, intervention participants who did not use the Health Buddy device could receive regular, scheduled phone calls.[66]

Both the TST and Health Buddy programs included a broader group of participants than the HNHC patient population. We present only the findings specific to the HNHC patient subgroup, defined as those with $6,000 or more in Medicare costs in the previous year and an HCC risk score of 1.7 or greater.[66, 138] This HCC score indicates that the patient was predicted to have 70 percent or higher total Medicare spending than an average Medicare patient.

The other two CMHCB RCTs were Phase I and Phase II of the Village Health program. In Phase I, Village Health tested a disease and care management program for chronic kidney disease (CKD) patients in three counties in New York City.[64] In Phase II, Village Health expanded their patient focus to target patients with ESRD and extended their geographical territory to include five New York regions.[65]

Village Health nurse care managers provided support only through the telephone for CKD participants and through telephone or in person for ESRD participants. This support was complemented by pharmacists, social workers, and dietitians and access to a 24-hour hotline.[64] In Phase II, Village Health retained the same intervention structure and added more frequent contact with patients; in-person education classes; an expanded clinical focus to include ESRD patients; and relationships with more nephrologists, local hospitals, skilled nursing facilities, rehabilitation facilities, and community organizations.[65] Both Village Health RCTs included patients who had $5,000 or more in Medicare costs in the previous year and a CKD diagnosis.[64, 65]

Three of the CMHCB programs, Health Buddy, Village Health Phase 1, and Village Health Phase 2, implemented the RCT in two separate samples, an original sample and a "refresh" sample. All samples were followed for at least 1 year. Both samples received the same intervention.[64-66] The refresh sample supplemented the original sample with additional, new patients to offset the impact of attrition, primarily due to death, in the original sample.[64-66]

The sixth telephonic/mail model study was observational. Compared with usual care, the Health Leads program, implemented at Kaiser Permanente Southern California, provided social needs screening and navigation of community-based services by telephone through nonclinical program staff.[172] Eligible patients were predicted to be in the top 1 percent of healthcare utilization in the upcoming year.[172]

Intervention Outcomes

Utilization Outcomes

Four of the six studies (6 samples) reported on the effect of the intervention on healthcare utilization (Appendix Tables B-25 and B-26).

ED visit outcomes were reported in the two Village Health studies (4 RCT samples; original and refresh samples in Phase I and Phase II) and in 1 observational study sample. In the four RCT samples, ED visits increased in both the intervention and comparison groups, but the change was not significantly different between the two groups.[64, 65] Pooled RRs for all-cause ED visits (RR, 1.01 [95% CI, 0.94 to 1.08]; 4 RCT samples; N=20,693; I^2=0%) and ACSC ED visits (RR, 0.99 [95% CI, 0.88 to 1.10]; 4 RCT samples; N=20,693; I^2=0%) also were not significantly different in these RCT samples (Appendix Figures B-3 and B-4). The evidence led to a grade of low strength of evidence for no difference for both all-cause and ACSC ED visits (Table 18; full strength of evidence can be found in Appendix Table B-27).

Inpatient-related outcomes were also limited to evidence from the Village Health samples and 1 observational study sample. Among the four Village Health RCT samples, differences between the intervention and comparison groups were not significantly different for all inpatient outcomes (both all-cause admissions and ACSC-related admissions).[64, 65] Pooled RRs for all-cause inpatient admissions (RR, 0.99 [95% CI, 0.92 to 1.06]; 4 RCT samples; N=20,693; I^2=0%) and ACSC inpatient admissions (RR, 0.95 [95% CI, 0.85 to 1.06]; 4 RCT samples; N=20,693; I^2=0%) showed no difference between groups and both were graded as low strength of evidence for no difference (Appendix Figures B-5 and B-6) (Table 18).

The Healthtrac RCT was the only telephonic/mail model study that measured outpatient visits. Changes in the number of visits were measured—for both the total sample and by chronic condition subgroup (arthritis, blood pressure, and diabetes).[144] At 6 months, the RCT did not observe any significant differences, but by 30 months, reductions were greater in the intervention group, predominately driven by the reduction in visits among arthritis patients.

The Health Leads program, the observational study, reported no differences in total utilization or the total number of ED, outpatient, and inpatient visits between the intervention and comparison groups.[172]

Table 18. Summary of findings for telephonic/mail models versus usual-care outcomes[a]

Outcome	Population	# Samples/Design (n Analyzed)	Findings[b]	Strength of Evidence (Direction of Effect)
ED visits, all cause	HNHC patients, RCTs all CKD or ESRD	4 RCTs[64, 65] (N=20,693) 1 OBS[172] (N=34,255)	4 of 4 RCT samples found no difference 1 of 1 OBS found no difference MA-pooled RR,1.01 (95% CI, 0.94 to 1.08); 4 RCT samples; N=20,693; I^2=0%	Low (No difference)
ED visits, ACSC	HNHC patients, all CKD or ESRD	4 RCTs[64, 65] (N=20,693)	4 of 4 RCT samples found no difference MA-pooled RR, 0.99 (95% CI, 0.88 to 1.10); 4 RCT samples; N=20,693; I^2=0%	Low (No difference)

Outcome	Population	# Samples/Design (n Analyzed)	Findings[b]	Strength of Evidence (Direction of Effect)
Inpatient admissions, all cause	HNHC patients, RCTs all CKD or ESRD	4 RCTs[64, 65] (N=20,693) 1 OBS[172] (N=34,255)	4 of 4 RCT samples found no difference 1 of 1 OBS found no difference MA-pooled RR, 0.99 (95% CI, 0.92 to 1.06); 4 RCT samples; N=20,693; I^2=0%	Low (No difference)
Inpatient admissions, ACSC	HNHC patients, all CKD or ESRD	4 RCTs[64, 65] (N=20,693)	4 of 4 RCT samples found no difference MA-pooled RR, 0.95 (95% CI, 0.85 to 1.06); 4 RCT samples; N=20,693; I^2=0%	Low (No difference)
Inpatient admissions, any	HNHC patients	2 RCTs[64] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[64] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Total cost	HNHC patients	7 RCTs[64-66, 138] (N=25,000)	7 of 7 RCT samples found no difference MA-pooled mean difference, -$8.52 (95% CI, -130.02 to 112.98); 7 RCT samples; N=25,000; I^2=22.4%	Low (No difference)
Mortality rate	HNHC patients	4 RCTs[64, 65] (N=20,693)	4 of 4 RCT samples found no difference MA-pooled mean difference, 0.34 (95% CI, -1.06 to 1.74); 4 RCT samples; N=20,693; I^2=0%)	Low (No difference)
Influenza vaccine	HNHC patients	2 RCTs[64] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Progression to ESRD	HNHC patients	2 RCTs[64] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Progression to ESRD	HNHC patients, CKD subgroup	2 RCTs[65] (N=4,822)	2 of 2 RCT samples found no difference	Insufficient
Graft or fistula prior to hemodialysis	HNHC patients, CKD subgroup	2 RCTs[65] (N=4,822)	1 of 2 RCT samples had favorable findings 1 of 2 RCT samples found no difference	Insufficient
Graft or fistula prior to hemodialysis	HNHC patients, ESRD subgroup	2 RCTs[64] (N=428)	2 of 2 RCT samples found no difference	Insufficient
HbA1c test	HNHC patients, diabetes subgroup	4 RCTs[64, 65] (N=7,931)	4 of 4 RCT samples found no difference	Insufficient
LDL test	HNHC patients, diabetes subgroup	4 RCTs[64, 65] (N=7,931)	4 of 4 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[64] (N=3,942)	2 of 2 RCT samples found no difference	Insufficient
Eye exam	HNHC patients, diabetes subgroup	2 RCTs[65] (N=7,931)	2 of 2 RCT samples found no difference	Insufficient
Nephrology test	HNHC patients, diabetes subgroup	2 RCTs[65] (N=7,931)	2 of 2 RCT samples found no difference	Insufficient

Outcome	Population	# Samples/Design (n Analyzed)	Findings[b]	Strength of Evidence (Direction of Effect)
Lipid panel	HNHC patients, IVD subgroup	2 RCTs[65] (N=4,092)	1 of 1 RCT sample had favorable findings 1 of 1 RCT sample found no difference	Insufficient

[a] Comparison group participants for Dally et al. received baseline education materials and incentives.[144]

[b] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

ACSC = ambulatory care sensitive conditions; CKD= chronic kidney disease; ED = emergency department; ESRD = end-stage renal disease; HbA1c = hemoglobin A1c; HNHC= high-need, high-cost; IVD = ischemic vascular disease; LDL = low-density lipoprotein; MA = meta-analysis; N = number; OBS = observational study; RCT = randomized controlled trial; RR = rate ratio.

Cost Outcomes

Four of six studies reported on the impact of the intervention on costs (Appendix Table B-28). The seven samples from the four CMHCB programs[64-66, 138] all found no significant differences in changes in total cost between the study arms. The pooled mean difference showed no difference between groups (mean difference, -$8.52 [95% CI, -130.02 to 112.98]; 7 RCT samples; N=25,000; I^2=22.4%) (Appendix Figure B-7).

The direction of change in costs over time varied across samples. The TST program observed reductions in costs for both intervention and comparison groups,[138] as did the two samples for the Health Buddy program.[66] The Phase I Village Health groups for both the original and refresh samples moved in tandem, with increased costs in all groups over time.[64] The original and refresh samples for Phase II Village Health moved in opposite directions: costs for both the intervention and comparison groups increased over time in the original sample and decreased over time in the refresh sample.[64] This evidence led to a grade of low strength of evidence for no difference in total cost (Table 18).

Clinical and Functional Outcomes

Clinical and functional outcomes for HNHC patients were reported only in the four samples in the two Village Health RCTs (Appendix Tables B-29 and B-30).[64, 65] Based on meta-analysis, we found no significant differences between groups in mortality rates (mean difference, 0.34 [95% CI, -1.06 to 1.74]; 4 RCT samples; N=20,693; I^2=0%) (low strength of evidence for no difference) (Table 16 and Appendix B Figure B-8). We also found no significant differences in any clinical measures among the Phase I original or refresh patients. For Phase II patients, findings were mixed. We graded all other clinical and functional outcomes as insufficient strength of evidence (Table 18).

Social Risk Outcomes

No social risk outcomes were reported among the telephonic/mail studies.

Community-Based Models

Overview

- Three RCT and six observational studies (9 samples) reported on community-based models, including three studies of the Camden Core Model.
- We found low strength of evidence that community-based interventions were not associated with changes in mortality, based on evidence from three RCT samples (low strength of evidence for no difference).
- The evidence is insufficient to judge all other healthcare outcomes, including inpatient admissions, inpatient days, readmissions, and healthcare cost.

Detailed Results

Nine studies in 11 publications, analyzing nine samples, reported on community-based models (Appendix Table B-31).[44, 140, 142, 149, 158, 160, 163, 170, 173, 175, 177] The defining characteristic of this type of model is that the intervention team provides care management or care coordination assistance inside and outside of the healthcare system, wherever the patients are.[45] All interventions were compared with usual care.

Three studies (1 RCT and 2 observational studies) evaluated the Camden Core Model, an intensive, relationship-based "hotspotting" program that used real-time data to identify and recruit HNHC patients. In the RCT (rated low risk of bias), four local-area hospital systems in Camden, NJ, implemented the model.[44] Similarly, the Rutgers Center for State Health Policy (CSHP) evaluated the Camden Core Model in a large observational study (rated some concerns for risk of bias) of provider groups in four states. Although the model was implemented across payers, the CSHP evaluation results were limited to Medicare FFS patients.[140, 173] Another observational study, Bridges to Care (B2C) (rated some concerns for risk of bias), also evaluated adoption of the Camden Core Model.[142] B2C was one of the CSHP sites, so there is likely some overlap with the larger CSHP study. However, B2C was not limited to Medicare FFS patients and primarily served Medicaid-eligible patients.

Another RCT (rated some concerns for risk of bias) evaluated Project Welcome Home (PWH), an intervention that provided chronically homeless adult participants in Santa Clara County, CA, with housing and intensive case management services.[160] A third RCT (also rated some concerns for risk of bias) evaluated the Kings County Care Partners (KCCP) program, a registered nurse-led care management intervention for Medicaid patients with disabilities or substance abuse problems.[163]

The other four studies were observational. One of these studies (rated some concerns for risk of bias) evaluated the Preventable Admissions Care Team program (PACT). PACT is a care coordination and transitional care program with the goal of reducing inpatient readmissions. PACT social workers, affiliated with one New York City hospital, collaborated with patients and their families to promote access to home, medical, and community care.[170]

The other three observational studies (all were rated high risk of bias and did not control for potential confounding) intervened by helping low-income patients with their medical and social needs.[149, 158, 175, 177] Among these, the Care Management Program (CMP) was implemented in a California safety net hospital. CMP assigned low-income uninsured patients a personal care manager to help them navigate and coordinate services in the healthcare and social services systems. Personal care managers met with patients at appointments, their homes, or resource centers.[158] The Familiar Faces program used community navigators (a blend of community health workers [CHWs] and patient navigators) to link HNHC patients in low-income neighborhoods with healthcare and community resources to reduce hospital utilization.[149] Dallas, Texas's Project Access Dallas (PAD) was a community-based care coordination program across healthcare providers, businesses, faith organizations, and public health entities. Through PAD, CHWs provided case management and access to primary and preventive services to low-income, uninsured individuals.[175, 177]

Intervention Characteristics

Across community-based intervention studies, HNHC patient eligibility differed. The Camden RCT enrolled participants with two or more chronic conditions and two traits or conditions that indicated medical complexity, in addition to the utilization criterion of one or more inpatient admissions in the past 6 months.[44] CSHP, B2C, and PACT focused on high healthcare use as the main eligibility criterion,[140, 142, 170, 173] while PWH focused on high use across multiple county-funded systems including ED, inpatient, and jail.[160] KCCP eligibility was based on an algorithm predicting future high cost, based on current costs and other criterion.[163] In addition to meeting utilization criteria, PAD and CMP targeted uninsured HNHC patients,[158, 175, 177] PWH targeted homeless individuals,[160]and Familiar Faces targeted residents of the poorest zip codes in Memphis.[149]

All community-based interventions reported providing services tailored to individual patient needs that could include developing care plans, scheduling appointments, facilitating communication with providers, managing medication, and transportation (Appendix Table B-32). Five interventions (Camden RCT, CSHP, B2C, KCCP, PAD) provided patients with education and coaching related to their health, chronic conditions, self-care, and self-sufficiency.[44, 140, 142, 149, 163, 173, 175, 177] All interventions except PACT connected participants to community-based services through referrals or enrollment assistance. While PWH provided supportive services such as medication management and mental health services, the intervention was unique in that it focused on providing participants with permanent housing.[160]

Care team composition differed across programs. The Camden Core Model was an intensive, face-to-face intervention. All three Camden Core Model studies sought to maintain frequent contact with patients through large, multidisciplinary teams of registered nurses, social workers, licensed practical nurses, CHWs, and health coaches.[44, 140, 142, 173] KCCP was a nurse-led intervention with support from social workers and counselors with drug and alcohol addiction training.[163] The other community-based interventions had smaller teams, but services were provided by similar types of staff. The majority of services were provided by CHWs,[175, 177] social workers,[170] care managers,[158] or community navigators.[177] PWH was notable in that the intervention did not include any physicians or nurses on the case management teams; instead, the teams were composed of social behavioral health providers, case managers, and staff with lived experience (peers).[160]

Intervention Outcomes

Utilization Outcomes

All nine interventions reported on at least one healthcare utilization outcome (Appendix Tables B-33 and B-34). The Camden RCT did not observe significant differences between groups in two inpatient measures—180-day readmissions and inpatient days.[44] PACT, the only other study reporting 180-day readmissions, also did not observe significant differences between groups.[170] The strength of evidence is insufficient for 180-day readmissions (Table 19; full strength of evidence can be found in Appendix Table B-35). The evidence on inpatient days is from the Camden and PWH RCTs and three high risk of bias observational studies. Of these, both RCTs and the CMP observational study reported no significant differences between groups in inpatient days. In contrast, PAD and Familiar Faces observed lower use of inpatient days in the intervention group.[149, 158, 175, 177] Because of the mixed findings, we graded the strength of evidence to be insufficient for inpatient days (Table 19).

Table 19. Summary of findings for community-based models versus usual-care outcomes

Outcome	**Population**	**# Samples/Design (n Analyzed)**	**Findings[a]**	**Strength of Evidence (Direction of Effect)**
180-day readmissions	HNHC patients	1 RCT[44] (N=800) 1 OBS[170] (N=1,158)	1 of 1 RCT sample found no difference 1 of 1 OBS sample found no difference	Insufficient
ED visits, all cause	HNHC patients	2 RCT[160, 163] (N=1,543) 4 OBS[140, 142, 158, 173, 175, 177] (N=5,913)	2 of 2 RCT samples found no difference 3 of 4 OBS samples had favorable findings 1 of 4 OBS samples found no difference	Insufficient
Inpatient admissions, all cause	HNHC patients	2 RCT[160, 163] (N=1,543) 3 OBS[140, 142, 158, 173] (N=5,339)	2 of 2 RCT samples found no difference 1 of 3 OBS samples had favorable findings 2 of 3 OBS samples found no difference	Insufficient
Inpatient days	HNHC patients	2 RCT[44, 160] (N=1,223) 3 OBS[149, 158, 175, 177] (N=1,271)	2 of 2 RCT samples found no difference 2 of 3 OBS samples had favorable findings 1 of 3 OBS samples found no difference	Insufficient
Total cost	HNHC patients	1 RCT[163] (N=1,120) 2 OBS[140, 149, 173] (N=1,271)	1 of 1 RCT sample found no difference 2 of 2 OBS samples found no difference	Insufficient
Inpatient costs	HNHC patients	1 RCT[163] (N=1,120) 1 OBS[140, 173] (N=1,279)	1 of 1 RCT sample found no difference 1 of 1 OBS sample found no difference	Insufficient
ED costs	HNHC patients	1 RCT[163] (N=1,120) 1 OBS[175, 177] (N=574)	1 of 1 RCT sample found no difference 1 of 1 OBS sample had favorable findings	Insufficient
Mortality	HNHC patients	3 RCT[44, 160, 163] (N=2.343)	3 of 3 RCT samples found no difference	Low (No difference)

[a] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

ED = emergency department; HNHC = high-need, high-cost; N = number; OBS = observational study; RCT = randomized controlled trial.

Six studies reported various ED visit outcomes. The PWH RCT and KCCP RCT reported ED visits over the length of their interventions and did not observe significant differences between the intervention and comparison groups. The PWH RCT did observe a significant reduction in psychiatric ED visits. The four observational studies reported ED visits at 1 year. CSHP did not find a significant difference, but B2C reported a significantly greater reduction.[140, 142, 173] Both CMP and PAD observed fewer ED visits in the intervention group.[158, 175, 177] The mixed findings across the studies led to a grade of insufficient strength of evidence for ED visits (Table 19). Sevak et al. hypothesized that the difference between two Camden Core Model findings, the CSHP and B2C models, may reflect the Camden Core Model being more likely to have an effect among certain subpopulations, like the Medicaid population that B2C targeted and CSHP did not evaluate.[140, 173]

Five studies reported inpatient admissions. As observed for ED visits, the PWH RCT and KCCP RCT did not result in significant differences between the intervention and comparison groups. Among the three observational studies, we found a similar pattern as ED visits in the CSHP and B2C studies. CSHP again did not find a significant difference.[140, 173] In contrast, B2C reported a significantly greater reduction in inpatient admissions in the intervention group and, at 180 days, among patients with a comorbid mental health diagnosis.[142] Like CSHP, CMP did not observe a significant differences between groups.[158] The strength of evidence is insufficient for inpatient admissions because of inconsistent findings (Table 19).

Several of the studies examined changes in outpatient or primary care visits. For these outcomes, the study authors hypothesized that the intervention would result in reductions in inpatient admissions or ED visits and corresponding increases in outpatient or primary care visits in the intervention group (more appropriate type of care). We did not assess the strength of evidence of these outcomes because no two studies assessed the same measure. Although neither the PWH RCT nor the KCCP RCT observed significant reductions in overall ED visits or inpatient admissions, both reported favorable utilization changes related to outpatient mental health visits.[160, 163] The PWH RCT reported a significantly greater increase in the *number* of outpatient mental health visits in the intervention group, while the KCCP RCT reported a significantly greater increase in *any* outpatient mental health visits in the intervention group. The B2C community-based model examined changes in primary care visits. As the study authors had hypothesized, primary care visits significantly increased in the intervention group, while ED visits decreased. B2C found this result for the intervention group overall and among those with a comorbid mental health diagnosis.[142]

Cost Outcomes

Five of nine studies reported the effect of the intervention on costs over 6 or more months of followup (Appendix Table B-36). The KCCP RCT and two observational studies (CSHP and Familiar Faces) observed no significant difference in total costs.[140, 149, 163, 173] We graded total costs as insufficient strength of evidence (Table 19). The Camden RCT observed no significant difference in hospital costs.[44] The KCCP RCT also observed no significant difference in ED costs or inpatient costs.[163] PAD (rated high risk of bias) observed a significantly greater reduction in the intervention group in ED costs, while CSHP did not observe any differences in inpatient costs.[140, 175, 177] Changes in inpatient costs and ED costs were graded as insufficient strength of evidence.

Clinical and Functional Outcomes

Among the community-based studies, all three RCTs reported mortality (Appendix Table B-37). The three RCTs observed no significant difference in mortality rate from the comparison group.[44, 160, 163] We graded mortality as low strength of evidence for no difference (Table 19).

Social Risk Outcomes

Even though each of the three community-based RCTs reported key social risk outcomes, no two studies reported the same outcome. Among three social risk measures reported by the Camden RCT (Appendix Table B-38), the authors reported a significant increase in participation in the Supplemental Nutrition Assistance Program 6 months after discharge, but no difference in participation in Temporary Assistance for Needy Families or General Assistance.[44] The PWH RCT and KCCP reported several outcomes related to housing and criminal justice. In line with a housing intervention, the PWH RCT reported significantly more intervention group participants being ever housed and having fewer shelter days compared with comparison group participants but no difference between the groups in jail stays. The care management–focused KCCP RCT did not observe a difference between the treatment and comparison groups in homelessness, criminal convictions, or drug and alcohol treatment.

Emergency Department–Based Models

Overview

- ED-based models were reported in seven studies (7 samples). The interventions differed across studies. One RCT examined clinical case management, one RCT examined CHW care coordination, two RCTs and one observational study examined patient navigation, one observational study examined case management and housing support, and one observational study examining care coordination.
- We found a greater reduction in ED visits in the intervention group, based on consistent and precise evidence from four RCTs and two observational studies (moderate strength of evidence for favorable findings).
- We found a reduction in inpatient admissions, based on consistent and precise evidence from one RCT and one observational study (low strength of evidence for favorable findings).
- We found an increase in primary care visits, based on consistent and precise evidence from one RCT and one observational study (low strength of evidence for favorable findings).
- We found a greater reduction in ED costs, based on consistent evidence from three RCTs and one observational study (low strength of evidence for favorable findings).
- We found that ED-based models were not associated with a change in inpatient costs, based on evidence from two RCTs and one observational study (low strength of evidence for no difference).
- The evidence is insufficient to judge all other outcomes.

Detailed Results

Seven studies in seven publications, analyzing seven samples, reported on ED-based models. All were evaluated in comparison with usual care (Appendix Table B-39).[161, 162, 167, 169, 171, 176, 178]

This type of model is described as one in which patients are recruited in the ED, and often an ED-affiliated team provides care.[45]

Four of the studies were RCTs conducted at urban EDs.[161, 162, 167, 169] One RCT, the ED-initiated Patient Navigation (ED-PN) program (rated low risk of bias), identified Medicaid patients in the ED with high ED use (4 to 18 visits in 12 months). The ED-PN intervention provided patients with a patient navigator with the goals of improving healthcare access and ultimately decreasing ED visits, inpatient admissions, and costs.[161] The other three RCTs were rated some concerns for risk of bias. One of these RCTs also tested a patient navigation program (hence referred to as "ED navigation RCT"), examining whether a trained patient navigator could reduce ED use and costs and increase primary care appointments and satisfaction among ED patients with high ED use (5 or more visits in 12 months).[169] Another RCT assessed the effectiveness of clinical case management for frequent users of the ED.[167] The intervention focused on addressing psychosocial problems common among frequent ED users, including homelessness, alcohol problems, lack of health insurance and income, and psychiatric conditions. The fourth RCT assessed a pilot intervention that used CHWs to assist high-ED-use patients with care coordination and addressing social issues.[162]

One observational study, the Emergency Room Decision-Support (ERDS) program (rated some concerns for risk of bias), provided care coordination to patients with high ED use (3 or more visits in the past year), who were enrolled in the UnitedHealthCare AARP Supplement Insurance Plan.[171] Through the ERDS program, nurse care managers, available via telephone, discussed treatment options and provided assistance with making appointments and navigating health resources.[171]

The remaining two observational studies were rated high risk of bias. One of the studies assessed an ED navigation program, conducted across nine EDs in one healthcare system. CHWs provided navigational services to promote appropriate primary care use and prevent or reduce primary care–related ED (PCR-ED) use among Medicaid and uninsured patients.[176] PCR-ED visits were defined as visits for conditions that are preventable or treatable with appropriate primary care (e.g., did not require medical care within 12 hours, could be addressed by immediate care in a primary care clinic, or emergent needs that could have been prevented by routine primary care).

The other high risk-of-bias observational study evaluated an ED-based case management and homeless outreach program for high-use ED patients (5 or more visits annually for 2 consecutive years) who were chronically homeless and alcohol dependent. In addition to providing case management, this intervention aimed to help patients access housing resources. Notably, this study compared intervention patients with both a retrospective control group and a prospective control group.[178]

Intervention Characteristics

HNHC patient eligibility across these interventions required high service use, but it was defined differently across studies. In the ED-PN RCT,[161] high use was defined as having 4 to 18 visits in the prior 12 months, while the ED case management RCT and the ED navigation RCT defined high use as five or more ED visits in the prior 12 months.[167, 169] The CHW RCT identified high-ED-use patients as patients with the most ED visits in both the past 12 month and in the past 30 days.[162] The case management RCT further limited enrollment to patients with psychosocial problems that could be addressed with case management.[167] PCR-ED included frequent users of the ED for primary care who were covered by Medicaid, a Texas program that subsidizes medical costs for eligible residents, or were uninsured/self-pay.[176] The ED and housing observational study defined high use as five or more ED visits for 2 consecutive years and one ED visit in the last 6 months. This study also selected individuals who were undomiciled without shelter for 9 to 24 months.[178]

Common elements across the interventions included staff to help patients address health and social services needs and improve access to community resources. Each of the interventions included initial patient needs assessments, followed by case management or patient navigator services (Appendix Table B-40).

In the ED case management RCT, over a 24-month period, psychiatric social workers collaborated with nurse practitioners and primary care physicians to help patients obtain stable housing, income entitlements, and referrals to mental health and substance abuse treatment. Case managers also provided links to medical care, conducted assertive community outreach, and assisted in obtaining stable housing.[167]

Across the ED patient navigator interventions, the service intensity varied. The navigators in the ED navigation RCT interacted with patients at ED visits and subsequent to the initial visit and followed up by telephone within 2 weeks and 12 months of the initial ED visit. The navigators reviewed prescriptions and diagnoses with patients, arranged followup appointments, and identified relevant community resources.[169] In the ED-PN RCT, patients received more intensive patient navigation services. Patient navigators met with patients every 2 weeks for the first month, then every 4 weeks for the rest of the year.[161] The navigators helped patients access primary care, accompanied patients to primary care appointments, connected patients with community resources, and helped patients overcome personal barriers. In the CHW RCT, the ED-based CHW met with patients during their ED visits and subsequently used telephone and home visits to help patients coordinate care, including accessing primary care and identifying and addressing unmet social and behavioral needs that contributed to high ED use.[162] In the PCR-ED observational study, the CHWs called patients within 3 to 10 days of the initial ED visit. They educated patients on the importance of primary care and making and keeping appointments, helped patients identify specific barriers to seeking and getting primary care, and connected patients with community resources or healthcare providers.[176]

In the ERDS program, a nurse helped patients make connections with health resources and care coordination programs and make appointments with providers.[171]

In the ED and housing observational study, social workers and an outreach team met with patients during ED visits to help them follow their care plan to obtain housing.[178]

Intervention Outcomes

Utilization Outcomes

All seven studies reported on healthcare utilization (Appendix Table B-41). All studies found ED visits decreased in both the intervention and comparison groups. The reduction was significantly larger in the intervention groups in three of four RCTs.[161, 167, 169, 171, 176, 178] The ED-PN RCT, ED navigation RCT, ED case management RCT, and the ERDS observational study all found the reduction in the number of ED visits to be significantly larger among patients with high ED use in the 12 months before the intervention. The CHW RCT observed a reduction in ED visits in the intervention group compared with the comparison group but this difference was not statistically different between the groups.[162] In the high risk-of-bias ED and housing observational study, the reduction in ED visits in the intervention group was statistically different than the reduction in ED visits when compared with the prospective control groups but not statistically different when compared with the retrospective control group.[178] We graded the strength of evidence of a reduction in ED visits as favorable finding because of the consistent findings among all four RCTs and precise findings among three of four RCT studies (moderate strength of evidence) (Table 20; full strength-of-evidence decisions can be found in Appendix Table B-42).

Table 20. Summary of findings for ED-based models versus usual-care outcomes

Outcome	Population	# Samples/Design (n Analyzed)	Findings[a]	Strength of Evidence (Direction of Effect)
ED visits, all cause	HNHC patients	4 RCTs[161, 162, 167, 169] (N=728) 2 OBS[171, 178] (N=14,200)	3 of 4 RCT samples had favorable findings 1 of 4 RCT samples found no difference 1 of 2 OBS samples had favorable findings 1 of 2 OBS samples had favorable findings compared with one control group and no difference compared with one control group	Moderate (Favorable: reduction)
Inpatient admissions, all cause	HNHC patients	1 RCT[161] (N=100) 1 OBS[171] (N=14,140)	1 of 1 RCT sample had favorable findings 1 of 1 OBS sample had favorable findings	Low (Favorable: reduction)
Primary care visits	HNHC patients	1 RCT[169] (N=304) 1 OBS[171] (N=14,140)	1 of 1 RCT sample had favorable findings 1 of 1 OBS sample had favorable findings	Low (Favorable: increase)
Outpatient visits	HNHC patients	2 RCTs[161, 167]	2 of 2 RCT samples found no difference	Insufficient
ED costs	HNHC patients	3 RCTs[162, 167, 169] (N=628) 1 OBS[171] (N=14,140)	2 of 3 RCT samples had favorable findings 1 of 3 RCT samples found no difference 1 of 1 OBS sample found no difference	Low (Favorable: reduction)
Inpatient costs	HNHC patients	2 RCTs[162, 167] (N=324) 1 OBS[171] (N=14,140)	2 of 2 RCT samples found no difference 1 of 1 OBS sample found no difference	Low (No difference)
Hospital costs of care	HNHC patients	2 RCTs[161, 167] (N=352)	2 of 2 RCT samples found no difference	Insufficient
Outpatient costs	HNHC patients	1 RCT[167] (N=252) 1 OBS[171] (N=14,140)	1 of 1 RCT sample found no difference 1 of 1 OBS sample found no difference	Insufficient

[a] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

ED = emergency department; HNHC= high-need, high-cost; N = number; OBS = observational study; RCT = randomized controlled trial.

Differences in inpatient admissions were reported by the ED-PN RCT and the ERDS observational study. Both studies reported significantly greater reductions in inpatient admissions among the intervention group compared with the comparison group. We graded inpatient admissions to have favorable findings (low strength of evidence) (Table 20).

Three of the RCTs and one of the observational studies examined whether the intervention affected use of healthcare services beyond reductions in ED use. The ED navigation RCT observed greater use of primary care visits in the intervention group, suggesting that the navigation program may positively influence patients to seek more appropriate care.[169] Similarly, the ERDS observational study reported a smaller reduction in primary care visits in the intervention group than the comparison group. The study authors suggested that the intervention helped ED patients seek care in a more appropriate setting, away from ED and inpatient care toward physician office visits.[171] We graded the increase in primary care visits as a favorable low strength of evidence finding. In contrast, the case management RCT and the ED-PN RCT tested, but did not find, a difference between groups in outpatient visits (insufficient strength of evidence).[161, 167]

Cost Outcomes

The four RCTs and the ERDS study reported changes in cost (Appendix Table B-43). The ED navigation RCT and case management RCT found that ED costs decreased in both intervention and comparison groups but were significantly lower in the intervention group.[167, 169] Both the CHW RCT and the ERDS study also reported a greater reduction in the intervention group than the comparison group, this difference was not statistically significant,[162, 171] The precise and consistent evidence in two RCTs supported by consistent evidence in one other RCT and one observational study led to a grade of favorable findings (low strength of evidence) for ED costs (Table 20). In relation to inpatient costs, the CHW RCT, case management RCT, and the ERDS observational study did not find a difference between groups; we graded this outcome as low strength of evidence for no difference. The ED-PN RCT, case management RCT, and the ERDS observational study found no differences in outpatient costs and hospital costs of care (or the actual cost to hospital), and both outcomes were graded as insufficient strength of evidence.

Clinical and Functional Outcomes

The case management RCT, ED navigation RCT, and ED and housing observational study reported clinical and functional outcomes, but no outcomes were reported across studies. The case management RCT found no differences in psychiatric symptom scores (Appendix Table B-44).[167] The ED navigation RCT reported no difference in patient satisfaction.[169] The ED and housing observational study reported mortality rate but did not determine whether the difference was significant. Although no deaths were reported among intervention patients during the followup period, one participant death that occurred 4 months after the study may have been study related.[178]

Social Risk Outcomes

Only the case management RCT and ED and housing observational study reported social risk outcomes. The case management RCT found that homelessness and social security income outcomes were significantly better in the intervention group (Appendix Table B-45).[167] The ED and housing observational study reported higher accepted shelter rates in the intervention group.[178]

Ambulatory Intensive Caring Unit Model

Overview

- One RCT and two observational studies (three samples) reported on aICU models.
- aICU models were associated with a greater reduction in total costs (low strength of evidence for favorable findings).
- Evidence was insufficient to judge all other outcomes.

Detailed Results

Three studies in four publications, analyzing three samples, reported on aICU models (Appendix Table B-46).[139, 141, 146, 150] This type of model is a separate clinic or a team within a clinic that provides care to a panel of complex HNHC patients.[45] One study was an RCT (rated some concerns for risk of bias) in which five VA facilities compared an aICU intervention, the Patient Aligned Care Team-Intensive Management (PIM) intervention, with usual care, the PACT PCMH.[141, 150] The other two studies were observational designs. Both were rated some concerns for risk of bias. One observational study compared an aICU model within one integrated delivery system, called the Intensive Outpatient Clinic (IOC), with care received by historic controls, HNHC patients in the regular primary care clinic during an earlier period.[139] The second observational study compared an aICU model called Care One, implemented in one medical center, with usual care.[146]

Intervention Characteristics

HNHC patients were eligible for these interventions based on inpatient service use: in PIM, high use over a 6-month period[141, 150] and in IOC, high use over a 12-month period.[139] Care One eligibility was based on high inpatient cost, measured over a 12-month period.[146] PIM and Care One further selected participants based on the team's judgment that an individual would be responsive and benefit from the services of an aICU.

Across programs, intervention components included an initial assessment, followed by an array of care management and healthcare services (Appendix Table B-47). In all three interventions, service intensity could vary across participants. Some participants received a high level of services, including multiple face-to-face encounters, which may have been in the home. In contrast, other participants received no services. Thirty-seven percent of individuals in the PIM intervention group and 33 percent of individuals in the IOC intervention group had no intervention encounters.[139, 150] Both studies primarily attributed this to inefficiencies in targeting participants who would be a good match for the program. Care One also provided incentives to primary care physicians for accepting complex, Care One patients in their panels.[146]

Intervention Outcomes

Utilization Outcomes

Two of the three studies reported the effect of the intervention on changes in utilization, but the same outcome was not reported across both studies (Appendix Table B-48). The PIM RCT did not observe any differences between the intervention and control groups for acute medical/surgery inpatient stays, other inpatient stays (including psychiatric and substance use disorder stays), and ED visits but reported significant favorable increases in several outpatient care measures: primary care, care management, and mental health. The observational IOC study reported only on inpatient admissions, a significantly lower number of admissions in the IOC group than the comparison group.

Cost Outcomes

Each of the three studies reported the effect of the intervention on changes in total costs/charges (Appendix Table B-49). All three found reductions in both the intervention and comparison groups. In the PIM RCT, the difference in the reduction between the two groups was not significantly different. A significantly greater increase in outpatient costs (primary care, care management, and mental healthcare) in the PIM group was offset by a larger, but not significantly different, reduction in inpatient costs. In the two observational studies, IOC and Care One, the reduction was significantly greater in the intervention than in the comparison group (Appendix Table B-49). The consistent evidence across the three studies and precise evidence from the two observational studies led to a grade of favorable findings (low strength of evidence) for reduction in total costs (Table 21; full strength of evidence can be found in Appendix Table B-50).

Table 21. Summary of findings for aICU-based models versus usual-care outcomes

Outcome	Population	# Samples/Design (n Analyzed)	Findings[a]	Strength of Evidence (Direction of Effect)
Total costs	HNHC patients	1 RCT[141] (N=2,210) 2 OBS[139, 146] (N=5,183)	1 of 1 RCT sample found no difference 2 of 2 OBS samples had favorable findings	Low (Favorable: reduction)
Mortality rate	HNHC patients	1 RCT[141] (N=2,210) 1 OBS[139] (N=3,636)	1 of 1 RCT sample found no difference 1 of 1 OBS sample had favorable findings	Insufficient

[a] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

aICU = Ambulatory Intensive Caring Unit Model; ED = emergency department; HNHC = high need, high cost; N = number; OBS = observational study; RCT = randomized controlled trial.

Clinical and Functional Outcomes

Change in mortality was the only clinical or functional outcome reported across studies (Appendix Table B-51). Results were mixed. The PIM RCT found no difference between groups, while the IOC study found lower mortality in the IOC group than the comparison group (insufficient strength of evidence) (Table 21).

Only the PIM RCT reported on additional clinical and functional outcomes. The PIM participants had significantly better outcomes for measures of trusted relationship with providers and patient assessment of chronic illness care score. No differences were reported between the groups on measures of access to care or satisfaction with care.

Social Risk Outcomes

No social risk outcomes were reported among the aICU model studies.

Primary Care–Based Interventions

Overview

- Five RCTs and four observational studies, representing 10 samples, reported on primary care–based models.
- We found a greater reduction in the number of patients with an inpatient admission among primary care–based interventions, based on evidence from two RCT samples (low strength of evidence for favorable findings).
- We found a reduction in total healthcare cost among primary care–based interventions, based on evidence from four RCT samples and one observational sample (low strength of evidence for favorable findings). We calculated a pooled mean difference from three RCT samples that measured cost similarly (mean difference, -$3,848.43 [95% CI, -5,514.24 to -2,182.61]; 3 RCT samples; N=7,196; I^2=0.0%). The fourth RCT sample reported no significant difference between the groups but did not report an effect estimate. The observational study reported an increase in total cost, but the effect was not significantly different from the control group.
- We found a reduction in influenza vaccine uptake among primary care–based interventions, based on evidence from two samples (low strength of evidence for unfavorable findings).
- The evidence is insufficient to judge other utilization, cost, and clinical and functional outcomes.

Detailed Results

Primary care–based interventions were reported in 10 samples in nine studies, published in 11 publications. (Appendix Table B-52).[68, 151-154, 159, 166, 168, 174, 179] This type of model is one in which the intervention team is embedded in one or more primary care practices.[45] Usual care was the comparison in all analyses.

Five of the nine studies were RCTs.[68, 152, 159, 166, 168] One RCT (rated low risk of bias), Primary Intensive Care (PIC), was a case management intervention at one site, with a strong mental health focus, implemented for a clinically heterogeneous group of patients.[166] A second RCT, the Massachusetts General Hospital and Massachusetts General Physicians Organization (MGH) CMP (rated low risk of bias), a CMHCB demonstration site, aimed to provide comprehensive, practice-based outpatient case management for high-risk patients.[68] This RCT included two intervention group samples, an original and a refresh sample.[68] The third RCT (rated some concerns for risk of bias) tested whether primary care group visits would lower ED use among older adults with chronic conditions.[168] The fourth RCT (rated some concerns for risk of bias) examined a depression management program (DMP) for high users of outpatient visits.[152] The fifth RCT (rated some concerns for risk of bias) tested the impact of a complex care management (CCM) intervention at one site for HNHC Medicaid patients.[159]

Four of the nine studies were observational designs.[72, 151, 153, 154, 174, 179] The first (rated some concerns for risk of bias) compared enrollment in Hennepin Health (HH), a Medicaid risk-sharing ACO, with enrollment in other Medicaid MCOs.[153, 174] The Hennepin Health Accountable Care Organization (HH ACO) created a network of providers, clinics, and hospitals that coordinated care for their enrollees, including multidisciplinary care coordination teams in their primary care clinics. The HH ACO was available to all their Medicaid enrollees. We present only the findings specific to the HNHC patient population. One observational study (rated some concerns for risk of bias) assessed the impact of the Community-Based Care Management (CBCM) program, an MCO-led care coordination and disease management intervention, on HNHC Medicaid patients enrolled in the MCO.[179]

The other two observational studies were rated high risk of bias because neither analysis controlled for potential confounding.[151, 154] The first, Bridges to Health, was a primary care team–based intervention that included group visits and case management for patients with complex medical and behavioral problems.[151] The other was a small pilot program (N=21) testing the effect of a clinic-based interdisciplinary care teams for patients who frequently visited a family medicine residency clinic.[154]

Intervention Characteristics

The levels of high use or cost required for patient inclusion varied across studies. Four of the studies used high use criteria to identify eligible patients. Criteria included two or more hospitalizations in the past year in the PIC RCT,[166] four or more ED visits or two or more hospitalizations for the HH ACO,[153] six or more ED visits in the past year for Bridges to Health,[151] and eight or more clinic visits for the interdisciplinary pilot study.[154] Two studies required both high use and diagnosis of a condition. The group-visit RCT included patients with 11 or more outpatient visits in the past 18 months and at least one self-reported chronic condition,[168] while the DMP used a positive depression screen and a percentile threshold (i.e., number of outpatient visits above the 85th percentile in the previous 2 years).[152] The CBCM observational study included participants based on high cost, those who were in the top 10 percent of total cost for at least 1 month of the 24-month study period.[179] The MGH RCT used a combination of a cost threshold and high risk for future costs for its inclusion criteria (annual Medicare costs of $2,000 or more and an HCC risk score ≥2.0 or costs of $1,000 or more and an HCC risk score ≥3.0.[68] Finally, the CCM RCT used a more complex algorithm that identified patients through cost, use, and need. Patients were included if (1) they were in the top 5 percent of costs in the prior 12 months, top 5 percent of predicted costs in the subsequent 12 months, or through team nomination and (2) had two or more inpatient admissions, three or more ED visits, or two or more chronic conditions.[159]

The nine studies tested various approaches to delivering and paying for care for HNHC patients through primary care (Appendix Table B-53). All of the interventions integrated care management, case management, and care coordination into their primary care practices. Care managers or coordinators were central to many interventions and help communication and collaboration across multidisciplinary care teams. One RCT[168] and one observational study[151] tested the effectiveness of group visits, while two RCTs included home visits as needed.[68, 166] Interventions generally included efforts to educate patients on health topics and available resources, connect patients with community services to meet social and health needs, share information with other healthcare providers, and collaborate with specialists, such as psychiatrists. In the group-visit RCT and the clinic-based interdisciplinary care teams observational study, all interactions between the care manager and the patient were face-to-face.[154, 168] The other studies described one-on-one interactions occurring in person or via telephone. The MGH and HH ACO interventions tested alternative payment approaches (i.e., care management fees and shared savings) to incentivize efficiency and higher-quality care.[68, 153, 174]

Intervention Outcomes

Utilization Outcomes

All nine studies reported one or more measures of healthcare utilization (Appendix Table B-54).[68, 151-154, 166, 168, 174] Because the pilot interdisciplinary care teams observational study was very small (N=21), the authors reported only numeric differences between the intervention and comparison groups and not the precision of the differences. Findings for this study are not described in the text.[154]

Six samples from five studies reported on changes in the number of ED visits. Results were mixed. Three analyses (the MGH RCT refresh sample and the two group-visit studies [the group-visit RCT and the Bridges to Health observational study]) reported significantly fewer ED visits in the intervention group compared with usual care.[68, 151, 168] In contrast, the CBCM observational study reported significantly more ED visits in the intervention group compared with the comparison group.[179] Unlike the MGH RCT refresh sample, the MGH RCT original sample did not report a statistically significant difference between the two groups.[68] The PIC RCT, CCM RCT, and HH ACO did not report any significant differences between the intervention and comparison groups.[153, 159, 166, 174] Because of the mixed results across the samples, we graded the strength of evidence for reduction in ED visits as insufficient (Table 22; full strength of evidence can be found in Appendix Table B-55). Both MGH RCT samples also reported change in ACSC ED visits and found no significant difference between the groups (insufficient strength of evidence).[68]

Table 22. Summary of findings for primary care–based models versus usual-care outcomes

Outcome	Population	# Samples/Design (n Analyzed)	Findings[b]	Strength of Evidence (Direction of Effect)
ED visits, all cause	HNHC patients	5 RCTs[68, 159, 166, 168] (N=7,587) 4 OBS[151, 153, 154, 174, 179] (N=NR[a])	2 of 5 RCT samples had favorable findings 3 of 5 RCT samples found no difference 1 of 4 OBS samples had favorable findings 2 of 4 OBS samples found no difference 1 of 4 OBS samples had unfavorable findings	Insufficient
ED visits, ACSC	HNHC patients	2 RCTs[68] (N=6,943)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, all cause	HNHC patients	6 RCTs[68, 152, 159, 166, 168] (N=7,994) 3 OBS[153, 154, 174, 179] (N=NR[a])	4 of 6 RCT samples had favorable findings 2 of 6 RCT samples found no difference 1 of 3 OBS samples had favorable findings 1 of 3 OBS samples found no difference 1 of 3 OBS samples had unfavorable findings	Insufficient
Inpatient admissions, any	HNHC patients	2 RCTs[68] (N=6,943)	2 of 2 RCT samples had favorable findings	Low (Favorable)

Outcome	Population	# Samples/Design (n Analyzed)	Findings[b]	Strength of Evidence (Direction of Effect)
Inpatient admissions, ACSC	HNHC patients	2 RCTs[68] (N=6,943)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[68] (N=6,943)	1 of 2 RCT samples had favorable findings 1 of 2 RCT samples found no difference	Insufficient
Inpatient days	HNHC patients	1 RCT[159] (N=253) 1 OBS[153, 174] (N=NR[a])	1 of 1 RCT sample had favorable findings 1 of 1 OBS sample found no difference	Insufficient
Primary care visits	HNHC patients	2 RCTs[166, 168] (N=391) 2 OBS[153, 174, 179] (N=NR[a])	2 of 2 RCT samples found no difference 1 of 2 OBS samples found no difference 1 of 2 OBS samples had unfavorable findings	Insufficient
Outpatient visits	HNHC patients	1 RCT[152] (N=407) 1 OBS[154] (N=21)	1 of 1 RCT sample had favorable findings 1 of 1 OBS sample found no difference	Insufficient
Total cost	HNHC patients	4 RCTs[68, 159, 166] (N=7,292) 1 OBS[179] (N=3,048)	3 of 4 RCT samples had favorable findings 1 of 4 RCT samples found no difference 1 of 1 OBS sample found no difference MA-pooled mean difference: -$3,848.43 (95% CI, -5,514.24 to -2,182.61); 3 RCT samples; N=7,196; I^2=0.0%	Low (Favorable)
Mortality rate	HNHC patients	2 RCTs[68] (N=6,943)	1 of 2 RCT samples had favorable findings 1 of 2 RCT samples found no difference	Insufficient
Influenza vaccine	HNHC patients	2 RCTs[68] (N=6,943)	2 of 2 RCT samples had unfavorable findings	Low (Unfavorable)
HbA1c test	HNHC patients, Diabetes subgroup	2 RCTs[68] (N=1,959)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, Diabetes subgroup	2 RCTs[68] (N=1,959)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[68] (N=1,923)	2 of 2 RCT samples found no difference	Insufficient

[a] The HH ACO[153, 174] study did not report sample sizes for their HNHC populations; the total sample size for the study was 92,891. The sample size for CBCM[179] was 3,048, 21 for the interdisciplinary pilot,[154] and 72 for Bridges to Health.[151]

[b] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

ACSC = ambulatory care sensitive conditions; CBCM = Community-Based Care Management; ED = emergency department; HbA1c = hemoglobin A1c; HH ACO = Hennepin Health Accountable Care Organization; HNHC= high-need, high-cost; IVD = ischemic vascular disease; LDL = low-density lipoprotein; MA = meta-analysis; N = number; OBS = observational study; RCT = randomized controlled trial.

Significantly greater reductions in the number of inpatient admissions in the intervention group were observed in five analyses: both MGH RCT samples,[67, 68] the group-visit RCT,[168] the CCM RCT,[159] and the HH ACO observational study.[153, 174] In contrast, the CBCM observational study reported significantly more inpatient admissions in the intervention group compared with the comparison group.[179] The PIC RCT and DMP RCT did not find significant differences in inpatient admissions.[152, 166] Because of the mixed results across the samples, we graded the strength of evidence for reduction in the number of inpatient admissions as insufficient (Table 22).

Both MGH RCT samples also reported whether patients had any inpatient admissions. Both samples reported a greater reduction in the number of patients having an inpatient admission in the intervention group compared with the comparison groups.[68] Based on consistent and precise evidence we graded the reduction in the probability of an inpatient admission as low strength of evidence for a favorable findings (Table 22).

The CCM RCT and the HH ACO reported on the number of inpatient days. The CCM RCT found a greater reduction in the number of inpatient days in the intervention group compared with the comparison group, while the observational HH ACO[153, 159, 174] did not report a different between the two groups. Based on mixed findings, we graded inpatient days as insufficient strength of evidence.

Evidence on ACSC inpatient admissions was also limited to the two MGH RCT samples. Both analyses found no significant difference in the number of admissions between the two groups.[68] However, in relation to any ACSC inpatient admissions, the original sample reported a greater reduction in number of patients with an ACSC inpatient admission in the intervention group, while the refresh sample reported no difference.[68] We graded both measures of ACSC inpatient admissions as insufficient strength of evidence.

Some of the studies also sought to determine if the interventions would increase use of outpatient office visits. Increases in office visits, coupled with reductions in ED and hospital visits, could indicate that the intervention resulted in patients seeking care in more appropriate settings. However, we found no significant differences in primary care visits compared with usual care across three studies (PIC RCT, group-visit RCT, and HH ACO)[153, 166, 168, 174] and significantly fewer primary care visits in the intervention group compared with the comparison group in the CBCM observational study.[179] These mixed findings led to a rating of insufficient strength of evidence (Table 22). Study authors of the CBCM observational study had not expected to see reductions in primary care visits because intervention patients received care coordination and disease management in outpatient settings.[179]

Consistent with the intervention's goal of improving primary care access for mental health patients, the DMP RCT reported favorable, increased use of outpatient visits, antidepressant prescriptions, and specialty mental health visits among intervention patients.[152] The interdisciplinary care team observational study also reported a positive effect on outpatient visits, but the sample was too small to report on precision. We graded the limited evidence to be insufficient.

Cost Outcomes

Cost outcomes were reported in four studies, representing five samples (Appendix Table B-56).[68, 159, 166, 179] The MGH RCT reported that increases in per-beneficiary per-month (PBPM) costs were significantly smaller in the intervention group than the comparison group in both the original sample and refresh samples.[68] Similarly, the CCM RCT reported a significantly lower annual total cost for the intervention group compared with the comparison group.[159] In contrast, the PIC RCT and the CBCM reported no differences in total cost between the two groups; the PIC RCT did not report a specific effect estimate.[166, 179] The pooled mean difference for annual total cost was -$3,848.43 (95% CI, -5,514.24 to -2,182.61; 3 RCT samples; N=7,196; I^2=0.0%) (Appendix Figure B-9). This evidence led to a grade of low strength of evidence for favorable findings for total cost (Table 22).

Clinical and Functional Outcomes

Clinical and functional outcomes were reported in three RCTs, representing four samples (Appendix Tables B-57 and B-58).[68, 152, 166] However, only the two samples of the MGH RCT reported the same outcomes.

In the MGH RCT, mortality rate and receipt of an influenza vaccine were measured in both the original and refresh samples.[68] The MGH RCT refresh sample reported a lower mortality rate in the intervention group, while the original sample did not observe any significant differences between groups. This mixed evidence led to a grade of insufficient strength of evidence for mortality (Table 22). For influenza vaccine, the vaccination rate increased for both the intervention and comparison groups, but the rate increased less for the intervention group. The study authors explained that this finding may be due to the much higher baseline rate in the intervention group compared with the comparison group.[68] The evidence led to a rating of low strength of evidence for unfavorable findings for likelihood of receiving an influenza vaccine (Table 22).

The MGH RCT also reported on nine outcomes assessed through a self-report survey from a more limited sample of 590 respondents. The survey reported significantly better outcomes for the intervention group in relation to discussion of treatment choices and communication with providers.

In the MGH RCT, subgroup analyses were conducted in the refresh and original samples.[68] No differences were found between groups for the following tests: HbA1c tests among diabetics, LDL-C test among diabetics, and LDL-C test among IVD patients (insufficient strength of evidence) (Table 22).

Social Risk Outcomes

Evidence on social risk outcomes was limited to one study (Appendix Table B-59). No differences were found between intervention and comparison groups in overall patient well-being in the interdisciplinary care team observational study.[154]

Home-Based Care Models

Overview

- One RCT with two samples and two observational studies, representing four samples, reported on home-based care models. Three samples were rated as having moderate risk of bias and one of the observational studies was rated high risk of bias.

- We found reductions in ACSC inpatient admissions among home-based care interventions. Based on evidence from two RCT samples and one observational sample, we found a reduction in the number of patients with any ACSC inpatient admissions (low strength of evidence for favorable findings). Based on evidence from two RCT samples, we also found a reduction in the number of ACSC inpatient admissions (low strength of evidence for favorable findings).
- We found no difference in the mortality rate, based on evidence from two RCT samples and one observational study (low strength of evidence for no difference).
- We found an increase in influenza vaccine uptake among home-based care intervention participants, based on evidence from two samples (low strength of evidence for favorable findings).
- The evidence is insufficient to judge all other outcomes.

Detailed Results

Home-based care models were reported in three studies with four samples in three publications. All were implemented for Medicare populations (Appendix Table B-60).[67, 72, 180] This type of model provides care in the home for patients who have difficulty leaving or who are unable to leave their homes.[45] Usual care was the comparison for all analyses.

One study was an RCT (rated some concerns for risk of bias) called Care Level Management (CLM) in which a care management organization in three states provided patients with multiple chronic conditions with physician home visits by a personal visiting physician that complemented care from their primary care practice.[67] CLM was a Medicare CMHCB Demonstration intervention. Two study populations were assessed: an original sample and a refresh sample.[67]

The other two studies are related to the IAH observational intervention. As previously mentioned in the System-Level Transformation section, CMS's IAH demonstration (rated some concerns for risk of bias) supported primary care at home for Medicare FFS patients who were chronically ill and functionally limited by providing financial incentives to home-based primary care practices.[72] The study analyzed two components of the model, the effectiveness of a demonstration payment incentive (included in the System-Level Transformation section) and the effectiveness of a home-based primary care services model (included in this section). In the home-based care services model, the IAH home-based primary care service was evaluated to determine if receipt of home-based primary care resulted in lower costs.[72] The analysis compared patients who newly received home-based primary care with patients who did not receive these services.[72]

The final observational study (rated high risk of bias) evaluated whether patients receiving home-based care with integrated long-term services and supports (LTSS) at three IAH practices had lower long-term institutionalization and mortality. The intervention group was compared to two comparison groups of patients who received care at non-intervention practices, concurrent patients who did not receive home-based care and concurrent patients who received home-based care.[180]

Intervention Characteristics

Across studies, HNHC patients eligibility for home-based primary care was based on hospital use over a 1-year period.[67, 72, 180] In the CLM RCT original sample, patients were eligible if they had two or more hospitalizations in the past 12 months, Medicare costs in the top 5 percent, high risk of future costs (high HCC risk score), and a chronic condition diagnosis.[67] In the CLM RCT refresh sample, the eligibility criteria were simplified; patients were eligible if they had two or more hospitalizations in the past 12 months. Patients with select psychosocial problems, such as drug/alcohol dependence or bipolar disorders, were explicitly excluded from the refresh sample.[67]

As a result of sample size concerns, the IAH home-based primary care analysis was expanded from Medicare patients at IAH practices to include all Medicare patients new to home-based primary care residing in the same region as IAH practices. These patients were not required to receive their home-based care from an IAH practice. For this review, we present the home-based primary care findings that include only patients who received home-based care from an IAH practice. In addition to being new to home-based primary care in an IAH region, Medicare patients were eligible for the IAH home-based primary care analysis if they had two or more chronic conditions, two or more difficulties in performing activities of daily living that require human assistance, a hospitalization and use of acute rehabilitation services in the previous 12 months, and the majority of their office visits took place at home or in an assisted living facility after the first home-based primary care visit.[72]

For the LTSS study, patients were eligible for inclusion if they were enrolled in one of three IAH sites, had two or more chronic conditions, had a hospitalization and used acute rehabilitation services in the previous 12 months, and had a JEN Frailty Index (JFI) score of six or higher.[180] The LTSS study differed from the IAH study by using the JFI to determine eligibility instead of an assessment of activities of daily living because the activities of daily living data were not available.

Across the studies, intervention components included an initial assessment, followed by face-to-face care management and medical care (Appendix Table B-61). Participants received care coordination and referral to community-based support services, as needed. Within each of the interventions, the intensity of services received varied across individual patients. In the CLM RCT, 75 percent of participants had one or more physician home visits. Eighty-eight percent received a telephone call from a nurse or physician, with 39 percent receiving 20 or more calls. Twelve percent of those enrolled received no contact from the intervention.[67] The IAH study tested a team-based primary care model for delivering home-based care. Clinician workload consisted of anywhere from 3 to 15 home visits per day, with the intensity of care per patient based on clinician judgment or patient risk stratification. A clinician was available for participants at all hours and used electronic health information systems to help provide comprehensive care.[72] The intensity of the home-based intervention provided to the patients in the LTSS study was not reported.[180] The three practices provided patients with integrated care coordination and community support using care managers or social workers who were part of a larger, interdisciplinary team.

Intervention Outcomes

Utilization Outcomes

Three of four samples reported the effect of the intervention on changes in healthcare utilization (Appendix Table B-62). Neither the two CLM RCT samples nor the IAH home-based care sample found a significant difference in change in ED visits when compared with a comparison group.[67, 72] Imprecise findings led to a grade of insufficient strength of evidence (Table 23; full strength of evidence can be found in Appendix Table B-63). Similarly, no significant differences in ACSC ED visits were observed in any of the three samples. The imprecise evidence led to a grade of insufficient strength of evidence (Table 23).

Table 23. Summary of findings for home-based care–based models versus usual-care outcomes

Outcome	Population	# Samples/Design (n Analyzed)	Findings[a]	Strength of Evidence (Direction of Effect)
ED visits, all cause	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[72] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS sample found no difference	Insufficient
ED visits, ACSC	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[72] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS sample found no difference	Insufficient
Inpatient admissions, all cause	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[72] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS sample had unfavorable findings	Insufficient
Inpatient admissions, ACSC	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[72] (N=181,001)	2 of 2 RCT samples had favorable findings 1 of 1 OBS sample found no difference	Low (Favorable)
Inpatient admissions, any all cause	HNHC patients	2 RCTs[67] (N=34,421)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[67] (N=34,421)	2 of 2 RCT samples had favorable findings	Low (Favorable)
Total cost	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[72] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS sample had unfavorable findings	Insufficient
Total cost	HNHC patients, high risk patient subgroup	2 RCTs[67] (N=15,400)	2 of 2 RCT samples found no difference	Insufficient
Total cost	HNHC patients, high cost only patient subgroup	2 RCTs[67] (N=5,758)	2 of 2 RCT samples found no difference	Insufficient
Mortality	HNHC patients	2 RCTs[67] (N=34,421) 1 OBS[180] (N=1,376)	2 of 2 RCT samples found no difference 1 of 1 OBS sample found no difference	Low (No difference)
Influenza vaccine	HNHC patients	2 RCTs[67] (N=34,421)	2 of 2 RCT samples had favorable findings	Low (Favorable)
Oxygen saturation test	HNHC patients, COPD subgroup	2 RCTs[67] (N=8,079)	2 of 2 RCT samples found no difference	Insufficient
HbA1c test	HNHC patients, Diabetes subgroup	2 RCTs[67] (N=10,452)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, Diabetes subgroup	2 RCTs[67] (N=10,452)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[67] (N=14,910)	2 of 2 RCT samples found no difference	Insufficient

[a] Findings were determined to be favorable or unfavorable based on the intent of the intervention. For example, if the intent of the intervention was to lower total cost, then a greater increase in total cost among intervention group patients compared with comparison group patients was classified as unfavorable. Similarly, changes in utilization may be identified as favorable or unfavorable depending on the intent of the intervention and the specific outcome. For studies that intended to reduce ED visits and shift service use to primary care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfavorable, while an increase in primary care visits would be favorable.

ACSC = ambulatory care sensitive conditions; COPD = chronic obstructive pulmonary disease; ED = emergency department; HbA1c = hemoglobin A1c; HNHC= high-need, high-cost; IVD = ischemic vascular disease; LDL = low-density lipoprotein; N = number; OBS = observational study; RCT = randomized controlled trial.

Neither of the two CLM RCT samples found differences from comparison groups for all-cause inpatient admissions.[67] In contrast, the IAH home-based care intervention group had an unfavorable, greater increase in all-cause inpatient admissions than the comparison group.[72] The strength of evidence was graded as insufficient because of mixed findings. Neither of the CLM RCT samples found a difference from the comparison group in having any inpatient admissions (insufficient strength of evidence).

In relation to ACSC inpatient admissions, the two samples of the CLM RCT reported significantly greater reductions in ACSC admissions in the intervention than the comparison group. In contrast, the IAH home-based care sample did not find a difference between the groups.[72] This consistent but imprecise evidence led to a rating of favorable findings for the number of ACSC inpatient admissions (low strength of evidence) (Table 23). Both samples of the CLM RCT also reported significantly greater reductions in the number of patients with an ACSC admissions in the intervention group than the comparison group. This consistent and precise evidence led to a rating of favorable findings for the number of patients with an ACSC inpatient admission (low strength of evidence) (Table 23).

Cost Outcomes

Three of four home-based samples reported on the effect of the intervention on cost (Appendix Tables B-64 and B-65). The two RCT samples found that the home-based care interventions did not significantly change total costs.[67, 72] In the IAH home-based primary care sample, total cost was higher among the IAH intervention group than the comparison group, indicating that the intervention increased Medicare costs relative to office-based care.[72] IAH study authors noted that intervention patients had higher costs in inpatient, physician or supplier, and hospice services, suggesting substantial differences not only in total costs, but in the mix of services paid for in the IAH intervention group relative to the matched comparison group.[72] We graded the evidence as insufficient because of imprecision (Table 23).

The CLM RCT also reported cost outcomes for population subgroups. In both samples, the total cost did not differ between the intervention and comparison groups within a high-cost, high-risk subgroup and a high-cost-only subgroup. We graded the total cost outcome as insufficient strength of evidence in both subgroups because of imprecision (Table 23).

Clinical and Functional Outcomes

In relation to clinical outcomes, change in mortality was reported in both the CLM RCT original sample and refresh sample and the LTSS study. Differences between the intervention and comparison groups were not significantly different, and we graded mortality as low strength of evidence for no difference (Appendix Tables B-66 and B-67).[67, 180] Several additional clinical and functional outcomes were reported for both RCT samples (Table 23). The CLM RCT original and refresh samples reported significantly greater increases in the rate of influenza vaccines in the intervention group. The consistent and precise evidence led to a rating of low strength of evidence for favorable findings (Table 23). Among surveyed original sample patients, significantly better outcomes for the intervention group were found for three additional measures: discussing treatment choices, communicating with providers, and doing 30 minutes of continuous physical activity.[67] No significant differences were found in relation to other measures.[67]

Social Risk Outcomes

No social risk outcomes were reported among the home-based care model studies.

Chapter 4. Discussion

Overview

In this review, we sought to inform policy and clinical practice about how to identify high-need, high-cost (HNHC) patients, who are some of the heaviest and costliest users of healthcare, and reduce their inappropriate healthcare use through answering three Key Questions (KQs). To answer KQ 1, we summarized the evidence from studies that sought to identify HNHC patient characteristics. A goal of the KQ 1 review was to inform the selection of patients for interventions that target HNHC patients. KQs 2 and 3 both examined interventions for HNHC patients but used different review approaches. KQ 2 used a realist review approach to develop theories, supported by evidence, to explain the mechanisms in complex interventions, in various contexts, that are instrumental to interventions changing HNHC patient healthcare use and quality. KQ 3 used a systematic review approach to summarize the evidence of the effectiveness of interventions that either focus solely on HNHC patients or include outcomes for HNHC patients as a subgroup of a larger initiative.

Below we present a separate discussion of our findings for each of the three KQs, followed by the strengths and limitations of the evidence, and the implications of our findings.

KQ 1: Identifying HNHC Patients

KQ 1 presents a synthesis of studies that examine characteristics of HNHC patient populations. An important assumption in identifying or predicting which patients will be HNHC (high users of preventable or modifiable healthcare) is that it is possible to distinguish between high use that is emergent and appropriate (particularly in the emergency department [ED] and inpatient) from use that is preventable or modifiable. If studies can isolate preventable or modifiable use, this information can be used to target specific groups of individuals for whom a reduction in its overuse is an appropriate goal.

We used a broad definition of HNHC to help ensure that we did not miss relevant studies. Studies that met our inclusion criteria for KQ 1 considered preventable or modifiable healthcare using different approaches. The most common approach was to simply identify the highest users, individuals with the most frequent care or highest cost of care. This approach assumes that individuals with high use or cost, above a particular threshold, are likely to be using some care inappropriately. These studies differed considerably in the thresholds they used to identify high use or cost. Studies that used a somewhat more refined approach to examining high use or cost excluded specific patient populations or diagnoses. Among these excluded patients, use of services or costs may be high but transient and unlikely to be modifiable, such as services related to pregnancy and elective surgery.

We identified a small number of studies that sought to define preventable or modifiable care more directly. Two studies examined the characteristics of patients with multiple ED visits who were triaged as being least urgent. However, the researchers found that frequent and less frequent users did not differ in their reports of why they used the ED. Another study distinguished individuals with higher-than-expected costs (rather than just those with the highest costs). These researchers found a positive correlation across consecutive years among individuals having higher than expected costs and a strong positive correlation between higher-than-expected costs and potentially preventable hospital readmission and ED visits.[76, 207] We found no quantitative studies that sought to distinguish which of a patient's individual visits might be considered preventable or modifiable and those that would be considered necessary.

The evidence for KQ 1 consists of 60 studies, including exposure, cluster, and qualitative analyses. The exposure studies used regression analyses to examine patient and health system characteristics associated with high use or cost of healthcare (being HNHC). Some exposure studies were considered predictive; that is, high cost or use outcomes were measured in a subsequent period. Others were cross-sectional designs. All exposure studies controlled for confounding variables but the selection of confounding variables differed across studies. Cluster analyses seek to identify "hidden" or unobservable groupings using observed variables and can aid in choosing HNHC patients to include together in interventions. Qualitative studies provide personal experience and informed opinion.

We used the "best fit" framework synthesis approach to organize our KQ 1 findings.[48] The "best fit" framework is a method for testing and building on an existing model. We selected the framework developed by the National Academy of Medicine (NAM), included in their publication *Effective Care for High-Need Patients: Opportunities for Improving Outcomes, Value and Health*.[20] As discussed in Chapter 1, the NAM framework provides a taxonomy for identifying HNHC patients. Of six clinical and functional categories, four were relevant to our review: 1) nonelderly disabled, 2) multiple chronic conditions, 3) major complex chronic conditions, and 4) frail elderly. The NAM framework further recognizes the potential impact of behavioral health factors (i.e., substance use, serious mental illness, cognitive decline, and chronic toxic stress) and social risk factors (i.e., low socioeconomic status, social isolation, community deprivation, and housing insecurity). Behavioral health and social risk factors are not stand-alone categories in the NAM framework but factors that span across, affect, and are affected by all the clinical and functional categories.

We found patterns of support for the association between some characteristics and HNHC patient outcomes. Prior high use and cost were consistent and strong predictors of the same, particularly in relation to ED visits and cost. Based on cluster analysis, frequent ED patients with chronic conditions and mental illness were found to form a distinct group, characterized by having the most frequent visiting pattern. Specific complex chronic conditions, such as congestive heart failure, chronic obstructive pulmonary disease, cardiovascular disease, dementia, and diabetes, were positively associated with high use and cost. Cluster analysis also identified frailty as a distinct clinical profile. Patients' scores on self-assessment tools were associated with high use.

We found consistent support for the importance of behavioral health risk factors across diagnostic and functional groups. Co-occurring mental health conditions (most notably, depression) and substance use disorder (SUD) were positively associated with high use across analyses. The results for serious mental illness (SMI) and alcohol use disorder (AUD) were mixed. However, one qualitative study clarified that unmet behavioral health needs and poorly managed SMI, not just the presence of SMI, were significant drivers of preventable high levels of healthcare use among HNHC patients.

We also found support for the consideration of social risk factors in identifying HNHC patients. Housing insecurity was a consistent predictor, while the role of poverty varied based on whether it was measured directly or at the neighborhood level. Among multipayer and population-based studies, Medicaid and Medicare coverage were predictive of high healthcare use compared with commercial coverage.

Several demographic characteristics were independent risk factors. Generally, being a HNHC patient is positively associated with older age. However, in the Medicare population, being a nonaged disabled enrollee was a greater risk, particularly in relation to ED use, where the youngest adult groups were more likely to have the highest use. Black race, compared with white race, was also a risk factor for higher ED use and lower inpatient use, controlling for other characteristics including poverty.

Final Framework in Relation to the NAM Taxonomy

On the whole, our findings supported NAM's taxonomy for identifying HNHC patients.[20] We found general support for the four NAM clinical and functional groups: nonelderly disabled, multiple chronic conditions, major complex chronic condition, and frail elderly. Our findings support that chronic conditions, disability, and frailty are associated with HNHC.

The effect of having multiple chronic and major complex chronic conditions proved difficult to assess. While the multiple chronic condition group is defined as having only one complex chronic condition (e.g., acute myocardial infarction, ischemic heart disease, chronic kidney disease, congestive heart failure) and/or between one and five noncomplex chronic conditions (e.g., arthritis, immune disorders, cancer, inflammatory bowel disease), the studies we reviewed included an inconsistent list of single conditions and assessed their independent and individual impacts on high use or cost outcomes. Some studies included a count of conditions and found a greater number to be positively related to higher use or cost. No study included interaction terms or other methods to assess the effect of having a combination of specific chronic conditions on outcomes.

We found evidence consistent with the NAM framework's support for the overarching role of behavioral health and social needs. The NAM framework acknowledged that "addressing clinical needs alone will not improve outcomes or reduce costs for this population"[185, p. 3] and that it is "necessary to address an individual's functional, social, and behavioral needs."[185, p. 4] Similarly, our review found that behavioral health factors, including mental health and SUD and social risk factors, particularly homelessness, have a central role in contributing to high healthcare use and cost.

In our final framework, we support the NAM taxonomy but we expand it to include several additional dimensions, prior healthcare service use and race. Although research has shown that regression to the mean (ebbs and flows of individual healthcare use) can limit the ability of prior use to predict future use, prior use was still the strongest predictor across studies. Considerations include identifying high use setting (e.g., ED, inpatient) and patterns of behavior, (i.e., chronic over multiple periods or more short-term groups or episodes of care).

We also found that race, particularly black compared with white race, was an independent predictor of high use (ED) or low use (inpatient), controlling for other characteristics, including income. Including race and ethnicity in a taxonomy could help focus attention on the role of structural racism in the healthcare system on access to care.

KQ 2: Understanding How and Why HNHC Patient Interventions Work

To answer KQ 2, we used a realist review approach to present theories, supported by evidence, to explain the mechanisms in complex interventions, in various contexts, that are intended to change HNHC patient healthcare use and improve their quality of care. To our knowledge, we have conducted the first realist review of interventions for HNHC patients. Most of the information we used to develop our theories was gathered from descriptive and qualitative findings concerning the interventions included in our KQ 3 effectiveness review and, to a lesser extent, KQ 1 studies that identified HNHC patient characteristics. Therefore, our findings from the realist review and systematic review are intended to be synergistic and informative to each other.

We developed three program theories, considering evidence from 49 studies. Overall, we found that individualization was a key theme, both in identifying participants for HNHC patient interventions and in developing the service mix of the interventions. Unlike disease management interventions that focus on one condition,[208] including patients with a heterogeneous mix of chronic diseases in interventions for HNHC patients was not considered a barrier. A key was identifying and addressing individual participant complexity, both in terms of chronic disease profile and risk factors that affect access to care (Program Theory 1). Unsurprisingly, providers expressed challenges in motivating this population to obtain adequate medical treatment for their chronic conditions. However, central to the interventions was the importance of building trusting relationships between patients and providers (Program Theory 2). Trusting relationships are considered key to being able to support and educate patients to gradually take on greater responsibility for self-managing their chronic conditions and to navigate other systems to address their behavioral health needs and social risk factors. The findings also suggest that successfully changing patients' behavior requires significant investments in staff time. Relationships require time to develop, and care providers are unlikely to successfully modify patients' long-held approaches to care, if the time allotted for the intervention is not sufficiently long. Evaluations measuring the impact of interventions may need to assess intermediate outcomes or extend their followup time.

Care providers cautioned that they feel significant stress because of the greater time and resources needed to provide and coordinate the care of HNHC patients. Although they believed that having additional time was necessary to serve this population, they often found that patients needed psychosocial and emotional support rather than medical care. Intervention sustainability is supported by supplementary processes and structures that protect and support care providers (Program Theory 3). Strategies may include healthcare system–wide modifications such as using payment models that provide higher reimbursements for sicker patients, gaining provider buy-in, redistributing workloads across staff members, and providing emotional and technical support for providers.

KQ 3: Assessing the Effectiveness of Interventions for HNHC Patients

To answer KQ 3, we conducted a systematic review of the evidence from 40 studies of the effectiveness of interventions for HNHC patients compared with usual care. For our synthesis, we categorized the studies into seven groups based on the intervention's primary setting. The largest number of patient samples was of primary care–based models (N=10), followed by telephonic/mail models and community-based models (both N=9), ED-based models (N=7), system-level transformation models (N=5), home-based models (N=4), and ambulatory intensive caring unit–based models (N=3). We found moderate to low strength evidence to support intervention effectiveness in relation to a small number of outcomes in some settings. We found the evidence for most outcomes across settings to be insufficient because of no or limited evidence or inconsistent results across studies.

ED-based models tended to have the most straightforward and least complex design. Interventions generally were conducted in the ED (a single setting). Interventions identified participants in the ED based on high frequency of ED use, and most provided all services in the ED as well. We found moderate strength of evidence that these interventions were able to reduce ED visits and low strength of evidence that they reduced ED costs. We also found low strength of evidence that ED interventions shifted service use and resulted in reduced inpatient admissions and increased primary care visits. However, we also found low strength of evidence that the intervention and comparison groups were not significantly different in relation to inpatient costs.

Primary care–based models all included multidisciplinary care teams to coordinate care, but they were otherwise more heterogenous in intervention design than ED models (e.g., some studies incorporated groups visits,[151, 168] while others included home visits[68, 166]). We found low strength of evidence that interventions for HNHC patients set in primary care were associated with reductions in inpatient admissions and, in turn, costs.

Ambulatory intensive caring unit models, interventions that provide care through a separate intensive clinic or intensive team within a clinic, were associated with a reduction in total costs (low strength of evidence). However, the evidence was insufficient to assess what changes in utilization explain the reductions.

Evidence about home-based care models was from two large and complex Centers for Medicare & Medicaid Services (CMS)–funded interventions. We found low strength of evidence that home-based care was associated with a reduction in inpatient admissions for ambulatory care sensitive conditions (ACSC), an increase in the uptake of influenza vaccinations, and no difference in mortality. Because ACSC admissions are a quality indicator for preventable admissions,[209] our findings suggest that home-based care models may reduce utilization of preventable and modifiable services. The evidence was insufficient to determine if the reduction in admissions also resulted in a reduction in costs.

Community-based models largely provide patients with services outside of the healthcare system. These interventions were heterogenous in design and in the patients they served. The community-based interventions took on the additional challenge of addressing participants' cross-sector nonmedical issues by helping them navigate access to community resources and social services, including one study that evaluated the impact of housing and criminal justice involvement.[160] The community-based models included three samples that tested the highly regarded Camden Core Model hotspotting intervention that used data to identify HNHC patients and provided them with intensive, relationship-based assistance.[44, 140, 142, 173] We found low strength of evidence that community-based models were associated with no difference in mortality. We were unable to judge the benefit for any cost or utilization outcomes because of imprecise and mixed findings.

For both system-level transformation and telephonic/mail models, we found low strength of evidence that cost-of-care outcomes were not significantly different in the intervention and comparison groups. For telephonic/mail models, we also found low strength of evidence that ED visits, inpatient admissions, and mortality did not differ between the groups. The evidence for these system-level transformation models was insufficient to judge all other outcomes.

All of the system-level transformation studies were funded by CMS and reflect the challenges of successfully assisting HNHC patients while meeting goals related to a broader patient population. These models were large-scale interventions that targeted an entire patient population of clinics and physician practices. The studies include evaluations of the

Comprehensive Primary Care Initiative (CPC) and CPC+. Except for the Independence at Home (IAH) study, HNHC patients were not similarly targeted for services across system-level transformation study sites.

In telephonic/mail models, the intervention was often initiated by a health plan and usually provided patients with services that were supplemental to those received from their primary providers. Given our realist review finding that providing opportunities for care team members to have face-to-face conversations about and with HNHC patients is an important context for the success of interventions, the lack of adjunct, integrated services embedded in patients' sites of care, and limited program intensity, may have presented a challenge to these telephonic/mail models.

In our analytic framework, we hypothesized that harms from interventions may arise from patients encountering increased barriers to accessing necessary care or providers experiencing insufficient resources or time to facilitate effective interventions. In our realist review, we identified insufficient provider resources and time as an important barrier to provider engagement and a key consideration when designing interventions for HNHC patients. However, in our KQ 3 review, no studies reported on participant harms. Therefore, we could not determine whether a lack of harms was related to lack of measurement or due to the true lack of harms. The sole exception was an incidental finding in one primary care intervention with two samples; the study found intervention participants to be less likely to receive an influenza vaccine than patients in usual care.[68] However, the difference was relative. The rates in both groups increased during the period of the intervention. The intervention leaders commented that they did not believe that this quality measure was a good reflection of the intervention's ability to provide care management services to HNHC patients.

Strengths and Limitations

Our review questions examined a breadth of issues concerning HNHC patients, from their identification to how interventions work to outcomes from these interventions. We used three methodological approaches to answer our three KQs. Each of these approaches, separately and considered across KQs, brings unique strengths and weaknesses to our findings.

KQ 1

For the KQ 1 analysis, we reviewed articles with four distinct methodological approaches: 1) predictive, in which data from one time period were used to predict future high healthcare use or cost; 2) cross-sectional, in which factors associated with high healthcare use and cost in one time period are examined; 3) cluster analysis, which identified latent or hidden groupings among HNHC patient populations; and 4) qualitative studies. We found that criteria associated with being a HNHC patient in cross-sectional studies generally supported the predictive findings, even though regression to the mean at the individual level is a real concern when selecting intervention participants. Regression to the mean is related to healthcare use often being cyclical, so very high use in one period is often followed by less care in a subsequent period, at a rate closer to the mean. The cluster analysis studies also generally confirmed the predictive and cross-sectional findings. Similar chronic diseases, behavioral health, and social factors appeared as characteristics of cluster groupings that were significant variables in predictive and cross-sectional studies. However, cluster analyses went one step further. They uncovered combinations of characteristics in individuals. Qualitative studies added insights about the impact of these characteristics on an individual patient's interaction with the healthcare system.

The value of each KQ 1 methodology lies in its respective usage. Predictive analyses are the strongest design for creating algorithms, screening, and other tools for identifying HNHC patients in future periods. Because significant patient characteristics were generally similar in cross-sectional studies, they may be useful for exploratory purposes. However, both predictive and cross-sectional exposure study designs that rely on regression analyses can have limited power to separately examine many unique diseases. As a result, rarer complex chronic conditions and combinations of conditions that might lend themselves to HNHC patient interventions may not be identified. Cluster analysis can be useful in identifying more homogenous HNHC patient subgroups when designing targeted interventions, after the broader HNHC population has been identified.

KQ 2

To answer KQ 2, the how and why of complex interventions for HNHC patients by attempting to describe and explain causal mechanisms, our analysis depended primarily on the KQ 3 effectiveness studies that included descriptive information and/or mixed-methods approaches. Therefore, our program theories are directly relevant to these interventions. However, many of the effectiveness studies were conducted at the system or organization level and included scant descriptive contextual information, such as patients' experience in the intervention, the availability of family and other supports, or assessments of patient-centered quality-of-care outcomes. Therefore, our realist review was unable to include evidence from all included KQ 3 interventions, and our theory development may be more reflective of the patient and provider experiences from the subset of studies that included a more descriptive component.

Our focus on many of the same studies for the realist and effectiveness reviews was due to the particulars of the topic and time and resource limitations. We are reasonably confident that we identified the available effectiveness literature on HNHC patient interventions. Additional studies that did not fit our KQ 3 inclusion criteria might have furthered or modified our program theories, but we would have been required to include other bodies of literature. For example, other literature might focus on a high need population where only some members are high cost, but interventions appear to be successful in keeping participants from becoming high cost, (e.g., Medicaid health homes for individuals with chronic conditions and behavioral health diagnoses.) Other literature to have considered might have been from the perspective of the identified needs of HNHC patients, such as support and ancillary services to support navigation, case management, and education. However, given our limited time and resources, we were not able to explore the potential value of this literature for this review.

Also, given the interpretive and inductive nature of realist methodology, other researchers might arrive at different interpretations of the data and resulting program theories to explain mechanisms and outcomes for interventions for HNHC patients. Further refinement, confirmation, and refutation of the program theories should and are expected to occur as additional evidence emerges in this literature.

KQ 3

Because we primarily identified complex interventions, meaningfully classifying and synthesizing of the literature to answer KQ 3 was particularly challenging. We followed a classification scheme developed by Bodenheimer, based on the principal site of the program.[45] We believed that categorizing the studies by primary setting would be the most useful for stakeholders, particularly health systems and others who are considering implementing proposed interventions in particular sites of care. However, while descriptions of studies included a broad overview of their components, few detailed the scope and intensity of the intervention that patients received. Interventions were generally large and complex; incorporated components used a variety of approaches and, as a result, cut across settings. Also, while interventions may be described as care management, disease management, case management, or care coordination, these terms were used inconsistently. These care delivery models overlap considerably.

We limited our effectiveness analyses to randomized controlled trials (RCTs) and observational studies that included a comparison population. We excluded observational studies without a comparison group (e.g., pre-post studies) despite their preponderance in the implementation literature because these studies cannot control for temporality and other confounders, limiting our ability to assess their effectiveness. Our Key Informants agreed with this exclusion decision but commented that this might result in our not considering some innovative initiatives.

Often included studies did not find a significant effect. In some cases, this may be related to the approach used for identifying HNHC patient participants. For comprehensiveness, this review did not predefine HNHC further than how study authors defined high use or high cost. This resulted in inclusion of a diverse set of interventions that targeted heterogenous populations, both within and across studies. By targeting patients with the highest prior costs or utilization, the regression to the mean phenomenon can affect findings. However, predicting which patients will be long-term chronic HNHC patients and which will have shorter episodes of high use is difficult. The result can be intervention and comparison groups not being comparable in ways that are difficult to measure and bias findings.

We considered our KQ 3 results in light of our KQ 1 analysis. Inclusion in the KQ 1 analysis required two or more utilization events in support of identifying high use, but generally studies classified the population based on much higher use. In contrast, the inclusion criteria across KQ 3 intervention studies were generally less stringent. For example, the use criterion in three studies was only one hospitalization, which may be insufficient to establish a pattern of high use. These studies are the Camden Core Model, CPC+, and IAH. All three studies required that participants have multiple chronic conditions and risk factors, but two of the three studies did not include a significant finding. Interventions may have identified HNHC patient participants who they determined had high need but baseline use may not have been high enough to easily see a significant change, relative to the comparison group, during the followup period.

Because of differences in outcomes reported across studies, a number of our strength-of-evidence grades were based on findings from one CMS demonstration.[64-68, 138] The evidence for several of the telephonic/mail, primary care–, and home-based model outcomes was solely from the Medicare Care Management for High Cost Beneficiaries (CMHCB) demonstration program. Because all CMHCB interventions were evaluated by the same group and reported the same large set of outcomes, the evidence from the studies was more likely to include outcomes that can be grouped to create a body of evidence. Although some of the outcomes (e.g., number of ACSC inpatient admissions) were also reported by other interventions within a model type, many of the outcomes were uniquely reported in only the CMHCB studies.

A second nuance of the CMHCB demonstration is that each intervention was often implemented within multiple samples. Because of this, many strength-of-evidence grades were based solely on two samples of a CMHCB study. For example, among home-based care models, the outcome of any ACSC inpatient admissions received a low strength-of-evidence grade for favorable finding (reported by 2 CMHCB samples). Similarly, the CMHCB demonstration's

Village Health Phases I and II each included two rounds of patient enrollment, so for purposes of grading strength of evidence, the model counted as four RCTs. Although each of these samples is considered independent, they may limit generalizability to other settings.

Applicability

Based on the NAM taxonomy, we sought to include four of their six identified groups of HNHC patients: the nonelderly disabled, individuals with multiple chronic conditions, individuals with major complex chronic conditions, and the frail elderly. Virtually all evidence we found was focused on chronic disease patient populations. As noted previously, even though the frail elderly is an HNHC patient population of particular interest for this review, our information focusing on this group was limited to two cluster analyses that found the frail elderly to be a distinct high-use group.

By design, we excluded children with complex needs and individuals with advancing illness (end-of-life care) from the review. We did not find that the interventions we identified for adults addressed the specific care needs of children. A review of care for children who are HNHC patients would need to account for differences in complex needs and context. That review would likely require a greater emphasis on family caregiver, as well as the child's age and developmental ability. We excluded HNHC adult patient interventions for advancing illness because the goals of end-of-life care interventions would also be different from those associated with more long-term management of chronic conditions.

We limited the included literature across KQs to studies conducted in the United States, and the review is intended to be relevant to the U.S. system. Because access to healthcare and social services in the United States differs from that in other countries, the success of intervention outcomes could vary among different national healthcare settings. For example, although the goals of improving care management and expanding navigational services may be similar across countries, the activities that are required to access healthcare services in the United States are often different from those of another country, such as a country with a national health service.

Implications for Clinical Practice, Education, Research, or Health Policy

Implications for Clinical Practice and Education

A single vein that runs through the studies included across our three KQs is patient characteristics and situations that can exacerbate inadequate management of multiple chronic conditions. These include mental health and substance abuse disorders. When coupled with homelessness and poverty, care providers face challenges that go beyond the healthcare system alone. To effectively care for these complex HNHC patients, care providers will need to identify and address their behavioral and cross-sector nonmedical needs. Delivery of these services is more likely to be assured by the healthcare provider creating ongoing direct relationships with organizations that provide these other services.

Based on our realist review, we found that building relationships with HNHC patients and gaining their trust is a key mechanism in interventions successfully changing patients' behaviors. A multipronged strategy to identify HNHC patients could account for the complexity of their prior healthcare experiences, systemic barriers to access, clinician judgment, and willingness to engage in an intervention. Finally, we found that successful interventions recognize that relationships require the engagement of care providers. To succeed, providers need the emotional, financial, logistical, and practical resources necessary to engage and maintain relationships with HNHC patients.

However, the findings from our systematic review were mixed concerning whether interventions could generate savings to healthcare systems and payers in the short term, such as1 year. Expectations of changing HNHC patient behaviors and resulting outcomes may need to take a longer view than was available through our included studies. Collecting and using patient-centered quality-of-care, satisfaction, and behavioral change outcomes could help interventions better anticipate whether they are likely to be on the path to achieving more global use and cost goals.

Implications for Research

Our review identified gaps in the literature that arise from the absence of studies, failures in the analytic methodology, and insufficient information on the content of interventions and outcomes. Although the results from each of the KQs are informative for policy and clinical decision making, we were less successful in our aim of closely linking findings across KQs in support of our analytic framework, which speaks to gaps in the field. The studies included for KQ 1 identify some patient characteristics that can be obtained through electronic data sources (claims, patient health records, and patient surveys) that are associated with high use of care. However, these data can only provide broad parameters of the characteristics of the population of interest. Commonly, the data do not directly identify care that is preventable and modifiable, only individuals where at least some of their care *may be* inappropriate and modifiable. Based on our realist review, we learned that patients need to be further identified individually to determine who is in the most need and best suited for an intervention.

More work is needed to support an understanding of targetable patient characteristics associated with modifiable and preventable high use. The single study that we found that addressed this distinction is insufficient to support clinical or policy-relevant conclusions. Future exposure study modeling needs to address multiple (and potentially correlated) factors at once, including the dynamic nature of high-cost service use among chronic, high- need patients, and be able to distinguish at the individual level between preventable or modifiable care and unavoidable service use. Relatedly, we found scant evidence explaining the role of patient health behaviors, such as self-efficacy, health literacy and activation. Because we know that individuals with the same clinical profile may use healthcare differently, direct measures of these dimensions would be informative. Based on our KQ 2 analysis, we know that these considerations need to be a primary focus in an intervention for HNHC patients.

Although behavioral health conditions were co-occurring disorders in many of the studies we reviewed, the presence and role of additional health concerns was not always clear. Additional research is needed to better understand the impact of behavioral health conditions on use of potentially preventable or modifiable high-cost medical care. The research should focus on clearly delineating behavioral health diagnosis or diagnoses, co-occurring chronic clinical conditions, the severity of the behavioral health condition, and whether the patient is actively engaged in treatment for their behavioral health problems.

Given the importance of building trusted relationships, future research may focus on developing tools to help measure patient trust in the healthcare system and in their care providers. This measure may be used to help identify patients whose lack of trust in the system needs to be intervened upon to obtain appropriate care. Similarly, intervention designers may want to specifically develop intervention components that support building trust between patients and care providers.

Additionally, our limited ability to fully understand the how and why interventions help HNHC patients speaks to the need for more qualitative and implementation research describing the process of care and patients' experiences. Better understanding of the experiences of individuals providing and receiving the intervention will help elucidate the often-unobservable mechanisms or responses to the resources provided by interventions. These insights can then be used to improve the design and implementation of future interventions for HNHC patients. For example, we sought to examine whether the subset of interventions that emphasize trust were more likely to have successful outcomes, but we found that the number of positive outcomes across all studies is too limited and too distal to make meaningful comparisons.

Although many of the intervention studies included for the systematic review provided services beyond healthcare, such as access to support and community resources, the outcomes they reported were largely limited to changes in global healthcare use and cost. Few studies reported changes in patients' clinical and social risk outcomes, quality of care or experience with care. Mortality was the only health outcome reported in more than one study. Only six intervention studies reported any social risk outcomes, such as receipt of temporary assistance, despite the focus on connecting patients to nonmedical resources among many of the interventions.[44, 154, 160, 163, 167, 178, 209] When patient care can go beyond clinical care to include nonmedical services, a truer, fuller evaluation of the impact of a complex intervention needs to include these other immediate and mediated outcomes. For example, some interventions included helping participants find stable housing because a stable living situation supports an individual's care management. If an outcome is measured only over a relatively short duration of time, patients could have obtained stable housing and be changing their health behaviors, but this intermediate outcome might not yet be reflected in changes in healthcare utilization and cost. Furthermore, studies did not report whether patients were more satisfied or happier after participating in interventions and what difficulties interventions may have faced in maintaining participant enrollment. Future research measuring and reporting more patient-centered and social risk–related outcomes would help our understanding of what interventions are accomplishing and why many are not achieving their ultimate healthcare use and cost goals.

Lastly, perhaps reflecting the relative newness of this field, we found no comparative effectiveness studies that directly compared individual interventions or types of interventions. Usual care was the comparison in virtually all studies, but the services received by patients in usual care were often unclear.

Implications for Health Policy

Based on our "best fit" framework synthesis approach, we found support for the categories included in the NAM taxonomy (chronic disease/functional limitations and across these, behavioral health and social risk factors). As discussed above, we believe that the framework would be enhanced by consideration of patterns and type of prior use and racial differences in experiences with the healthcare system.

We found strong support for including behavioral health conditions as an overarching contributor for identifying HNHC patients. However, because of the variation in behavioral health conditions and how they interact with each other and physical health conditions, a more nuanced framework than the one developed by NAM could be useful. For one, the diagnosis of depression stood out as a distinct predictor of high use in our review, while not reaching the same level of importance in the NAM framework. We also conclude that additional refinement of SUDs would be informative. SUDs can encompass multiple conditions, including many different substances, polysubstance use, and AUD, with each substance potentially having a distinctly different impact on physical health over the life span.[210] For one, our review identified AUD as a potentially separate and distinct condition contributing to high utilization; however, the contribution was unclear. Lastly, the studies in our review did not allow us to clarify whether the relationship between behavioral health conditions and high utilization and cost considered whether individuals were in treatment for these conditions. One qualitative study emphasized that it is specifically the unmet or poorly managed behavioral health needs that were significant drivers of preventable high levels of healthcare use among HNHC patients, not just the presence of a behavioral health diagnosis.[135]

The findings from the KQ 1 analysis may yield support for policies for enhanced data collection efforts to identify and target HNHC patients across payers and healthcare settings. While many of the studies reviewed provided evidence for specific characteristics of HNHC patients, few studies outside of those conducted in the Veterans Health Administration system adequately and openly integrated clinical, payment, and social risk data to identify the HNHC patient population. Successfully targeting these patients may be improved through integrated data networks with timely data and evidence-based algorithms to assist providers and enhance their clinical decision making. Public sharing of algorithm would support their comparison across studies and patient populations. Increased use of existing tools such as International Statistical Classification of Diseases and Related Health Problems-10 Z codes to capture information on social determinants of health could help identify HNHC patients. We also found evidence that patient self-report about how they are managing their healthcare can provide useful information.

The findings from the KQ 1 analysis, that behavioral health characteristics are generally independent predictors of being HNHC patients, support increased efforts for the integration of behavioral health and physical health services. While the integration of behavioral healthcare is an aspect of some existing interventions, placing higher priority on the identification and treatment of behavioral health conditions, along with physical health management, could be explored.

Many of the interventions that were included in our review were large programs, implemented across multiple sites. Some showed reductions in healthcare use and cost, while many did not. Studies generally reported little information that can help us understand why some worked better than others. Although they are likely to have different mechanisms of action, the relative success of ED-based models in reducing unnecessary utilization and costs for HNHC patients suggests that current intervention strategies based in the ED may be more likely to be effective. However, it was clear that given the complexity of HNHC patient needs, interventions need a multipronged approach to simultaneously address medical needs and reach out to other sectors to address social risk factors. Based on our realist review, we conclude that key mechanisms of success at the care delivery level are the approach to patient identification and recruitment, engagement of patients and providers, and patient-provider relationships. More detailed descriptions of interventions, patient-centered outcomes, and qualitative assessments of both patient and provider experiences would support further policy development of best practices.

Our system-level transformation and telephonic/mail findings, of no difference in costs and use, speak to the challenges that stakeholders can face in modifying healthcare use patterns of

HNHC patients through larger patient population-based interventions. Given recent provider and patient experience in using telehealth care because of the COVID-19 pandemic, telephone-based care management systems might consider greater reliance on video calls. Video calls can support more intimate connections between providers and patients without the time and logistical requirements of office visits. Video calls could also be used in these and other intervention formats for integrating connections with nonmedical services.

For interventions for HNHC patients to succeed, a payment model should financially support care providers in their efforts to help HNHC patients reduce use of preventable or modifiable services. Some healthcare systems are testing a delivery model that combines intensive medical and nonmedical service delivery with full-risk capitation payments that pay care providers for each patient, regardless of the amount of care provided.[211-213] This model aims to provide incentives for care providers to provide HNHC patients with services that address social risk factors in hopes of preventing the use of more costly medical services. Although early reports of these models are promising, rigorous evaluations are needed to determine their effectiveness in reducing preventable or modifiable utilization among HNHC patients, while maintaining quality of care.

Conclusions

A central decisional dilemma facing interventions intended to reduce the healthcare use and cost of HNHC patients is how to reliably identify the patient population and to do so prior to a future period of high use that is preventable or modifiable. Electronic data can identify pools of patients who have characteristics associated with being HNHC. Further identification of specific HNHC patients who would be good candidates for programs is improved through individualized participant selection. Similarly, programs themselves are more complex than disease management programs and need to be able to address the complex needs of individual HNHC patient participants—some of which are likely to not be related to their medical conditions. Effectively addressing these challenges requires additional support for providers. The time needed to effect change may be lengthy and will vary by participant. Because of this, desired reductions in costs and use may take longer to realize than has been measured in many current interventions. Intermediate process outcomes and patient-centered outcomes may provide earlier results that can help predict the likelihood of clinical and more distal policy outcomes.

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Appendix A. Detailed Methods

Details of Data Sources and Searches

We conducted focused searches of MEDLINE via PubMed, the Cochrane Clinical Trials Central Register, CINAHL, Embase, PsycINFO, Web of Science, Academic Search Premier, and Scopus from January 1, 2000, to March 4, 2021. Medical subject headings were used as search terms when available and keywords when appropriate, focusing on terms to describe relevant populations. Our search strategy identified high-need, high-cost (HNHC) patient populations with a combined approach of text terms of "high utilizer/medically complex/high needs" and similar terms; terms of "high health care cost/high cost;" and terms for identifying multiple chronic conditions or similar terms limited to individuals with functional limitations, behavioral factors, or social risk factors.

Targeted searches for unpublished literature were conducted by searching ClinicalTrials.gov, SIREN Evidence Library, HSRProj, National Academy of Medicine, Center for Health Care Strategies, Centers for Medicare & Medicaid Services, Camden Coalition, Commonwealth Fund, Robert Wood Johnson Foundation, California HealthCare Foundation, Institute for Healthcare Improvement, Centers for Disease Control and Prevention, Health Resources and Services Administration, Social Work Abstracts, Kaiser Family Foundation, Milbank Memorial Fund, and Patient-Centered Outcomes Research Institute. A targeted search for dissertations was also conducted by searching ProQuest. The search strategy was developed by an experienced librarian with inputs from the study investigators. To supplement electronic searches, we conducted snowball searches by reviewing the reference lists of included studies, identified if included studies are cited in newer articles, and searched for related studies such as those suggested by PubMed. We also consulted content experts to help identify relevant literature. A *Federal Register* notice was posted on December 16, 2019, as well as a request for supplemental evidence and data on January 16, 2020. We updated the literature search during the public posting period of the draft report on March 4, 2021.

Study Selection

Table A-1 lists inclusion and exclusion criteria.

Table A-1. Inclusion/exclusion criteria

PICOTS	Inclusion	Exclusion
Population	KQs 1, 2, and 3: Noninstitutionalized adults, 18 years of age or older KQ 1: Six or more months of potentially preventable or modifiable high healthcare cost and/or use KQs 2 and 3, two groups: a) HNHC patients with 6 or more months of potentially preventable or modifiable high healthcare cost and/or use b) HNHC patients with 6 or more months of potentially preventable or modifiable high healthcare cost and use AND either 2 or more chronic physical health conditions or a combination of 1 or more chronic physical health conditions and 1 or more behavioral health conditions	Patients receiving a high level of healthcare services that are considered appropriate for their condition OR high level of healthcare services are measured for less than 6 months OR end-of-life care

PICOTS	Inclusion	Exclusion
Intervention	KQ 1: Not relevant, interventions not necessary for inclusion KQs 2 and 3: Alternative delivery models (e.g., ACOs, coordinated care organizations, health homes, home-based primary care, behavioral health integration) System- or practice-level interventions (e.g., ED alerts, hotspotting) Patient supportive services (e.g., community health workers, social workers, patient navigators, care coordinators, case and care managers, intensive primary care support, medication management, health reliance specialists, self-management instruction, and peer-to-peer support) Social determinants of health-related interventions (e.g., transportation, health literacy, housing support, caregiver support)	KQs 2 and 3: Interventions for which the relevance for and impact on HNHC patients cannot be determined
Comparator	KQ 1: Comparison population or no comparator KQ 2: Any intervention, treatment as usual, or no comparator intervention KQ 3: Any intervention or treatment as usual	KQ 3: No comparator
Outcomes	KQ 1: Population characteristics described or predicted KQs 1, 2, and 3: Healthcare use: decreases in ED visits, EMS use, and hospitalizations; changes in primary care or specialist visits or other necessary and appropriate types of care (e.g., care manager visits, telephone followup) and use of support services Patient health behavior (e.g., treatment adherence, activation, empowerment, knowledge, self-care) Patient health outcomes: all-cause mortality, disease and condition-specific outcomes, health indicators, quality of life Patient satisfaction with care Physicians' and health professionals' satisfaction with clinical practice Costs Patient and health professional harms such as increased barriers to necessary care, clinician time, or resource trade-offs of other duties	All other outcomes
Time frame	Potentially preventable or modifiable high cost healthcare use measured for 6 months or more KQ 3: Measurement of outcomes at 6 months or more after implementation of the intervention.	Shorter time periods
Settings	Healthcare and support services delivery settings, including outpatient, ED, the broader healthcare delivery environment, the home, or the community United States	Institutional care settings, such as hospitals, skilled nursing, long-term care facilities, and prisons or jails

PICOTS	Inclusion	Exclusion
Study design	KQs 1 and 2: All study designs except reviews summarizing across original studies or interventions KQ 3: Randomized controlled trials, cluster randomized trials, cohort studies, case-control studies, quasi-experimental designs with a comparison group	KQs 1 and 2: Descriptive quantitative studies that do not control for potential confounding KQ 3: All other designs
Language	Studies published in English	Studies published in languages other than English
Publication type	All publications that allow abstraction and interpretation of findings	Abstract-only publications

ACO = Accountable Care Organization; ED = emergency department; EMS = emergency management services; HNHC = high-need, high-cost; KQ = Key Question; PICOTS = population, intervention, comparator, outcomes, time frame, settings

We imported all citations identified through searches and other sources into EndNote v.X9. Independent reviewers screened the titles and abstracts of all citations using the inclusion and exclusion criteria using Abstrackr software. Studies included by either reviewer were retrieved for full-text screening. Independent reviewers then screened the full-text version of eligible references. Discrepancies between the reviewers were resolved through discussions and consensus or consultation with a third senior reviewer. In relation to studies included for the realist review, in keeping with realist review principles, we evaluated articles for their relevance and robustness in answering Key Question (KQ) 2 and their contribution to theory building and testing.[1] Excluded studies are listed in the Results Appendix.

For each KQ, we used a different methodological approach to evidence synthesis. We used "best fit" framework synthesis approach for KQ 1, realist review methodology for KQ 2, and a systematic review approach for KQ 3.

Data Abstraction

We developed and pilot tested standardized data extraction forms for each KQ. For KQ 1, we extracted study characteristics, including study goal, design, methodological approach, data source setting, sample size, inclusion and exclusion criteria; population characteristics, including characteristics on service use, healthcare costs, clinical health conditions, behavioral conditions, social risk factors, demographic conditions, and health system; and key outcomes of interest. For KQ 3, we abstracted study characteristics, population characteristics, intervention characteristics, intervention effectiveness, subgroup intervention effectiveness, and study risk-of-bias assessment. Trained reviewers abstracted the relevant data from each included article into the evidence tables; a second member of the team reviewed all data abstractions for completeness and accuracy for KQ 1 and KQ 3.

To answer the realist review question, KQ 2, data items were driven by our purpose to refine our program theories through context-mechanism-outcome (CMO) configurations. Data were abstracted in NVivo software using a coding framework grounded in our initial program theory of CMO. Coding of all included studies using the coding framework proceeded as both an inductive and deductive process; that is, we continued to identify and add to the coding framework as we proceeded. The team developed the initial program theory by identifying categories of interventions for HNHC patients from an initial scan of the literature and articulating the underlying theory that supports those interventions. Subsequently, we refined the initial program theory into a realist program theory by creating a map of a patient journey, with corresponding lists of mechanisms operating at the patient and provider levels. We then identified additional theoretical frameworks that could inform our program theory by explaining mechanisms of both patients and providers and that drew from a variety of health behavior theories, most notably the Theory of Planned Behavior.

Assessment of Methodological Risk of Bias and Risk of Rigor of Individual Studies

KQ 1

We did not assess the risk of bias or strength of evidence for studies relevant to KQ 1. The studies we included for KQ 1 were mostly quantitative observational studies of exposures (multivariate predictive or cross-sectional designs) and fewer were cluster analyses or qualitative studies. Because no validated tool is available for evaluating the risk of bias of cross-sectional observational designs or cluster analyses (the majority of our included studies), we did not evaluate the risk of bias of any studies included for KQ 1.[2] However, we limited observational studies of exposures to those using a multivariate design that controlled for confounding. We appraised the rigor of qualitative studies included to answer KQ 1 (methodological strength and limitations) as recommended in the Cochrane handbook.[3] We conducted the assessment using the Critical Appraisal Skills Programme tool.[4]

KQ 2

For KQ 2, the studies also included for KQ 3 received a risk-of-bias assessment. Specific to KQ 2, to keep with realist review principles, we used RAMESES project standards to guide our judgments in quality appraisal tasks.[1, 5-7] More specifically, data were appraised based on relevance (whether included articles can contribute to theory building and testing), trustworthiness (whether the data in a study have been obtained empirically, using methods that are clearly stated, and whether the information could be found in more than one source), plausibility of the argument underlying the theory (the coherence of the argument, including its breadth in explaining the data, its simplicity and fit with existing theory), and rigor (whether included articles are methodologically credible with regard to outcomes reported and methods used for testing propositions).

KQ 3

The criteria set forth by the Agency for Healthcare Research and Quality's (AHRQ's) *Methods Guide for Comparative Effectiveness Reviews* guided our assessment of methodological risk of bias for KQ 3. To assess the risk of bias (i.e., internal validity), we used the ROBINS-I[8] tool for observational studies and the Cochrane RCT[9] tool for randomized controlled trials (RCTs). For both observational studies and RCTs, risk-of-bias assessment included questions to assess selection bias, confounding, performance bias, detection bias, and attrition bias; concepts covered include those about adequacy of randomization (for RCTs only), similarity of groups at baseline, masking, attrition, whether intention-to-treat analysis was used, method of handling dropouts and missing data, validity and reliability of outcome measures, and treatment fidelity.[10]

For each study included for KQ 3, two independent reviewers assigned risk-of-bias ratings for each study with disagreements resolved by discussion and consensus. Reviewers assigned a rating of low risk of bias (study met all criteria), some concerns (study met some criteria), high risk of bias (methodological shortcomings leading to high risk of bias in one or more categories), or unclear risk of bias (methods not reported clearly).

Data Synthesis

We summarized all included studies for KQs 1 and 3 in narrative form and in summary tables that tabulate the important features of the study populations, design, intervention, comparison, outcomes, setting (including geographic location), and results.

Describing the HNHC patient population (KQ 1): To achieve our aim of describing the approach to identifying the HNHC patient population, we conducted a “best fit” framework synthesis.[11] Consistent with this approach, we began from an a priori identified framework that we used to sort evidence into themes across included studies (i.e., the distinguishing characteristics and reasons why some patients are HNHC). During our review of the evidence, we used an iterative process to consider new themes that were not captured in the initial framework. In the end, we present a summary of the data and syntheses of the evidence and our conclusions within a framework corresponding to our final conceptual model.

We began the synthesis using the taxonomy developed by the National Academy of Medicine in their report *Effective Care for High-Need Patients: Opportunities for Improving Outcomes, Value, and Health* as our a priori framework.[12] This taxonomy groups HNHC patients first based on their clinical and functional characteristics. Among the six patient groups presented in the taxonomy, four met the inclusion criteria for this review: nonelderly disabled, multiple chronic conditions, major complex chronic condition, and frail elderly. (The additional two categories, children with complex needs and individuals with advancing illness/end-of-life care, are outside the scope of the review.) Within these assigned groups, the taxonomy proposed additional, cross-patient group assessment based on behavioral health factors and social risk factors that are believed to influence how individuals use healthcare and increase the risk of receiving fragmented care. Behavioral health factors included serious mental illness, substance use disorder, cognitive decline, and chronic toxic stress. Social risk factors included low socioeconomic status, low health literacy, social isolation, community deprivation, and housing insecurity.

Understanding interventions for HNHC patients (KQ 2): To gain a greater understanding of the complex alternative payment and delivery models, social interventions, and health programs that are used to address healthcare utilization among HNHC patients, we used a realist review approach. Consistent with this approach, our goal is to explain what works (or fails), for whom, under what circumstances, and why.[13] We sought to identify, elucidate, and refine several underlying theories that could explain the approach of different complex interventions, explore implementation chains, assess intermediate outcomes, and examine modifications or adaptations applied in various circumstances.[13]

Review of the evidence supporting the effectiveness of interventions for HNHC patients (KQ 3): To further support the goal of producing actionable information, we also used traditional Evidence-based Practice Center (EPC) systematic review methods to synthesize the evidence of the overall effectiveness of the included interventions. We conducted a quantitative synthesis of results by calculating a pooled treatment effect when three or more samples with the same study design had similar treatment and comparison groups and reported the same outcome measure within a setting. We used Stata® 16 (StataCorp, College Station, TX) to calculate effect sizes and associated 95 percent confidence intervals. Because of the diversity of intervention designs and outcomes, most results were synthesized qualitatively.

Grading the Strength of Evidence

For KQ 3, we graded the strength of evidence based on the guidance established for the EPC Program.[14] Developed to grade the overall strength of a body of evidence, this approach incorporates five key domains: study limitations (includes study design and risk of bias), consistency, directness, precision of the evidence, and reporting bias. This approach requires looking beyond statistical significance alone, even when studies are consistent and of high quality and outcomes are direct and clinically relevant. It emphasizes the adequacy of the sample size to rule out spurious associations and results that are not clinically relevant. It also considers other optional domains that may be relevant to increasing the strength of evidence for some scenarios, such as a dose-response association, plausible confounding that would decrease the observed effect, and strength of association (magnitude of effect).

Table A-2 describes the grades of evidence that can be assigned. Grades reflect the strength of the body of evidence to answer KQs on the benefits and harms of the interventions included in this review. Two reviewers assessed each domain for each key outcome with differences resolved by consensus.

Table A-2. Definitions of the grades of overall strength of evidence[14]

Grade	Definition
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate.
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit estimation of an effect.

Assessing Applicability

We assessed the applicability of individual studies as well as the applicability of a body of evidence following guidance from the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[15] For individual studies, we examined conditions that may limit applicability based on the PICOTS (population, intervention, comparisons, outcomes, timing, and setting) structure. The assessment of applicability is integral to a realist review through its consideration of context within CMO configurations. We indicated patterns across studies and when the context does not appear to operate similarly in particular settings.

Peer Review and Public Commentary

Experts in research on care for individuals with complex chronic conditions, in health systems, and qualitative and realist review methods were invited to provide external peer review of the draft systematic review that was entitled “Management of High-Need, High-Cost Patients: A “Best Fit” Synthesis, Realist Review, and Systematic Review.” AHRQ staff and an Associate Editor reviewed the draft systematic review before it went out for peer review. The EPC Associate Editors are leaders in their respective fields and are actively involved as directors or leaders at their EPCs. Their role is to assess adherence to established methodology and guidelines for EPC-based research. We revised the report in response to AHRQ staff, the Associate Editor, peer reviewer, and public comments.

Search Strategy

Published Literature Searches

PubMed

09-07-2019

Search	Query	Items Found
#1	Search (((“high utilizer” OR “high utilizers of health care” OR “high utilizing” OR “super utilizers” OR “super utilizing” OR “frequent utilization” OR “frequent utilisation” OR “frequent utilizers” OR “heavy utilization” OR “heavy utilizers” OR “high attenders” OR “repeat users” OR “hyperusers” OR “revolving door patients” OR “hyperutilization” OR “overutilization” OR “recividism”)) OR “frequent users”) OR “frequent user” OR “medically complex” OR “high need” Sort by: Best Match	3545
#2	Search ((“Africa”[Mesh]) OR “India”[Mesh] OR “Developing Countries”[Mesh])) Sort by: Best Match	398504
#3	Search (#1 NOT #2) Sort by: Best Match	3506
#4	Search (#1 NOT #2) Sort by: Best Match Filters: Publication date from 2000/01/01; Humans; English; Adult: 19+ years	1332

PubMed

03-04-2021

Search	Query	Items Found
#1	Search ((("high utilizer” OR "high utilizers of health care" OR "high utilizing" OR "super utilizers" OR "super utilizing” OR "frequent utilization" OR "frequent utilisation" OR "frequent utilizers" OR "heavy utilization" OR "heavy utilizers" OR "high attenders” OR "repeat users” OR "hyperusers" OR "revolving door patients" OR "hyperutilization" OR "overutilization" OR "recividism")) OR "frequent users") OR "frequent user" OR "medically complex" OR “high need” Sort by: Best Match	4341
#2	Search (("Africa"[Mesh]) OR "India"[Mesh] OR "Developing Countries"[Mesh])) Sort by: Best Match	431583
#3	Search (#1 NOT #2) Sort by: Best Match	4279
#4	Search (#1 NOT #2) Sort by: Best Match Filters: Publication date from 2019/03/01; Humans; English; Adult: 19+ years	266

PubMed

03-04-2021

Search	Query	Items Found
#1	Search: ("high health care cost"[Title]) OR ("high cost"[Title]) Filters: Humans, English, Adult: 19+ years, from 2000/1/1 - 3000/12/12	211
#2	Search: ((("high utilizer" OR "high utilizers of health care" OR "high utilizing" OR "super utilizers" OR "super utilizing" OR "frequent utilization" OR "frequent utilisation" OR "frequent utilizers" OR "heavy utilization" OR "heavy utilizers" OR "high attenders" OR "repeat users" OR "hyperusers" OR "revolving door patients" OR "hyperutilization" OR "overutilization" OR "recividism")) OR "frequent users") OR "frequent user" OR "medically complex" OR "high need" Filters: Humans, English, Adult: 19+ years, from 2000/1/1 - 3000/12/12	1704
#3	Search: #1 NOT #2 Filters: Humans, English, Adult: 19+ years, from 2000/1/1 - 3000/12/12	186
#4	Search: (("Africa"[Mesh]) OR "India"[Mesh] OR "Developing Countries"[Mesh])) Filters: Humans, English, Adult: 19+ years, from 2000/1/1 - 3000/12/12	105772
#5	Search: #3 NOT #4 Filters: Humans, English, Adult: 19+ years, from 2000/1/1 - 3000/12/12	182

Cochrane Clinical Trials Central Register

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	40

Cochrane Clinical Trials Central Register

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	93

CINAHL

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	27

CINAHL

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	62

Embase

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	28

Embase

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	62

PsycINFO

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	27

PsycINFO

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	49

Web of Science

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	194

Web of Science

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	96

Academic Search Premier

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	25

Academic Search Premier

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	10

Scopus

09-07-2019

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	61

Scopus

03-04-2021

Search	Query	Items Found
#1	Search (“high utilizers” OR “high need” OR “complex patients”)	60

Gray Literature Searches

ClinicalTrials.gov results = **11**
SIREN Evidence Library = **10**
HSRProj = **18**
National Academy of Medicine = **3**
Center for Health Care Strategies = **12**
Centers for Medicare and Medicaid Services = **4**
Camden Coalition = **2**
Commonwealth Fund = **62**
Robert Wood Johnson Foundation = **9**
California HealthCare Foundation = **8**
Grey Literature Report= **94**
Institute for Healthcare Improvement = **3**
Centers for Disease Control and Prevention = **3**

Human Resources Services Administration = **0**
Social Work Abstracts = **2**
Kaiser Family Foundation = **3**
Milbank Memorial Fund = **0**
Patient-Centered Outcomes Research Institute = **2**
Search-based Investigative Intelligence Platform = **41**

Search Strategy for All Gray Literature

03-2021
“high utilizers” OR “high need” OR “complex patients”

Search Strategy for All Gray Literature

03-2021
“high utilizers” OR (“high need” AND “high cost”) OR “complex patients”

Appendix B. Results

Results of Literature Searches

The electronic search, grey literature, and reference mining identified 2,923 citations. After title and abstract screening, 873 citations were retrieved for full-text review. A total of 110 studies (117 articles) met eligibility criteria. A total of 110 studies (117 articles) were included in the analyses.

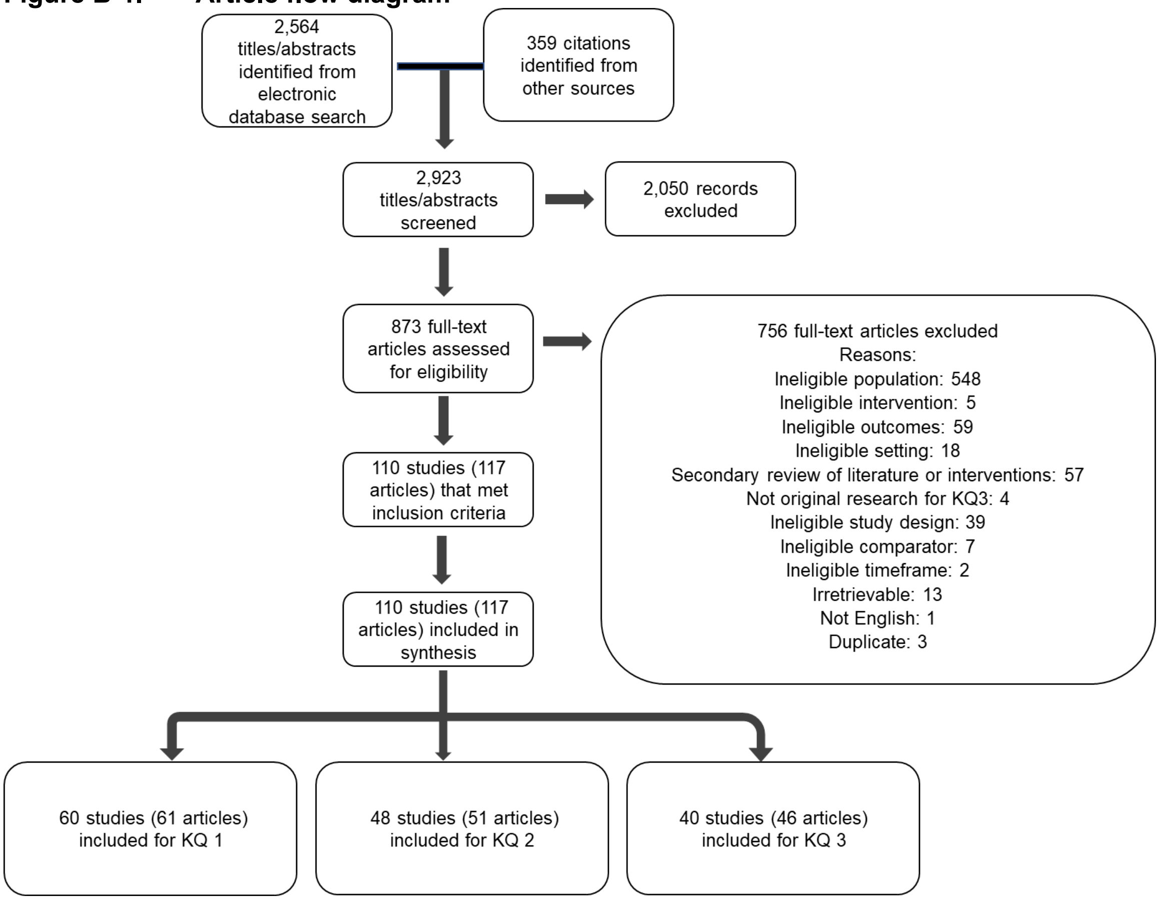
Description of Included Studies

For KQ 1, we identified 60 studies (61 articles), of which 33 were cross sectional, 10 latent class, 11 predictive, and 6 qualitative.[16-76]

For KQ 2, we identified we identified 48 studies (51 articles).[12, 17, 22, 27-29, 31, 49, 53, 55, 58, 61, 62, 77-114] As for unique KQ 2 includes, we identified 10 studies (10 articles).[12, 78, 91, 93, 94, 104-106, 113, 114]

For KQ 3, we identified 19 trials and 21 observational studies (46 articles). Five RCTs were assessed as having low risk of bias, and 14 RCTs (15 articles) were assessed as having some concerns for bias,[79-82, 84, 86, 87, 90, 96, 97, 99, 108-112, 115-118] No observational studies were assessed as having low risk of bias, 13 observational studies (17 articles) were assessed as having some concerns for bias, and eight observational studies (9 articles) were assessed as having high risk of bias.[83, 85, 88, 92, 95, 98, 100-103, 107, 119-133]

Figure B-1. Article flow diagram



Note: The sum of the number of studies per KQ exceeds the total number of studies because some studies were applicable to multiple KQs.
KQ = Key Question.

List of Excluded Studies

X1: Ineligible Population

X2: Ineligible Intervention

X3: Ineligible Comparator

X4: Ineligible Outcome

X5: Ineligible Time Frame

X6: Setting/Country

X7: Secondary Review of Literature or Interventions

X8: Not Original Research for KQ 3

X9: Study Design

X10: Not English

X11: Irretrievable

X12: Duplicate

1. Magellan initiative targets high utilizers in private plans. Mental Health Weekly. 2000;10(32):1. PMID: 3493535. Exclusion Code: X1.
2. Hand-held devices ease burden of behavioral health assessment. Dis Manag Advis. 2002;8(10):152-6, 45. Exclusion Code: X1.
3. Medicaid best buys: improving care management for high-need, high-cost beneficiaries. Hamilton, N.J.: Center for Health Care Strategies, Inc.; 2008. Exclusion Code: X4.
4. Medicaid best buys: critical strategies to focus on high-need, high-cost beneficiaries. Hamilton, N.J.: Center for Health Care Strategies, Inc.; 2010. Exclusion Code: X1.
5. Building the national care service. Norwich: Great Britain Stationary Office; 2010. Exclusion Code: X1.
6. ED diversion: multidisciplinary approach engages high utilizers, helps them better navigate the health care system. ED management: the monthly update on emergency department management. 2011;23(11):127-30. Exclusion Code: X1.
7. CM program keeps high utilizers out of hospital. Hosp Case Manag. 2012;20(7):108-9. PMID: 104470969. Language: English. Entry Date: 20120711. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Nursing. Exclusion Code: X1.
8. Hospitals collaborate to reduce ED overuse. Hosp Case Manag. 2012 Oct;20(10):151-3. PMID: 23084509. Exclusion Code: X1.
9. Patient navigation for Medicaid frequent ED users. Yale University. 2013. https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01579091/full. PMID: CN-01579091. Exclusion Code: X4.
10. Identifying high utilizers of surgical care after colectomy. J Surg Res. 2014;186(2):495-. doi: 10.1016/j.jss.2013.11.036. PMID: 93484679. Exclusion Code: X1.
11. Programs focusing on high-need, high-cost populations. [Trenton, N.J.]: Center for Health Care Strategies, Inc.; 2016. Exclusion Code: X1.
12. Understanding the needs of different types of high-need patients and their caregivers. Commonwealth Fund; 2019. Exclusion Code: X1.
13. Community Care For High-Need Patients. Health Aff (Millwood). 2019 Jun;38(6):892-3. doi: 10.1377/hlthaff.2019.00473. PMID: 31454082. Exclusion Code: X8.

14. Evaluation of a Multidisciplinary Care Coordination Program for Frequent Users of the Emergency Department. Prof Case Manag. 2019 Sep/Oct;24(5):E1-e2. doi: 10.1097/ncm.0000000000000388. PMID: 30593912. Exclusion Code: X1.

15. Extreme consumers of health care: patterns of care utilization in patients with multiple chronic conditions admitted to a novel integrated clinic. Journal of multidisciplinary healthcare. 2019;12:1075-83. doi: 10.2147/JMDH.S214770. PMID: CN-02136481. Exclusion Code: X6.

16. Assertive Community Treatment for Alcohol Misuse Disorder Patients Who Are High Utilizers of Emergency Department Services (ARFA). Khoo Teck Puat Hospital. Jun 25, 2020. Exclusion Code: X11.

17. Ackroyd-Stolarz S, Read Guernsey J, Mackinnon NJ, et al. The association between a prolonged stay in the emergency department and adverse events in older patients admitted to hospital: a retrospective cohort study. BMJ Qual Saf. 2011 Jul;20(7):564-9. doi: 10.1136/bmjqs.2009.034926. PMID: 21776300. Exclusion Code: X1.

18. Acosta AM, Lima MA. Frequent users of emergency services: associated factors and reasons for seeking care. Rev Lat Am Enfermagem. 2015 Feb-Apr;23(2):337-44. doi: 10.1590/0104-1169.0072.2560. PMID: 26240244. Exclusion Code: X1.

19. Adler-Milstein J. Assessing the impact of Medicare advantage on high-cost, high-need beneficiaries and exploring an intervention to improve outcomes. Michigan: Commonwealth Fund; 2017. Exclusion Code: X1.

20. Agarwal G, Lee J, McLeod B, et al. Social factors in frequent callers: a description of isolation, poverty and quality of life in those calling emergency medical services frequently. BMC Public Health. 2019 Jun 3;19(1):684. doi: 10.1186/s12889-019-6964-1. PMID: 31277151. Exclusion Code: X1.

21. Agarwal G, McDonough B, Angeles R, et al. Rationale and methods of a multicentre randomised controlled trial of the effectiveness of a Community Health Assessment Programme with Emergency Medical Services (CHAP-EMS) implemented on residents aged 55 years and older in subsidised seniors' housing buildings in Ontario, Canada. BMJ Open. 2015 Jun 11;5(6):e008110. doi: 10.1136/bmjopen-2015-008110. PMID: 26206441. Exclusion Code: X1.

22. Agterberg J, Zhong F, Crabb R, et al. Cluster analysis application to identify groups of individuals with high health expenditures. Health Services & Outcomes Research Methodology. 2020;20(2/3):140-82. doi: 10.1007/s10742-020-00214-8. PMID: 145263707. Exclusion Code: X4.

23. Aird P, Hansford P, O'Brien R, et al. The impact of frequent users of OOH services. Br J Gen Pract. 2001 Jun;51(467):494-5. PMID: 15094029. Exclusion Code: X1.

24. al Yousif N, Hussain HY, El Din Mhakluf MM. Health care services utilization and satisfaction among elderly in Dubai, UAE and some associated determinants. Middle East Journal of Age & Ageing. 2014;11(3):25-33. PMID: 96513555. Exclusion Code: X1.

25. Alderwick H, Hood-Ronick CM, Gottlieb LM. Medicaid Investments To Address Social Needs In Oregon And California. Health Aff (Millwood). 2019 May;38(5):774-81. doi: 10.1377/hlthaff.2018.05171. PMID: 31059356. Exclusion Code: X1.

26. Alexander Billioux KV, Susan Anthony, Dawn Alley. Standardized Screening for Health-Related Social Needs in Clinical Settings The Accountable Health Communities Screening Tool. 2017. Exclusion Code: X2.

27. Alghanim SA, Alomar BA. Frequent use of emergency departments in Saudi public hospitals: implications for primary health care services. Asia Pac J Public Health. 2015 Mar;27(2):Np2521-30. doi: 10.1177/1010539511431603. PMID: 25547107. Exclusion Code: X1.

28. Allen CG, Escoffery C, Satsangi A, et al. Strategies to improve the integration of community health workers into health care teams: "a little fish in a big pond". Prev Chronic Dis. 2015 Sep 17;12:E154. doi: 10.5888/pcd12.150199. PMID: 26875022. Exclusion Code: X1.

29. Althaus F, Paroz S, Hugli O, et al. Effectiveness of interventions targeting frequent users of emergency departments: a systematic review. Ann Emerg Med. 2011 Jul;58(1):41-52 e42. doi: 10.1016/j.annemergmed.2011.03.007. PMID: 21689565. Exclusion Code: X1.

30. Althaus F, Stucki S, Guyot S, et al. Characteristics of highly frequent users of a Swiss academic emergency department: a retrospective consecutive case series. Eur J Emerg Med. 2013 Dec;20(6):413-9. doi: 10.1097/MEJ.0b013e32835e078e. PMID: 25139183. Exclusion Code: X1.

31. Altman D. A small group of patients account for a whole lot of spending. Axios. 2019. https://www.axios.com/drug-prices-health-care-costs-spending-employers-63a65abc-0148-4f98-bd39-b30e4d3c9caf.html. Exclusion Code: X7.

32. Alvarado LP. Mobile psychiatric services decrease readmission rates among high utilizers of emergency treatment services: ProQuest Information & Learning; 2021. Exclusion Code: X3.

33. Amarasingham R, Xie B, Karam A, et al. Using community partnerships to integrate health and social services for high-need, high-cost patients. Commonwealth Fund. 2018. https://www.commonwealthfund.org/publications/issue-briefs/2018/jan/using-community-partnerships-integrate-health-and-social. Exclusion Code: X1.

34. Anderson DR, Mangen DJ, Grossmeier JJ, et al. Comparing alternative methods of targeting potential high-cost individuals for chronic condition management. J Occup Environ Med. 2010 Jun;52(6):635-46. doi: 10.1097/JOM.0b013e3181e31792. PMID: 15175823. Exclusion Code: X9.

35. Anderson GM. Program delivery for high-needs, high-cost populations: international perspectives on the way forward, phase I. University of Toronto, Faculty of Medicine, Institute of Health Policy, Management and Evaluation 2017. https://hsrproject.nlm.nih.gov/view_hsrproj_record/20191229. Exclusion Code: X7.

36. Andrews G, Sunderland M. Telephone case management reduces both distress and psychiatric hospitalization. Aust N Z J Psychiatry. 2009 Sep;43(9):809-11. doi: 10.1080/00048670903107617. PMID: 17515738. Exclusion Code: X1.

37. Angelelli J, Gifford D, Intrator O, et al. Access to postacute nursing home care before and after the BBA (Balanced Budget Act). Health Aff (Millwood). 2002 Sep-Oct;21(5):254-64. doi: 10.1377/hlthaff.21.5.254. PMID: 12450957. Exclusion Code: X1.

38. Armstrong G, De Marchis E, Mix R, et al. Using Social Needs Screening and Patient Feedback for Complex Care. National Center for Complex Health and Social Needs; 2020. alcomplex.care/research-policy/resources/webinars/using-social-needs-screening-and-patient-feedback-for-complex-care/2020. Exclusion Code: X1.

39. Avila J, Jupiter D, Chavez-MacGregor M, et al. High-Cost Hospitalizations Among Elderly Patients With Cancer. J Oncol Pract. 2019 May;15(5):e447-e57. doi: 10.1200/jop.18.00706. PMID: 30354887. Exclusion Code: X1.

40. Azogil-López LM, Pérez-Lázaro JJ, Ávila-Pecci P, et al. Effectiveness of a new model of telephone derivation shared between primary care and hospital care. Atencion primaria / Sociedad Espanola de Medicina de Familia y Comunitaria. 2019;51(5):278-84. doi: 10.1016/j.aprim.2018.02.006. PMID: CN-02133656. Exclusion Code: X10.

41. Bagnall AM, South J, Forshaw MJ, et al. Self-care in primary care: findings from a longitudinal comparison study. Prim Health Care Res Dev. 2013 Jan;14(1):29-39. doi: 10.1017/s1463423612000199. PMID: 24568286. Exclusion Code: X1.

42. Bailey JE, Surbhi S, Wan JY, et al. Effect of Intensive Interdisciplinary Transitional Care for High-Need, High-Cost Patients on Quality, Outcomes, and Costs: a Quasi-Experimental Study. J Gen Intern Med. 2019 Sep;34(9):1815-24. doi: 10.1007/s11606-019-05082-8. PMID: 32245460. Exclusion Code: X1.

43. Baker JM, Grant RW, Gopalan A. A systematic review of care management interventions targeting multimorbidity and high care utilization. BMC Health Serv Res. 2018 Jan 30;18(1):65. doi: 10.1186/s12913-018-2881-8. PMID: 29382327. Exclusion Code: X1.

44. Balaban RB, Zhang F, Vialle-Valentin CE, et al. Impact of a Patient Navigator Program on Hospital-Based and Outpatient Utilization Over 180 Days in a Safety-Net Health System. J Gen Intern Med. 2017 Sep;32(9):981-9. doi: 10.1007/s11606-017-4074-2. PMID: 28523476. Exclusion Code: X1.

45. Balfour ME, Zinn TE, Cason K, et al. Provider-payer partnerships as an engine for continuous quality improvement. Psychiatr Serv. 2018;69(6):623-5. doi: 10.1176/appi.ps.201700533. PMID: 129890973. Language: English. Entry Date: In Process. Revision Date: 20180609. Publication Type: Article. Journal Subset: Biomedical. Exclusion Code: X1.

46. Barker SL, Maguire NJ, Das S, et al. Values-Based Interventions in Patient Engagement for Those with Complex Needs. Popul Health Manag. 2020;23(2):140-5. doi: 10.1089/pop.2019.0084. PMID: 142272277. Language: English. Entry Date: 20200320. Revision Date: 20200324. Publication Type: Article. Exclusion Code: X1.

47. Barsky AJ, Ahern DK, Bauer MR, et al. A randomized trial of treatments for high-utilizing somatizing patients. J Gen Intern Med. 2013;28(11):1396-404. doi: 10.1007/s11606-013-2392-6. PMID: CN-00909578. Exclusion Code: X1.

48. Bauman CA, Fillingham J, Keely-Dyck E, et al. An approach to interprofessional management of complex patients: a case report. Journal of the Canadian Chiropractic Association. 2019;63(2):119-25. PMID: 138594442. Language: English. Entry Date: 20190916. Revision Date: 20190926. Publication Type: Article. Exclusion Code: X6.

49. Bayliss EA, Ellis JL, Powers JD, et al. Using self-reported data to segment older adult populations with complex care needs. EGEMS (Wash DC). 2019 Apr 12;7(1):12. doi: 10.5334/egems.275. PMID: 31065556. Exclusion Code: X1.

50. Beach SR, Schulz R, Friedman EM, et al. Adverse Consequences of Unmet Needs for Care in High-Need/High-Cost Older Adults. J Gerontol B Psychol Sci Soc Sci. 2020 Jan 14;75(2):459-70. doi: 10.1093/geronb/gby021. PMID: 30522388. Exclusion Code: X3.

51. Becker T, Steffen S, Puschner B. Discharge planning, an intervention study - and where to go next? Eur Psychiatry. 2011;26. doi: 10.1016/S0924-9338(11)73744-0. PMID: CN-01782093. Exclusion Code: X1.

52. Bedoya P, Neuhausen K, Dow AW, et al. Student Hotspotting: Teaching the Interprofessional Care of Complex Patients. Acad Med. 2018 Jan;93(1):56-9. doi: 10.1097/acm.0000000000001822. PMID: 28700461. Exclusion Code: X1.

53. Beesley VL, Smithers BM, O'Rourke P, et al. Variations in supportive care needs of patients after diagnosis of localised cutaneous melanoma: a 2-year follow-up study. Support Care Cancer. 2017 Jan;25(1):93-102. doi: 10.1007/s00520-016-3378-9. PMID: 26389982. Exclusion Code: X1.

54. Beima-Sofie K, Begnel ER, Golden MR, et al. "It's Me as a Person, Not Me the Disease": Patient Perceptions of an HIV Care Model Designed to Engage Persons with Complex Needs. AIDS Patient Care STDS. 2020 Jun;34(6):267-74. doi: 10.1089/apc.2019.0310. PMID: 31670693. Exclusion Code: X1.

55. Bélanger E, McHugh J, Meyers DJ, et al. Characteristics of Top-Performing Hospitals Caring for High-Need Medicare Beneficiaries. Popul Health Manag. 2020;23(4):313-8. doi: 10.1089/pop.2019.0145. PMID: 144824249. Language: English. Entry Date: 20200813. Revision Date: 20200813. Publication Type: Article. Exclusion Code: X1.

56. Bellon JA, Rodriguez-Bayon A, Luna JD, et al. Successful GP intervention with frequent attenders in primary care: randomised controlled trial. Br J Gen Pract. 2008 May;58(550):324-30. doi: 10.3399/bjgp08X280182. PMID: WOS:000256654700006. Exclusion Code: X1.

57. Bergenstal TD, Reitsema J, Heppner P, et al. Personalized Care Plans: Are They Effective in Decreasing ED Visits and Health Care Expenditure Among Adult Super-Utilizers? J Emerg Nurs. 2020 Jan;46(1):83-90. doi: 10.1016/j.jen.2019.09.001. PMID: 32750132. Exclusion Code: X1.

58. Bergeron P, Courteau J, Vanasse A. Proximity and emergency department use: multilevel analysis using administrative data from patients with cardiovascular risk factors. Can Fam Physician. 2015 Aug;61(8):e391-7. PMID: 26747456. Exclusion Code: X1.

59. Bergh H, Marklund B. Characteristics of frequent attenders in different age and sex groups in primary health care. Scand J Prim Health Care. 2003 Sep;21(3):171-7. doi: 10.1080/02813430310001149. PMID: WOS:000185314100010. Exclusion Code: X1.

60. Berghofer A, Hartwich A, Bauer M, et al. Efficacy of a systematic depression management program in high utilizers of primary care: a randomized trial. BMC Health Serv Res. 2012 Sep 3;12:298. doi: 10.1186/1472-6963-12-298. PMID: 25527472. Exclusion Code: X1.

61. Berghöfer A, Roll S, Bauer M, et al. Screening for depression and high utilization of health care resources among patients in primary care. Community Ment Health J. 2014;50(7):753-8. doi: 10.1007/s10597-014-9700-4. PMID: 103896118. Language: English. Entry Date: 20140924. Revision Date: 20151001. Publication Type: Journal Article. Exclusion Code: X1.

62. Berkowitz SA. Capsule Commentary on Schickedanz et al., Impact of Social Needs Navigation on Utilization Among High-Utilizers in a Large Integrated Health System: a Quasi-Experimental Study. JGIM: Journal of General Internal Medicine. 2019;34(11):2582-. doi: 10.1007/s11606-019-05296-w. PMID: 139599661. Exclusion Code: X8.

63. Bertoli-Avella AM, Haagsma JA, Van Tiel S, et al. Frequent users of the emergency department services in the largest academic hospital in the Netherlands: a 5-year report. Eur J Emerg Med. 2017 Apr;24(2):130-5. doi: 10.1097/mej.0000000000000314. PMID: 28863030. Exclusion Code: X1.

64. Bieler G, Paroz S, Faouzi M, et al. Social and medical vulnerability factors of emergency department frequent users in a universal health insurance system. Acad Emerg Med. 2012 Jan;19(1):63-8. doi: 10.1111/j.1553-2712.2011.01246.x. PMID: 21701913. Exclusion Code: X1.

65. Bilazarian A. High-need high-cost patients: A Concept Analysis. Nurs Forum. 2020. doi: 10.1111/nuf.12500. Exclusion Code: X1.

66. Billett J, Cowie MR, Gatzoulis MA, et al. Comorbidity, healthcare utilisation and process of care measures in patients with congenital heart disease in the UK: cross-sectional, population-based study with case-control analysis. Heart. 2008 Sep;94(9):1194-9. doi: 10.1136/hrt.2007.122671. PMID: 17610000. Exclusion Code: X1.

67. Bischoff RJ, Hollist CS, Patterson J, et al. Providers' perspectives on troublesome overusers of medical services. Families, Systems, & Health. 2007;25(4):392-403. doi: 10.1037/1091-7527.25.4.392. PMID: 2007-19994-004. Exclusion Code: X1.

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Detailed Results Tables

Key Question 1: What criteria identify or predict that patients will be high-need, high-cost (HNHC)?

KQ 1a: How do criteria incorporate patient clinical characteristics?

Table B-1. Descriptive multivariate, ED visits outcome (n=13)

Author, Year	Population	Arthritis	Cancer	^{a}Cerebrovascular Disease	^{a}Congestive Heart Failure	^{a}COPD	^{a}Cardiovascular Disease	^{a}Dementia	^{a}Diabetes	^{a}Heart Disease	Hep C	Hepatobiliary Disease	HIV Seropositive	Hypertension	Pancreatic Disease	Pulmonary Circulation Disorder	Seizure	Sickle Cell	^{a}Vascular Disease	# of Conditions	Charlson Comorbidity Index	Charlson Severity Index	General Health Score	Global Physical Health Score	Health Status	Hierarchic Categorical Condition Score	Morse Fall Score	Quan-Charlson Score
Buhumaid, 2015[32]	Hospital/ health system																				+							
Hasegawa, 2014[35]	Hospital/ health system					+			+								+											
Hasegawa, 2014[36]	Hospital/ health system				+		+		+						+													
Chang, 2014[40]	Hospital/ health system									NS		+				NS				NS								
Chukmaitov, 2012[134]	Hospital/ health system																						+					
Milbrett and Halm, 2009[42]	Hospital/ health system	NS																										
Mandelberg, 2000[46]	Hospital/ health system	+				+					+						+	+	+									

Author, Year	Population	Arthritis	Cancer	[a]Cerebrovascular Disease	[a]Congestive Heart Failure	[a]COPD	[a]Cardiovascular Disease	[a]Dementia	[a]Diabetes	[a]Heart Disease	Hep C	Hepatobiliary Disease	HIV Seropositive	Hypertension	Pancreatic Disease	Pulmonary Circulation Disorder	Seizure	Sickle Cell	[a]Vascular Disease	# of Conditions	Charlson Comorbidity Index	Charlson Severity Index	General Health Score	Global Physical Health Score	Health Status	Hierarchic Categorical Condition Score	Morse Fall Score	Quan-Charlson Score
Surbhi, 2020[69]	Hospital/ health system		NS																		+							
Vinton, 2014[34]	Population based	+	+	+			+		+					NS												+		
Hunt, 2006[43]	Population based																											+
Friedman, 2009[44]	Population based																										+	
Zuckerman and Shen, 2004[47]	Population based																									+		
Kanzaria, 2019[67]	Population based				+	+			+	+			+			+												
Thakarar, 2015[33]	Single program										+	+																
Doran, 2013[59]	VA				+	+											+				-		+					

[a]Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

COPD = chronic obstructive pulmonary disease; ED = emergency department; HIV = human immunodeficiency virus; NS = not statistically significant; n = number; VA = Veterans Health Administration.

Table B-2. Predictive, ED visits outcome (n=3)

Author, Year	Population	Arthritis	[a]Congestive Heart Failure	[a]COPD	[a]Dementia	[a]Diabetes	Hypertension	Renal Disease	# of Conditions	CCI	Hierarchic Categorical Condition Score
Billings and Raven, 2013[41]	Medicaid									-	
Colligan, 2016[31]	Medicare	+	+	+	+	+	+	NS	-		+
Brannon, 2018[77]	Hospital/health system								+		

[a]Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not in the model.

CCI = Charlson Comorbidity Index; COPD = chronic obstructive pulmonary disease; ED = emergency department; NS = not statistically significant; n = number.

Table B-3. Descriptive multivariate, IP visits outcome (n=2)

Author, Year	Population	# of Conditions	CCI	Morse Fall Score
Bell, 2017[18]	Hospital/health system	+		
Porter, 2019[50]	Hospital/health system	+	+	+
Surbhi, 2020[69]	Hospital/health system		+	

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

CCI = Charlson Comorbidity Index ; IP = inpatient; n = number.

Table B-4. Predictive, IP visits outcome (n=3)

Author, Year	Population	Arthritis	Cancer	[a]Chronic Kidney Disease	[a]Congestive Heart Failure	[a]Cardiovascular Disease	[a]Diabetes	Hypertension	# of Conditions
Hempstead, 2014[135]	Hospital/health system								+
Leininger, 2014[136]; Leininger, 2015[137]	Medicaid								+
Chang, 2019[54]	VA	+	+	+	+	+	+	+	

[a]Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

IP = inpatient; n = number; VA = Veterans Health Administration.

Table B-5. Descriptive multivariate, all visits outcome (n=2)

Author, Year	Population	Charlson Severity Index	Global Physical Health Score
Rohrer, 2008[20]	Hospital/health system	+	
Blumenthal, 2017[48]	Hospital/health system		+

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

n = number.

Table B-6. Predictive, all visits outcome (n=3)

Author, Year	Population	[a]COPD	[a]Diabetes	Hypertension	# of Conditions	CCI	Other
Meek, 2000[24]	Commercial (including HMO)	+	+	NS			
Wherry, 2014[138]; Leininger and Avery, 2015[137]	Population based					+	
Reichard, 2015[23]	Population based				+/NS		Disability +

[a] Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model. +/NS denotes performance across multiple models within the study, ranging from a positive significant association to no significance.

CCI = Charlson Comorbidity Index; COPD = chronic obstructive pulmonary disease; HMO = health maintenance organization; NS = not statistically significant; n = number.

Table B-7. Descriptive multivariate, cost outcome (n=3)

Author, Year	Population	Cancer	[a]Cerebrovascular Disease	[a]Cardiovascular Disease	[a]Diabetes	Condition	General Health Score	Quan-Charlson Score	Other
Bayliss, 2016[56]	Commercial (including HMO)					+			+
Robinson, 2016[19]	Commercial (including HMO)	NS	NS	+	-		NS	+	
Figueroa, 2019[71]	Medicare		+	+	+				

[a] Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

HMO = health maintenance organization; NS = not statistically significant; n = number.

Table B-8. Predictive, cost outcome (n=1)

Author, Year	Population	[a]Diabetes	Hypertension	Pulmonary Circulation Disorder
Yang, 2018[25]	Medicaid	+	+	+

[a]Complex chronic condition

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

n = number.

KQ 1b: How do criteria incorporate patient demographic, behavioral health, and social risk factors?

Table B-9. Multivariate descriptive results

Author, Year	Outcome	Population	Female	Age	Race/Ethnicity	Depression	Severe Mental Illness	Other Mental Illness	Substance Use	Alcohol Use	Homelessness	Employment	Other Social Risk Factors
Bayliss, 2016[56]	Cost (top 25%)	Commercial (including HMO)	+	Over 55+		+							
Robinson, 2016[19]	Cost (top 10% of all-cause total costs)	Commercial (including HMO)	NS	NS		NS		NS/+	+	NS		NS	
Sterling, 2018[21]	Cost (top 20%)	Commercial (including HMO)						+					Any financial burden +
Walker, 2003[51]	Cost (adjusted annual cost ratios of median healthcare costs)	Commercial (including HMO)	NR	NR	NR			PTSD+					
Berkowitz, 2018[70]	Cost (top 10%, 5% & 2%)	Population based	NS	+	Black: + White: + Hispanic:								Food insecurity: + Ed: NS Income: NS
Figueroa, 2019[71]	Cost (top 10%)	Medicare	-	-	Black: + Hispanic: +	+							Income: + Dual elig: +
Behr, 2016[30]	ED visits (2+, 3+, 4+, 5+)	Hospital/health system	+		Black +/NS			+	+			Employed +	
Bell, 2017[18]	Inpatient visits (3+)	Hospital/health system	NR	NR	NS				+	+	+		Community-level income <48k NS
Blumenthal, 2017[48]	All utilization (ED visits, acute hospitalizations)	Hospital/health system	NR	NR	NR			Lowest quartile in Global Mental Health score NS					
Buhumaid, 2014[32]	ED visits (4+)	Hospital/health system	NS	Age (40+) NS	Black +				-	+	+		

Author, Year	Outcome	Population	Female	Age	Race/Ethnicity	Depression	Severe Mental Illness	Other Mental Illness	Substance Use	Alcohol Use	Homelessness	Employment	Other Social Risk Factors
Chang, 2014[40]	ED visits (4+ in 12 months)	Hospital/health system	NS	NS	Not in model			Personality dx +	SUD dx NS Positive cocaine screen+	NS	+		
Chukmaitov, 2012[134]	ED visits (1+, 1-3, 4+)	Hospital/health system	+	Age (30-39) - (40-49) NS (50-64) + (65-74) + (75-84) + (>85) -	Black + Hispanic + Other -								
Doran, 2014[38]	ED visits (3+)	Hospital/health system	NR	NR	NR								
Hasegawa, 2014[35]	ED visits (3+ ED, 30-day ED revisit, IP visit)	Hospital/health system	-	Age (<74) +	Black + Hispanic + Other NS	+			+				Quartiles for median household income of patient's zip code 1 (lowest) and 2 + 3 NS
Hasegawa, 2014[36]	ED visits (3+)	Hospital/health system	-	Over 54+	+/NS	+	+		+				Lowest quartile median income +
Hasegawa, 2014[37]	ED visits (0, 1-2, 3-5, 6+)	Hospital/health system	NS/-	40-54 NS/+	NS								Lowest quartile median income NS
Liu, 2013[39]	ED visits (4+, 4-7, 8-18, 19+)	Hospital/health system	NR	NR	NR			+	+	+			
Mandelburg, 2000[46]	ED visits (5+)	Hospital/health system	NS	Age (30-59) +	Black + Hispanic - Native American + Asian - Other -					+	+		
Surbhi, 2020[69]	ED visits	Hospital/health system	NS		Black +			+					

Author, Year	**Outcome**	**Population**	**Female**	**Age**	**Race/Ethnicity**	**Depres-sion**	**Severe Mental Illness**	**Other Mental Illness**	**Sub-stance Use**	**Alcohol Use**	**Home-less-ness**	**Employ-ment**	**Other Social Risk Factors**
Castillo, 2018[65]	ED visits (>5) vs 1-5	326 hospitals in CA	-	75-84 & 85+ vs 65-73 -	Black: + Hispanic + Asian/Pacific Islander -			+	+				
Millbrett, 2009[42]	ED visits (>6)	Hospital/health system	-		Nonblack +		NS					Part-time employment retired/unemployed,+	
Porter, 2019[50]	Inpatient visits (3+)	Hospital/health system	NR	Under 40+	NR			+	+				
Emechebe, 2019	Inpatient visits (2+)	Medicaid managed care and Medicare Advantage health plan	NR	NR	NR	NR	NR	NR	NR	NR	Housing support need +		Needs: Financial assistance +; food +; transport-ation +, medication assistance +
Surbhi, 2020[69]	Inpatient visits	Hospital/health system	NS		Black – Black: NS			+					
Rohrer, 2008[20]	All utilization (27+ outpatient visits)	Hospital/health system	NS	NS	Not in model								
Ruger, 2004[45]	ED visits (1, 2, 20+)	Hospital/health system	NR	NR	Not in model								
Kanzaria, 2019[67]	ED visits (4-7)	Medicaid MCO in one city	-	Older: -	Black: + Hispanic: NS Asian: -	+	+	+	+	+	+		Interaction with county jail system: +
Thakarar, 2015[33]	ED visits (2+)	Hospital/health system (single program)	NS	55+ NS	Minority NS			NS	NS	NS			More than 1 housing change NS
Freidman, 2009[44]	ED visits (4+)	Population based		NS		NS							Income <\$40k + <\$90k NS
Hunt, 2006[43]	ED visits (1-3, 4+)	Population based			NS			+					Income by poverty threshold 200-399% + 100-199% + Below threshold +

Author, Year	Outcome	Population	Female	Age	Race/Ethnicity	Depression	Severe Mental Illness	Other Mental Illness	Substance Use	Alcohol Use	Homelessness	Employment	Other Social Risk Factors
Vinton, 2014[34]	ED visits (0, 1-3, 4-9, 10+)	Population based	+	>44-	Black + Hispanic - Asian - Other NS			+		NS		Currently employed -	Poverty–income ratio (Ref is ≥4) +
Zuckerman, 2004[47]	ED visits (3+)	Population based			Black + Hispanic NS Asian NS								Near poor and poor + Single parent +
Doran, 2013[59]	ED visits (0, 1, 2-4, 5-10, 11-25, >25))	VA	-			+	+	+	+	+	+		
Levinson, 2005[139]	All utilization (3+ ED; 2+ specialty clinic visits)	VA	NR	NR	NR								

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

CA = California; dx = diagnosis; Ed = education; ED = emergency department; HMO = health maintenance organization; IP = inpatient; k = thousand; NR = not reported; NS = not statistically significant; PTSD = post-traumatic stress disorder; Ref = reference group; SUD = substance use disorder; VA = Veterans Health Administration; vs = versus.

Table B-10. Predictive results

Author, Year	Outcome	Population	Female	Age	Race/Ethnicity	Depres-sion	Severe Mental Illness	Other Mental Illness	Substance Use	Alcohol Use	Homeless-ness	Employment	Other Social Risk Factors
Meek, 2000[24]	All utilization (6+ visits in 6 months)	Commercial (including HMO)	+	Under 40 -	NR			+/NS/-					
Brannon, 2018[77]	ED visits (1+, 2+, 3+, 4+, 5+)	Hospital/health system		Age + but not defined									Zip code+ but not defined
Hempsted, 2014[135]	Inpatient visits (1+, 2, 3+)	Hospital/health system	-	Age (Ref is 80+) 18-34 + 35-49+ 50-64 + 65-79 +	Race/ethnicity (Ref is white) Asian/PI - Black - Hispanic - Other +			+	+				HH income < $34.999k +
Hwang, 2014[140]	ED visits (4+ visits in both years; 4+visits either year; <4 visits in both years)	Hospital/health system	-		Nonwhite+	NR				NR			Low median household income+
Billings, 2007[62]	Inpatient visits (1+ hospital admission in next 12 months)	Medicaid	NR	NR	NR		+	+	+				
Billings, 2013[41]	ED visits (3+)	Medicaid			Not in model								
Leninger, 2014, 2015[136, 137]	Inpatient visits (1+ inpatient hospitalization)	Medicaid	NR	NR	NR			+	+		+		
Raven, 2008[60]	Inpatient visits (1+ readmission)	Medicaid											
Yang, 2017[22, 53]	Cost (persistent top 10% decile)	Medicaid	NR	NR	NR								
Yang, 2018[25]	Cost (top 10% expenditures in next 12 months)	Medicaid	NR	NR	NR								

Author, Year	Outcome	Population	Female	Age	Race/Ethnicity	Depres-sion	Severe Mental Illness	Other Mental Illness	Substance Use	Alcohol Use	Homeless-ness	Employment	Other Social Risk Factors
Colligan, 2016[31]	ED visits (0, 1-3, 4+)	Medicare		≤64 + ≥75 +	Race (Ref is white) Black + Asian - Hispanic - Native American + Unknown/other -			+					
Kanzaria, 2017[28]	ED visits (4+ visits in 12 months)	Population based			Black +/NS Hispanic + Other -/NS	+/NS	-/NS	+/NS	+/NS	+/NS			Poverty indicator NS
Reichard, 2015[23]	All utilization (≥75th percentile)	Population based	NR	NR	NR								
Wherry, 2014[137, 138]	All utilization (top decile)	Population based						NS					
Chang, 2019[54]	Inpatient visits (persistently high risk, intermittent, or low risk in 2 years)	VA	-	Over 45+	Race (ref Hispanic) White - Black - Other - ($p<0.05$)			+	+ (tobacco)		-		Number of zip code changes + Urban+

+ denotes significant positive association, - denotes significant negative association, NS denotes no significance, NR denotes not reported, and a blank cell denotes not included in the model.

ED = emergency department; HH = household; HMO = health maintenance organization; NR = not reported; NS = not statistically significant; PI = Pacific Islander; Ref = reference group; VA = Veterans Health Administration.

Key Question 2: What are the mechanisms that lead to reductions in potentially preventable or modifiable healthcare use and result in improved health outcomes and cost savings in interventions serving HNHC patients?

Table B-11. Full list of CMO configurations and supporting data for Program Theory 1: Identifying and targeting HNHC patients for inclusion in interventions

Summary: Identifying and targeting HNHC patients for interventions intended to reduce potentially preventable or modifiable healthcare use and costs requires capturing their complexity based on a combination of prior use of healthcare services, chronic disease, nonmedical barriers to accessing care, experience with the healthcare system, clinician judgment, and patient willingness to participate.[a]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.1. Including historic information obtained from claims and other electronic health records, that can identify prior high cost and/or use of healthcare services [C], adds to intervention designers' confidence in creating an algorithm [M] that will result in targeting patients who are at the greatest risk of being HNHC in the future [O].	Participants were drawn from adult Medicaid patients attributed to CareMore primary care physicians (PCPs). Program eligibility criteria were aimed at identifying patients at risk for poor outcomes and unnecessary spending, as well as those most likely to benefit from complex care management. The criteria drew from analyses suggesting that combining predictive models, historical claims, and clinician judgment is the most effective approach to identifying patients for complex care management. Eligible patients were first required to meet at least 1 of the following criteria: top 5% of total medical expenditures (TME) in the prior 12 months, top 5% of Chronic Illness Intensity Index (CI3) score, or care team member nomination.[108] Predicted future health care costs are based on the Predictive Risk Intelligence SysteM (PRISM) medical cost risk score developed and implemented by Washington State Medicaid programs (Court et al. 2011). PRISM combines diagnostic and pharmacy data to predict future expenditures based on grouping algorithms from two risk adjustment models widely used by State Medicaid programs, the Chronic Illness and Disability Payment System (Kronick et al. 2000) and Rx-Medicaid (Gilmer et al. 2001), both of which have predictive accuracy comparable to commercial alternatives. The PRISM risk score is a ratio calculated by dividing the individual's expected monthly future expenditures by the average monthly future expenditures of all Medicaid SSI recipients. The risk score equals 1.0 if the individual's expected expenditures equal the average expenditures of the group.[112] Rely on more than 1 type of data-because it may be vulnerable to inaccuracies: One program said they use predictive modeling so that they are not "held hostage waiting for claims to come down the road." Washington State uses predictive modeling to begin to identify the target population. Using its Health Service Encounter algorithm, the state examines 15 months of integrated health care claims to determine future medical costs and inpatient risk scores. The state has found that conditions such as diabetes, cardiovascular disease, MH and substance abuse are common among the superutilizing subset of patients. It uses different approaches to further stratify subgroups for complex care management including identifying individuals with extreme emergency department utilization (e.g., approximately 80 to 130 ED visits in 15 months), high expected future

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[a] Theory and guidance from National Academy of Medicine report: "Determining an ideal definition for a high-need patient requires a delicate balance. A highly constrained definition will risk missing people, potentially depriving them of needed resources. On the other hand, casting an overly broad definition might include people who are not high-need and do not need additional resources. Abrams noted that basing identification of high-need patients exclusively on cost will miss many people, and if the focus is exclusively on chronic conditions, a large number of people may be identified whose chronic conditions are under control."[12]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.1. Including historic information obtained from claims and other electronic health records, that can identify prior high cost and/or use of healthcare services [C], adds to intervention designers' confidence in creating an algorithm [M] that will result in targeting patients who are at the greatest risk of being HNHC in the future [O]. (continued)	medical costs (predicted by high utilization and costs in the past), high prospective inpatient risk scores, and sign gaps in care and quality indicators.[49] The programs represented at the Summit generally use historical claims data as a foundation to understand the size and scope of super-utilization. Claims analysis is an iterative process and includes identifying areas of high cost and high utilization, and/or identifying groups of recipients with a high number of diagnoses. With this initial broad brush information, programs are able to further shape and define the target population. For example, Community Care of North Carolina (CCNC), which includes 14 regional networks that manage the care of Medicaid beneficiaries, will analyze at least 12 months of data in order to understand which chronic illness and mental health indicators are contributing to a high number of ED visits.[49] "After an individual's records were linked across data sets, the process of flagging individuals as ''high utilizers'' began. Instead of using charges or receipts to define high utilizers, the decision was made to rely on the number of emergency department (ED) and inpatient visits made by an individual over the prior 12-month period."[78] "From the best-fit synthesis we conducted to answer KQ 1, we identified some characteristics that are often available through electronic databases that can be used to help identify patients." (Discussion section of this report. Also see full results for KQ 1) During the first site visit, physicians at both sites reported that they were initially very enthusiastic about the Health Buddy® program, because it offered a promising way to effectively support patients with chronic disease….. Once the physicians received the list of patients who were eligible for the Health Buddy® program, they reported that they became frustrated with the project because they felt that many of the patients selected would not benefit from participating. Further, physicians reported disappointment that many of the patients they believed could be helped by the program were not eligible to participate in the program because they had not been identified through the claims based algorithm developed by HHN.[80] Risk assessments of the TST participant population were conducted to inform the development of individualized care plans and assign participants to one of three risk categories to determine the level of service to be provided to each participant.…TST reported that the high-risk intervention was provided to approximately 5% to 7% of the TST participant population that had depression and/or potentially critical health problems that required immediate attention....What might explain the lack of success in TST's demonstration? Ineffective Targeting. One explanation may be the inability to accurately target beneficiaries at greatest risk of intensive, costly, service use (as distinct from the need for general care management). ...When TST learned that one of its participants was admitted to the hospital, it reassigned this individual to its high-risk intervention, and when appropriate, a care manager visited the beneficiary in the hospital to determine the cause of the hospitalization and identify any new health or social issues to be addressed. Not surprisingly, TST adopted a strategy of targeting beneficiaries at greatest risk of a hospitalization and higher costs. Their targeting strategy was unsuccessful—and costly. The program was unable to predict future complications with any precision for those with initially stable, less costly, conditions. Lacking direct access to patients' medical records, the health coaches often began working with beneficiaries with incomplete information.[79] There are two key elements to the success of these new efforts to target and improve care for high-cost Medicaid cases. First, it is essential to be able to identify in advance patients who are likely to have high costs in the future. Many high-cost occurrences (such as injury, acute illness, or cancer) might be episodic, and high spending in one year might not mean high spending in subsequent years.[62]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.1. Including historic information obtained from claims and other electronic health records, that can identify prior high cost and/or use of healthcare services [C], adds to intervention designers' confidence in creating an algorithm [M] that will result in targeting patients who are at the greatest risk of being HNHC in the future [O]. (continued)	We conducted a retrospective analysis of secondary data from the Medicare program and other linked sources. We used 3 databases, including the Chronic Condition Data Warehouse, hierarchic categorical condition scores, and timeline files. The Chronic Condition Data Warehouse includes fee-for-service billing history for services reimbursed under Medicare Parts A, B, and D, as well as data about beneficiary demographic characteristics, linked at the beneficiary level with a unique identification number.[31] We used data from three health systems to develop, evaluate, and implement a model for the prediction of high ED utilization in Washtenaw and Livingston counties: Michigan Medicine and St. Joseph Mercy Health System (operators of all EDs in Ann Arbor and Livingston County) and Integrated Health Associates (IHA), a multispecialty medical practice with clinical sites in both counties.[77] Administrative data from DH's data warehouse were used to obtain demographic, medical, psychological/behavioral health and service utilization and claims data. The tight administrative and clinical integration among all care settings facilitates data capture across the continuum of care.[83] After an individual's records were linked across data sets, the process of flagging individuals as ''high utilizers'' began. Instead of using charges or receipts to define high utilizers, the decision was made to rely on the number of emergency department (ED) and inpatient visits made by an individual over the prior 12-month period. This step eliminated potential variability related to differences in treatments and payers. Rather than assigning an artificial cutoff, the nuances of the local population were allowed to set the threshold for what constituted high utilization. The Coalition defined high utilization as ''any individual with total emergency or inpatient visits greater than 1.5 standard deviations above the mean.'' This definition resulted in any individual with 3 or more inpatient visits, or 6 or more ED visits, being flagged in the database as a high utilizer.[78] The site for this study was the Duke Outpatient Clinic (DOC), a large primary care safety net clinic in Durham, North Carolina. Patients at the DOC have a high prevalence of multimorbidity, mental illness, and socioeconomic challenges. Beginning in 2012, the clinic initiated an extensive redesign process to better meet complex population health needs and reduce avoidable utilization of ED and inpatient care. This study was conducted to direct further quality improvement efforts. Multiple methods were applied, including both retrospective quantitative analysis of clinical data and an in-depth chart review. The study team extracted electronic health record data for all patients enrolled at the DOC between July 1, 2014, and June 30, 2015. The team matched these data to ED encounter data for the same year period from 2 local hospitals within the Duke University Health System, where DOC patients receive a vast majority of their emergency and hospital care. Lastly, the team conducted 30 chart reviews for 10 of the highest ED utilizers for each of the 3 leading chief complaints to uncover additional details surrounding their frequent ED use patterns.[17] The literature contains varying definitions for super-utilizer. The definition used for this analysis was adapted from the work of Johnson, et al. and defined super-utilizers as adult patients (≥ 18 years of age) who, along with having an admission (analysis index admission) during the requisite timeframe, had at least two other admissions in the year prior, or at least one other admission along with a serious mental health diagnosis… In order to focus the analysis on cost savings that could be linked to our interventions, patients on chemotherapy, patients with orthopedic complications, patients diagnosed with HIV, and patients who had repeated admissions for emergency dialysis were excluded from analysis.[83]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.2 Capturing a patient’s use of services in “real time,” if possible, while the patient is still hospitalized [C], adds to the intervention service provider’s confidence that a patient is identified during a period of urgent need for the services [M], resulting in intervention services being initiated prior to or during a period of high use and not during a later period, when service use may have already declined (regression to the mean) [O].	More than half of patients approached in the ED refused to participate, possibly due to competing concerns about their illness or participating in research. Those who enrolled may have been more engaged, and thus, more likely to respond to the intervention, than those who declined. Identifying and approaching patients in real time may be time consuming and resource intensive, but this approach has been found to be more effective in addressing the needs of some populations of high utilizers than using historical claims data to identify and ‘‘segment’’ high utilizers with aligned interventions.[110] To be most effective, complex care management programs should target patients at risk of persistently high spending and those whose spending and health outcomes are amenable to complex care planning and engagement. Many complex care management programs use claims data and historical utilization patterns to identify eligible patients. Recent research has highlighted the limitations of this approach—historically high-cost patients often return to normal patterns or spending, or they have drivers of high spending not amenable to complex care management.[108] In order to identify chronic frequent users, rather than those with an isolated health event requiring multiple visits, we identified patients with the most ED visits during both the 30-day period and the 12-month period preceding the introduction of the program.[111] The Summit participants unanimously agreed that access to real-time information—such as notifications of ED visits or inpatient admissions—and a strong analytics team provide a critical foundation for super-utilizer programs. One leader referred to data as “oxygen for our program.” Programs place a high priority on developing a robust data repository that can be mined to identify groups of patients that might respond well to complex care management.[49] Eligible patients were identified through real-time automated methods and recruitment occurred while patients were still hospitalized. Patient intake included an in-depth patient assessment to determine nonmedical barriers to improved health.[83] This “real time” approach of using a hospital admission as a triggering event was perceived as useful for two reasons. First, patients with a hospital admission are much more likely to have a subsequent admission in the next twelve months than patients without an admission, which improves the potential case-finding capacity of the algorithm. But, equally important, effective discharge planning is likely to be a critical component of any intervention strategy for high-cost, high risk patients. However, because of limited resources and lag time in acquiring data, our experience in other environments has suggested that some providers and payers are interested in non–“real time,” retrospective analyses. Accordingly, we also examined patients with any claims in 2000–2003, to predict subsequent admissions in 2004 (regardless of whether they had a hospital admission in 2003 or any prior year). This “archival” approach to case finding is somewhat less robust (it finds fewer patients) than the “real time” method and only brief findings for this approach are presented for comparative purposes.[62] Risk assessments of the TST participant population were conducted to inform the development of individualized care plans and assign participants to one of three risk categories to determine the level of service to be provided to each participant….TST reported that the high-risk intervention was provided to approximately 5% to 7% of the TST participant population that had depression and/or potentially critical health problems that required immediate attention....What might explain the lack of success in TST’s demonstration? Ineffective Targeting. One explanation may be the inability to accurately target beneficiaries at greatest risk of intensive, costly, service use (as distinct from the need for general care management). ...When TST learned that one of its participants was

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.2 Capturing a patient's use of services in "real time," if possible, while the patient is still hospitalized [C], adds to the intervention service provider's confidence that a patient is identified during a period of urgent need for the services [M], resulting in intervention services being initiated prior to or during a period of high use and not during a later period, when service use may have already declined (regression to the mean) [O]. (continued)	admitted to the hospital, it reassigned this individual to its high-risk intervention, and when appropriate, a care manager visited the beneficiary in the hospital to determine the cause of the hospitalization and identify any new health or social issues to be addressed. Not surprisingly, TST adopted a strategy of targeting beneficiaries at greatest risk of a hospitalization and higher costs. Their targeting strategy was unsuccessful—and costly. The program was unable to predict future complications with any precision for those with initially stable, less costly, conditions. Lacking direct access to patients' medical records, the health coaches often began working with beneficiaries with incomplete information.[79] What might explain the lack of success in the Phase II KTBH Demonstration? One explanation may be the targeting of beneficiaries at greatest risk of intensive, costly, service use (as distinct from the need for general care management). Responding to KTBH's request, CMS staff selected a very costly, complex set of Medicare beneficiaries for their intervention and comparison groups. As a result, the comparison group exhibited substantial regression-to-the-mean (RtoM) effects. While the randomized experimental design should cancel out RtoM effects and isolate a pure intervention effect, the large churning of beneficiaries from lower (higher) to higher (lower) cost groups over time adds considerable statistical noise to the test of savings. Even still, we would have considered the Phase II original intervention to be a success if it had saved 5.4% of costs. Large increases in demonstration period costs in less costly beneficiaries in the base period make it very difficult for intervention staff to target those at highest financial risk. It is much easier to target beneficiaries during the intervention period who actually incur major flare-ups and hospitalizations. Unfortunately, these beneficiaries have already incurred major expenditures by the time they receive intensive disease management services.[82]
CMO 1.3. Considering patients' chronic conditions, functional limitations, and clinical severity scores [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2].	Three categories of high-cost users—beneficiaries who had multiple chronic conditions, were hospitalized, or had high total costs—were identified by CBO for study of persistence of Medicare expenditures over time. Beneficiaries that were selected based upon hospitalization or being in the high total cost groups had baseline expenditures that were four times as high as expenditures for a reference group. Beneficiaries selected based upon presence of multiple comorbid conditions had baseline expenditures that were roughly twice as high as expenditures for a reference group. Subsequent years of costs remained higher for all three cohorts than the reference group; however, total expenditures declined the most for those beneficiaries who were identified as high cost due to a hospitalization followed by beneficiaries who had had high total costs in the base year. Subsequent costs were virtually unchanged for beneficiaries with multiple chronic conditions.[81] Denver Health reported challenges in using utilization data alone to find patients at chronic high risk of acute care use—but identifying these patients was important for the success of 21st Century Care. That is, Denver Health assumed that 21st Century Care could reduce service use (such as hospitalizations and ED visits) by identifying patients with chronic care needs and then delivering preventive care to preempt higher-cost acute care later on.…Over the course of the award, however, Denver Health learned that many of its highest-cost patients were only temporarily high cost, suggesting that many of them would have returned to moderate- or low-cost status even without intervention. For example, under its risk stratification algorithm, Denver Health identified so-called super utilizers—all of whom were Tier 4—as people with three or more hospital admissions in a 12-month period, or two or more admissions and a mental health diagnosis. These people accounted for about 30 percent of adult facility costs. By analyzing pre-intervention data, however, research staff at Denver Health showed that, even without special intervention, fewer than half of these super utilizers at a single point in time were still in the category seven months later, and only 28 percent were in the category at the end of 12 months (Johnson et al. 2015b). Because of this challenge using utilization data alone to find chronic high-risk patients, Denver Health, as noted previously, added clinical information (in the form of both CRGs and clinical data such as lab results) to its second and third iterations of the risk-stratification algorithm (although lab results were later removed in subsequent algorithm iterations). Denver Health reported that each revision to the algorithm helped to identify patients who would benefit most from 21st Century Care's intensive services.[85]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.3. Considering patients' chronic conditions, functional limitations, and clinical severity scores [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	Denver Health recognized that people with exceptionally high service use at one time did not necessarily continue to have exceptional service use in the future. Over the course of the award, Denver Health integrated clinical information into its risk-stratification algorithm to try to better identify patients who would benefit from intervention.[85] Key Finding #1: Several vulnerable subpopulations of Medicare FFS beneficiaries were less likely to agree to participate in the CLM demonstration program. Of all CLM intervention beneficiaries, 65% verbally consented to participate in the CMHCB demonstration at some point during the intervention period. We found that Medicaid enrollees and institutionalized beneficiaries were less likely to be participants; both groups are costly and high users of acute care services. In general, participants tended to be healthier than nonparticipants using baseline characteristics including the prospective HCC score. However, beneficiaries with higher concurrent HCC scores based on the first 6 months of the demonstration were more likely to participate than healthier beneficiaries. This suggests that CLM made some inroads into engaging those with acute clinical deterioration. Further, as CLM's program matured, they appeared to be more successful engaging sicker and more costly beneficiaries based on baseline health status; however, those with Medicare/Medicaid dual enrollment and the institutionalized were still less likely to become participants. These findings suggest alternative recruiting and outreach strategies are needed to reach dual Medicare/Medicaid enrollees and beneficiaries who are institutionalized.[84] Key Finding #1: The HBC program was able to engage beneficiaries who were at higher risk of acute clinical deterioration as measured by the concurrent HCC score. Of the HBC original intervention beneficiaries, 45% verbally consented to participate in the CMHCB demonstration at some point during the intervention period; 40% of the refresh population agreed to participate. For the HBC program, we find that beneficiaries with medium and high concurrent HCC scores were more likely to be participants. Beneficiaries with higher prospective HCC scores and baseline Charlson comorbidity scores were less likely to be participants. This suggests that the HBC program was less able to engage the historically sicker Medicare beneficiaries but more able to engage those at higher risk of acute clinical deterioration as measured by the concurrent HCC score.[80] While the high-need patient population is diverse, a synthesis of analyses reported in the literature identified three criteria that could form a basis for defining and identifying this population: total accrued health care costs, intensity of care utilized for a given period of time, and functional limitations.[12] Medicare FFS beneficiaries with a primary residence in one of five designated counties including Boston, Massachusetts, and surrounding areas, and a high level of disease severity as indicated by Hierarchical Condition Categories (HCC) scores and high health care costs based on Medicare claims filed during calendar year 2005. Beneficiaries with HCC risk scores >=2.0 and annual costs of at least $2,000 or HCC risk scores >=3.0 and a minimum of $1,000 annual medical costs are eligible for the MGH's CMP.[86] Eligible patients were identified by using standard criteria: a risk score in the 90th percentile for 90-day hospitalization from a validated risk-prediction algorithm (13) and a recent hospitalization or emergency department visit.[87]Although high utilizers differed significantly from other patients in their medical and behavioral health needs, their presenting complaints were not categorically different from those of low utilizers—they simply had more visits for the same types of complaints utilizers were more likely to present to the ED multiple times for the same complaint. However, most high utilizers had 4 unique chief complaints, suggesting that these patients generally have several, rather than a few, reasons for seeking emergency care. No clearly defined pattern of complaints

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.3. Considering patients' chronic conditions, functional limitations, and clinical severity scores [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	existed for high utilizers. High utilization in such patients is less likely to be caused by clearly defined disease processes and more by a complex mix of multiple chronic medical conditions and psychosocial factors, making it difficult to predict future utilization or identify specific patient needs based on their chief complaint.[17] Predictive modeling is a common tool used by super-utilizer programs to identify who might be at risk for super-utilizing in the future. One program said they use predictive modeling so that they are not "held hostage waiting for claims to come down the road." Washington State uses predictive modeling to begin to identify the target populations. Using its Health Service Encounter algorithm, the state examines 15 months of integrated health care claims to determine future medical costs and inpatient risk scores. The state has found that conditions such as diabetes, cardiovascular disease, mental health and substance abuse are common among the super-utilizing subset of patients. It uses different approaches to further stratify subgroups for complex care management including identifying individuals with extreme ED utilization (e.g., approximately 80 to 130 ED visits in 15 months), high expected future medical costs (predicted by high utilization and costs in the past), high prospective inpatient risk scores, and significant gaps in care and quality indicators.[49]
CMO 1.4. Considering patients' behavioral health and social risk factors (e.g., mental health and substance use disorder diagnoses and social needs) [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2].	The screening process includes administrative data screening to determine eligibility by usage criteria, followed by an in-person screening to determine other eligibility criteria and ability to consent. Randomization occurred after consent. A proprietary platform integrates study data with real-time data feeds from multiple sources. Staff screened potential participants based on their use of county-funded services over the prior 1-2 years. Our research team developed an electronic triage tool that uses administrative data to predict the likelihood of future high use of county-funded services. To meet criteria, potential participants must have used various combinations of the ED and psychiatric ED, medical and psychiatric inpatient stays in the County-funded public hospital, and/or jail over the past 1-2 years, at high enough levels to meet a threshold score. We embedded the triage tool into the study database and generated a list of potentially eligible participants with the highest scores, redoing the calculation throughout the enrollment period. All county agencies or service providers could refer individuals they suspected met eligibility criteria, but study staff always used the list generated by the triage tool to confirm initial eligibility. County staff used this list to outreach to the highest using individuals.[109] Individuals with disability, transportation challenges, homelessness, mental health conditions, and with substance abuse or chemical addiction may be hard to find and engage when they are not actively in treatment. Partnering with public health agencies and community-based organizations was identified as an approach that allows health care organizations to more successfully identify and engage these hard-to-reach populations, some of whom harbor mistrust of health care professionals. Although such partnerships would ideally build on shared data for surveillance, programs had developed approaches in the absence of a formal data sharing system. For example, the Gatekeeper program in Ohio developed a community referral model to identify high risk individuals in partnership with a network of trained community volunteers such as bank tellers, police officers, paramedics, and pharmacists. Volunteers initiated referrals directly to the Gatekeeper program for older adults who identified as being potentially at risk or who might benefit from community services.[113] The data on diagnostic history and characteristics of subsequent admissions may also provide some help in conceptualizing intervention design. The relatively high rates of chronic disease suggest the importance of a comprehensive, multidisciplinary approach to any intervention, using what we already know about improving chronic disease management (such as the chronic care model). But the extraordinarily high levels of substance abuse among high-risk patients and the history of mental illness even among the population without serious and persistent mental illness make clear that any intervention will have to take these factors into account. Whatever is on the shelf from chronic disease management vendors for commercial plans and Medicare will require a serious overhaul for adaptation to these populations.[62]

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CMO 1.4 Considering patients' behavioral health and social risk factors (e.g., mental health and substance use disorder diagnoses and social needs) [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	There are also other important questions that remain unanswered. From claims records we can say little about the social and personal characteristics of these patients. This is a population living in extreme poverty, and a broad range of factors (educational, behavioral, and coping capacity) likely complicate their lives. We have documented their mental illness and substance abuse problems, and there are also potentially high levels of homelessness and housing instability. Getting more and better information about these issues will require further work, but it is clearly critical to any intervention design. However, the potential impact of solving these problems may also be large, even for the most apparently daunting problems such as the high number of mental illness admissions. For some high-risk patients, an effective, supportive housing environment might be enough to tip the balance, allowing sufficient life stabilization to address previously intractable health and mental health problems. An emerging body of research indicates that these "social service" interventions can have a major impact on the use of health services.[62] Our findings also show the importance of including patients with mental health disorders in an intervention program. John Billings and Maria Raven noted that more than a third of high utilizers have at least one claim with a mental health disorder diagnosis. Other studies have However, more than half noted that people with mental health disorders have higher rates of receiving ED and inpatient care.20 Most of the patients enrolled in our study had either depression or anxiety. While B2C did not target people with severe mental health needs (such as those recently hospitalized at a psychiatric facility), to our knowledge, the program is unique in having a behavioral health provider screen every enrollee for mental health disorders—and then address those conditions as appropriate.[88] Participating super-utilizer programs reported a high prevalence of behavioral health diagnoses in high-utilizers through claims data. Indeed per capita Medicaid costs increase significantly with the addition of a mental health diagnosis, substance abuse diagnosis, or mental health plus substance abuse diagnosis[49] All stakeholders identified poorly managed serious mental illness among HNHC patients as a significant driver of preventable high health care utilization. Patients often had inadequate access to mental-health and substance-abuse resources. This was because outpatient programmes did not exist, were inconveniently located or were not financially feasible to attend. This left patients without any options other than the ED for care. Additionally, several patients acknowledged that feeling depressed negatively impacted their care routines and contributed to missing provider appointments which, over time, compounded the severity of their diseases. Importantly, patients also pointed out that the stigma surrounding mental illness was detrimental to their desire to seek out treatment even if it were available. Some patients also felt that policies such as the Florida Mental Health Act (known as the Baker Act) and its equivalent in New York State (known as Kendra's Law),20,21 which allow for involuntary institutionalization and examination of an individual with possible mental illness for up to 72 hours, did not adequately address or help mitigate the root causes of substance abuse and mental-health disorders. This increased preventable ED and/or hospital utilization for psychiatric needs.[61] "Most high utilizers had ≥4 unique chief complaints, suggesting that these patients generally have several, rather than a few, reasons for seeking emergency care. No clearly defined pattern of complaints existed for high utilizers. High utilization in such patients is less likely to be caused by clearly defined disease processes and more by a complex mix of multiple chronic medical conditions and psychosocial factors, making it difficult to predict future utilization or identify specific patient needs based on their chief complaint." Most high utilizer ED visits appeared to occur close together in clusters presenting complaints not categorically diff from low utilizers: more visits for same type of complaints. Most common complaint across utilizer groups: abdominal pain, chest pain,

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CMO 1.4 Considering patients' behavioral health and social risk factors (e.g., mental health and substance use disorder diagnoses and social needs) [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	and shortness of breath. " The chart review in this study highlighted the inherent difficulty in determining whether patterns of high utilization for these 3 complaints are related more to medical conditions or social/behavioral factors. Although nearly all of the patients in the chart review had mental illness and/or substance abuse, far fewer visits than expected were clearly linked to these conditions.[17] The Camden Coalition conducts a cluster analysis to ID the various subpopulations. This involves sorting cases (usually by patient utilization history) into groups, or clusters, so that the degree of association is strong between people in the same cluster, and weak between members in diff ones. Some programs stratify the typologies by the different social needs faced by the patients such as homelessness, joblessness, and language preference—further indicating what interventions would be the most effective.[49] Both the taxonomy developed by the Harvard T.H. Chan School of Public Health and the one developed by The Commonwealth Fund segment high-need individuals based on medical characteristics because this is a feasible starting point for most health care systems. Recognizing that a taxonomy focused on medical characteristics may neglect other factors that are key drivers of need, the taxonomy working group built on these efforts to offer a conceptual starter taxonomy that incorporates functional, social, and behavioral factors into a medically oriented taxonomy, not as independent segments but as factors that influence the care model or care team composition most likely to benefit particular patient segments (Figures S-2 and Table S-1). This starter taxonomy can provide guidance for health system leaders and payers on how to embed social risk factors, behavioral health factors, and functional limitations in a taxonomy for high-need patients. Patients would first be assigned to a clinical segment, with follow-on assessment of behavioral health issues and social services needs to determine the specific type of services that are required. Key behavioral health factors most likely to affect care delivery decisions include substance abuse, serious mental illness, cognitive decline, and chronic toxic stress and key social risk factors include low socioeconomic status, social isolation, community deprivation, and house insecurity.[12] In the early stages of the CMHCB demonstration, CMP leadership learned that many high-cost, complex patients have mental health issues that were not effectively addressed by the current model of health care delivery or its pilot program. As a result, the program allocated greater resources to support mental health, hiring a social worker to assess the mental health needs of CMP participants and support them in accessing psychiatric care as needed or provide treatment if appropriate.[86]
CMO 1.5 Considering patients' self-assessments of "subjective" characteristics about themselves [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2].	Using the Medicare Health Risk Assessment, we explored two data-driven methods to segment a heterogeneous population of older adults with potentially complex care needs into clinically meaningful subgroups using self-reported information. Input variables for the segmentation analyses were patient-reported variables drawn from the Medicare HRA, a component of the Medicare Annual Wellness Visit designed to identify patient-reported modifiable risk factors and health needs [8]. Required elements include self-assessment of health status, psychosocial risks, depression, behavioral risks, and Activities of Daily Living and Instrumental Activities of Daily Living. Care delivery systems can add additional questions. The Medicare HRA is designed to help clinicians address patient-reported risks for preventable adverse outcomes. Although the HRA is most commonly applied at the point of care, if data are systematically collected, representative, and stored in extractable formats, they can be used to inform program development, population health, and outcomes research. Although content collected through patient-reported outcomes may duplicate content obtainable through more traditional clinical data such as ICD codes, ICD codes alone are unlikely to capture subjective responses to questions about pain, loneliness, and independent activities of daily living (for example). In this project, HRA data

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CMO 1.5 Considering patients' self-assessments of "subjective" characteristics about themselves [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	revealed meaningful subgroups that might not have been obvious from other electronic clinical data and could inform specific clinical interventions. Important differentiators included function, falls, perceived health status, emotional well-being, pain, and presence or absence of an advance directive. Two large subgroups comprised relatively healthy individuals who could benefit from watchful waiting and routine preventive care plus (for one group) life care planning. Much smaller subgroups could be targeted for more intensive and tailored care management. The size of these subgroups can inform resource allocation within delivery systems.[89] As we enrolled patients into the group we found that, despite a broad range of medical and behavioral health problems, the common feature they shared and what ultimately served to bring them together as a group was their status of being "on the fringe," as they described themselves. Nearly every patient had experienced a number of barriers and frustrations in accessing medical care that the DIGMA team seems to have successfully addressed.[98] Traditional electronic data such as diagnostic codes and laboratory values may not capture essential information on factors that drive care needs, including function, personal preferences, and social resources, that can only be reported by individuals themselves. Identifying and characterizing complex needs subpopulations requires patient-reported information to help match care delivery to personal needs. Although newer data from electronic health records (EHRs) such as symptom assessments and ICD-10 codes that capture functional status can improve our ability to identify complex needs subpopulations, subjective information can add a level of specificity unlikely to be captured with objective coding.[89] Moreover, recognition that computer-based designations of being at risk for costly care (also decorously called predictive analytics) vary considerably, furnish no specific guidance, and are inaccurate is increasing. Most patients in the small, at-risk subgroup will not use such care, whereas care becomes relatively rationed for most patients not designated as such—including those who may require it.... Nevertheless, health care executives embrace the paradigm of high-risk intensive management despite its flaws....Meanwhile, many of its shortcomings can be remedied by a few standardized, patient-reported measures that forecast a patient's risk for costly care in a similar manner to predictive analytics, specifically the risk for direct services. For example, patients may simply indicate that they are only somewhat or not very confident that they can manage and control most of their health problems; have had moderate or severe pain during the past 4 weeks; have been bothered extremely or quite a bit during the past 4 weeks by emotional problems, such as anxiety, irritability, depression, or sadness; believe that the medications they are receiving may be causing illness; and have been prescribed more than 5 medications. Although some payers and providers may disagree with the specific metrics, none should assert that a patient's standardized self-report is an improper tool for guiding care. They may consider this method too old-fashioned or novel for implementation, but its modesty and low cost are remarkable.[87] Dr. Wasson notes the limitations of relying on risk scores derived from electronic data. We agree that patient-reported indices have many advantages. Electronic indices, such as the Veterans Health Administration's Care Assessment Needs Score (1), also have potential advantages as a screening method in health care systems in which such data can be calculated on a population level. Some high-risk patients identified by the Care Assessment Needs Score did not need or were unlikely to benefit from intensive management, and intensive management teams in our study spent substantial time triaging the heterogeneous populations by reviewing health records, contacting primary care providers, and having telephone or in-person visits. Our results suggest that selecting patients for intervention would ideally combine the use of algorithm-based risk scores with measures focused on such issues as those raised by Dr. Wasson, including whether patients believe that they are activated in managing their health or have difficulty managing their prescriptions.[87]

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CMO 1.5 Considering patients' self-assessments of "subjective" characteristics about themselves [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	Data were collected through computerized administrative databases and HRA questionnaires to measure outcomes for utilization, health risk scores, and self-efficacy.[90] Social determinants of health. All stakeholders emphasized the importance of inadequate health literacy, unstable housing conditions, and lack of adequate social support in driving preventable high health care utilization. Low health literacy made it difficult for many HNHC patients to manage complex medical conditions on their own, adversely impacting their ability to follow through with day-to-day self-care regimens. They also felt that for some HNHC patients with unstable housing conditions, being in the ED or an inpatient care setting was desirable, as it was the only avenue, as one HNHC patient put it, to 'get a meal.. .have a television... stay overnight'. Finally, health system leaders as well as most physicians felt that the interplay between lack of social support and poor disease control was often a reason for presenting to the ED. Physician: 'Health literacy and overall education level is probably the biggest impact on the ability to self-manage these conditions'. Unstable housing: Physician: 'Eventually, [many] of them become homeless or [have] poor living conditions and those patients.. .arrive because of weather conditions or for other reasons to the ED to seek shelter and respite'. Limited social support Health system leader: '[Workable solutions] probably have to do with…social support and reduction of isolation and helping them negotiate the complexities'. Insurance challenges Patient: 'I have Medicaid and some of the doctors don't take [it], and so you say to yourself, well, even if I get an appointment, are they going to take me? So just go to the emergency room and let them handle it from there'. Financial burden Patient: 'A lot of times [we're] on a fixed income and you need to see a specialist.. .You may have a co-pay with your specialist. It could add up if you go excessively. It's easier to go to the [ED] and get what you need'.[61] Patient activation refers to an individual's knowledge, skills, and confidence related to self-management. The construct is commonly measured using the Patient Activation Measure, which is a thirteen-item interval-level scale with strong psychometric properties that generates a score between 0 and 100. A Patient Activation Measure level may be assigned based on the score, from level 1 (least activated) to level 4 (most activated). Studies show that Patient Activation Measure results are predictive of most health behaviors, clinical indicators, and hospital and emergency department (ED) use. Research also shows that less activated patients with chronic illness are more likely to experience care coordination problems, compared to more activated patients. Numerous studies also indicate that compared to more activated patients, less activated ones with chronic disease are less likely to effectively manage their conditions (for example, they are less likely to adhere to medication regimens), have healthy diets and get regular exercise, regularly monitor symptoms and clinical measurements, ask questions in the medical encounter, and report satisfactory care experiences. These findings suggest that less activated patients may benefit more from care coordination and care management services than patients who have equal disease burden but are more proactive about managing their health.[104] In this study we used the four Patient Activation Measure levels. Level 1 indicates that a person does not yet understand the important role that patients play in determining their health, and level 4 indicates that a person is proactive about his or her health and engages in many positive health-related behaviors. Compared with lower-risk patients, high-risk patients were twice as likely to be sixty years or older and were somewhat more likely to be lower income (Exhibit 1). High-risk patients were also almost twice as likely to be depressed and more than twice as likely to be at the lowest Patient Activation Measure level. Furthermore, in 2011 high-risk patients were three times more likely to have had an ED visit and fourteen times more likely to have had a hospitalization. Fairview Health Services, a Pioneer ACO, uses the Patient Activation Measure to allocate its resources

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CMO 1.5 Considering patients' self-assessments of “subjective” characteristics about themselves [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	more efficiently to support patients. For example, Fairview's care coordinators and health coaches, who manage high-risk patients, use the Patient Activation Measure level to decide how intensely to follow and manage specific patients. Nurses supporting patients during care transitions use a similar approach, in which the Patient Activation Measure score determines the frequency and focus of their posthospital support efforts.[104] As we demonstrated in a previous article, although they are very sick, these patients remain surprisingly functional despite their illness(s) (Roberts et al., 2012). Additional important general observations include the following: these individuals are very resilient, highly resourceful, and are extraordinarily patient with the healthcare system. At enrollment, many are overwhelmed; disengaged; nontrusting; and lacking in a feeling of self worth or deserving of services (making it critical to have psychology expertise integrated into the team structure). Furthermore, this patient group wants to be perceived as agreeable (e.g., may know they will be unable to keep their next appointment for some reason but would not offer that unless asked).[91] "We found in our case series that trust was a key theme in the relationship between patients and their clinicians or the health system. Lack of trust in individual doctors or institutions, as well as unrealistically high expectations of the same, appeared to be an important driver of higher costs Patient trust seemed to be informed by both patient factors (prior experience, socioeconomic status, activation) and clinician factors (quality of care, communication skills). Among the five patients, trust appeared to mediate the interaction between patient activation and cost: higher activation was associated with lower costs when patients or families had trust in their clinicians or when needed care was low acuity or standard; however, higher activation (in particular, the confidence and ability to advocate for care) was associated with higher costs when trust seemed lacking, particularly when the stakes were high (in critical illness) and the course uncertain.”…. Observations highlight challenges with trust in the setting of increasing medical complexity, specialization, and team-based care. Important to teach docs communication skills that earn trust, particularly around goals of care, and to better match patients to appropriate docs and care managers to ensure trusting relationships.”[29]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.6 Considering patients' self-assessments of health system-related risk factors and experience [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2].	At enrollment, the concept of self-management is not familiar to most of them. Systems, like the Housing Authority, Medicaid, and health systems, often add to their burden. Examples include applications for benefits are frequently difficult to figure out and time consuming to file, applicants often feel disrespected or treated as if they were helpless, and agency staff are often not adequately sensitive to client issues regarding low/no literacy. In addition, for non-English speaking, translation services can be inadequate, cultural competency is a problem, and mailed annual reapplication notices (such as for Medicaid) are difficult to recognize as something official and may be disregarded.[91] Example from CSHP illustrating the program's theory of action "Patient A in Kansas City has multiple chronic conditions and poly-substance abuse, a history of homelessness, frequent ED visits, and no PCP [primary care provider]. At the initial contact with the care team, the patient stated that he would "never want to conform to the rules." The care team's strategy is to first establish firm trust. They accomplished this by identifying opportunities to provide basic help, such as involving family members in explaining the impact on diet of modifying cooking practices, supplying a scale and log to support the modification, organizing and explaining the purpose of medications, arranging for transportation and enabling the patient to do so, scheduling and accompanying patients to medical and social service appointments.[85] Long wait times Patient: 'When I go to the emergency room, they [say], "When you get out of here go see your GI doctor". But, that's not the way it works..Last time I called to get in the next day, they told me he had 17 patients, and couldn't see me. In three months, you don't know what could happen. So, the next thing is [back to] the ED'.[61] Mismatch arises from patients' social circumstances limiting access to services, behavioral issues interfering with care engagement, and lack of health system flexibility to address these barriers. A staff member reflected on the inability for a patient to receive services due to homelessness: "He was homeless when we made the referral and doesn't…fit into [the] standard hospice system.… Health care systems are designed for these neat packages of people that are housed, have family support, have access to other resources, are not actively using substances.…The services aren't really designed for complex folks, so that can be really frustrating and exhausting." (SUMMIT LCSW)[61] A few [stakeholders] even suggested that sometimes it felt easier to take an ambulance to the ED and access different services at the same place and time rather than arrange transport for multiple visits including PCP, specialists, bloodwork, etc.[61] Economic determinants of health care. Patients identified insurance-related factors and financial burden of upfront costs (such as co-payments) as reasons for frequent ED visits and hospitalizations. For example, several patients on Medicaid reported knowing that many physicians in their community did not accept their insurance. To avoid losing time by contacting multiple primary care offices, they would go to the ED directly. Also, for underinsured and uninsured patients, the ED was the only health care setting where they could receive health care without having to deal with implications of their insurance status or co-pays right away. Many patients also reported the negative impact of financial burden on their medication adherence as a driver of frequently presenting to the ED. They felt that some of these visits can be prevented if medications and essential medical devices were not so expensive.[61]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.6 Considering patients' self-assessments of health system-related risk factors and experience [C] adds to intervention designers' confidence in identifying HNHC patients [M] who will benefit from intervention services [O1] and who are at risk of having future high healthcare use and cost [O2]. (continued)	Survey of frequent ED patients while in ED Barriers to care: % agree, could have multiple barriers It is easy for me to make time to get to necessary med appts: 78% I always remember to schedule my annual check-ups, tests, and/or screenings: 65% I feel like I receive better quality health care in the ED than I do in my usual place of care (PCP, clinic): 48% whether certain services would be helpful to the patient, in the event the ED or health system decided to offer the service: After-hours options for minor health issues besides the ED: 63% A nurse to work with you one-on-one to help manage health care needs: 53% Transportation to get to medical appointments on-time: 46% While 42% did not think that a PCP would be helpful, many said that they had one.[27]
CMO 1.7 An enrollment process that includes an extensive period of outreach and trust building [C] adds to an intervention provider's confidence [M] in determining a participant's willingness and ability to participate in the intervention [O].	The purpose of community navigators in the Familiar Faces program is to bridge the gaps between their clients and the healthcare and social systems that are often fragmented and difficult to navigate. Furthermore, integration of community navigators into the healthcare system, specifically the information flow offered by EHRs, ensures that community navigators are able to engage with patients during acute episodes of care, when their needs are greatest. In addition to the expertise that community navigators provide to clients in navigating healthcare and social systems, they may build trust between clients and the healthcare system, as they live in the same communities as their Familiar Faces clients. Mistrust of the healthcare system is often high in minority and low socioeconomic populations and may result in delayed medical treatment and use of fewer preventive services…. Because the community navigator was simultaneously a member of the community and the healthcare system, it is possible that they were able to reach community members particularly mistrustful of the healthcare system and start to build a foundation of trust.[95] The outreach to ESRD beneficiaries, however, was entirely new in Phase II since ESRD was not part of the clinical focus in Phase I. KTBH program leadership found that when a nurse had an in-person contact with an ESRD beneficiary, the beneficiary was more than twice as likely to enroll in the program. As a result, KTBH program leadership decided to send a nurse to every dialysis facility with more than two eligible beneficiaries. Prior to the visit, the care manager sent a packet to the facility's administrator, placed a call to the administrator, and tried to make an appointment to conduct an informational breakfast or lunch session with the entire staff to introduce the KTBH program and assuage any concerns about the program. The goal of the informational sessions was to explain to staff that the care managers hoped to accomplish things with the beneficiary that would enable the intervention participants to better manage their condition. They tried to convey to staff that the care managers were not there to make their lives more difficult or to take the place of the existing staff that provided services to beneficiaries. KTBH staff reported receiving the biggest pushback from facility social workers. KTBH staff believed that there was a direct correlation between having the support of social workers and beneficiary participation in that when they received the support of the social workers, prospective participants were more likely to join the KTBH program.[82] That's been the difficult piece, finding people who are appropriate and they want our help at the same time. That's been the trickiest piece. CCM Nurse[94] CCM providers in our study actively looked for positive and negative indicators that patients were willing to engage in care. Providers often found these explicit signs to be inadequate for detecting patients' desire or readiness to engage in care and therefore looked for more subtle signs and tried to make intuitive assessments.[94] The enrollment criteria for the CCM programs included a willingness to engage in care.[94]

CMOs	Relevant Data Extracts/Summary Information From Included Literature
CMO 1.7 An enrollment process that includes an extensive period of outreach and trust building [C] adds to an intervention provider's confidence [M] in determining a participant's willingness and ability to participate in the intervention [O]. (continued)	CCM providers looked for indicators that patients were willing to engage during initial patient encounters and enrollment, and looked for signs of successful engagement in ongoing assessments of patients' communication and actions. When CCM providers first met patients, positive indicators that they were willing to engage included verbally agreeing to take part in the program, returning phone calls to the CCM team or answering the phone when CCM team members call, being receptive to a home visit, and showing up to an initial appointment. CCM providers continued to assess engagement over time by considering how frequently patients missed appointments, how well they adhered to medication and treatment regimes, how much progress they made towards behavioral changes such as reducing substance use or increasing exercise, and how candidly and regularly they communicated with the CCM team. A social worker said that she considers patients likely to engage over time when "we reach out to them by phone and we make an appointment and they show up."[94] We learned that for B2C to reduce the use of acute care, outreach to and enrollment of high utilizers had to happen in real time in the ED.[88] Judgment about whether the patient is amenable to management is based on an interview with the patient by the care team and a review of medical records. The assessment of whether the patient is entered into Care One is based on a judgment that the patient has a chronic medical condition, is at high risk for future hospitalization, and is willing to attend outpatient visits and comply with therapy. Other specific exclusions from the Care One program include a single high-cost medical event (e.g., a trauma), residence outside of the hospital's catchment area, and chronic alcohol or drug abuse.[92] Most deep-dive practices indicated that risk-stratification improved the organization and delivery of care. Clinicians and staff continued to report that risk-stratification increased their awareness of high-risk patients' needs and helped them better allocate staffing resources to different patient populations. For example, in a few practices, patients with a single chronic condition (such as patients with diabetes who needed basic monitoring and health education) received care management from a medical assistant. This enabled the care manager to focus on higher-risk patients (such as patients with poorly controlled diabetes and additional chronic conditions). Risk-stratification continued to help practices identify and prioritize high-risk patients and schedule longer appointments for them as needed. In contrast, respondents in one small deep-dive practice questioned the utility of risk-stratification; they perceived that clinicians knew their patients well enough to determine whether they were high-risk and they believed that the time they spent risk-stratifying patients would be better spent delivering direct patient care.[101] Text box III.1. Example from CSHP illustrating the program's theory of action "Patient A in Kansas City has multiple chronic conditions and poly-substance abuse, a history of homelessness, frequent ED visits, and no PCP [primary care provider]. At the initial contact with the care team, the patient stated that he would "never want to conform to the rules." The care team's strategy is to first establish firm trust. They accomplished this by identifying opportunities to provide basic help, such as involving family members in explaining the impact on diet of modifying cooking practices, supplying a scale and log to support the modification, organizing and explaining the purpose of medications, arranging for transportation and enabling the patient to do so, scheduling and accompanying patients to medical and social service appointments.[85]

C = context; M= mechanism; O = outcome

Table B-12. Full list of Context-Mechanism-Outcome (CMO) configurations with supporting data for Program Theory 2: Engaging HNHC patients in interventions to improve their management of their chronic conditions, supporting CMO relationships

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Patients' challenges to self-care prior to and during the intervention	CMO 2.1. Past experiences with the healthcare system including encountering barriers accessing medical care and disrespect from providers [C] cause patients to distrust the system and providers [M] which inhibit patients from accepting and seeking appropriate help and medical care [O].	More than half of participants (n = 12) related stories of encounters that had upset them; several explicitly mentioned withdrawing from outpatient providers by choosing not to attend appointments with those providers as a result. Over a third of participants switched providers because of dissatisfaction with those relationships. Others who had not switched chose not to follow a given provider's instructions as a result of these negative interactions. Most of the stories of negative health care encounters focused on feeling disrespect from providers, while others specifically described feeling discriminated against by providers because of race or sex.[105] Several participants in this study expressed that they felt that their care sometimes was compromised by perceived disrespect from health care providers, citing race-, sex- or SES [socioeconomic status]-based discrimination.[105] When answering questions about trusting their health care providers, almost half (n = 9) of participants stated that they distrusted a particular (usually hospital-based) provider. Respondents generally expressed trust in their primary care providers.[105] Nearly every patient had experienced a number of barriers and frustrations in accessing medical care that the DIGMA team seems to have successfully addressed.[98] "Patient A in Kansas City has multiple chronic conditions and poly-substance abuse, a history of homelessness, frequent ED [emergency department] visits, and no PCP [primary care provider]. At the initial contact with the care team, the patient stated that he would "never want to conform to the rules."...His sister reflects, "He used to use the ER [emergency room] for everything...."[85] Challenges associated with accessing health care delivery systems Transportation barriers. Some patients reported that primary care offices were inconveniently located and difficult to access due to transportation barriers. A few even suggested that sometimes it felt easier to take an ambulance to the ED and access different services at the same place and time rather than arrange transportation for multiple visits including primary care, specialists, bloodwork, etc. For patients who could utilize private or public transportation to get to a primary care clinic, the distance often made the trip extremely time-consuming as well as costly. Preventability of ED use appeared contingent upon logistic ease of access to services. Long wait times. All stakeholders identified scheduling challenges at primary care clinics as an important driver. Many patients reported that they were unable to schedule first-time or follow-up appointments quickly (same-day, next day or even in upcoming weeks) and instead had to wait several months. Furthermore, if a disease exacerbation occurred after regular clinic hours or overnight, patients felt that they had no other options but to seek care in the ED.[61]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Patients' challenges to self-care prior to and during the intervention (continued)	CMO 2.2. Previous and current personal life circumstances and characteristics (e.g., mental illnesses, substance abuse, emotional or physical traumas, extreme poverty, and low literacy) [C] results in feelings of stigma in patients [M] that inhibit them from seeking help and medical care [O].	A predominance of the participants (n= 12) told stories of childhood instability...Significant subthemes included early life traumas, such as death of a parent or other loved one, and abusive relationships with primary caregivers throughout childhood. Some described state agencies as their primary caregivers. Transiency was noted, often in the context of escape from abusive relationships (n = 5), and often resulted in living on the streets or gang and drug involvement, even as children. Only 2 individuals specifically described how events in childhood affected their health during adulthood. Nevertheless, many participants related stories of how this instability may have manifested in health issues, especially with regard to mental health. For example, one woman described: ''I had sexual and physical abuse from my parents since I was a baby, since I was 3 or 4. Mother has been very abusive over the years. Every time we went somewhere she was hitting me, punching me, scratched me, and I'd cover it up.'' This individual described ongoing difficulty obtaining effective treatment for the post-traumatic stress disorder that repeatedly sent her to the ED. She reported being frequently ''suicidal'' and ''in crisis'' as a specific result of childhood abuse, for which she was ''in and out of hospitals too much.'' She reported a shared goal with her therapist of accessing consistent community-based mental health care rather than relying solely on the ED. Nearly half of the respondents (n = 8) named their mother or a mother figure as their most important primary caregiver. The other half referred to a variety of other caregivers, such as grandparents, other relatives, or the state, or they declined to answer; these situations were described by some participants as traumatic, and by others as a normal course of events. Of participants who described instability in childhood, half noted familial estrangement in adulthood (n = 6). When asked if there was someone they could depend on now for help, most participants spoke of having only 1 or 2 individuals that they could rely on, if any, suggesting a lack of social support in adulthood for nearly all of these respondents.[105] Patients may have a variety of barriers that prevent them from accessing traditional primary care venues, particularly those settings that do not allow patients to walk in at their convenience or patients who may need intensive services during a personal crisis. Patients with difficult life circumstances also may be more likely to not show for an appointment.[98] Patients in this quality improvement program tend to be younger than those targeted by previously described care transition models and many have unstable health insurance, a history of substance use, and significant mental illness. Nearly all are from socially disadvantaged communities plagued by poor health status, and low literacy is common. Many are struggling with difficult life circumstances such as an alarming number have been emotionally or physically traumatized;...and many have inadequate, or no, family and social support systems. At enrollment, the concept of self-management is not familiar to most of them.[91]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Patients' challenges to self-care prior to and during the intervention (continued)	CMO 2.2 Previous and current personal life circumstances and characteristics (e.g., mental illnesses, substance abuse, emotional or physical traumas, extreme poverty, and low literacy) [C] results in feelings of stigma in patients [M] that inhibit them from seeking help and medical care [O]. (continued)	There are two key elements to the success of these new efforts to target and improve care for high-cost Medicaid cases. First, it is essential to be able to identify in advance patients who are likely to have high costs in the future. Many high-cost occurrences (such as injury, acute illness, or cancer) might be episodic, and high spending in one year might not mean high spending in subsequent years. Second, and equally critical, is the ability to actually affect the care pathways and outcomes of these patients. Because of the circumstances that define their Medicaid eligibility (extremely low income and medical disability) and other factors that are likely to be associated with their social and personal environment (such as homelessness, substance use, or low educational achievement), these patients will undoubtedly present major challenges.[62] All stakeholders identified poorly managed serious mental illness among HNHC patients as a significant driver of preventable high health care utilization. Patients often had inadequate access to mental-health and substance-abuse resources. This was because outpatient programmes did not exist, were inconveniently located or were not financially feasible to attend. This left patients without any options other than the ED for care. Additionally, several patients acknowledged that feeling depressed negatively impacted their care routines and contributed to missing provider appointments which, over time, compounded the severity of their diseases. Importantly, patients also pointed out that the stigma surrounding mental illness was detrimental to their desire to seek out treatment even if it were available. Some patients also felt that policies such as the Florida Mental Health Act (known as the Baker Act) and its equivalent in New York State (known as Kendra's Law),20,21 which allow for involuntary institutionalization and examination of an individual with possible mental illness for up to 72 hours, did not adequately address or help mitigate the root causes of substance abuse and mental-health disorders. This increased preventable ED and/or hospital utilization for psychiatric needs.[61] Low health literacy made it difficult for many HNHC patients to manage complex medical conditions on their own, adversely impacting their ability to follow through with day-to-day self-care regimens.[61] Economic determinants of health care. Patients identified insurance-related factors and financial burden of upfront costs (such as co-payments) as reasons for frequent ED visits and hospitalizations. For example, several patients on Medicaid reported knowing that many physicians in their community did not accept their insurance. To avoid losing time by contacting multiple primary care offices, they would go to the ED directly. Also, for underinsured and uninsured patients, the ED was the only health care setting where they could receive health care without having to deal with implications of their insurance status or co-pays right away. Many patients also reported the negative impact of financial burden on their medication adherence as a driver of frequently presenting to the ED. They felt that some of these visits can be prevented if medications and essential medical devices were not so expensive.[61]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Patients' challenges to self-care prior to and during the intervention (continued)	CMO 2.3. System-level barriers including inadequate systemic support (e.g., Medicaid, translation services, housing) and lack of cultural competency [C] engenders feelings of distrust and marginalization among patients [M] that inhibit their ability to access appropriate healthcare services [O1] and to participate in interventions [O2].	…some have no income while others have income that it is insufficient to meet basic survival needs making it challenging to pay even minimal co-pays for prescriptions; many live in unstable housing or in dangerous neighborhoods....Systems, like the Housing Authority, Medicaid, and health systems, often add to their burden. Examples include applications for benefits are frequently difficult to figure out and time consuming to file, applicants often feel disrespected or treated as if they were helpless, and agency staff are often not adequately sensitive to client issues regarding low/no literacy. In addition, for non-English speaking, translation services can be inadequate, cultural competency is a problem, and mailed annual reapplication notices (such as for Medicaid) are difficult to recognize as something official and may be disregarded.[91] Many participants faced a variety of barriers to appropriate care, including lack of stable income, health insurance, legal residency, English language proficiency, knowledge of the health system and chronic disease management, stable housing, social support, and transportation. Many also had issues with cultural barriers, mental illness and substance abuse (despite informal program eligibility criteria that excluded some patients with these conditions), and traumatic experiences that made stabilizing their chronic conditions more difficult.[85] Many patients are unable to afford even a minimal copayment that may be expected at time of a nonemergent outpatient visit and may choose to access the ED where a copayment may not be required.[98] We found that patients with low health literacy (measured by the REALM-SF) reduced ED utilization to a greater degree than patients with higher health literacy. We hypothesize that patients with lower health literacy may have encountered more barriers to accessing primary care or had greater social needs than those with higher literacy and thus, differentially benefitted from individualized assistance from a patient navigator. These preliminary results suggest that care coordination programs that aim to reduce avoidable ED use and hospital admissions may have a greater impact among patients with lower health literacy.[110] In the current study, KCCP Care Managers identified multiple barriers to active participation in the intervention including basic needs for food, shelter, and transportation that took precedence over program participation; depression; not having a phone or being unable to manage a phone due to mental illness or addiction; language or other cultural barriers; and mistrust of the system (Cristofalo et al. unpublished data).[112]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Patients' challenges to self-care prior to and during the intervention (continued)	CMO 2.3. System-level barriers including inadequate systemic support (e.g., Medicaid, translation services, housing) and lack of cultural competency [C] engenders feelings of distrust and marginalization among patients [M] that inhibit their ability to access appropriate healthcare services [O1] and to participate in interventions [O2].	Social determinants of health. All stakeholders emphasized the importance of inadequate health literacy, unstable housing conditions, and lack of adequate social support in driving preventable high health care utilization…. They also felt that for some HNHC patients with unstable housing conditions, being in the ED or an inpatient care setting was desirable, as it was the only avenue, as one HNHC patient put it, to 'get a meal.. .have a television... stay overnight'. Finally, health system leaders as well as most physicians felt that the interplay between lack of social support and poor disease control was often a reason for presenting to the ED.[61]
Relationship building with care providers	CMO 2.4. Interventions and care team members initially address patients' basic needs and explain things in lay terms [C] to establish trust with the patient [M] resulting in building a relationship with their patients [O].	Patients generally had positive impressions of their care managers. During semi-structured interviews with a sample of high-risk patients and caregivers from deep-dive practices, patients who reported having regular contact with their care manager or who were open to working with their care manager felt that the care manager was an asset to their team. Patients particularly valued care managers who listened to them and explained things in lay terms, helped to manage medications and chronic conditions, followed up after a hospitalization, and helped to navigate the health care delivery system and community resources.[101] "…The patients that have been on SUMMIT [Streamlined Unified Meaningfully Managed Interdisciplinary Team] for a while who have a really solid relationship with us, that makes a huge difference. They are able to call. They are telling us what their needs are. They can make it to appointments and…coordinate all of those needs a little bit better when they know that we're going to be reliable and [here] is where they can come for help." (SUMMIT Physician).[58] They [the program staff] expected that its program would have the greatest impact by preventing acute health care events among beneficiaries who were initially not having significant health issues; however, case managers found that they spent a lot of time dealing with urgent issues for patients who "spiraled out of control." Although initially some patients were skeptical about the MGH [Massachusetts General Physicians Organization] CMP [Care Management Program], overall, patients quickly formed relationships with case managers, including several who requested daily contact with their case managers to help them with their numerous issues. The care team's strategy is to first establish firm trust. They accomplished this by identifying opportunities to provide basic help, such as involving family members in explaining the impact on diet of modifying cooking practices, supplying a scale and

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Relationship building with care providers (continued)	CMO 2.4 Interventions and care team members initially address patients' basic needs and explain things in lay terms [C] to establish trust with the patient [M] resulting in building a relationship with their patients [O]. (continued)	log to support the modification, organizing and explaining the purpose of medications, arranging for transportation and enabling the patient to do so, scheduling and accompanying patients to medical and social service appointments. Within weeks, the patient has started scheduling transportation and keeping his appointments independent of the care team, and now states that he cares about his health. His sister reflects, “He used to use the ER [emergency room] for everything. Now he asks when his appointment is.”[85] Convenience And Access Our model emphasizes convenience and access, starting with location. Our centers—in the range of 6,500–10,000 square feet—are located in urban areas with a high density of low-to-moderate-income seniors. For our patients’ convenience, we offer a broad set of additional services on site, including dental care, digital x-ray, ultrasound, and acupuncture, as well as five to fifteen high-volume specialists. Our average health maintenance organization (HMO) patient received 86 percent of his or her ambulatory encounters at our centers in 2011, although the most expensive aspects of care occurred outside of our centers— for instance, hospitalizations, surgeries, and imaging. Patients find the one-stop-shop approach to care highly appealing.[114]
	CMO 2.5. When care managers support patients with medical and non-medical problems [C], patients are reassured [M1] and gain confidence [M2] in their ability to manage their own care [O].	Care management is a vital piece of the puzzle, pulling together community resources without which recovery would be impossible....Successful case management also includes assisting with teaching some of these patients basic life skills, for example, not to find housing for them, but rather direct them where to go to get housing assistance. These small, positive steps are then shared with the group, which further reinforces a growing sense of confidence.[98] Additionally, efforts to tailor-make health education programs to improve health literacy and numeracy may be warranted for patients to effectively self-manage some of their care needs.[61]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
	CMO 2.6. Patients are more motivated [M] to improve their health behaviors [O] when they feel cared for by their providers and other support groups [C].	...participants reported that ‘‘caring’’ providers were particularly important in the trajectories of their illnesses and lives, emphasizing the compassion of the Care Management Team. Providers from the intervention were described as dependable, sensitive, and thoughtful, suggesting that these traits in providers may resonate for individuals whose childhoods lacked caregivers with these qualities.[105] Conversely, participants emphasized the importance of caring, trusting, and longitudinal relationships with providers, both on the Care Management Team and with primary care providers. Comorbid mental illness, especially depression, makes managing chronic illnesses such as diabetes more challenging.34–37 Consistent, positive relationships with primary care providers have been shown to decrease rates of hospitalization and ED use for complex patients who struggle with a combination of multiple chronic illnesses, mental illness, and psychosocial challenges.[105] Frequent, longer visits built relationships with the care team and other patients. The emotional support provided by the group seemed to be a key factor in assisting patients to find solutions to their health and social problems.[98] Half of participants indicated the importance of ‘‘feeling cared for’’ by providers (n = 10). This theme recurred throughout the interviews, especially during descriptions of the Care Management Team. When asked about the best part of the intervention, rather than describing specific services, most participants described the importance of the emotionally supportive interactions they experienced. These participants reported that the experience of feeling cared for was a motivation to improve their own health behaviors (n = 10) (Table 2). Diabetes, depression, and hypertension were the most commonly reported conditions. Despite the natural history of these complex chronic diseases and their tendency to reflect a pattern of deterioration over time, 7 participants reported improvements in their own perceived health status after the intervention. Five of those participants specifically attributed this improvement to the intervention. ‘‘They make you feel like you’re not alone, and they understand you and the things you’re going through. And they actually help explain why you’re going through these things…you don’t feel like just a patient.’’ - 24-year-old African American woman with depression and Type 1 diabetes.[105]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Relationship building with care providers (continued)	CMO 2.7. When intervention care providers build trusting relationships with patients [C], patients have confidence in their providers' desire to help [M] resulting in patients seeking advice from their intervention care provider before going to the ED/hospital [O]	During the early months of CLM's [Care Level Management's] program implementation, nurse care managers focused on building relationships with the patients during telephone contact between PVP visits, so that patients would be comfortable calling the nurses if health problems arose. Patients at highest risk were to receive calls on a weekly basis, whereas those at moderate and low risk were to receive calls on a monthly or bimonthly basis....Over the course of the first year of operations, CLM reported ...that they reorganized their patient care teams to include more nursing support. CLM believed that this arrangement would allow patients to bond with the nurse care manager over time, whereas CLM had observed that the clinical specialists were not able to forge a sufficient bond as evidenced by the fact that some of their participants were going to the hospital rather than calling the clinical specialists when problems arose.[84] In addition to connecting clients to health and social resources in their community, the community navigators focus on building trust between the client and navigator and subsequently with other healthcare entities and social systems in the community.[95] The care manager is an experienced, calm, trusted professional patients can call when they are frightened or in crisis between groups visits, which is often the difference between going to the ED to seek immediate care or waiting a day or 2 until the next group visit.[98] These participants articulated an appreciation for continuity in relationships with providers, including members of the Care Management Team. A majority of respondents (n = 14) described their preference for office-based primary care with their usual providers, reserving the ED for emergent medical necessity or after-hours needs.[105]
Individualized care for HNHC patients	CMO 2.8. Designing flexible interventions that could be tailored and individualized to specific HNHC patient's needs and circumstances [C] empowers providers [M] to be responsive to each patient's needs and circumstances.	Care transitions are normally linear and finite (e.g., from Provider A to Provider B), but in our care coordination programs, the number and nature of care transitions are circular, overlapping, and continual. They involve cross-sectoral care givers including social services, government workers, and church and community members—in addition to medical, social work, and behavioral health providers in one or more health systems—and they take place at multiple locations. Because the interventions need to be tailored to each patient individually, based on their medical and life situations, they are not predictable at the outset, and "model fidelity," as required by most care transition models, is not feasible.[91] Specific interventions were tailored to each patient in collaboration with the patients and their family, reflecting the patient's unique needs.[119] Patient intake at IOC included an in-depth patient assessment to determine non-medical barriers to improved health. Care plans and activity to address needs were individualized.[83, 85]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Individualized care for HNHC patients (continued)	CMO 2.8 Designing flexible interventions that could be tailored and individualized to specific HNHC patient's needs and circumstances [C] empowers providers [M] to be responsive to each patient's needs and circumstances. (continued)	The ability to tailor care to patients' individual needs was another ingredient staff members felt they provided to complex patients. A SUMMIT care coordinator described a strategy to assist patients with attending specialty appointments: "I'll have appointments with patients just with myself if patients need help with scheduling outside the clinic and scheduling transportation.… If a patient chronically no-shows to a (specialty) appointment…I'll make an appointment for them to come [see] me and we'll schedule together and…give them an appointment planner or write up all their appointments for them."[58] Each enrollee gets a tailored 60 day care plan and associated patient services they might need including assistance obtaining housing resources, insurance, disability benefits, refugee services, transportation, coordinating primary and specialty care; and filling prescriptions.[88] The housing patterns we found, however, suggest the need for flexibility. Consistent with the experience of many Housing First programs, over two-thirds of the housed intervention participants required rehousing after their first placement did not succeed. The ability to offer a new housing placement is a key component of successful Housing First strategies when working with high complexity populations. With the widespread use of Coordinated Entry that will require that counties place individuals with similar risk profiles into PSH, our findings provide support for the need for flexibility, including the ability to rehouse individuals, in order to serve those at highest risk. Our results offer a measured sense of expected changes in their use of other services.[109] Another feature of our program was the flexibility in the range and intensity of services we offered to patients. Some patients required infrequent contact to assist with scheduling and attending primary care appointments. Other patients benefited from more intensive contact, including multiple accompanied clinic visits or home visits.[111]
	CMO 2.9. Having interventions address underlying mental health conditions concurrently or before managing other health conditions [C] helps patients' ability to cope with their health conditions [M] and allows them to benefit from interventions addressing their chronic conditions [O].	Theme 3: Addressing Both Psychosocial and Clinical Needs Participants noted that it wasn't possible to separate provision of psychosocial support from traditional medical care. This can run counter to what occurs in usual care. "I spent an hour with a patient last week and we didn't talk about medical problems.… It was a therapeutic session. I'm not a trained therapist, but [that's] what it was. We didn't talk about diabetes. We didn't talk about her foot ulcers.…A lot of times we end up doing the work of social workers, but when you do primary care, you have to do that. It's not 'oh hold on,… I'm not getting into that. I'm only here for the medical stuff.' It all wraps up into one." (SUMMIT Physician)[58] But the extraordinarily high levels of substance abuse among high-risk patients and the history of mental illness even among the population without serious and persistent mental illness make clear that any intervention will have to take these factors into account.[62]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Individualized care for HNHC patients (continued)	CMO 2.9 Having interventions address underlying mental health conditions concurrently or before managing other health conditions [C] helps patients' ability to cope with their health conditions [M] and allows them to benefit from interventions addressing their chronic conditions [O]. (continued)	In the early stages of the CMHCB [Care Management for High Cost Beneficiaries] demonstration, CMP [Care Management Program] leadership learned that many high-cost, complex patients have mental health issues that were not effectively addressed by the current model of health care delivery or its pilot program. As a result, the program allocated greater resources to support mental health, hiring a social worker to assess the mental health needs of CMP participants and support them in accessing psychiatric care as needed or provide treatment if appropriate.[86] Many participants faced a variety of barriers to appropriate care, including lack of stable income, health insurance, legal residency, English language proficiency, knowledge of the health system and chronic disease management, stable housing, social support, and transportation. Many also had issues with cultural barriers, mental illness and substance abuse (despite informal program eligibility criteria that excluded some patients with these conditions), and traumatic experiences that made stabilizing their chronic conditions more difficult.[85] ...the program is unique in having a behavioral health provider screen every enrollee for mental health disorders—and then address those conditions as appropriate.[88] We found a significant reduction in use of psychiatric emergency services and a concomitant increase in scheduled mental health visits. Project Welcome Home included Intensive Case Management with a low client-staff ratio led by licensed staff with behavioral health training. Research has shown that experiencing homelessness is one factor that leads to ED visits among psychiatric patients, suggesting an unmet need for mental health care.5,18 Our findings suggest that these visits are amenable to prevention by providing housing with associated low-barriers mental health services.[109]
	CMO 2.10. Connecting patients and supporting them in navigating services that cross medical sectors (e.g., geriatrics, substance disorder treatment) and non-medical sectors (e.g., employment, housing, transportation) [C] help patients gain the confidence [M] to learn how to navigate multiple systems for themselves [O].	Through the CMP, patients are assigned to a personal care manager who assists with access to social and medical resources, helps patients schedule PCP appointments, and helps bridge barriers between patients and the healthcare system. Enrolled patients are assigned to 1 of 3 outpatient primary care clinics. Components of the CMP include: goal creation/assistance in reaching goals, ranging from applying for benefits and receiving stable housing to losing weight and receiving specialty care appointments; assistance with care navigation (schedule appts, follow-up on referrals, and help refill medications); arranging for social services (make personal connections with staff at various agencies in the community and refer patients to appropriate services, including transportation resources, Legal Aid, homeless shelters, faith-based services, and substance abuse resources); care transitions (meet with patients daily while they are admitted and work with discharge planners to assist patients in receiving recommended follow-up care and understanding discharge instructions); and communication with providers (accompanying them to appointments, creating and prioritizing problems lists, coaching patients about questions to ask, and sitting with patients after their visit to explain follow-up instructions).[107]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Individualized care for HNHC patients (continued)	CMO 2.10 Connecting patients and supporting them in navigating services that cross medical sectors (e.g., geriatrics, substance disorder treatment) and non-medical sectors (e.g., employment, housing, transportation) [C] help patients gain the confidence [M] to learn how to navigate multiple systems for themselves [O]. (continued)	After the visit, the patient navigator and patient created a task list based on the provider's recommendations. For example, if the PCP ordered additional tests or specialist referrals, the navigators assisted in scheduling these additional appointments, phoned patients to remind them, identified and addressed any barriers such as transportation, and encouraged patients to follow PCP recommendations. When needed, navigators helped patients to access medical transportation assistance through the state Medicaid system. If the patient identified social needs such as precarious housing, food insecurity, or insurance questions, they were provided with information to connect with local resources.[110] The team (1) conducted home visits, (2) scheduled and accompanied patients to initial primary and specialty care visits to ensure that such appointments are kept and that the patient understands any instructions given during the appointment, (3) coordinated follow-up care and medication management (medication reconciliations), (4) measured blood pressure and blood sugar levels when appropriate, (5) coached patients in disease-specific self care, (6) helped patients apply for social services (e.g. housing support, Social Security (including SSI), Supplemental Nutrition Assistance Program (SNAP), Temporary Aid for Needy Families (TANF), and General Assistance (GA)) and appropriate behavioral health programs. provides disease specific education, coaches the patient in self-care, and works to empower patients to manage their health issues. During subsequent home visits, the team evaluates the patient and team's progress. The care team works to connect the patient with stable, continuing, and appropriate primary and specialty care. Coalition staff may help schedule further medical appointments as necessary, continue to help organize transportation, accompany patients to medical appointments, check-in after medical appointments to help the patient implement the instructions given by the provider, and continue to organize medications. Home visits in later stages increasingly focus on self-care management skills, health care navigation skills, enhancement of self-efficacy and independence, care plan adjustment and coaching.[96] The most frequently used intensive management services were social work and mental health care, highlighting the importance intensive management teams placed on these services on the basis of their comprehensive assessments of patients' needs. The intensity of services varied greatly among patients assigned to the intervention group; patients who used more services tended to be older and to have more comorbid conditions, higher rates of baseline primary care utilization, and lower rates of substance use disorders and serious mental illnesses. These findings suggest that other models of intensive management may be more appropriate for patients whose mental health and substance use conditions are severe and are likely to prevent effective engagement with the intensive management team.

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Individualized care for HNHC patients (continued)	CMO 2.10 Connecting patients and supporting them in navigating services that cross medical sectors (e.g., geriatrics, substance disorder treatment) and non-medical sectors (e.g., employment, housing, transportation) [C] help patients gain the confidence [M] to learn how to navigate multiple systems for themselves [O]. (continued)	By design, the intensive management programs seem to have facilitated referrals to home-based primary, palliative or hospice, geriatrics telephone, specialty mental health, and telehealth care. Because sites performed comprehensive assessment of patients' social issues, treatment plans, and care goals, our results suggest that the intensive management programs could identify unmet needs and connect patients to important resources. Home visits seemed to play a key role in patient assessments, because patients with more intensive services had an average of 1.5 home visits.[87] • Some patients with experience in residential or other intensive management programs need support when trying to complete programs, and need housing/support once programs end • Patients desire support when trying to return to school, find employment, or find housing: "I wish someone would help me navigate the system. I don't know what resources or programs are available to me."[106] Successful case management also includes assisting with teaching some of these patients basic life skills, for example, not to find housing for them, but rather direct them where to go to get housing assistance.[98]
	CMO 2.11. Because patients' burden of coexisting chronic diseases and social and behavioral issues are heterogeneous, allowing the length of the intervention to vary across participants [C] helps patients feel supported [M] by providing them with sufficient time to demonstrate intervention goals (e.g., self-management behaviors) [O].	Patients are continually enrolled at different times, resulting in different lengths in the post-enrollment time frame. Patient diagnoses that are driving admissions, and their burden of coexisting chronic diseases, are heterogeneous. The natural history of these common chronic diseases is such that the patients have ever evolving health conditions intermixed with periods of disease decompensation. Length of time in the intensive intervention period is variable and determined by demonstrated need and functionality: socially, medically, and behaviorally. Our intervention is not administered by number of days exposed but instead is administered until the patient demonstrates the behavior criteria we have defined ("graduates"), the patient expires, or transitions. Because the patients are graduated according to demonstration of objective self-management behaviors (Figure 2), the resultant postgraduation time frames are also variable.[91] Participants' issues often took longer to resolve than the intervention's time line typically allowed.[85]
Barriers to HNHC patient change through interventions	CMO 2.12. Despite successful engagement with the intervention and relationships between members of the care team and HNHC patients [C], HNHC patients may continue to prefer seeking primary care at the hospital or ED [M]. Therefore, interventions may not be able to achieve goals such as reducing use of potentially preventable or modifiable healthcare services [O].	One challenge for the demonstration was that a sizable minority of beneficiaries and caregivers would prefer to visit the ED [emergency department]—instead of contacting the IAH [Independence at Home] practice—if they were unsure whether symptoms required emergency care (Table III.3). Beneficiaries provided a number of reasons for preferring to go to the ED, including that they or their caregivers thought it was the best place to receive care. Even though three-quarters of beneficiaries reported that the IAH practice visited about as often as the patient wanted them to visit (Appendix C, Table C.8), some beneficiaries' preference for the ED in uncertain situations might contribute to the demonstration's lack of an effect on outpatient ED visits.[103]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Barriers to HNHC patient change through interventions (continued)	CMO 2.12 Despite successful engagement with the intervention and relationships between members of the care team and HNHC patients [C], HNHC patients may continue to prefer seeking primary care at the hospital or ED [M]. Therefore, interventions may not be able to achieve goals such as reducing use of potentially preventable or modifiable healthcare services [O]. (continued)	Engagement with the program was high (95% of patients had at least three encounters with program staff), and patients received an intensive intervention (averaging 7.6 home visits), but two program goals related to the timing of services — a home visit within 5 days after hospital discharge and a visit to a provider's office within 7 days after discharge — were achieved less than 30% of the time. Challenges in reaching these goals included patients' lack of stable housing or a telephone and their behavioral health complexities and providers' few available appointments. The difficulties that this pioneering, data-driven organization had in achieving rapid assistance for patients may portend difficulties in achieving it at scale.[96] Patients randomized to PIM were more likely than patients in PACT to strongly agree that they have a VA healthcare provider whom they trust...Survey findings suggest that the program may have influenced some patients' experiences with patient-centered care and chronic illness care, and increased the number of patients who reported having a trusted provider, but did not influence satisfaction, perceived access, or most measures of care coordination.[97] Though the SUMMIT intervention was developed as a way to address high ED and hospital utilization, staff members did not mention reduced utilization as a marker of success. "We are dealing with a pretty sick population.…These are patients that maybe do need to be in the hospital.… A hospitalization is not necessarily a bad outcome for a lot of these patients." (SUMMIT Physician)[58]
	CMO 2.13. Improvements in patients' experiences with their care providers through participation in HNHC patient interventions [C] gradually rebuilds patients' trust in the health care system [M] that may lead to long-term benefits in health behaviors and clinical outcomes [O]	Furthermore, relationships are at the core of primary care, so this finding suggests that augmenting a medical home with an intensive management program may help fulfill the promise or primary care. In fact, analyses of satisfaction suggest that the program improved patients' experiences with primary care, but not with other services. Improving primary care processes could potentially have positive long term consequences, including changes in health behaviors and clinical outcomes.[97]

C = context; M= mechanism; O = outcome

Table B-13. Full list of Context-Mechanism-Outcome (CMO) configurations with supporting data for Program Theory 3: Care provider engagement in interventions for HNHC patients

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Gaining and maintaining support from physicians and other care providers	CMO 3.1. Strong leadership support that facilitates systemic coordination of the intervention and its components smooth the entry of care managers into practices [C] provides credibility of their services to existing practice staff [M], so care managers are more easily incorporated into primary care teams [O].	Once MGH [Massachusetts General Physicians Organization] had generated lists of CMP [Care Management Program]-eligible beneficiaries receiving care from each physician, the CMP medical director met with each practice to introduce the program and discuss which patients were at highest risk for acute events and should receive priority for enrollment. The medical director also met with specialty practices such as the oncology, cardiology, emergency, and orthopedics departments to explain the resources available through the program, because case managers would likely interact with these providers as they facilitated patient access to these services.[86] At the time of the program launch, strong integration support from MGH leadership afforded the case managers physical entry into the primary care practice settings whereby the case managers were co-located with the primary care physicians ultimately becoming a part of the beneficiaries' primary health care teams.[86]
	CMO 3.2. Program leaders' use of tailored strategies and physician champions to explain intervention services [C] helps endorse the intervention [M] and results in physicians participating in the intervention [O].	A second round of focus groups was conducted with physician groups to specifically discuss how the CMP could add value to their practices. In addition to providing input about the design of the CMP, the capstone groups provided an opportunity to obtain physician buy-in to the PBCM [practice-based care management] program. Despite the fact that some physician practices already had case managers, CMP management observed that most physician practices were apprehensive about changes such as the introduction of new staff into their practice. CMP leadership used a tailored approach to discuss the project with each practice, offering positive anecdotes from the PBCM pilot project as appropriate. In addition, CMP leadership identified a physician champion for the CMP within each physician practice that had at least 25 or more CMP patients at the start if the project to further ease the transitions involved in the introduction of a case manager into the practice. During program implementation physician champions provided insight about the best way to incorporate case managers into the practice and encourage colleagues to take advantage of services available from the case managers.[86] Dr. Fishbane underscored the importance of establishing effective partnerships with the partner nephrologists during [Village Health's] Phase II and was optimistic about the efforts to secure physician champions, garner enthusiasm and support, and improve physician engagement at the first Medical Advisory Board meeting.[82]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Gaining and maintaining support from physicians and other care providers	CMO 3.3. Face-to-face outreach to physicians and their staff by program leaders and/or nurse care managers [C] effectively garners support of the intervention from existing care providers [O] by helping existing care providers understand the value of the intervention [M].	Case managers assigned to each practice met with physicians at the practices to describe the program, the skills that they bring to the physician practice, and their interest in collaborating to support patients in their efforts to manage their medical conditions. Case managers collected information from providers about how they could add value to the medical practice.[86] Acquiring buy-in from participating physician practices was viewed as very important. However, it was recognized early on that buy-in was needed on all levels. There was some concern among practice-based nurses, particularly at smaller practices, that there would be a duplication of effort. To obtain buy-in from the nurses, the CMP case managers spent time working with the practice-based nurses to educate them that the goal of the program was to augment and not to replicate their efforts.[86] In addition to distributing marketing materials and conducting group presentations, a TST [Texas Senior Trails] nurse with utilization management and provider relations experience visited the offices of the 250 doctors in the Lubbock and Amarillo areas with the highest numbers of CMHCB [Care Management for High Cost Beneficiaries] demonstration-eligible patients. This nurse was largely successful in gaining physician support for the program, often as a result of spending time with physician office staff and administrators who conveyed information about the program to the physicians…Similarly, the TST medical director in Amarillo had so much difficulty obtaining physician support via phone calls to these individuals that he ceased conducting these outreach calls. At the time of our site visit, the TST medical director and managing director were continuing to look for ways to market the program to providers who were not supportive initially. In particular, they were developing messages that conveyed the fact that the program can serve as a resource for physicians, by providing support for patients who are hard to manage because of mental health and/or social issues.[79]
	CMO 3.4. Using a multi-pronged approach to provide physicians with information about intervention services [C] made it more likely to reach doctors to get their support and engagement [M] in the intervention necessary for the program to succeed [O]	The program only works well when physicians are highly engaged.[86] MGH enlisted physician support to help ensure the success of its CMP in providing high-quality care to patients. Physicians were asked to conduct the following activities: encourage beneficiaries to participate in the program and enroll them in the program when possible; collaborate with case managers to review initial assessment findings and develop care plans for each patient; inform case managers about patient events and refinements to patient care plans during the demonstration period; and discuss advance directives with enrolled patients...MGH physicians received information about the CMP from a variety of sources, including the program's medical director, the MGH electronic newsletter, and case managers assigned to each practice.[86]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Gaining and maintaining support from physicians and other care providers (continued)	CMO 3.5. When an intervention includes an insufficient number of patients the physicians [C], physicians do not fully engage and participate in the program [O] because they feel the intervention is not a good investment in time and resources [M].	The staff also suggested implementing a physician referral model to gain physician buy-in and to identify sufficient numbers of patients to make a financially viable care management program. A physician referral model could increase enrollment by more than 10 times, according to one physician's estimate, with which others agreed. Interviewed physicians and care managers felt that a physician referral model would increase the appropriateness of patients referred for care management services. It was recommended that patient-specific clinical or educational goals accompany an open physician referral model in order to ensure that participants have clearly identified goals against which to measure their progress.[80] Although most physicians were supportive of the outreach efforts, they generally only had one or two patients participating in the program. The program had greatest success with offices that had approximately 30 patients participating in the program...To the extent that patients were concentrated with providers, program staff felt that the physicians were better allies and facilitated the clinical interventions. "A couple things we've gotten a little bit smarter about—one is the alignment to the provider. . . One of the things I would definitely do differently is for ESRD [end-stage renal disease] patients, I would do DaVita only and see what kind of change we could drive there. Then if we had a great solution, we could think about how we could scale it. That was probably 70% of the operational hassle that didn't actually do anything for patients but took a lot of time and energy. The same is true on the CKD [chronic kidney disease] side with the nephrologists."[82] Although the nephrologists were very engaged initially, the program had less of a renal focus than anticipated given that the beneficiary population did not have the extent of CKD that was originally projected. As a result, the program did not maintain as high visibility among physicians during Phase I as the KTBH [Village Health's Key to Better Health] program leadership would have liked.[82] During the first site visit, physicians at both sites reported that they were initially very enthusiastic about the Health Buddy® program, because it offered a promising way to effectively support patients with chronic disease. The Health Buddy® technology coupled with telephonic care management support was viewed as an effective way to maintain and improve patient health and identify symptoms of complications early, so that timely medical intervention could be used to prevent serious problems requiring hospitalization. Once the physicians received the list of patients who were eligible for the Health Buddy® program, they reported that they became frustrated with the project because they felt that many of the patients selected would not benefit from participating. Further, physicians reported disappointment that many of the patients they believed could be helped by the program were not eligible to participate in the program because they had not been identified through the claims based algorithm developed by HHN [Health Hero Network]…Using information gleaned from its early experience with the program, the HBC [Health Buddy Consortium] made a series of changes and enhancements to its operations and as reported to us at our second site visit.[80]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Gaining and maintaining support from physicians and other care providers (continued)	CMO 3.6. Developing and implementing a financially supportive system or model for physicians and their practice [C] encourages and motivates physicians and other care providers [M] to spend time with their patients and to continue supporting innovative intervention activities [O].	The Care One program provides incentives to primary care providers by valuing a Care One patient as equal to 5 normal primary care patients when adjusting panel size.[92] MGH provided physicians with a $150 financial incentive per patient in Year 1 and $50 in Years 2 and 3 to help cover the cost of physician time for these activities.[86] Thus, for such team care to be sustainable, time needs to be carved out for the work involved and systems need to support the follow through.[102] The staff also suggested implementing a physician referral model to gain physician buy-in and to identify sufficient numbers of patients to make a financially viable care management program. A physician referral model could increase enrollment by more than 10 times, according to one physician's estimate, with which others agreed.[80] Physician: 'When your hospital is basically saying.. . 'Here is 15 minutes for a repeat visit for another patient', I mean how are you gonna be able to actually provide the kind of care they need?'[61] Recent changes in the Medicare Advantage program (nearly all of ChenMed's patients are enrolled in Medicare Advantage) have created a favorable environment for delivery system innovation. In particular, the 2004 introduction of the Hierarchal Condition Categories risk adjustment model created a mechanism that reduced the financial risk of taking care of high cost patients with multiple chronic conditions. Patients with multiple chronic conditions have higher risk scores and, accordingly, higher reimbursement. Although not perfect, risk adjustment has alleviated participating payers' and providers' concerns about attracting sicker and costly patients without receiving commensurate reimbursement.[114] In addition, Medicare Advantage's capitation model is more favorable to delivery system innovation than traditional fee-for-service Medicare because it eliminates the process of negotiating reimbursement for cost-reducing delivery system innovations. Because providers are paid according to the size of their patient panel in a capitated system, they have an incentive to develop and test innovations to determine which ones lower the cost of care without compromising quality—and, ideally, increase it. For those innovations judged to be cost reducing without compromising quality, providers in a capitated system have the flexibility to deploy the innovations across their network. Providers in the fee-for-service system do not have such flexibility because they must negotiate with payers for the reimbursement of care delivery innovations—a step that can delay or even block such efforts.[114] Administrative pressures in health care delivery systems. Physicians and health system leaders felt existing payment structures and administrative pressures (such as the impetus to maximize the number of patients seen while minimizing visit time) negatively impacted the way they could interact with patients. Many agreed that when such a limited time frame is

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
	CMO 3.6 (continued)	allotted for each patient, it barely gives providers time to think, resulting in the delivery of 'bad care'. This also affected the way physicians communicate with their patients in key situations including discussions of illness, treatment options and care plans. Finally, stakeholders felt that the current care delivery model significantly dis-incentivized physicians from going into primary care, leading to a primary care physician shortage. The underlying sentiment was that if there are fewer primary care doctors overall, then HNHC patients will be at a greater disadvantage to have continuity of care at a primary care site, their diseases will not be well-controlled, leading to more ED visits and inpatient admissions.[61]
Staffing arrangements in care management interventions	CMO 3.7. Reducing providers' workload and responsibilities associated with the implementation of complex intervention activities [C] will reduce provider stress [M] so providers are more satisfied [O1] and more willing and able to engage with their patients and in participate intervention activities [O2] such as attending care team meetings, and carrying out care plans.	At baseline, members were divided in the anticipated effect of team care on their workload and stress levels. At 3 months, one member noted a decrease in workload, and three perceived an increase. Two indicated that the intervention "increased my stress by adding to my many responsibilities." Getting to Care Team meetings on time was difficult for about half of the team members.[102] Some team members felt their work increased by participating in the team.[102] Early on, we determined that certain tasks the HC RNs [Health Coach Registered Nurses] and LCSWs [Licensed Clinical Social Workers] were performing could be offloaded as these did not require their level of licensure, training, and skill. By doing so, we could free up the HC RNs and LCSWs to serve more patients and increase their job satisfaction.[91] Respondents from both independent and system-owned practices described turnover that occurred because care managers felt overwhelmed with numerous responsibilities.[101] Patient And Physician Time We also emphasize physician and patient time. Our primary care physicians, all internists, have a panel of 350–450 patients. By comparison, physicians at many commercial "concierge" practices, where patients pay sizable out-of-pocket retainers for the additional physician time, have larger panels. Small panel sizes allow our physicians to spend more time with their patients. Our physicians average fewer than eighteen visits a day; in contrast, primary care physicians average nearly thirty.[114] Physician: 'Need more primary care physicians who can manage outpatient things... And so you end up not being able to fill the need, and then we see them in the emergency department.'[61]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Staffing arrangements in care management interventions (continued)	CMO 3.8. Case managers, social workers, and high functioning administrative assistants in turn take on many time-consuming tasks (e.g., medication management, identifying community services, outreach, engagement) to help engage and manage HNHC patients and their paperwork [C] so that providers can focus their efforts [M] on providing continuous, comprehensive care to patients [O].	Early on, we determined that certain tasks the HC RNs and LCSWs were performing could be offloaded as these did not require their level of licensure, training, and skill...To address this, we worked with the teams to identify tasks that could be done by high functioning Administrative Assistants (AAs) and we now use AAs for tasks such as maintaining telephone contact with patients to remind them of appointments, check up on them when they have not been heard from, and assist the team members in entering and retrieving data related to the patients they serve. This is effective as long as there are intermittent face to face opportunities for the patients with the HC RNs, LCSWs, and CCLs [Client-Community Liaison].[91] "…Case managers take care of things like preauthorization, gathering documentation, medication tracking and other time-consuming issues, allowing PCPs [primary care providers] to focus on the relationship with patients and provide real continuity of care.;…The program does what every PCP needs to be doing but cannot do anymore because of the medicine practice and reimbursement realities and primary care provider shortages.;…Both patients and physicians love the program as case managers take a lot of burden off both sides.;…Key value of the program is in the help they provide PCPs with medication review and management, the most difficult to resolve issue when PCPs do not have any help;…" [Summary from a focus group of multiple physicians][86] The care manager served primarily as an adjunct to the patients' primary physicians.[80] As in 2015, deep-dive practice respondents described approaches to improving support for care managers, to clarify their roles and enhance staffing resources to help them feel less overwhelmed...A few practices were monitoring care managers' caseloads to determine whether they needed more staff to support high-risk patients, or to reduce (or even eliminate) activities focused on lower-risk patients. These practices brought in social workers to help meet patients' social needs and medical assistants to assume logistical or administrative tasks.[101] Navigators shared information about individual patients utilizing a team-based navigation model that provided flexibility in dividing the workload and providing cross coverage.[110] The program was staffed by a multidisciplinary care team consisting of a community health worker (CHW), a social worker (SW), and a PCP [primary care provider]…With guidance and support from the SW and the PCP, the CHW was responsible for patient outreach, engagement, activation, and accompaniment. The SW was responsible for counseling and brief interventions for patients with behavioral health needs and for coordinating referrals to social service agencies and other medical providers. The PCP was responsible for providing comprehensive care for acute and chronic conditions and for coordinating with specialists and inpatient providers.[108]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Staffing arrangements in care management interventions (continued)	CMO 3.8 (continued)	The CHW was able to identify unmet social needs contributing to acute care utilization that may not be apparent to busy clinicians and are not readily addressed during a single ED or clinic visit. For example, one patient with chronic restrictive lung disease who was dependent on home oxygen experienced financial insecurity and anxiety related to his inability to make on-time utility payments. The CHW was able to enroll him in a financial assistance program to prevent utility shutoffs, provide a list of local food pantries, and accompany him to primary care appointments where he was connected with the pulmonology clinic social worker who assisted with ongoing needs.[111]
	CMO 3.9. Providing training for staff members [C] gives them the confidence and skills [M] to function effectively as a care team [O1] and to understand and work with HNHC patients [O2].	"…The program has done a remarkable job in training and cultivating case managers who are very good at breaking barriers and making it work for the most difficult patients;…" [Summary from a focus group of multiple physicians][86] ...our team members received minimal training in ways to decrease frequent attendance and did not follow a systematic approach in assessing the patient...A more systematic approach, however, would have improved the function of our team.[102] Both navigators completed training at the Harold Freeman Institute for Patient Navigation, a 2-day intensive training program that teaches navigators to identify and eliminate barriers to care and serve as a support hub for patients moving through the health care system (22). The PN also completed local training at Gateway Community College, which emphasized needs and resources within the local community (23).[110]
	CMO 3.10. When care managers have regular opportunities to talk across offices and health care systems [C], they are more emotionally and technically prepared [M] to work with HNHC patients [O].	As in 2015, deep-dive practice respondents described approaches to improving support for care managers, to clarify their roles and enhance staffing resources to help them feel less overwhelmed. In some practices affiliated with health systems, respondents described providing opportunities for care managers embedded in practices across the health system to meet regularly, share best practices, and offer one another support.[101] CMP leadership also emphasized team support and peer counseling by developing infrastructure that provided opportunities for mutual support among CMP case managers and peer counseling from the members of the mental health team as the emotional toll on staff of working with a highly frail and sick population are substantial.[86]
	CMO 3.11. Having small care teams [C] helps teams members develop awareness of each HNHC patient's entire complex care [M] which can improve the coordination of patient care [O].	In addition, the ability for a team to be small and nimble was seen as a strength as it allowed for increased cohesion. "One of the issues with complex care is [it's] spread out amongst a bunch of different people.… There's a learning curve each time the patient meets with a different provider.… With SUMMIT [Streamlined Unified Meaningfully Managed Interdisciplinary Team], it's a small team.… Everybody knows what's going on with the patients in terms of their conditions and it really cuts through the confusion." (Usual Care LCSW)[58]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Communication across the care team	CMO 3.12. Leadership-supported, regular communication across all staff [C] builds collaborative feelings among teams [M] that results in job satisfaction for care team members [O], and facilitates implementation success [O].	Team communication was important for program implementation, although sites had different levels of success in this area over time. Care teams with a solid supervisory structure and frequent collaboration across all levels of staff experienced greater implementation success and staff satisfaction.[85] Due to the complexity of the CMP demonstration population, CMP leadership felt that constant and good communication between all staff within the program was essential.[86]
	CMO 3.13. Having transparent and supportive communication among care team members [C] fosters shared values and commitment [M] that results in stronger, more cohesive care team [O].	Team members caring for HNHC patients noted the importance of shared values and commitment, citing mutual respect for other disciplines and appreciation of the need for teamwork. “We respect one another’s clinical view.... We come at this from different backgrounds and feel like we get more out of our patient care experience if we hear what everyone else has to say…. We have a very supportive and inclusive team environment” (SUMMIT Physician) The importance of the team comes through particularly when patients aren’t faring as well as hoped: “They [other team members] really listen and they really care and we all really feel it when someone does fail…or something bad happens. It’s a very empathetic group of people....” (SUMMIT Nurse)[58] Our finding that staff members value a sense of unity and esprit de corps speaks to the value of cohesive multidisciplinary teams doing this work. As prior studies have shown, individual members of multidisciplinary teams may have different conceptualizations of which disciplines are part of a care team—often these are only a team in name.[58]
	CMO 3.14. Regular, multidisciplinary care team meetings that include physicians and staff [C] gave care team members the openness [M] to discuss patient cases [O1] and the practices' performance on quality metrics, outcomes, and other performance goals [O2].	Our CHAs [Community Health Advocates] provide perspectives in huddles that often enlighten licensed staff and offer a better understanding for the team regarding the unique needs of the patients we serve.[91] VPA [Visiting Physicians Association] corporate medical directors conducted weekly company-wide, web-based meetings with all clinicians, and regional managers conducted individual meetings with IAH practices, to review clinicians’ performance on IAH [Independence at Home] quality metrics and outcomes and consider broader implications for all of their patients.[103] Common themes and issues from the Virtual Rounds were also presented at bimonthly management meetings. The bi-monthly management meetings were used to review protocols, present resources, provide training, and identify issues and brainstorm solutions.[86] In addition to tracking metrics, most practices reported conducting care team meetings. Care team meetings provided a forum for clinical teams and staff to review quality metrics and progress toward performance goals, discuss an individual beneficiary’s case, and receive information on clinical topics.[103]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Communication across the care team (continued)	CMO 3.14 Regular, multidisciplinary care team meetings that include physicians and staff [C] gave care team members the openness [M] to discuss patient cases [O1] and the practices' performance on quality metrics, outcomes, and other performance goals [O2]. (continued)	We have designed processes and structures that promote a physician culture of collaboration, transparency, and accountability for high-quality care. For example, our primary care physicians meet three times a week to review hospitalized patients and discuss complex cases practice approaches. Specialists and hospitalists join these meetings as well. We use these sessions to conduct traditional morbidity and mortality review as well as to review each hospitalization and ask, “Could this hospitalization have been prevented?” Physicians are prepared to discuss each hospitalized case and explain to their peers the circumstances involved and their clinical thinking.[114] The team met weekly throughout the course of the intervention. One- or two-page patient summaries were prepared by the navigators, including a detailed, written summary of the patient’s medical history, prior ED use, barriers to accessing primary care services, life stressors that could be impacting their health, and type of help the patient wished to receive from the program. Each new patient was discussed by the team after the initial enrollment and on an as-needed basis (e.g., emergence of a new or challenging need or a repeat ED visit). The team discussed ways to support the patient’s clinical and social needs, brainstormed specific resources that might be helpful for the patient, and provided guidance to the patient navigators (24).[110] We held multidisciplinary team meetings weekly to develop care plans to support patients’ clinical and social needs.[110]
	CMO 3.15. Having regular care team meetings to discuss HNHC patients [C] may increase provider workloads [M] causing providers' to be arrive late for meetings [O1] and to not carry out care plans [O2].	The primary barriers to conducting regular Care Team meetings were the lack of time to meet and carry out the Care Plan and the difficulty of involving the patient...The team met for 40 min on a weekly basis to discuss one or two of the cases. The physicians were the most likely to arrive late and as noted by the chart review, were at times unable to follow through on the Care Plans.[102]
	CMO 3.16. When providers are given practical, constructive feedback about patient care approaches [C], providers are provided with the clinical knowledge or resources they need [M] to improve the care they provide to their patients [O]	“[Care team meetings] give us an opportunity to look back upon our encounter with the patient and really be able to gauge, ‘Was there a reason why the hospitalization happened, could it have been prevented, is there something that I missed?’ … It can be a little bit unnerving … but it [has] actually … strengthened my practice quite a bit. Because you learn a lot from that feedback.”[103] Clinicians valued receiving performance feedback and appreciated the opportunity to discuss cases with other clinicians and share ideas to improve care.[103] The CMP leadership implemented Virtual Rounds, regular e-mail reports that went to all staff, as a mechanism of providing feedback on a weekly basis. Case managers used Virtual Rounds to report on difficult patients and unnecessary admissions, and to describe both positive and negative events. Virtual Rounds were also used for case reviews with forms that staff filled out at the end of the week. These case reviews were then discussed with physicians in weekly face-to-face meetings.[86] Physicians in our study acknowledged their frustration in caring for frequent attenders, but also received specific, practical suggestions for changing their approach to care.[102]

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Communication across the care team (continued)	CMO 3.16 (continued)	Peer consultation provides much needed perspective, more objective assessment and support for the difficulties of the case.[102]
	CMO 3.17. Having patients who received care from providers in other healthcare systems or locations [C] creates challenges for care teams [M] to be able to effectively and efficiently communicate with the patient's providers [O].	TST staff reported that most participants had a primary provider that was associated with TTUHSC [Texas Tech University Health Sciences Center]; however, many patients, particularly in Amarillo, received care from additional providers that were not associated with the university. These providers typically operated independent practices, so TST care managers had to establish relationships with a number of different practices.[79] The second proposed improvement had to do with excluding beneficiaries from practices outside the care management organizations, if a systematic means of communicating with clinicians from these practices is not established.[80] Further, not all intervention beneficiaries had primary care physicians in the two study sites, therefore the care managers had to interact with community-based providers with whom they had little or no prior relationship. During our site visits, the care managers cited several challenges working with these physicians, in particular, because of communication barriers.[80]
	CMO 3.18. Providing opportunities for face-to-face conversations among care team members (e.g., being co-located, creating spaces that allow for provider conversations) [C] helps build strong working relationships [M] that improve team communication in support of coordination of patient care [O].	Our findings speak to the importance of co-located, embedded teams that “hear what everyone else has to say.”[58] ...the Health Buddy® nurse care managers often were not in direct proximity to their beneficiaries’ primary care physicians, thereby potentially affecting their interactions with the beneficiaries’ primary providers, changing medical care plans, or mitigating deterioration in health status...Interviewed physicians felt that care management would be more effective and efficient if care managers were colocated with primary care physicians.[80] Later, they returned patient care coordinators to local practice sites after clinicians and patients expressed dissatisfaction with the centralized system. According to one respondent, locating at the practice enables patient care coordinators to have more inperson contact with clinicians and to build relationships with patients. This change promoted strong working relationships among teams of clinicians, medical assistants, and care coordinators. Those strong working relationships help to address patients’ needs and avoid unnecessary readmissions and hospital and ED [emergency department] visits. Another practice changed where the physicians and other staff on the care team sat in the office. This practice clustered the care team together so they could discuss patients’ concerns and care delivery more easily.[103] We have also designed our centers to promote physician collaboration and conversation. They look more like an inpatient setting or intensive care unit than a traditional physician office. There is a large nurses’ station in the middle of the center where specialists do their paperwork, which is a sufficient distance from the patient exam rooms to allow for spontaneous discussions between specialists and primary care physicians after the specialist has seen the patient. In addition, there is a cluster of four to six individual primary care physician workstations away from direct patient view, where private conversations among physicians can readily happen. In the vast majority of cases, a specialist is able to have a brief face-to-face conversation with the patient’s primary care physician after

Program Theory Issue	CMOs	Relevant Data Extracts From Included Literature
Communication across the care team (continued)	CMO 3.18 (continued)	she or he sees the patient. The face-to-face conversation allows for more rapid alignment between primary care physician and specialist than the traditional faxed consult and voice mail.[114]
	CMO 3.19. Embedding care/case managers into primary care practices [C] makes it more efficient [M1] and convenient [M2] for physicians to use case managers services [O].	One improvement proposed was featuring a care management structure that pairs care managers and participants' primary care physicians in the same physical location.[80] CPC [Comprehensive Primary Care] practices greatly increased their use of dedicated care managers who were members of the primary care practice team over time. The number of practice survey respondents from CPC practices who reported that "care managers who were members of the practice team systematically provided care management services to high-risk patients" increased from 20 percent in 2012 to 88 percent in 2014 and 2015, and 89 percent in 2016. In comparison, fewer than half of comparison practices reported in 2016 that care managers who were practice care team members systematically provided these services to high-risk patients[101] Most physicians supported the general concept and potential benefits of the program but also expressed frustration with several aspects of the current demonstration design...care managers were not embedded in their physical practice locations.[80] At the time of the program launch, strong integration support from MGH leadership afforded the case managers physical entry into the primary care practice settings whereby the case managers were co-located with the primary care physicians ultimately becoming a part of the beneficiaries' primary health care teams.[86]

C = context; M= mechanism; O = outcome

Key Question 3: Overall, what is the effectiveness and what are the harms of interventions for HNHC patients in reducing potentially preventable or modifiable healthcare use and costs and in improving health outcomes?

Table B-14. Summary of strength of evidence by outcome and study model type (by primary setting)

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Utilization outcomes	ED visits, all cause[a]	HNHC patients	I	L-ND	I	M-F	I1	I	I
	ED visits at 270 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	ED visits at 180 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	ED visits, ACSC	HNHC patients	I1	L-ND	-	-	-	I	I
	ED visits, outpatient	HNHC patients	I1	-	-	-	-	-	-
	ED visit resulted in inpatient admission	HNHC patients	I1	-	-	-	-	-	-
	ED, any (%)	HNHC patients	-	-	I1	-	-	I1	-
	Psychiatric emergency visits	HNHC patients	-	-	I1	I1	-	-	-
	Inpatient admissions, all cause[a]	HNHC patients	I	L-ND	I	L-F	I1	I	I
	Inpatient admissions, any (%)	HNHC patients	-	I	I1	-	-	L-F	I
	Inpatient admissions at 270 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	Inpatient admissions at 180 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	Inpatient admissions, ACSC	HNHC patients	I1	L-ND	I1	-	-	I	L-F
	Inpatient admissions, any ACSC (%)	HNHC patients	-	I	-	-	-	I	L-F
	Acute medical/surgery stays	HNHC patients	-	-	-	-	I1	-	-
	Other inpatient stays	HNHC patients	-	-	-	-	I1	-	-
	Inpatient days	HNHC patients	-	-	I	I1	-	I	-
	Medical inpatient admissions	HNHC patients	-	-	-	I1	-	-	-
	Medical inpatient days	HNHC patients	-	-	-	I1	-	-	-
	Psychiatric inpatient admissions	HNHC patients	-	-	I1	I1	-	-	-
	Psychiatric inpatient days	HNHC patients	-	-	-	I1	-	-	-
	Total hospital encounters	HNHC patients	-	-	I1	-	-	-	-
	Hospital encounter resulted in discharge to hospital or observation stay	HNHC patients	-	-	I1	-	-	-	-
	Hospital encounter resulted in discharge from ED	HNHC patients	-	-	I1	-	-	-	-
	Outpatient visits	HNHC patients	-	-	I1	I	-	I	-
	Outpatient visits at 6 months	HNHC patients	-	I1	-	-	-	-	-
	Outpatient visits at 12 months	HNHC patients	-	I1	-	-	-	-	-
	Outpatient visits at 30 months	HNHC patients	-	I1	-	-	-	-	-
	Outpatient substance use treatment visits	HNHC patients	-	-	I1	-	-	-	-
	Outpatient mental health visits	HNHC patients	-	-	I1	-	-	-	-
	Outpatient mental health visit, any	HNHC patients	-	-	I1	-	-	-	-
	Primary care visits	HNHC patients	I1[b]	-	-	L-F[c]	I1	I	-
	Primary care visits at 360 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	Primary care visits at 270 days, all cause	HNHC patients	-	-	I1	-	-	-	-

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Utilization outcomes (continued)	Primary care visits at 180 days, all cause	HNHC patients	-	-	I1	-	-	-	-
	Total utilization	HNHC patients	-	I1	-	-	-	I1	-
	180-day readmission, count	HNHC patients	-	-	I	-	-	-	-
	180-day readmission, any (%)	HNHC patients	-	-	I1	-	-	-	-
	180-day readmission, ≥2 (%)	HNHC patients	-	-	I1	-	-	-	-
	Specialist visits	HNHC patients	I1	-	-	-	I1	I1	-
	Prescription drugs, any	HNHC patients	-	-	I1	-	-	-	-
	Long-term care, any	HNHC patients	-	-	I1	-	-	-	-
	FQHC visits	HNHC patients	I1	-	-	-	-	-	-
	Filled ≥3 antidepressant prescriptions in first 6 months	HNHC patients	-	-	-	-	-	I1	-
	Specialty mental health visit in first 6 months	HNHC patients	-	-	-	-	-	I1	-
	Cancelled visits and/or no shows	HNHC patients	-	-	-	-	-	I1	-
	Intensive care unit visits	HNHC patients	-	-	-	-	-	I1	-
	Dental visits	HNHC patients	-	-	-	-	-	I1	-
	Care center visits	HNHC patients	-	-	-	-	-	I1	-
	Probability of entering institutional long-term care within the demonstration year	HNHC patients	I1	-	-	-	-	-	-
	Long-term institutionalization rate	HNHC patients	-	-	-	-	-	-	I1
	Probability of hospice use	HNHC patients	I1	-	-	-	-	-	-
	Probability of SNF use	HNHC patients	I1	-	-	-	-	-	-
	Probability of home health use	HNHC patients	I1	-	-	-	-	-	-
	Home health days	HNHC patients	I1	-	-	-	-	-	-
	Home health visits	HNHC patients	I1	-	-	-	-	-	-
	Visits in nonacute settings by primary care clinicians	HNHC patients	I1	-	-	-	-	-	-
	Visits in nonacute settings by specialists	HNHC patients	I1	-	-	-	-	-	-
	Care management visits	HNHC patients	-	-	-	-	I1	-	-
	Mental healthcare visits	HNHC patients	-	-	-	-	I1	-	-
	Homeless care visits	HNHC patients	-	-	-	-	I1	-	-
	ED visits at 180 days, all cause	HNHC patients with a mental health diagnosis	-	-	I1	-	-	-	-
	Inpatient admissions at 180 days, all cause	HNHC patients with a mental health diagnosis	-	-	I1	-	-	-	-
	Primary care visits at 180 days, all cause	HNHC patients with a mental health diagnosis	-	-	I1	-	-	-	-

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Utilization outcomes (continued)	Outpatient visits at 6 months	HNHC patients with arthritis	-	I1	-	-	-	-	-
	Outpatient visits at 6 months	HNHC patients with high blood pressure	-	I1	-	-	-	-	-
	Outpatient visits at 6 months	HNHC diabetes patients	-	I1	-	-	-	-	-
	Outpatient visits at 12 months	HNHC patients with arthritis	-	I1	-	-	-	-	-
	Outpatient visits at 12 months	HNHC patients with high blood pressure	-	I1	-	-	-	-	-
	Outpatient visits at 12 months	HNHC diabetes patients	-	I1	-	-	-	-	-
	Outpatient visits at 30 months	HNHC patients with arthritis	-	I1	-	-	-	-	-
	Outpatient visits at 30 months	HNHC patients with high blood pressure	-	I1	-	-	-	-	-
	Outpatient visits at 30 months	HNHC diabetes patients	-	I1	-	-	-	-	-
	Total utilization (%)	HNHC patients living in a low income area	-	I1	-	-	-	-	-
	Total utilization (%)	HNHC patients living in a low education area	-	I1	-	-	-	-	-
	Total utilization (%)	HNHC patients with Medicaid	-	I1	-	-	-	-	-
Cost outcomes	Total costs	HNHC patients	L-ND	L-ND	I	I1	L-F	L-F	I
	Inpatient costs	HNHC patients	-	-	I	L-ND[c]	I1	I1	-
	ED costs	HNHC patients	-	-	I	L-F	I1	I1	-
	Hospital costs of care	HNHC patients	-	-	-	I	-	-	-
	Hospital charges	HNHC patients	-	-	I1	-	-	-	-
	Hospital payments received	HNHC patients	-	-	I1	-	-	-	-
	Indirect ED costs	HNHC patients	-	-	I1	-	-	-	-
	Medicaid cost	HNHC patients	-	-	-	I1	-	-	-
	Psychiatric emergency costs	HNHC patients	-	-	-	I1	-	-	-
	Psychiatric hospital costs	HNHC patients	-	-	-	I1	-	-	-
	All non-ED case management costs	HNHC patients	-	-	-	I1	-	-	-
	Acute costs	HNHC patients	I1	-	-	-	-	-	-
	Post-acute costs	HNHC patients	-	-	-	-	-	I1	-
	Outpatient department cost	HNHC patients	I1	-	-	-	-	-	-
	Outpatient costs	HNHC patients	I1	-	I1	I[c]	I1	I1	-
	Prescription or pharmacy costs	HNHC patients	-	-	I1	I1	-	I1	-
	Primary care physician cost	HNHC patients	I1	-	-	-	-	-	-
	Long-term care costs	HNHC patients	-	-	I1	-	-	-	-

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Cost outcomes (continued)	Other costs	HNHC patients	-	-	-	-	-	I1	-
	Total costs	High-cost, high-risk HNHC patients	-	-	-	-	-	-	I
	Total costs	High-cost HNHC patients	-	-	-	-	-	-	I
	Total costs	HNHC patients with dementia	I1	-	-	-	-	-	-
	Total costs	HNHC patients without dementia	I1	-	-	-	-	-	-
Clinical and functional outcomes	Mortality rate	HNHC patients	I1	L-ND	L-ND	I1	I	I	L-ND
	Influenza vaccine	HNHC patients	-	I	-	-	-	L-U	L-F
	Progression to ESRD	HNHC patients	-	I	-	-	-	-	-
	PHC score (physical health)	HNHC patients	-	I1	-	-	-	I1	I1
	MHC score (mental health)	HNHC patients	-	I1	-	-	-	I1	I1
	PQH-2 score (depression)	HNHC patients	-	I1	-	-	-	I1	I1
	Number of ADLs difficult to do	HNHC patients	-	I1	-	-	-	I1	I1
	Number ADLs receiving help	HNHC patients	-	I1	-	-	-	I1	I1
	Helping to cope with a chronic condition	HNHC patients	-	I1	-	-	-	I1	I1
	Number of helpful discussion topics	HNHC patients	-	I1	-	-	-	I1	I1
	Discussing treatment choices	HNHC patients	-	I1	-	-	-	I1	I1
	Communicating with providers	HNHC patients	-	I1	-	-	-	I1	I1
	Getting answers to questions quickly	HNHC patients	-	I1	-	-	-	I1	I1
	Multimorbidity Hassles score	HNHC patients	-	I1	-	-	-	I1	I1
	Percent receiving help setting goals	HNHC patients	-	I1	-	-	-	I1	I1
	Percent receiving help making a care plan	HNHC patients	-	I1	-	-	-	I1	I1
	Self-efficacy: Take all medications	HNHC patients	-	I1	-	-	-	I1	I1
	Self-efficacy: Plan meals and snacks	HNHC patients	-	I1	-	-	-	I1	I1
	Self-efficacy: Exercise 2 or 3 times weekly	HNHC patients	-	I1	-	-	-	I1	I1
	Self-care activities: Prescribed medications taken (mean # of days)	HNHC patients	-	I1	-	-	-	I1	I1
	Self-care activities: Followed healthy eating plan (mean # of days)	HNHC patients	-	I1	-	-	-	I1	I1
	Self-care activities: 30 minutes of continuous physical activity (mean # of days)	HNHC patients	-	I1	-	-	-	I1	I1
	Patient satisfaction	HNHC patients	-	-	-	I1	I1	I1	-

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Clinical and functional outcomes (continued)	Psychiatric symptoms (total BSI)	HNHC patients	-	-	-	I1	-	-	-
	Access to care	HNHC patients	-	-	-	-	I1	-	-
	SF-36 Summary Score	HNHC patients	-	-	-	-	-	I1	-
	SF-36 Mental Health Function Score	HNHC patients	-	-	-	-	-	I1	-
	SF-20 subscale: Social Functioning	HNHC patients		-	-	-	-	I1	-
	SF-20 subscale: Mental Health	HNHC patients	-	-	-	-	-	I1	-
	SF-20 subscale: General Health	HNHC patients	-	-	-	-	-	I1	-
	SF-20 subscale: Physical Functioning	HNHC patients	-	-	-	-	-	I1	-
	SF-20 subscale: Role Functioning	HNHC patients	-	-	-	-	-	I1	-
	SF-20 subscale: Pain Perception	HNHC patients	-	-	-	-	-	I1	-
	Change in HAM-D score	HNHC patients	-	-	-	-	-	I1	-
	In remission (HAM-D < 7)	HNHC patients	-	-	-	-	-	I1	-
	Patient-centered care coordination	HNHC patients	-	-	-	-	I1	-	-
	Relationship with providers: trusted provider	HNHC patients	-	-	-	-	I1	-	-
	Relationship with providers: feel respected by provider	HNHC patients	-	-	-	-	I1	-	-
	Healthcare hassles summary score (challenges in getting care)	HNHC patients	-	-	-	-	I1	-	-
	Patient assessment of chronic illness care (PACIC) Summary Score (receipt of care for chronic illness)	HNHC patients	-	-	-	-	I1	-	-
	Progression to ESRD	HNHC CKD patients	-	I	-	-	-	-	-
	Graft or fistula prior to hemodialysis	HNHC CKD patients	-	I	-	-	-	-	-
	Graft or fistula prior to hemodialysis	HNHC ESRD patients	-	I	-	-	-	-	-
	HbA1c test	HNHC patients, diabetes subgroup	I1	I	-	-	-	I	I
	LDL-C test	HNHC patients, diabetes subgroup	I1	I	-	-	-	I	I
	LDL-C test	HNHC IVD patients	-	I	-	-	-	I	I
	Eye exam	HNHC patients, diabetes subgroup	I1	I	-	-	-	-	-
	Nephrology/nephropathy test	HNHC patients, diabetes subgroup	I1	I	-	-	-	-	-
	Lipid test	HNHC patients, IVD subgroup	I1	I	-	-	-	-	-
	Oxygen saturation test	HNHC COPD patients	-	-	-	-	-	-	I

Outcome Group	Outcome Measure	Population	System Level (N=5)	Tele-phonic/ Mail (N=9)	Com-munity Based (N=9)	ED Based (N=7)	Ambulatory Intensive Caring Unit (N=3)	Primary Care (N=10)	Home Based (N=4)
Social risk outcomes	Participation in Supplemental Nutrition Assistance Program, any	HNHC patients	-	-	I1	-	-	-	-
	Receipt of temporary assistance for needy families, any	HNHC patients	-	-	I1	-	-	-	-
	Receipt of general assistance, any	HNHC patients	-	-	I1	-	-	-	-
	Ever housed	HNHC patients	-	-	I1	I1	-	-	-
	Jail stays	HNHC patients	-	-	I1	-	-	-	-
	Criminal convictions, any	HNHC patients	-	-	I1	-	-	-	-
	Criminal convictions	HNHC patients	-	-	I1	-	-	-	-
	Shelter days	HNHC patients	-	-	I1	-	-	-	-
	Drug/alcohol treatment, any	HNHC patients	-	-	I1	-	-	-	-
	Overall wellbeing	HNHC patients	-	-	-	-	-	I1	-
	Problem alcohol use, any	HNHC patients	-	-	-	I1	-	-	-
	Homelessness, any	HNHC patients	-	-	I1	I1	-	-	-
	Homeless months	HNHC patients	-	-	I1	-	-	-	-
	No health insurance, any	HNHC patients	-	-	-	I1	-	-	-
	No social security income, any	HNHC patients	-	-	-	I1	-	-	-
	Basic financial needs unmet	HNHC patients	-	-	-	I1	-	-	-

I1: Insufficient, only one sample reporting on the outcome; I: Insufficient, 2+ samples reporting on the outcome within the model type; L-F: Low strength of evidence for favorable findings for the outcome; L-ND: Low strength of evidence for no difference for the outcome; L-U: Low strength of evidence for unfavorable findings for the outcome; -: No eligible evidence; M-F: Moderate strength of evidence for favorable findings for the outcome.

[a] Includes visits at 12 months.

[b] Defined as evaluation and management primary care visits by Kahn et al.[122]

[c] Shumway et al. specified the outpatient and inpatient costs as medical outpatient costs and medical hospital costs.[116]

ACSC = ambulatory care sensitive conditions; ADL = activities of daily living; BSI = brief symptom inventory; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; ED = emergency department; ESRD = end-stage renal disease; FQHC = Federally Qualified Health Center; HAM-D = Hamilton Depression Rating Scale.; HbA1c = hemoglobin A1c; HNHC = high-need, high-cost; IVD = ischemic vascular disease; LDL-C = low-density lipoprotein cholesterol; MHC = mental health composite; PACIC = patient assessment of chronic illness care; PHC = physical health composite; PQH-2 = patient health questionnaire-2; SF = short form; SNF = skilled nursing facility; SOE = strength of evidence.

Table B-15. Study characteristics for system-level transformation models

First Author, Year, Site(s)	Brief Description (Sample Size)	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Kahn et al., 2016[122] 503 FQHCs	Support for FQHCs obtaining PCMH status (HNHC high ED use patient sample N=NR out of 730,353 beneficiaries total) Intervention (N=NR out of 269,364 beneficiaries total) Comparison (N=NR out of 360,989 beneficiaries total)	Observational study (RoB: some concerns)	Utilization of ED visits at baseline: 90th percentile vs. <90th percentile	NA	Medicare FFS beneficiaries; attribution to the practice or clinic responsible for the greatest number of primary care services over the 12-month period preceded the demonstration	NA
Kimmy et al., 2019[103, 132] National: 14 practices	Incentive payment (N=42,132) Intervention (N=8,216) Comparison (N=33,916)	Observational study (RoB: some concerns)	Hospitalization and use of acute or subacute rehabilitation services	2+ chronic conditions 2+ ADLs that require human assistance	Medicare FFS beneficiaries; all IAH-eligible patients of the IAH practices, including those who received home-based care before the demonstration began; not in hospice or long-term care for the entire time they were eligible for the intervention in a given year	Number of chronic conditions in Year 4 Total <6: 9.8% 6-9: 43.7% >9: 46.6% HCC: 3.90 Depression: 54.3%
Peikes et al., 2018[101] AR, CO, NJ, OR, NY, OH, KY, OK: 502 practices and 40 payers	Primary care model Shared savings: APM (N=1,730,958) Intervention (N=565,674) Comparison (N=1,165,284) Subgroups (N=NR)	Observational study (RoB: some concerns)	2+ hospitalizations in previous 2 years	2+ of 13 eligible chronic conditions including congestive heart failure, COPD, acute myocardial infarction, ischemic heart disease, diabetes, any cancer other than skin cancer, stroke, depression, dementia, atrial fibrillation, osteoporosis, rheumatoid arthritis or osteoarthritis, chronic kidney disease	Received care in a CPC practice	NR

First Author, Year, Site(s)	Brief Description (Sample Size)	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Peikes et al., 2019[123, 133] AR, CO, HI, KC, KY, MI, MT, NJ, NY (Greater Buffalo); NY (North Hudson-Capital), ND, NE, OH, OK, OR, PA, RI, TN: 1,373 practices	Primary care model Shared savings: APM Track 1 multiple chronic condition subgroup (N=NR of 5,163,969) Intervention (N=NR of 1,189,438) Comparison (N=NR of 3,974,531)	Observational study (RoB: some concerns)	1+ hospitalizations in past 1 year	2+ of 12 eligible chronic conditions including congestive heart failure, COPD, history of acute myocardial infarction, ischemic heart disease, diabetes, severe cancer, history of stroke, depression, dementia, atrial fibrillation, rheumatoid arthritis or osteoarthritis, chronic kidney disease	Enrolled in Medicare Parts A and B, Medicare FFS as primary payer, do not have ESRD and not enrolled in hospice, are not institutionalized or incarcerated, and are not attributed to a PCP for a nonoverlap CMS service	NR
Peikes et al., 2019[123, 133] AR, CO, HI, KC, KY, MI, MT, NJ, NY (Greater Buffalo); NY (North Hudson-Capital), ND, NE, OH, OK, OR, PA, RI, TN: 1,515 practices	Primary care model Shared savings: APM Track 2 multiple chronic condition subgroup (N=NR of 4,804,265) Intervention (N=NR of 1,443,553) Comparison (N=NR of 3,360,712)	Observational study (RoB: some concerns)	1+ hospitalizations in past 1 year	2+ of 12 eligible chronic conditions including congestive heart failure, COPD, history of acute myocardial infarction, ischemic heart disease, diabetes, severe cancer, history of stroke, depression, dementia, atrial fibrillation, rheumatoid arthritis or osteoarthritis, and chronic kidney disease	Enrolled in Medicare Parts A and B, Medicare FFS as primary payer, not ESRD and not in hospice, not institutionalized or incarcerated, and are not attributed to a PCP for a nonoverlap CMS service	NR

ADL = activities of daily living; APM = advanced alternative payment model; AR = Arkansas; CMS = Centers for Medicare & Medicaid Services; CO = Colorado; COPD = chronic obstructive pulmonary disease; CPC = comprehensive primary care; ED = emergency department; ESRD = end-stage renal disease; FFS = fee-for-service; FQHC = Federally Qualified Health Center; HI = Hawaii; HNHC = high-need, high-cost; IAH = Independence at Home; KC = Kansas City; KY = Kentucky; MI = Michigan; MT = Montana; N = number; NA = not applicable; ND = North Dakota; NE = Nebraska; NJ = New Jersey; NR = not reported; NY = New York; OH = Ohio; OK = Oklahoma; OR = Oregon; PA = Pennsylvania; PCMH = patient-centered medical home; PCP = primary care provider; RI = Rhode Island; RoB = risk of bias; TN = Tennessee; vs. = versus.

Table B-16. Intervention characteristics for system-level transformation models

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Impact on Clinician Workload/ Clinical Practice	Comparison
Kahn et al., 2016[122] 503 FQHCs	Three intervention components to support FQHC transformation into PCMHs: quarterly care management fee payments, technical assistance (TA), and data and performance feedback reports	3 years	Periodically received three types of feedback reports: the biannual NCQA RAS report, the quarterly cost and utilization data reports, and the quarterly claims-based beneficiary-level report summarizing cost, utilization, and health. FQHCs were offered TA to prepare documentation for NCQA PCMH recognition through extensive learning systems involving varying partners	Intervention goals based on PCMH principles, which are designed to encourage doctors, hospitals, and other healthcare providers to work together to better coordinate care for patients	NR	PCMHs are physician- or nurse practitioner–directed medical practices	NR	NR	NR	Usual care at comparison FQHCs

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(S)	Intensity	Impact on Clinician Workload/ Clinical Practice	Comparison
Kimmy et al., 2019[103] Effect of incentive payment National: 14 practices	Practices may earn an additional payment if their chronically ill, functionally limited patients' Medicare expenditures are below an estimated spending target and if the practice meets required standards for a set of quality measures	Up to 4 years	Clinicians are available at all hours of the day; carry out individualized care plans; and use electronic health information systems, remote monitoring, and mobile diagnostic technology	Report on other measures, including fall risk assessments and depression screenings, to promote the provision of such care	Some practices added social workers or other staff to coordinate care for their patients with other organizations	Physicians or nurse practitioners. Team may have also included physician assistants, clinical staff, and other health and social services staff	Face-to-face	Clinicians made 3-15 home visits per day, varied by site	≤1 home visit and no visit from a participating practice in study year	Usual care of Medicare-eligible beneficiaries living in IAH regions

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(S)	Intensity	Impact on Clinician Workload/ Clinical Practice	Comparison
Peikes et al., 2018[101] AR, CO, NJ, OR, NY, OH, KY, OK: 502 practices and 40 payers	Comprehensive Primary Care (CPC) Initiative	51 months	CPC practices received financial support, data feedback, and learning support	Practices required to address access and continuity, planned care for chronic conditions and preventive care, risk-stratified care management, patient and caregiver engagement	Practices required to address coordination of care across the medical neighborhood	CPC practices, multiple contractors and organizations provided different intervention elements to CPC practices Patients received intervention services from regular practice staff and from specialized staff (e.g., care coordinators, care managers, social workers)	CMS sent reports on practice and patient-level data; learning support was peer-to-peer, didactic, and one-on-one	Reports and financial support were sent quarterly, frequency of learning support varied	Practices perceived that a big benefit of CPC participation was increased capacity to provide care management services to high-risk patients; practices shared with CMS any net savings in healthcare costs beyond amount required to cover their care management fee payments; within practices, care managers were increasingly integrated into clinicians' work	Usual care at non-CPC practices

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(S)	Intensity	Impact on Clinician Workload/ Clinical Practice	Comparison
Peikes et al., 2019[123] AR, CO, HI, KC, KY, MI, MT, NJ, NY (Greater Buffalo); NY (North Hudson-Capital), ND, NE, OH, OK, OR, PA, RI, TN: 2,888 practices	Comprehensive Primary Care Plus (CPC+)	2 years	Practice-focused intervention; CPC+ practices received financial support, data feedback, health IT support, and learning support; track 2 CPC+ practices received enhanced payments and replacement of some fee-for-service payments with prospective payments	Required to address access and continuity, care management, comprehensiveness and coordination, patient and caregiver engagement, and planned care and population health CMS-specified care delivery requirements within each of these functions; they were considered a starting point and practices could choose which care delivery requirements or other changes to adopt first, which personnel would be involved and which tactics they would pursue	Care management, comprehensiveness and coordination are 2 of the 5 key functions of a CPC+ practice	CPC+ practices; CMS partnered with 79 public and private payers across 18 CPC+ regions; various contractors and organizations provided intervention elements to CPC+ practices Practices hired new staff to support CPC+ activities: care managers, behavioral health specialists, clinical pharmacists, social workers, data analysts, dietitians, diabetes educators, and QI staff	Practices received data reports; learning was delivered in groups and in-person practice coaching	Reports and financial support were sent quarterly, frequency of learning support NR	NR	Usual care at non-CPC+ practices

AR = Arkansas; CMS = Centers for Medicare & Medicaid Services; CO = Colorado; CPC = Comprehensive Primary Care; CPC+ = Comprehensive Primary Care Plus; FQHC = Federally Qualified Health Center; HI = Hawaii; IT = information technology; KC = Kansas City; KY = Kentucky; MI = Michigan; MT = Montana; NCQA = National Committee for Quality Assurance; ND = North Dakota; NE = Nebraska; NJ = New Jersey; NR = not reported; NY = New York; OH = Ohio; OK = Oklahoma; OR = Oregon; PA = Pennsylvania; PCMH = patient-centered medical home; QI = quality improvement; RAS = Readiness Assessment Survey; RI = Rhode Island; TA = technical assistance; TN = Tennessee.

Table B-17. Healthcare utilization outcomes for system-level transformation model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Inpatient admissions	Observational	NR	NR	FQHC: adjusted year 3 difference in visits: -5.32 (SE: 28.60) (p>0.10)[122]
	Observational	NR	NR	IAH incentive payment 5-year average annual effect DiD=-0.08 (SE: 0.05) (p>0.10)[103, 132]
Inpatient admissions, ACSC	Observational	NR	NR	Greater reduction in G1 than G2: IAH incentive payment 5-year average annual effect DiD=-0.04 (SE: 0.02) (p<0.05)[103, 132]
ED visits	Observational	NR	NR	FQHC: adjusted year 3 difference in visits: -80.75 (SE: 87.65) (p>0.10)[122]
	Observational	NR	NR	Greater reduction in G1 than G2: IAH incentive payment 5-year average annual effect DiD=-0.14 (SE: 0.06) (p<0.01)[103, 132]
ED visits, outpatient	Observational	NR	NR	IAH incentive payment 5-year average annual effect DiD=-0.02 (SE: 0.06) (p>0.10)[103, 132]
ED visits resulted in inpatient admission	Observational	NR	NR	Greater reduction in G1 than G2: IAH incentive payment 5-year average annual effect DiD=-0.11 (SE: 0.05) (p<0.05)[103, 132]
ED visits, ACSC	Observational	NR	NR	IAH incentive payment 5-year average annual effect DiD=-0.00 (SE: 0.01) (p>0.10)[103, 132]
Primary care visits[b]	Observational	NR	NR	FQHC: adjusted year 3 difference in visits: -132.58 (SE: 84.18) (p>0.10)[122]
Specialist visits	Observational	NR	NR	FQHC: adjusted year 3 difference in visits: -29.67 (SE: 78.82) (p>0.10)[122]
FQHC visits	Observational	NR	NR	FQHC: adjusted year 3 difference in visits: -15.90 (SE: 54.65) (p>0.10)[122]
Probability of entering institutional long-term care within the demonstration year	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=-0.38 (SE: 0.37) (p>0.10)[132]
Probability of hospice use	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=-0.83 (SE: 0.68) (p>0.10)[103]
Probability of SNF use	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=0.19 (SE: 0.82) (p>0.10)[103]
Probability of home health use	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=-0.45 (SE: 0.70) (p>0.10)[103]
Home health days	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=-0.58 (SE: 5.67) (p>0.10)[103]
Home health visits	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=0.14 (SE: 2.43) (p>0.10)[103]
Visits in nonacute settings by primary care clinicians	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=0.59 (SE: 0.57) (p>0.10)[103]
Visits in nonacute settings by specialists	Observational	NR	NR	IAH incentive payment 4-year average annual effect DiD=-0.39 (SE: 0.32) (p>0.10)[103]

[a] The reported p-value reflect the authors' adjustment for multiple comparisons.

[b] Defined as Evaluation and Management primary care visits by Kahn et al.[122]

ACSC = ambulatory care sensitive conditions; DiD = difference-in-difference; ED = emergency department; FQHC = Federally Qualified Health Center; G = group; IAH = Independence at Home; NR = not reported; SE = standard error; SNF = skilled nursing facility.

Table B-18. Strength of evidence for system-level transformation model versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	ED visits	FQHC: adj diff=-80.75 (p>0.10);[122] IAH incentive payment: lower use in G1 than G2: DiD=-0.14 (p<0.01)[103]	2 OBSs, N=NR[a]	Moderate study limitations, inconsistent, direct, imprecise	Insufficient
HNHC patients	Inpatient admissions	FQHC: adj diff=-5.32 (p>0.10);[122] IAH incentive payment DiD=-0.08 (SE: 0.05) (p>0.10)[103]	2 OBSs, N=NR[a]	Moderate study limitations, consistent, direct, imprecise	Insufficient
HNHC patients	Total cost	FQHC: adj diff=$387.23 (p>0.10);[122] CPC: DiD=-$45 (p=0.23);[101] CPC+ sample 1: DiD=6.2 (p>0.10);[133] CPC+ sample 2: DiD=43.0 (p=04);[133] IAH incentive payment DiD=-200 (SE: 151) (p>0.10)[103] Pooled mean difference: -$5.41 (95% CI, -38.28 to 49.10); 5 observational samples; I^2=44.6%	5 OBSs, N=NR[a]	Moderate study limitations, inconsistent, direct, imprecise	Low (No difference)

[a] The FQHC,[122] CPC,[101] and CPC+[123] studies did not report sample sizes for their HNHC patient populations; the total sample size for the FQHC was 730,353, 1,730,958 for CPC, 5,163,969 for CPC+ Sample 1, and 4,804,265 for CPC+ Sample 2. The sample size was 42,132 for the Independence at Home study.[103]

Note: CPC+ sample 1: HNHC patients in CPC+ practices making less advanced care delivery changes; CPC+ sample 2: HNHC patients in CPC+ practices making more advanced care delivery changes.

adj diff = adjusted difference; CI = confidence interval; DiD = difference-in-difference; ED = emergency department; FQHC = Federally Qualified Health Center; HNHC = high need, high cost; IAH = Independence at Home; N = number; NR = not reported; OBS = observational study; vs. = versus.

Table B-19. Cost outcomes for system-level transformation model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost ($)	Observational	NR	NR	FQHC: adjusted difference=387.23 (SE: 494.62) (p>0.10)[122]
	Observational	NR	NR	IAH incentive payment 5-year average annual effect DiD=-200 (SE: 151) (p>0.10)[103, 132]
	Observational	NR	NR	CPC DiD=-45 (p=0.23)[101]
	Observational	NR	NR	CPC+ Sample 1 2-year impact DiD=6.2 (SE: 19.2) (p>0.10))[123, 133]
	Observational	NR	NR	Greater increase in G1 than G2: CPC+ Sample 2 2-year impact DiD=43.0 (SE: 20.5) (p=0.04)[123, 133]
Outpatient cost	Observational	NR	NR	FQHC: adjusted differences in visits: 290.07 (SE: 178.26) (p>0.10)[122]
Acute cost	Observational	NR	NR	FQHC: adjusted for differences in visits: 292.47 (SE: 315.40) (p>0.10)[122]
OPD cost	Observational	NR	NR	FQHC: adjusted for differences in visits: 218.92 (SE: 150.97) (p>0.10)[122]
Primary care physician cost	Observational	NR	NR	FQHC: adjusted differences in visits: 18.99 (SE: 26.65) (p>0.10)[122]

Note: CPC+ sample 1: HNHC patients in CPC+ practices making less advanced care delivery changes; CPC+ sample 2: HNHC patients in CPC+ practices making more advanced care delivery changes.

CPC+ = Comprehensive Primary Care Plus; DiD = difference-in-difference;; FQHC = Federally Qualified Health Center; G = group; HNHC = high-need, high-cost; IAH = Independence at Home; NR = not reported; OPD = outpatient department; SE = standard error.

Table B-20. Cost outcomes for system-level transformation model studies: Subgroup outcomes

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost (PBPM)	Observational	NR	NR	Beneficiaries with dementia subgroup: IAH incentive payment DiD=-222 (SE: 143)(p=NS)[103]
	Observational	NR	NR	Beneficiaries without dementia subgroup: IAH incentive payment DiD=-347 (SE: 279) (p=NS)[103]

DiD = difference-in-difference; G = group; IAH = Independence at Home; NR = not reported; NS = not statistically significant; PBPM = per beneficiary per month; SE = standard error.

Table B-21. Clinical and functional outcomes for system-level transformation model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality rate	Observational	IAH incentive payment 5-year average annual effect DiD: -0.32 (SE: 0.55) (p>0.10)[103, 132]

DiD = difference-in-difference; G = group; IAH = Independence at Home; NR = not reported; SE = standard error.

Table B-22. Clinical and functional outcomes for system-level transformation model studies: Subgroup outcomes

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
HbA1c test	Observational	FQHC diabetes subgroup: adjusted year 3 difference in visits: 0.35 (SE: 1.16) (p>0.10)[122]
LDL test	Observational	FQHC diabetes subgroup: adjusted year 3 difference in visits: -1.17 (SE: 1.37) (p>0.10)[122]
Eye exam	Observational	FQHC diabetes subgroup: adjusted year 3 difference in visits: 1.09 (SE: 1.53) (p>0.10)[122]
Nephropathy test	Observational	FQHC diabetes subgroup: adjusted year 3 difference in visits: 2.88 (SE: 1.60) (p>0.10)[122]
All 4 recommended diabetes tests	Observational	FQHC diabetes subgroup: adjusted year 3 difference in visits: -0.51 (SE: 0.45) (p>0.10)[122]
Lipid test	Observational	FQHC IVD subgroup: adjusted year 3 difference in visits: -0.81 (SE: 1.80) (p>0.10)[122]

FQHC = Federally Qualified Health Center; G = group; HbA1c = hemoglobin A1c; IVD = ischemic vascular disease; LDL = low-density lipoprotein; NR = not reported; SE = standard error.

Table B-23. Study characteristics for telephonic/mail models

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
McCall et al., 2010[79] 48 counties in western TX	HNHC patients only (N=2,815) Intervention (N=1,986) Comparison (N=1,969)	RCT (RoB: some concerns)	Medicare costs of $6,000 or more in past 1 year	NA	Medicare FFS beneficiaries, majority of visits to TX Tech U Health Sciences Center or Physician Network Services (a PCP)	NR
McCall et al., 2010[81] Suffolk, Nassau, and Queens, NY: 6 nephrology practices	Original sample (N=6,996) Intervention (N=4,996) Comparison (N=2,000) Diabetes subgroup (N=2,165) ESRD subgroup (N=331) IVD subgroup (N=2,434)	RCT (RoB: some concerns)	Medicare costs of $5,000 or more in past 1 year	Chronic kidney disease diagnosis on at least one claim, HCC > 1.7 (high risk for future healthcare utilization), excluded ESRD patients	Medicare FFS beneficiaries with primary residence in the intervention county/region	NR
McCall et al., 2010[81] Suffolk, Nassau, and Queens, NY: 6 nephrology practices	Refresh sample (N=3,341) Intervention (N=2,385) Comparison (N=956) Diabetes subgroup (N=1,280) ESRD subgroup (N=97) IVD subgroup (N=1,508)	RCT (RoB: some concerns)	Medicare costs of $5,000 or more in past 1 year	CKD diagnosis as evidence by at least one claim, HCC > 1.7 (high risk for future healthcare utilization), excluded ESRD patients	Medicare FFS beneficiary with primary residence in the intervention county/region, excluded patients institutionalized from March to May 2006 (part of the baseline period)	NR

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Urato et al., 2013[82] Sites in NY counties: Nassau, Suffolk, Queens, Kings, Westchester, Richmond, Rockland, and Bronx	Original sample (N=5,889) Intervention (N=2,945) Comparison (N=2,944) Diabetes subgroup (N=2,284) CKD subgroup (N=3,159) Intervention IVD subgroup (N=2,030)	RCT (RoB: some concerns)	Medicare costs of $5,000 or more for CKD beneficiaries and $12,000 or more for ESRD beneficiaries in past 1 year	Stage 3 CKD diagnosis, as evidence by at least one claim	Medicare FFS beneficiaries with primary residence in the intervention county/region	Mean HCC score: 2.65
Urato et al., 2013[82] Sites in NY counties: Nassau, Suffolk, Queens, Kings, Westchester, Richmond, Rockland, and Bronx	Refresh sample (N=4,467) Intervention (N=2,234) Comparison (N=2,233) Diabetes subgroup (N=2,202) CKD subgroup (N=1,663) IVD subgroup (N=2,061)	RCT (RoB: some concerns)	Medicare costs of $5,000 or more for CKD beneficiaries and $12,000 or more for ESRD beneficiaries in past 1 year	Stage 3 CKD diagnosis, as evidence by at least one claim	Medicare FFS beneficiaries with primary residence in the intervention county/region	NR
Dally et al., 2002[90] OH	(N=593) Intervention (N=297) Comparison (N=296)	RCT (RoB: some concerns)	11+ outpatient visits in 2 years	1+ visit with a diagnosis of at least 1 of 3 targeted conditions (arthritis, hypertension, diabetes)	Age: 18-64; Kaiser Permanente Ohio patient	
McCall et al., 2011[80] Central OR and central WA: 2 large multispecialty group practices	Original HNHC patient sample (N=125) Intervention (N=66) Comparison (N=59)	RCT (RoB: some concerns)	Medicare costs of $6,000 or more in 1 year	HF, diabetes, or COPD diagnosis on at least 1 claim	Medicare FFS beneficiaries; 2+ visits to the HBC medical practices	NR

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
McCall et al., 2011[80] Central OR and central WA: 2 large multispecialty group practices	Refresh HNHC patient sample (N=227) Intervention (N=120) Comparison (N=107)	RCT (RoB: some concerns)	Medicare costs of $6,000 or more in 1 year	HF, diabetes, or COPD diagnosis on inpatient, outpatient hospital, or physician claims only	Medicare FFS beneficiaries; 2+ visits to the HBC medical practices	NR
Schickedanz et al., 2019[121] Southern CA: 1 health system including 13 medical centers	(N=34,225) Intervention (N=7,107) Comparison (N=27,118)	Observational (RoB: some concerns)	Predicted to be in top 1% of healthcare utilization in health system in the next 1 year	NA	Age: 18+; Kaiser Permanente Southern California patient	Nonwhite: 50% Cancer: 46% Diabetes: 13% CAD/CHF: 33% Asthma: 6% Charlson Comorbidity score: 7 (3) Depression: 6% Lives in low-income census tract: 14%; Medicare: 60%; Commercial insurance: 25%

CA = California; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; ESRD = end-stage renal disease; FFS = fee-for-service; HF = heart failure; HBC = Health Buddy Consortium; HCC = hierarchical condition category; HNHC = high-need, high-cost; IVD = ischemic vascular disease; N = number; NA = not applicable; NR = not reported; NY = New York; OH = Ohio; OR = Oregon; PCP = primary care practice; RCT = randomized controlled trial; RoB = risk of bias; TX = Texas; U = University; WA = Washington.

Table B-24. Intervention characteristics for telephonic/mail models

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
McCall et al., 2010[79] 48 counties in western TX	TX Senior Trails Program: Care Management for High-Cost Beneficiaries Demonstration: TX Tech University Health Sciences Center Shared savings and care management	NR; up to 16 months	Patient education and coaching of chronic conditions and self-management skills	Facilitate communication with providers, care plan compliance, hospital discharge planning, medication adherence, access to clinics; sharing information with physicians	Care team drew on community resources to assist with social issues	Nurse care managers, nurses for telephone support, social workers	Telephone, face-to-face, written: in patient homes, physician offices, or in the hospital, as needed	Mean contacts per beneficiary: 6 (median: 4) 97% of participants had 1+ contacts with a care manager or physician, 50% had 2-4 contacts, and 25% had 5-9 contacts. Written contact was most frequent, face-to-face was least frequent (20% had face-to-face contact with the care manager)	Usual care: comparison group was not contacted

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
McCall et al., 2010[81] Suffolk, Nassau, and Queens, NY: 6 nephrology practices	Care Management for High-Cost Beneficiaries Demonstration: VillageHealth I Shared savings and one-on-one nurse care manager support	Up to 36 months for original sample, up to 24 months for refresh sample	Initial and continuous risk evaluation, telemonitor health failure patients, 24-hour hotline for assistance requests, develop care plan, renal disease education	Coordinated care, referral to nephrologist when reach stage IV CKD, support from pharmacist, medication therapy management	NR	Care managers (phone and field RNs), pharmacists, dietitians: telephone support and education materials; social workers: telephone psychosocial support (e.g., insurance, transportation); health service assistants provided admin support for patients and providers	Telephone, face-to-face: NR	On average, participants were contacted about every 1.4 months or had 13 contacts over 18 months. Nearly all had a telephone or in-person contact during the last 18 months, mostly by telephone	Usual care: comparison group was not contacted

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Urato et al., 2013[82] Sites in NY counties: Nassau, Suffolk, Queens, Kings, Westchester, Richmond, Rockland, and Bronx	Extended Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration: VillageHealth II Shared savings and disease management/ case management through a care management organization	Up to 21 months for original sample, up to 11 months for refresh sample	Provided individualized assessment, including risk stratification, and tailored care plans; education related to self-management activities to decrease risk for acute exacerbations of chronic diseases	Facilitated patient relationships with physicians, helped patients comply with physician care plans, hospital discharge planning support, medication management	Referrals or provision for ancillary services (drugs, community services)	Nurse care managers, nurses for telephone support, registered dietitian, pharmacist, social worker	Face-to-face or telephone contact with nurse care manager, in-person educational classes: in-patient home or over telephone • CKD patients provided telephone support only • ESRD patients provided phone or in- person support	At least monthly contact with care manager; >50% of beneficiaries did not get a call or in-person meeting with a care manager in the last 15 months Telephonic contact was the dominant form of contact (about 70%)	Usual care: comparison group was not contacted

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Dally et al., 2002[90] OH	Mailed health promotion program	90% remained enrolled for 30 months	Health risk appraisal (HRA) questionnaire, personalized letter and report with feedback after each questionnaire with recommendations to reduce the health risks identified by the questionnaire, and condition-specific health education pamphlets and books	NR	NR	A vendor provided all intervention-related materials	All materials were mailed to participants' homes	After initial HRA questionnaire, 3 additional HRA questionnaires and individualized feedback letters/reports were delivered approximately every 3 months	Controls also received and completed the baseline HRAs, education materials, and an incentive to complete the final questionnaire
McCall et al., 2011[80] Central OR and central WA: 2 large multispecialty group practices	Care Management for High-Cost Beneficiaries Demonstration: Health Buddy Consortium Shared savings and Health Buddy® disease management (Health Buddy® device allowed for daily, routine communication with program staff)	Up to 38 months for original population, up to 26 months for refresh population	Daily Health Buddy questionnaire to assess health condition, followup from nurse CM as appropriate	13 disease-specific care management programs; triaged and coordinated medical, psychological, or social services	Coordinated social services, as needed	Nurse care managers, physicians	Telephone, over Health Buddy device	Nearly all intervention group members who used the device received at least one call from a care manager during the demo and nearly 60% received >20 contacts during this same period. Over 60% of participants never had a device and scheduled regular telephone calls with a nurse care manager	Usual care: comparison group was not contacted

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Schickedanz et al., 2019[121] Southern CA: 1 health system including 13 medical centers	Health Leads Program: social needs screening and navigation intervention	NR; up to 14 months (followup time)	Social needs screener, intake assessment	NR	Tailored referral to community-based services (i.e., food banks, housing programs, or other resources to address the identified social need) immediately or during followup calls	Program associates provided screening and navigation	Telephone	Followup calls at minimum every 2 weeks until call were no longer needed or loss to followup	Usual care

CA = California; CKD = chronic kidney disease; CM = case manager; CMHCB = Care Management for High Cost Beneficiaries; ESRD = end-stage renal disease; HRA = health risk appraisal; NR = not reported; NY = New York; OH = Ohio; OR = Oregon; RN = registered nurse; TX = Texas; WA = Washington.

Table B-25. Healthcare utilization outcomes for telephonic/mail model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Inpatient admissions, all cause	RCT	⇧	⇧	Original sample DiD: IRR=0.94 (95% CI, 0.82 to 1.07)[81]
	RCT	⇧	⇧	Refresh sample DiD: IRR=0.96 (95% CI, 0.80 to 1.15)[81]
	RCT	⇧	⇧	Original sample DiD: IRR=1.06 (95% CI, 0.95 to 1.19)[82]
	RCT	⇩	⇩	Refresh sample DiD: IRR=0.98 (95% CI, 0.86 to 1.11)[82]
Inpatient admissions, ACSC	RCT	⇧	⇧	Original sample DiD: IRR=1.05 (95% CI, 0.87 to 1.28)[82]
	RCT	⇧	⇩	Refresh sample DiD: IRR=0.98 (95% CI, 0.80 to 1.20)[82]
	RCT	⇧	⇧	Original sample DiD: IRR=0.83 (95% CI, 0.67 to 1.04)[81]
	RCT	⇧	⇧	Refresh sample DiD: IRR=1.02 (95% CI, 0.77 to 1.36)[81]
Inpatient admissions, any (%)	RCT	⇧	⇧	Original sample DiD: OR=0.98 (95% CI, 0.82 to 1.18)[81]
	RCT	⇩	--	Refresh sample DiD: OR=0.94 (95% CI, 0.74 to 1.18)[81]
Inpatient Admissions, ACSC (%)	RCT	⇧	⇧	Original sample DiD: OR=0.86 (95% CI, 0.69 to 1.08)[81]
	RCT	⇧	⇧	Refresh sample DiD: OR=0.93 (95% CI, 0.70 to 1.25)[81]
ED visits, all cause	RCT	⇧	⇧	Original sample DiD: IRR=1.04 (95% CI, 0.91 to 1.19)[81]
	RCT	⇧	⇧	Refresh sample DiD: IRR=1.01 (95% CI, 0.82 to 1.24)[81]
	RCT	⇧	⇧	Original sample DiD: IRR=1.03 (95% CI, 0.90 to 1.17)[82]
	RCT	⇧	⇧	Refresh sample DiD: IRR=0.97 (95% CI, 0.85 to 1.10)[82]
ED visits, ACSC	RCT	⇧	⇧	Original sample DiD: IRR=1.09 (95% CI, 0.90 to 1.33)[82]
	RCT	⇩	⇩	Refresh sample DiD: IRR=1.00 (95% CI, 0.81 to 1.23)[82]
	RCT	⇧	⇧	Original sample DiD: IRR=0.87 (95% CI, 0.71 to 1.08)[81]
	RCT	⇧	⇧	Refresh sample DiD: IRR=1.07 (95% CI, 0.79 to 1.45)[81]
Outpatient visits at 6 months	RCT	NR	NR	Total sample: Poisson coefficient =-0.0328 (p=0.27)[90]
Outpatient visits at 12 months	RCT	⇧	⇩	Total sample: Poisson coefficient =-0.0341 (p=0.11)[90]

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Outpatient visits at 30 months	RCT	NR	NR	Total sample: Lower use in G1 than G2: Poisson coefficient =-0.0260 (p=0.04)[90]
Total Utilization (%)	Observational	NR	NR	Total sample DiD:[a] -2.2 (95% CI, -4.5 to 0.1)[121]

[a] Total utilization includes a count of all visits in emergency department, outpatient, and/or inpatient settings. The subgroups were based on the census tract estimates of patients' home address. The low-income subgroup included patients who lived in census tracts where a plurality of residents had income below $34,575. The low-education subgroup included patients who lived in census tracts where a plurality of residents had less than a high school education.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

ACSC = ambulatory care sensitive conditions; CI = confidence interval; DiD = difference-in-difference; ED = emergency department; G = group; IRR = incidence rate ratio; NR = not reported; OR = odds ratio; RCT = randomized controlled trial.

Table B-26. Healthcare utilization outcomes for telephonic/mail model studies: Subgroup outcomes

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Outpatient visits at 6 months	RCT	NR	NR	Arthritis subgroup: Poisson coefficient= -0.0710 (p=0.16)[90]
	RCT	NR	NR	Blood pressure subgroup: Poisson coefficient=0.0838 (p=0.15)[90]
	RCT	NR	NR	Diabetes subgroup: Poisson coefficient= -0.0879 (p=0.07)[90]
Outpatient visits at 12 months	RCT	⬇	⬆	Arthritis subgroup: Lower use in G1 than G2: Poisson coefficient =-0.1130 (p<0.01)[90]
	RCT	⬇	⬇	Blood pressure subgroup: Higher use in G1 than G2: Poisson coefficient=0.0938 (p=0.02)[90]
	RCT	⇩	⇧	Diabetes subgroup: Poisson coefficient= -0.0651 (p=0.06)[90]
Outpatient visits at 30 months	RCT	NR	NR	Arthritis subgroup: Lower use in G1 than G2: Poisson coefficient =-0.1004 (p<0.01)[90]
	RCT	NR	NR	Blood pressure subgroup: Poisson coefficient=0.0317 (p=0.21)[90]
	RCT	NR	NR	Diabetes subgroup: Poisson coefficient= -0.0146 (p=0.50)[90]
Total utilization (%)	Observational	NR	NR	Low-income area subgroup DiD:[a] Greater reduction in G1: -7.0 (95% CI -11.9 to -1.9)[121]
	Observational	NR	NR	Low-education area subgroup DiD:[a] Greater reduction in G1: -11.5 (95% CI, -17.6 to -5.0)[121]
	Observational	NR	NR	Medicaid insurance subgroup DiD:[a] Greater reduction in G1: -12.1 (95% CI, -18.1 to -5.6)[121]

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

CI = confidence interval; DiD = difference-in differences; G = group; NR = not reported; RCT = randomized controlled trial.

Table B-27. Strength of evidence for telephonic/mail models versus usual-care outcomes[a]

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	ED visits, all cause	VH I: Original sample DiD: IRR=1.04 (95% CI, 0.91 to 1.19)[81] VH I: Refresh sample DiD: IRR=1.01 (95% CI, 0.82 to 1.24)[81] VH II: Original sample DiD: IRR=1.03 (95% CI, 0.90 to 1.17)[82] VH II: Refresh sample DiD: IRR=0.97 (95% CI, 0.85 to 1.10)[82] Pooled rate ratio: 1.01 (95% CI, 0.94 to 1.08); 4 RCT samples; I^2=0%	4 RCTs, N=20,693	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	ED visits, ACSC	VH II: Original sample DiD: IRR=1.09 (95% CI, 0.90 to 1.33)[82] VH II: Refresh sample DiD: IRR=1.00 (95% CI, 0.81 to 1.23)[82] VH I: Original sample DiD: IRR=0.87 (95% CI, 0.71 to 1.08)[81] VH II: Refresh sample DiD: IRR=1.07 (95% CI, 0.79 to 1.45)[81] Pooled rate ratio: 0.99 (95% CI, 0.88 to 1.10); 4 RCT samples; I^2=0%	4 RCTs, N=20,693	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Inpatient admissions, all cause	VH I: Original sample DiD: IRR=0.94 (95% CI, 0.82 to 1.07)[81] VH I: Refresh sample DiD: IRR=0.96 (95% CI, 0.80 to 1.15)[81] VH II: Original sample DiD: IRR=1.06 (95% CI, 0.95 to 1.19)[82] VH II: Refresh sample DiD: IRR=0.98 (95% CI, 0.86 to 1.11)[82] Pooled rate ratio: 0.99 (95% CI, 0.92 to 1.06); 4 RCT samples; I^2=0%	4 RCTs, N=20,693	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Inpatient admissions, ACSC	VH II: Original sample DiD: IRR=1.05 (95% CI, 0.87 to 1.28)[82] VH II: Refresh sample DiD: IRR=0.98 (95% CI, 0.80 to 1.20)[82] VH I: Original sample DiD: IRR=0.83 (95% CI, 0.67 to 1.04)[81] VH I: Refresh sample DiD: IRR=1.02 (95% CI, 0.77 to 1.36)[81] Pooled rate ratio: 0.95 (95% CI, 0.85 to 1.06); 4 RCT samples; I^2=0%	4 RCTs, N=20,693	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Inpatient admissions, any (%)	VH I: Original sample DiD: OR=0.98 (95% CI, 0.82 to 1.18)[81] VH I: Refresh sample DiD: OR=0.94 (95% CI, 0.74 to 1.18)[81]	2 RCTs, N=10,337	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	Inpatient admissions, ACSC (%)	VH I: Original sample DiD: OR=0.86 (95% CI, 0.69 to 1.08)[81] VH I: Refresh sample DiD: OR=0.93 (95% CI, 0.70 to 1.25)[81]	2 RCTs, N=10,337	Moderate study limitations, consistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Total cost	TST: DiD=120 (p>0.05)[79] HB: Original sample DiD=-308 (p>0.05)[80] HB: Refresh sample DiD=178 (p>0.05)[80] VH I: Original sample DiD=-111 (p>0.05)[81] VH I: Refresh sample DiD=-142 (p>0.05)[81] VH II: Original sample DiD=206 (p>0.05)[82] VH II: Refresh sample DiD=-99 (p>0.05)[82] Pooled mean difference: -$8.52 (95% CI, -130.02 to 112.98); 7 RCT samples; I^2=22.4%	7 RCTs, N=25,000	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Mortality rate	VH I: Original sample diff=0.8 (p=0.51)[81] VH I: Refresh sample diff=-1.1 (p=0.49)[81] VH II: Original sample diff=0.6 (p=0.61)[82] VH II: Refresh sample diff=0.3 (p=0.76)[82] Pooled mean difference: 0.34 (95% CI, -1.06 to 1.74); 4 RCT samples; I^2=0%	4 RCTs, N=20,693	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Influenza vaccine	VH I: Original sample DiD: OR=1.12 (95% CI, 0.93 to 1.34);[81] VH I: Refresh sample DiD: OR=0.91 (95% CI, 0.72 to 1.15)[81]	2 RCTs, N=10,337	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients	Progression to ESRD	VH I: Original sample diff: -0.75 (95% CI, -1.90 to 0.41)[81] VH I: Refresh sample diff: 0.91 (95% CI, -2.23 to 0.41)[81]	2 RCTs, N=10,337	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients CKD subgroup	Progression to ESRD	VH II: Original sample diff: Greater in G1: 2.92 (95% CI, 0.30 to 5.54)[82] VH II: Refresh sample diff: 0.37 (95% CI, -2.53 to 3.28)[82]	2 RCTs, N=4,822	Moderate study limitations, imprecise, inconsistent, direct	Insufficient
HNHC patients CKD subgroup	Graft or fistula prior to hemodialysis	VH II: Original sample diff: Lower in G1: -3.09 (95% CI, -5.93 to -0.24)[82] VH II: Refresh sample diff: -2.05 (95% CI, -6.39 to 2.30)[82]	2 RCTs, N=4,822	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients ESRD subgroup	Graft or fistula prior to hemodialysis	VH I: Original sample diff: -6.08 (95% CI, -15.75 to 3.59)[81] VH I: Refresh sample diff: 2.87 (95% CI, -16.72 to 22.46)[81]	2 RCTs, N=428	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients Diabetes subgroup	HbA1c test	VH II: Original sample DiD: OR=1.22 (95% CI, 0.73 to 2.03)[82] VH II: Refresh sample DiD: OR=0.76 (95% CI, 0.47 to 1.23)[82] VH I: Original sample DiD: OR=1.02 (95% CI, 0.68 to 1.54)[81] VH I: Refresh sample DiD: OR=0.95 (95% CI, 0.56 to 1.61)[81]	4 RCTs, N=7,931	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients Diabetes subgroup	LDL test	VH II: Original sample DiD: OR=1.05 (95% CI, 0.70 to 1.58)[82] VH II: Refresh sample DiD: OR=1.15 (95% CI, 0.80 to 1.67)[82] VH I: Original sample DiD: OR=1.19 (95% CI, 0.84 to 1.68)[81] VH I: Refresh sample DiD: OR=0.72 (95% CI, 0.42 to 1.24)[81]	4 RCTs, N=7,931	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients IVD subgroup	LDL test	VH I: Original sample DiD: OR=0.98 (95% CI, 0.72 to 1.35)[81] VH II: Refresh sample DiD: OR=0.88 (95% CI, 0.54 to 1.43)[81]	2 RCTs, N=3,942	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients Diabetes subgroup	Eye exam	VH II: Original sample DiD: OR=1.05 (95% CI, 0.81 to 1.137)[82] VH II: Refresh sample DiD: OR=1.25 (95% CI, 0.94 to 1.66)[82]	2 RCTs, N=4,486	Moderate study limitations, imprecise, consistent, direct	Insufficient
HNHC patients Diabetes subgroup	Nephrology	VH II: Original sample DiD: OR=0.92 (95% CI, 0.71 to 1.18)[82] VH II: Refresh sample DiD: OR=1.30 (95% CI, 1.01 to 1.67)[82]	2 RCTs, N=4,486	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients IVD subgroup	Lipid panel	VH II: Original sample DiD: OR=1.10 (95% CI, 0.85 to 1.44)[82] VH II: Refresh sample DiD: OR=1.22 (95% CI, 0.17 to 0.92)[82]	2 RCTs, N=4,091	Moderate study limitations, consistent, imprecise, direct	Insufficient

[a] Comparison group participants for Dally et al. received baseline education materials and incentives.[90]

ACSC = ambulatory care sensitive conditions; CI = confidence interval; CKD = chronic kidney disease; DiD = difference-in-difference; diff = difference; ED = emergency department; ESRD = end-stage renal disease; G = group; HB = Health Buddy; HbA1c = hemoglobin A1c; HNHC = high-need, high-cost; IRR = incidence rate ratio; IVD = ischemic vascular disease; LDL = low-density lipoprotein; N = number; OR = odds ratio; RCT = randomized controlled trial; TST = Texas Senior Trails; VH = Village Health; vs. = versus.

Table B-28. Cost outcomes for telephonic/mail model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost	RCT	⇩	⇩	DiD=120 (SE:99.6) (p>0.05)[79]
	RCT	⇩	⇩	Original sample DiD=-308 (SE: 311.2) (p>0.05)[80]
	RCT	⇩	⇩	Refresh sample DiD=178 (SE: 257.5) (p>0.05)[80]
	RCT	⇧	⇧	Original sample DiD=-111 (SE: 83.2) (p>0.05)[81]
	RCT	⇧	⇧	Refresh sample DiD=-142.1 (SE: 138.7) (p>0.05)[81]
	RCT	⇧	⇧	Original sample DiD=206 (SE: 152.2) (p>0.05)[82]
	RCT	⇩	⇩	Refresh sample DiD=-99 (SE: 206.6) (p>0.05)[82]

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

DiD = difference-in-difference;; G = group; RCT = randomized controlled trial; SE = standard error.

Table B-29. Clinical and functional outcomes for telephonic/mail model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality rate	RCT	Original sample difference=0.8 (p=0.51)[81]
	RCT	Refresh sample difference=-1.1 (p=0.49)[81]
	RCT	Original sample difference=0.6 (p=0.61)[82]
	RCT	Refresh sample difference=0.3 (p=0.76)[82]
Influenza vaccine	RCT	Original sample DiD: OR=1.12 (95% CI, 0.93 to 1.34)[81]
	RCT	Refresh sample DiD: OR=0.91 (95% CI, 0.72 to 1.15)[81]
Progression to ESRD	RCT	Original sample difference=-0.75 (95% CI, -1.90 to 0.41)[81]
	RCT	Refresh sample difference=-0.91 (95% CI, -2.23 to 0.41)[81]
PHC score (physical health)	RCT	ANCOVA-adjusted IE=-0.1 (p>0.05)[81]
MHC score (mental health)	RCT	ANCOVA-adjusted IE=0.0 (p>0.05)[81]
PHQ-2 (depression, 0 to 6)	RCT	Lower score in G1 than G2:[a] ANCOVA-adjusted IE=-0.45 (p<0.05)[81]
Number of ADLs difficult to do (0 to 6)	RCT	ANCOVA-adjusted intervention effect=-0.02 (p>0.05)[81]
Number of ADLs receiving help (0 to 6)	RCT	ANCOVA-adjusted IE=0.21 (p>0.05)[81]
Helping to cope with a chronic condition (1 to 5)	RCT	ANCOVA-adjusted IE=0.10, (p>0.05)[81]
Number of helpful discussion topics (0 to 5)	RCT	ANCOVA-adjusted IE=0.08 (p>0.05)[81]
Discussing treatment choices (1 to 4)	RCT	Lower score in G1 than G2:[b] ANCOVA-adjusted IE=-0.19 (p<0.05)[81]
Communicating with providers (0 to 100)	RCT	ANCOVA-adjusted IE=2.7 (p>0.05)[81]
Getting answers to questions quickly (0 to 100)	RCT	ANCOVA-adjusted IE=-0.8 (p>0.05)[81]
Multimorbidity Hassles score (0 to 24)	RCT	ANCOVA-adjusted IE=0.15 (p>0.05)[81]
Percent receiving help setting goals	RCT	ANCOVA-adjusted IE=9.5 (p>0.05)[81]
Percent receiving help making a care plan	RCT	ANCOVA-adjusted IE=4.0 (p>0.05)[81]
Self-efficacy: Take all medications (1 to 5)	RCT	ANCOVA-adjusted IE=0.03 (p>0.05)[81]
Self-efficacy: Plan meals and snacks (1 to 5)	RCT	ANCOVA-adjusted IE=-0.08 (p>0.05)[81]
Self-efficacy: Exercise 2 or 3 times weekly (1 to 5)	RCT	ANCOVA-adjusted IE=0.14 (p>0.05)[81]
Self-care activities: Prescribed medications taken (mean # of days)	RCT	ANCOVA-adjusted IE=-0.15 (p>0.05)[81]
Self-care activities: Followed healthy eating plan (mean # of days)	RCT	ANCOVA-adjusted IE=-0.03 (p>0.05)[81]
Self-care activities: 30 minutes of continuous physical activity (mean # of days)	RCT	ANCOVA-adjusted IE=-0.30 (p>0.05)[81]

[a] Lower scores in the PHQ-2 indicate fewer depressive symptoms.

[b] Lower scores indicate worse experience, satisfaction, or self-management.

ADL = activities of daily living; ANCOVA = analysis of covariance; CI = confidence interval; DiD = difference-in-difference; ESRD = end-stage renal disease; G = group; IE = intervention effect; MHC = mental health composite; OR = odds ratio; PHC = physical health composite; PHQ-2 = patient health questionnaire-2; RCT = randomized controlled trial.

Table B-30. Clinical and functional outcomes for telephonic/mail model studies: Subgroup outcomes

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Progression to ESRD	RCT	Chronic kidney disease patients subgroup: Original sample difference: Greater in G1: 2.92 (95% CI, 0.30 to 5.54)[82]
	RCT	Chronic kidney disease patients subgroup: Refresh sample difference: 0.37 (95% CI, -2.53 to 3.28)[82]
Graft or fistula prior to hemodialysis	RCT	Chronic kidney disease patients subgroup: Original sample difference: Lower in G1: -3.09 (95% CI, -5.93 to -0.24)[82]
	RCT	Chronic kidney disease patients subgroup: Refresh sample difference: -2.05 (95% CI, -6.39 to 2.30)[82]
	RCT	End-stage renal disease patients subgroup: Original sample difference: -6.08 (95% CI, -15.75 to 3.59)[81]
	RCT	End-stage renal disease patients subgroup: Refresh sample difference: 2.87 (95% CI, -16.72 to 22.46)[81]
HbA1c test	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.22 (95% CI, 0.73 to 2.03)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=0.76 (95% CI, 0.47 to 1.23)[82]
	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.02 (95% CI, 0.68 to 1.54)[81]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=0.95 (95% CI, 0.56 to 1.61)[81]
LDL-C test	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.05 (95% CI, 0.70 to 1.58)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=1.15 (95% CI, 0.80 to 1.67)[82]
	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.19 (95% CI, 0.84 to 1.68)[81]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=0.72 (95% CI, 0.42 to 1.24)[81]
	RCT	IVD patient subgroup: Original sample DiD: OR=0.98 (95% CI, 0.72 to 1.35)[81]
	RCT	IVD patient subgroup: Refresh sample DiD: OR=0.88 (95% CI, 0.54 to 1.43)[81]
Eye exam	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.05 (95% CI, 0.81 to 1.137)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=1.25 (95% CI, 0.94 to 1.66)[82]
Nephrology	RCT	Diabetes patients subgroup: Original sample DiD: OR=0.92 (95% CI, 0.71 to 1.18)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: Greater increase in G1 than G2: OR=1.30 (95% CI, 1.01 to 1.67)[82]
All 4 measures[a]	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.01 (95% CI, 0.80 to 1.29)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=1.18 (95% CI, 0.93 to 1.52)[82]
None of the measures[b]	RCT	Diabetes patients subgroup: Original sample DiD: OR=1.74 (95% CI, 0.35 to 8.70)[82]
	RCT	Diabetes patients subgroup: Refresh sample DiD: OR=0.60 (95% CI, 0.16 to 2.33)[82]
Lipid panel	RCT	IVD patient subgroup: Original sample DiD: OR=1.10 (95% CI, 0.85 to 1.44)[82]
	RCT	IVD patient subgroup: Refresh sample DiD: greater increase in G1 than G2: OR=1.22 (95% CI, 0.17 to 0.92)[82]

[a] The "All 4 measures" is the rate at which beneficiaries receive all of the following four diabetes measures: rate of annual HbA1c testing, low-density lipoprotein cholesterol (LDL-C) screening, receipt of a retinal eye exam, and medical attention for nephropathy.

[b] The "None of the measures" is the rate at which beneficiaries did not receive any of the four diabetes measures.

CI = confidence interval; DiD = difference-in-difference; ESRD = end-stage renal disease; G = group; HbA1c = hemoglobin A1c; IVD = ischemic vascular disease; LDL-C = low-density lipoprotein cholesterol; OR = odds ratio; RCT = randomized controlled trial.

Table B-31. Study characteristics for community-based models

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Finkelstein et al., 2020[96] Camden, NJ; 4 local-area hospital systems	(N=800) Intervention (N=399) Comparison (N=401)	RCT (RoB: Low)	1 or more IP admissions in past 6 months	2 or more chronic conditions	At least 2 of the following traits or conditions constituting medically and socially complex needs: use of 5 or more active outpatient medications, difficulty accessing services, lack of social support, a coexisting MH condition, an active drug habit, and/or homelessness; 18-80 years of age Exclusion criteria: uninsured, cognitively impaired, oncology patient, admitted for a surgical procedure for an acute health problem, for mental healthcare (with no comorbid physical health conditions), or for complications of a progressive chronic disease that has limited treatments	≥65 years: 28% Nonwhite: 85% Medicare: 48% Medicaid: 45% Hypertension: 80.6%; CHF: 33.9%; diabetes: 53.1% Needs help with mobility: 62% Self-reported health: poor: 54% Depression: 30% Substance abuse: 44%

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Raven et al., 2020[109] Santa Clara, CA: 1 site	(N=423) Intervention (N=199) Comparison (N=224)	RCT (ROB: some concerns)	Various combinations of the ED and psychiatric ED, medical and psychiatric inpatient stays in the county-funded public hospital, and/or jail in past 1-2 years at high enough levels to meet a threshold score (threshold score NR)	NR	Met the Federal definition of chronic homelessness (homeless for 1+ years or 4+ episodes in the prior 3 years that last for more than a year total, with a disabling condition), lived in Santa Clara County, not incarcerated, not engaged in another intensive case management program or other permanent supportive housing program, did not require nursing home level care, and did not have metastatic cancer or qualify for hospice care	Mean age: 51.5 Nonwhite: 35% Medicaid: 35% Medicare: 27%
Bell et al., 2015[112] King County, Washington: 1 site	(N=1,120) Intervention (N=557) Comparison (N=563)	RCT (ROB: low)	Determined to be at risk for high future healthcare costs	Disabled with mental health and/or substance abuse problems	Medicaid beneficiaries	Mean age: 51 Nonwhite: 43% Medicaid: 100% Medicare: NR Serious mental illness: 50%
Sevak et al., 2018[85, 124] Aurora, CO; San Diego, CA; Allentown, PA; Kansas City, MO: 1 site per location	(N=1,279) Intervention (N=149) Comparison (N=1,130)	Observational study (RoB: some concerns)	Initial inclusion criteria: 2+ inpatient admissions in 6 months 2 of 4 sites amended criteria: 1 site expanded criteria to also include 3+ inpatient admissions in past 12 months, 1 site expanded criteria to 3+ hospital events (admissions or ED visits) in past 6 months	NA	Medicare FFS beneficiaries Exclusion: patients whose conditions could not be managed with existing program resources	Mean age: 59 years Black: 48.4% Hispanic: 8.5% Zip code poverty rate: 25.6% Dual coverage at enrollment: 69% Alzheimer's: 8.5% Cancer: 5.3% CHF: 56.0% CKD: 63.0% COPD: 56.3% Diabetes: 71.1%

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Capp et al., 2017[88] Colorado: 1 site	(N=3,802) Intervention (N=406) Comparison (N=3,396)	Observational study (RoB: some concerns)	2+ ED visits or inpatient admissions in past 180 days	NA	Age: 18+ years Exclusion criteria: pregnant, primary diagnosis of substance use disorder, active malignancy, or ESRD; have a caregiver or power of attorney who was making primary decisions; psychiatric hospitalization in the previous 180 days; undergone major surgery in the past month	Nonwhite: 54% ≥56 years: 15% Medicaid or Colorado Indigent Care Program: 69% Medicare: 15% Self-pay: 12% CKD: 3% Congestive heart failure: 5% COPD: 7% Diabetes: 19% Hypertension: 38% Mental health comorbidity: 43%
Weerahandi et al., 2015[119] NYC: 1 hospital	(N=1,158) Intervention (N=579) Comparison (N=579)	Observational study (RoB: some concerns)	At time of index hospitalization: 1 admission in past 30 days or 2 in past 6 months	NA	≥18 years of age, excluded determined to be too medically acute to benefit from behavioral intervention	Hypertension: 69% Diabetes without chronic complication: 25% Chronic pulmonary disease: 49% Congestive heart failure: 23% Diabetes w/chronic complication: 8% Depression: 10.5% Drug abuse: 6% Psychoses: 3% Alcohol abuse: 3% Nonwhite: 77%
Shah et al., 2011[107] Kern County, CA: 3 sites	(N=258) Intervention (N=98) Comparison (N=160)	Observational study (RoB: High)	4+ ED visit or IP admissions OR 3+ IP admissions OR 2+ IP admissions and 1 ED visit in past 1 year	NA	Age: 18-64 years, below 200% FPL, uninsured, not eligible for any public insurance programs	Charlson comorbidity index: 1.14 nonwhite: 51%
DeHaven et al., 2012[126, 128] Dallas, TX: 1 study site	(N=574) Intervention (N=265) Comparison (N=309)	Observational study (RoB: high)	Exceeded average ED visit rate of 1.5 ED visits in past 12 months	NA	Below 200% FPL, uninsured, not eligible for health insurance through local hospital system, not receiving Medicaid or Medicare	Nonwhite: 89.5%

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Thompson et al., 2018[95] Memphis, TN: 1 site	(N=439) Intervention (N=159) Comparison (N=280)	Observational study (RoB: high)	11+ hospital encounters originating in the ED in past 1 year	NA	Resident of Memphis, TN, in 38109 zip code	Moderate or severe Charlson comorbidity index (>3): 13% Nonwhite: 97% None/missing PCP: 21%

CA = California; CHF = congestive heart failure; CKD = chronic kidney disease; CO = Colorado; COPD = chronic obstructive pulmonary disease; ED = emergency department; ESRD = end-stage renal disease; FFS = fee-for-service; FPL = federal poverty line; IP = inpatient; MH = mental health; MO = Missouri; N = number; NA = not applicable; NJ = New Jersey; NR = not reported; NYC = New York City; PA = Pennsylvania; PCP = primary care provider; RCT = randomized controlled trial; RoB = risk of bias; TN = Tennessee; TX = Texas.

Table B-32. Intervention characteristics for community-based models

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Finkelstein et al., 2020[96] Camden, NJ; 4 local-area hospital systems	Camden Core Model: hotspotting	Median: 92 days; tailored to patient needs and responsiveness	Disease-specific self-care coaching, patient education	Scheduled and accompanied patients to initial post-IP primary and specialty care visits and followup care, medication reconciliation, medication management	Assistance applying for social services and BH programs	Multidisciplinary: RNs, social workers, LPNs, CHWs, and health coaches	Face-to-face Enrollment in the hospital; subsequent service delivery through home visits, PCP, and specialty care	Received both a home visit within 14 days and provider visit within 60 days: 75% of participants; further contact tailored to individual	Usual post-discharge care that could include home visits or other outreach
Raven et al., 2020[109] Santa Clara, CA: 1 site	Project Welcome Home (PWH), a permanent supportive housing intervention with intensive case management services	Up to 4 years	Voluntary support services included mental health and substance use services; medication support, community living skills, educational and vocational support, and money management	Community-based case management services	Connected participants to temporary housing, permanent supportive housing, and rehousing	Master's level social behavioral health providers, bachelor's level case managers, and staff with lived experience (peers)	NR	NR	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Bell et al., 2015[112] King County, Washington: 1 site	Kings County Care Partners (KCCP) Program, a registered nurse-led care management intervention	Up to 24 months	Completed a comprehensive in-person assessment of their medical and social needs with their RN care manager and frequent in-person and phone monitoring	Care manager arranged to join the participant at 1+ clinic appointments, provided participants with chronic disease self-management coaching, and coordinated care across the medical and mental health systems	Care manager connected participants to community resources	Three full-time RNs, two social workers (MSWs) with drug/alcohol treatment training, and a bachelor's-level chemical dependency counselor	Mixture of face-to-face, telephone, and letter	NR	Usual care
Sevak et al., 2018[85, 124] Aurora, CO; San Diego, CA; Allentown, PA; Kansas City, MO: 1 site per location	Health Care Innovation Award: Rutgers Center for State Health Policy (CSHP) community-based care management/care coordination for high-risk patients, replication of Camden Coalition model	Mean: 4.2 months (site means ranged from 2.4 months to 6.3 months)	Sites received technical assistance to implement the intervention Pt education about the importance of using primary and specialty care instead of, or as a followup to, emergency and hospital care and about managing medical and social needs	Developed individualized care plans, integrated care management services through mobile care teams	Assisted in enrollment in social service and BH service programs	Differing combination of RNs, NPs, social workers, CHWs, peer health coaches, medical assistants, and BH providers	Face-to-face, telephone calls to physicians or other service providers care teams met with participants in their homes or in other community locations (e.g., library)	Mean staff contacts=10.3 per participant per month, almost 6 hours per participant per month	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Capp et al., 2017[88] Colorado: 1 site	Bridges to Care (B2C), an ED-initiated, multidisciplinary, community-based program that provides intensive medical, behavioral health, and social care coordination services following an ED visit or hospital discharge	60 days	Depression screening, behavioral health screening, helping patient learn empowerment skills and using "teach back" opportunities to ensure the patient understands results and next steps	Patient services include coordinating primary and specialty care	Care plan and associated patient services can include assistance with obtaining housing resources, insurance or disability benefits, refugee services, and access to transportation, and filling prescriptions	Primary care provider, care coordinator, health coach, behavioral health evaluator, and community health worker	Face-to-face	First home visit occurs 24-72 hours post-enrollment date; second visit is conducted by PCP within 1 week of ED visit/discharge; third and fourth visits are conducted within 30 days of enrollment. Fifth and sixth visits depend on patient specific needs. Final two visits help patient transition out of program.	Usual care
Weerahandi et al., 2015[119] NYC: 1 hospital	Preventable Admissions Care Team (PACT) program: social work transition of care.	35 days	Comprehensive psychosocial assessment during hospitalization	Facilitated communication with PCP and specialists; collaborated with caregivers; scheduled PCP appointment within 10 days of discharge	NR	MSWs with experience and training working with at-risk, vulnerable populations	Phone; face-to-face: home visits and while attending appointments	NR	Usual care: social worker assistance only during IP

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Shah et al., 2011[107] Kern County, CA: 3 sites	Care Management Program (CMP) for low-income high utilizers of hospital services	NR	Assisted in goal creation/reaching goals	Care navigation (schedule appts, referral follow up, refill meds), care transitions (assistance in IP and discharge), and communication with providers (accompany to appointments and followup).	Arranged for social services (connect with agency staff, referrals)	Care managers with experience as case workers or medical office assistants	Face-to-face: at appoint-ments, patients' homes, or resource centers	Met at least monthly	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
DeHaven et al., 2012[128] Dallas, TX: 1 study site	Project Access Dallas (PAD): community faith-health partnership to improve access to care and preventive services to the uninsured, care coordination Participants received $750 a year in pharmacy benefits and were eligible for laboratory tests, ancillary procedures, and IP hospital care. CCC pts: more complex and chronic problems, assigned a CHW Self-care pts: less serious illnesses, access to a telephone help line for medical care questions and CHW services on request	Up to 1 year	Intake interview and HRA to assign to CCC or self-care CCC pts: CHWs developed care coordination plan, taught health education and self-sufficiency	CCC pts: identified and addressed social concerns, identified patients with or at risk of developing type 2 diabetes, identified patients with depression, provided ED and referrals for cancer screening, provided care coordination and other support services (e.g., transportation, translation)	CCW link patients to other service organizations	HRA: community-clinic or hospital-based coordinator Services: CHWs, volunteer PCPs, and specialists	Face-to-face for CCC pts; phone for self-care pts: in primary care and specialty care offices Volunteer PCPs and specialists met with CHWs monthly to discuss patients	CCC pts: at least monthly self-care: as needed	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Thompson et al., 2018[95] Memphis, TN: 1 site	Familiar Faces Program Community navigators (blend of CHWs and patient navigators) to bridge gap between patients and the healthcare and social systems	Up to 1 year	Created a plan for patients' health behaviors, tailored health information to client needs, and motivated them to make healthy choices	Helped to identify and eliminate barriers to health, coordinated care	Connecting patients to health and social resources in their community	Community navigators employed in the hospital system and received the training	Initial engagement was face-to-face at the ED/hospital. The mode of delivery of other services was not reported	NR	Usual care

B2C = Bridges to Care; BH = behavioral health; CA = California; CCC = community care coordination; CCW = community care worker; CHW = community health worker; CMP = Care Management Program; CO = Colorado; CSHP = Rutgers Centers for State Health Policy; ED = emergency department; HRA = health risk appraisal; IP = inpatient; KCCP = King County Care Partners; LPN = licensed practical nurse; MO = Missouri; MSW = master of social worker; NJ = New Jersey; NP = nurse practitioner; NR = not reported; NYC = New York City; PA = Pennsylvania; PACT = Preventable Admissions Care Team; PAD = Project Access Dallas; PCP = primary care provider; Pt = patient; RN = registered nurse; TN = Tennessee; TX = Texas.

Table B-33. Healthcare utilization outcomes for community-based model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
180-day readmissions, count	RCT	NR	NR	aBGD=0.01 (95% CI, -0.25 to 0.27)[96]
	Observational	NR	NR	G1 vs. G2: p=0.32[119]
180-day readmissions, any (%)	RCT	NR	NR	aBGD=0.82 (95% CI, -5.97 to 7.61)[96]
180-day readmissions, ≥2 (%)	RCT	NR	NR	aBGD=0.27 (95% CI, -6.22 to 6.77)[96]
ED visits, all cause[a]	RCT	NR	NR	IRR=0.85 (95% CI, 0.67 to 1.08) (p>0.05)[109]
	RCT	NR	NR	DiD=-0.3 (95% CI, -5.0 to 4.5) (p=0.91)[112]
	Observational	NR	NR	DiD=0.057 (90% CI, -0.194 to 0.309) (p=0.704)[85, 124]
	Observational	⬇	NR	Greater reduction in G1: RR=0.6748 (p<0.0001)[107]
	Observational	NR	NR	Greater reduction in G1: NR (p<0.01)[126, 128]
	Observational	NR	NR	Greater reduction in G1 than G2: DiD=-1.623 (p<0.01)[88]
ED visits at 270 days, all cause	Observational	NR	NR	Greater reduction in G1 than G2: DiD=-1.091 (p<0.01)[88]
ED visits at 180 days, all cause	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD=-1.005 (p<0.01)[88]
ED visit, any	RCT	NR	NR	DiD=0.96 (95% CI, 0.67 to 1.38) (p=0.82)[112]
Emergency psychiatric visits	RCT	NR	NR	Greater reduction in G1 than G2: IRR=0.62 (95% CI, 0.43 to 0.91) (p<0.05)[109]
Inpatient admissions, all cause[a]	RCT	NR	NR	IRR=0.97 (95% CI, 0.70 to 1.35) (p>0.05)[109]
	RCT	NR	NR	DiD=0.3 (95% CI, -1.2 to 1.9) (p=0.68)[112]
	Observational	NR	NR	DiD: -0.116 (90% CI, -0.252 to 0.020)[85, 124]
	Observational	⇩	NR	RR: 0.8070 (p=0.3771)[107]
	Observational	NR	NR	Greater reduction in G1 than G2: DiD=-0.906 (p<0.01)[88]
Inpatient admissions at 270 days, all cause	Observational	NR	NR	Greater reduction in G1 than G2: DiD=-0.438 (p<0.01)[88]
Inpatient admissions at 180 days, all cause	Observational	⇩	⇩	DiD=-0.159 (p<0.1)[88]
Inpatient admissions, any	RCT	NR	NR	DiD=0.92 (95% CI, 0.66 to 1.27) (p=0.60)[112]
Inpatient admissions, ACSC	Observational	NR	NR	DiD=-0.027 (90% CI, -0.081 to 0.028)[85, 124]
Inpatient psychiatric stays	RCT	NR	NR	IRR=0.73 (95% CI, 0.36 to 1.45) (p>0.05)[109]
Inpatient days	RCT	NR	NR	aBGD=-0.32 (95% CI, -2.17 to 1.53)[96]
	RCT	NR	NR	IRR=1.12 (95% CI, 0.79 to 1.59) (p>0.05)[109]
	Observational	⇩	NR	RR: NR (p=NS)[107]
	Observational	NR	NR	Greater reduction in G1: NR (p<0.05)[126, 128]
	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD: -8 (95% CI, -14 to -2)[95]

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total hospital encounters	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD: -13 (95% CI, -19 to -6)[95]
Hospital encounter resulted in discharge to hospital or observation stay	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD: -12 (95% CI, -19 to -5)[95]
Hospital encounter resulted in discharge from ED	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD: -12 (95% CI, -19 to -4)[95]
Outpatient visit	RCT	NR	NR	DiD=-0.11 (95% CI, -0.51 to 0.28) (p=0.58)[112]
Outpatient substance use treatment visits	RCT	NR	NR	IRR=0.76 (95% CI, 0.46 to 1.24) (p>0.05)[109]
Outpatient mental health visits	RCT	NR	NR	Greater increase in G1 than G2: IRR=1.84 (95% CI, 1.43 to 2.37) (p<0.01)[109]
Outpatient mental health visit, any	RCT	NR	NR	Greater increase in G1 than G2: DiD=1.30 (95% CI, 1.07 to 1.58) (p<0.01)[112]
Primary care visits at 360 days, all cause	Observational	NR	NR	Greater increase in G1 than G2: DiD=1.932 (p<0.01)[88]
Primary care visits at 270 days, all cause	Observational	NR	NR	Greater increase in G1 than G2: DiD=1.517 (p<0.01)[88]
Primary care visits at 180 days	Observational	⬆	⬇	Greater increase in G1 than G2: DiD=1.218 (p<0.01)[88]
Prescription drugs, any	RCT	NR	NR	DiD=1.99 (95% CI, 0.29 to 13.70) (p=0.49)[112]
Long-term care, any	RCT	NR	NR	DiD=1.09 (95% CI, 0.88 to 1.35) (p=0.42)[112]

[a] Followup time for the outcomes was 12 months for CHSP,[85, 124] CMP,[107] and PAD[126, 128] and 360 days for B2C.[88]

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

aBGD = adjusted between-group difference; ACSC = ambulatory care sensitive conditions; CI = confidence interval; DiD = difference-in-difference; ED = emergency department; G = group; IRR = incidence rate ratio; NR = not reported; NS = not statistically significant; RCT = randomized controlled trial; RR = relative risk.

Table B-34. Healthcare utilization outcomes for community-based model studies: Subgroup outcomes

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
ED visits at 180 days, all cause	Observational	↓	↓	Patients with a mental health diagnosis subgroup: Greater reduction in G1 than G2: DiD=-1.377 (p<0.01)[88]
Inpatient admissions at 180 days, all cause	Observational	↓	↑	Patients with a mental health diagnosis subgroup: Greater reduction in G1 than G2: DiD=-0.417 (p<0.01)[88]
Primary care visits at 180 days	Observational	↑	↓	Patients with a mental health diagnosis subgroup: Greater increase in G1 than G2: DiD=1.404 (p<0.01)[88]

↑ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

↓ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

DiD = difference-in-difference; ED = emergency department; G = group.

Table B-35. Strength of evidence for community-based models versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	180-day readmissions	Camden RCT: aBGD=0.01 (95% CI, -0.25 to 0.27);[96] PACT: RR: NR (p=0.32)[119]	1 RCT, N=800 1 OBS, N=1,158	Moderate study limitations, consistency unknown, imprecise, direct	Insufficient
HNHC patients	ED visits, all cause	PWH: IRR=0.85 (95% CI, 0.67 to 1.08)[109] KCCP: DiD=-0.3 (95% CI, -5.0 to 4.5)[112] CSHP DiD: 0.057 (90% CI, -0.194 to 0.309) (p=0.704)[85, 124] B2C: Greater reduction in G1: DiD=-1.623 (p<0.01)[88] CMP: Greater reduction in G1: RR=0.6748 (p<0.0001)[107] PAD: Greater reduction in G1: NR (p<0.01)[126, 128]	2 RCTs, N=1,543 4 OBSs, N=5,913	High study limitations (two high RoB OBS studies),[107, 126, 128] inconsistent, imprecise, direct	Insufficient (Mixed findings)
HNHC patients	Inpatient admissions, all cause	CSHP DiD: -0.116 (90% CI, -0.252 to 0.020)[85, 124] CMP: RR: 0.8070 (p=0.38)[107] B2C: Greater reduction in G1: DiD=-0.906 (p<0.01)[88]	3 OBSs, N=5,339	Moderate study limitations (one high RoB OBS studies),[107] consistent, imprecise, direct	Insufficient
HNHC patients	Inpatient days	Camden RCT: aBGD=-0.32 (95% CI, -2.17 to 1.53)[96] PWH: IRR=1.12 (95% CI, 0.79 to 1.59)[109] CMP: RR: NR (p=NS)[107] PAD: Greater reduction in G1: NR (p<0.05)[126, 128] Familiar Faces: Greater reduction in G1 than G2: DiD: -8% (95% CI, -14% to -2%)[95]	2 RCTs, N=1,223 3 OBSs, N=1,271	High study limitations (three high RoB studies),[95, 107, 126, 128] inconsistent, imprecise, direct	Insufficient (Mixed findings)
HNHC patients	Total costs	KCCP: DiD=51 (95% CI, -242 to 344)[112] CSHP DiD: -1405 (90% CI, -3509 to 700) (p=0.268);[85, 124] Familiar Faces: DiD: -4903 (95% CI, -$13,579 to $3774)[95]	1 RCT, N=1,120 2 OBSs, N=1,718	High study limitations (one high RoB OBS studies),[95] inconsistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Inpatient costs	KCCP: DiD=-12 (95% CI, -260 to 236)[112] CSHP DiD=-120 (90% CI, -1891 to 1652)[85, 124]	1 RCT, N=1,120 1 OBS, N=1,279	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	ED costs	KCCP: DiD=-8 (95% CI, -26 to 10)[112] PAD: Lower costs in G1: NR (p=0.01)[126, 128]	1 RCT, N=1,120 1 OBS, N=574	High study limitations (one high RoB OBS studies),[126, 128], consistent, imprecise, direct	Insufficient
HNHC patients	Mortality	Camden RCT: adjusted difference=-1.17 (95% CI, -5.25 to 2.91)[96] PWH: Difference=3.9% (P NR)[109] KCCP: aOR=0.65 (95% CI, 0.39 to 1.09)[112]	3 RCTs, N=2,343	Moderate study limitations, consistent, imprecise, direct	Low (No difference)

aBGD = adjusted between-group difference; aOR = adjusted odds ratio; B2C: Bridges to Care; CI = confidence interval; CMP = Care Management Program; CSHP = Rutgers Center for State Health Policy; DiD = difference-in-difference; ED = emergency department; G = group; HNHC = high-need, high-cost; IRR = incidence rate ratio; KCCP = King County Care Partners; N = number; NR = not reported; NS = not statistically significant; OBS = observational study; PAD = Project Access Dallas; PWH = Project Welcome Home; RCT = randomized controlled trial; RoB = risk of bias; RR = rate ratio; vs. = versus.

Table B-36. Cost outcomes for community-based model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Hospital charges	RCT	NR	NR	aBGD=3,722 (95% CI, -23,438 to 30,882)[96]
Hospital payments received	RCT	NR	NR	aBGD=680 (95% CI, -3,415 to 4,775)[96]
Total costs	RCT	NR	NR	DiD=51 (95% CI, -242 to 344) (p=0.73)[112]
	Observational	NR	NR	DiD: -1,405 (90% CI, -3,509 to 700) (p=0.268)[85, 124]
	Observational	⇩	⇩	DiD: -4,903 (95% CI, -$13,579 to $3774) [95]
Inpatient costs	RCT	NR	NR	DiD=-12 (95% CI, -260 to 236) (p=0.92)[112]
	Observational	NR	NR	DiD: -120 (90% CI, -1,891 to 1,652) (p=0.911)[85, 124]
ED costs	RCT	NR	NR	DiD=-8 (95% CI, -26 to 10) (p=0.38)[112]
	Observational	NR	NR	Lower costs in G1:[a] NR (p=0.01)[126, 128]
Indirect ED costs	Observational	NR	NR	Lower costs in G1:[b] NR (p=0.03)[126, 128]
Outpatient costs	RCT	NR	NR	DiD=31 (95% CI, -47 to 109) (p=0.43)[112]
Prescription drug costs	RCT	NR	NR	Greater increase in G1 than G2: DiD=74 (95% CI, 3 to 145) (p=0.048)[112]
Long-term care costs	RCT	NR	NR	DiD=36 (95% CI, -35 to 107) (p=0.33)[112]

[a] Direct ED costs include costs associated with the delivery of care during an ED visit or inpatient admission in the 12 months following enrollment.

[b] Indirect ED costs are the fixed costs related to building, maintenance, staffing, and utilities in the 12 months following enrollment.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

aBGD = adjusted between-group difference; CI = confidence interval; DiD = difference-in-difference; ED = emergency department; G = group; NR = not reported; RCT = randomized controlled trial.

Table B-37. Clinical and functional outcomes for community-based model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality	RCT	Difference=-1.17 (95% CI, -5.25 to 2.91)[96]
	RCT	G1: 18.6% vs. G2: 14.7%, p=NR[109]
	RCT	aOR=0.65 (95% CI, 0.39 to 1.09) (p=0.10)[112]

aOR = adjusted odds ratio; CI = confidence interval; G = group; NR = not reported; RCT = randomized controlled trial.

Table B-38. Social risk outcomes for community-based model studies

Social Risk Outcomes	Study Design	Difference
Participation in supplemental nutrition assistance program (%)	RCT	AD=4.59 (95% CI, 0.52 to 8.65)[96]
Receipt of temporary assistance for needy families (%)	RCT	AD=0.69 (95% CI, -0.34 to 1.71)[96]
Receipt of general assistance (%)	RCT	AD=0.68 (95% CI, -1.82 to 3.18)[96]
Ever housed	RCT	Greater increase in G1 than G2: IRR=1.84 (95% CI, 1.43 to 2.37) ($p<0.01$)[109]
Any homeless months	RCT	DiD=0.83 (95% CI, 0.60 to 1.17) (p=0.29)[112]
Homeless months (mean per 1,000 months)	RCT	DiD=-1.5 (95% CI, -4.3 to 1.3) (p=0.29)[112]
Jail stays	RCT	IRR=1.01 (95% CI, 0.73 to 1.40) ($p>0.05$)[109]
Any criminal convictions	RCT	DiD=1.95 (95% CI, 1.10 to 3.44) (p=0.02)[112]
Criminal convictions (mean per 1,000 months)	RCT	DiD=8.9 (95% CI, -1.5 to 19.3) (p=0.09)[112]
Shelter days	RCT	Greater reduction in G1 than G2: IRR=0.30 (95% CI, 0.17 to 0.53) ($p<0.01$)[109]
Any drug/alcohol treatment	RCT	DiD=0.92 (95% CI, 0.65 to 1.30) (p=0.62)[112]

AD = adjusted difference; CI = confidence interval; DiD = difference-in-difference; G = group; IRR = incidence rate ratio; RCT = randomized controlled trial.

Table B-39. Study characteristics of ED-based care model interventions

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Kelley et al., 2020[110] New Haven, CT: 1 site	(N=100) Intervention (N=49) Comparison (N=51)	RCT (ROB: low)	4-18 ED visits in past year	NA	18-62 years, active Medicaid insurance, resident of one of 12 surrounding towns, and English or Spanish speaking	Mean age: 40 Nonwhite: 82% Medicaid: 100% Medicare: NR
Lin et al., 2017[111] Boston, MA: 1 site	(N=72) Intervention (N=36) Comparison (N=36)	RCT (ROB: some concerns)	Most ED visits during the 30-day period and 12-month period preceding the introduction of the program	NA	NA	Mean age: 48 Nonwhite: 57% Medicaid: 44% Medicare: 43%
Shumway et al., 2008[116] San Francisco, CA: 1 hospital	(N=252) Intervention (N=167) Comparison (N=85)	RCT (RoB: some concerns)	5+ ED visits in past 1 year	NA	Age: 18+; psychosocial problems that could be addressed with case management	Nonwhite: 87%; Homeless: 81% Alcohol problems, alcohol use: 57% Lack health insurance: 67% Charlson Comorbidity Index (Mean [SD]): 1.4 (2.2) Most common diagnosis in prior 1 year: mental disorders, 22%
Seaberg et al., 2017[118] Chattanooga, TN metro area: 5 sites	(N=304) Intervention (N=163) Comparison (N=141)	RCT (RoB: some concerns)	5+ ED visits in past 1 year	NA	NA	NA

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: high Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Enard and Ganelin, 2013[127] Houston, TX: 1 site	(N=13,642) Intervention (N=1,905) Comparison (N=11,737)	Observational study (RoB: high)	Frequent use of the ED for primary care, data included visits to any of the 9 EDs in the healthcare system, receiving urgent or primary care in the ED (levels 3, 4, and 5 medical decisions of minimal to moderate complexity but may be considered PCP patients) in past 1 year	NA	Age: 18-64; on Medicaid, uninsured/self-pay, or covered by TX public health benefit	Nonwhite: 82% Age 18-34: 58.6% Uninsured: 62.7%
McCormack et al., 2013[129] New York, NY: 1 site	(N=60) Intervention (N=20) Prospective controls (N=20) Retrospective controls (N=20)	Observational study (RoB: high)	5+ ED visits annually for 2 consecutive years and 1 within 6 months	Alcohol dependence	Undomiciled without shelter use for 9 of 24 months	Mean age: 50.0 +/- 10.0 years Nonwhite: NR Medicaid: NR Medicare: NR
Navratil-Strawn et al., 2014[120] National	(N=14,140) Intervention (N=7,070) Comparison (N=7,070)	Observational study (RoB: some concerns)	3+ ED visits in past 1 year	NA	Age: 65+; UnitedHealth-Care's AARP Medigap insurance	Live in area with medium/high Minority status: 38%

CA = California; CT = Connecticut; ED = emergency department; MA = Massachusetts; N = number; NA = not applicable; NR = not reported; NY = New York; PCP = primary care provider; RCT = randomized controlled trial; RoB = risk of bias; SD = standard deviation; TN = Tennessee; TX = Texas.

Table B-40. Intervention characteristics of ED-based care model interventions

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Kelley et al., 2020[110] New Haven, CT: 1 site	Project Access-New Haven: ED-initiated patient navigation program (ED-PN)	12 months	Completed a detailed questionnaire with the patient (via interview) about demographics, socioeconomic status, health literacy, medical conditions, clinical and social needs, health-related quality of life, utilization of healthcare services, access/barriers to care, and reasons for ED use. Open-ended questions were also asked to elucidate ways in which the patient could most benefit from patient navigator services	Patient navigators connected patients to primary care by meeting face-to-face with patients, offering accompaniment to PCP visit(s), phoning each patient regularly to remind them of medical appointments, and problem-solving to overcome personal barriers such as transportation. Patient navigator and patient created a task list based on the provider's recommendations including assisting in scheduling any additional appointments recommended by PCP	Connected patients to local resources to address social needs such as precarious housing, food insecurity, or insurance questions	Nurse navigator and a trained patient navigator	Face-to-face or over the phone	Patient navigators scheduled regular phone calls to each patient every 2 weeks during weeks 0-4 and every 4 weeks during weeks 13-52	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Lin et al., 2017[111] Boston, MA: 1 site	Pilot ED-based care coordination and community health worker program	7 months	ED physicians performed a detailed chart review for all patients to identify unmet medical and social issues driving frequent ED visits and CHWs reviewed each patient's chart and called patients to conduct a standardized intake assessment to determine unmet needs	Acute care plans developed in conjunction with the patient's longitudinal providers including PCPs and uploaded to EHR to be visible to all clinicians and assignment of an ED-based CHW who assisted with care coordination and other tailored needs (e.g., connect with primary care, provide transportation)	CHW addressed unmet social and behavioral needs that contributed to ED utilization (e.g., food banks)	ED physician and physician assistant, ED community health worker, and nurse care coordinator	Face-to-face or phone including home visits	NR	Usual care
Shumway et al., 2008[116] San Francisco, CA: 1 hospital	Case management	24 months	Psychosocial problems and functioning were assessed at study entry and at 6, 12, 18, and 24 months. Psychosocial assessment included homelessness, problem alcohol use, lack of health insurance, lack of Social Security income, unmet basic financial needs, and psychiatric symptoms.	Provided linkage to medical care providers and ongoing assertive community outreach to maintain continuity of care	Assistance in obtaining stable housing, income entitlements, and referral to substance abuse services when needed	Master's-level psychiatric social workers provided most case management services in collaboration with a nurse practitioner, a primary care physician, and a psychiatrist	Face-to-face individual and group sessions	NR	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Seaberg et al., 2017[118] Chattanooga, TN metro area: 5 sites	Patient navigation for ED patients	12 months	Reviewed diagnoses and prescriptions	NR	Arranged followup appointments and identified relevant community resources	Patient navigator with hospital case management training	In person and via telephone	Initial ED visit, subsequent ED visits, followup calls within 2 weeks and 12 months of initial ED visit	Usual care
Enard and Ganelin, 2013[127] Houston, TX: 1 site	ED-based patient navigation program	≤10 days	Initial assessment to determine barriers to appropriate primary care use. Educate patients on importance of making and keeping appointments and receiving preventive health care. Help patients identify barriers to primary care and identify local, state, and federal resources appropriate for their needs	Patient navigators maintain relationships with community-based providers to bolster referral relationships ensure that contact information is current	Connect patients with neighborhood providers or clinics and assess their needs for specific types of referrals based on access issues and health conditions.	CHWs as patient navigators	In person and via telephone	Initial ED visit and a followup call 3 to 10 days later	Usual care
McCormack et al., 2013[129] New York, NY: 1 site	Coordinated case management and facilitated access to homeless outreach services	6 months	Social workers approached patients and, if authorized, faxed intake and medical release forms to the outreach team. On a subsequent visit, the outreach team came to the ED to confirm eligibility and complete enrollment	Social worker and outreach team met with participants to relocate patients into supportive settings, coordinate multidisciplinary care, and update plans based on participants' medical, psychosocial, and housing needs	Care plans to offer shelter on discharge	Social worker and outreach team	Face-to-face	Frequency based on number of visits to the ED	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Navratil-Strawn et al., 2014[120] National	Emergency Room Decision-Support (ERDS) program	NR; up to 12 months (followup time)	Assessment of health needs and treatment options	Make appointments with providers, refer to care coordination programs	Provide connections with health resources	Nurse	Telephone	NR	Usual care

CA = California; CHW = community health worker; ED = emergency department; ED-PN = ED-initiated Patient Navigation; EHR = electronic health record; ERDS = Emergency Room Decision-Support; MA = Massachusetts; NR = not reported; NY = New York; PCP = primary care provider; TN = Tennessee; TX = Texas.

Table B-41. Healthcare utilization outcomes for ED-based care model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
ED visits	RCT	⬇	⬇	Greater reduction in G1 than G2: DiD=-1.37 (95% CI, -2.40 to -0.34) (p=0.01)[110]
	RCT	NR	NR	Between group difference (G1-G2): -35% (p=0.10)[111]
	RCT	⬇	⬇	Lower use in G1 than G2[a] (p<0.01)[116]
	RCT	⬇	⬇	Greater reduction in G1 than G2 (p<0.0001)[118]
	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD=-178 (p=0.033)[120]
	Observational	NR	NR	Greater reduction in G1 than G2: DiD (prospective controls): -12.1 (95% CI, -22.1 to -2.0) (p=0.02) DiD (retrospective controls): -12.8 (95% CI, -26.1 to 0.6) (p=0.06)[129]
ED visits, any	Observational	⬇	⬇	Lower use in G1 than G2 among patients with PCR-ED visits in prior 24 months ≥1: OR=0.55 (95% CI, 0.47 to 0.63); ≥2: OR=0.46 (95% CI, 0.37 to 0.57); ≥3: OR=0.32 (95% CI, 0.24 to 0.44); ≥4: OR=0.29 (95% CI, 0.19 to 0.44); or ≥5: OR=0.31 (95% CI, 0.17 to 0.54)[127]
	Observational	⬇	⬇	G1 vs. G2 among patients with PCR-ED visits in prior 12 months ≥1: OR=0.83 (95% CI, 0.71 to 0.98); ≥2: OR=0.72 (95% CI, 0.57 to 0.93); ≥3: OR=0.90 (95% CI, 0.60 to 1.3); ≥4: OR=0.98 (95% CI, 0.52 to 1.8); or ≥5: OR=0.96 (95% CI, 0.39 to 2.3)[127]
Inpatient admissions, all cause	RCT	⬇	⬆	Greater reduction in G1 than G2: DiD=-0.97 (95% CI, -1.56 to -0.38) (p=0.001)[110]
	Observational	⬇	⬇	Greater reduction in G1 than G2: DiD=-53 (p=0.002)[120]
Inpatient days	Observational	NR	NR	DiD (prospective controls): -8.5 (95% CI, -22.8 to 5.8) (p=0.24) DiD (retrospective controls): -19.0 (95% CI, -34.3 to -3.6) (p=0.06)[129]
Medical inpatient admissions	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Medical inpatient days	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Psychiatric emergency visits	RCT	⇩	--	G1 vs. G2[a] (p=NS)[116]
Psychiatric inpatient admissions	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Psychiatric inpatient days	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Outpatient visits	RCT	⇧	⇧	DiD: 0.60 (95% CI, -0.43 to 1.63) (p=0.25)[110]
	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Primary care visits	RCT	⬆	⬇	Greater use in G1 than G2 (p=0.001)[118]
	Observational	⬇	⬇	Smaller reduction in G1 than G2: DiD=897 (p<0.001)[120]

[a] Interaction between level of prior ED use (5 to 11 or ≥12 visits in prior 12 months) and group: p=NS.

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

CI = confidence interval; DiD = difference-in differences; ED = emergency department; G = group; NR = not reported; NS = not statistically significant; OR = odds ratio; PCR-ED = primary care-related emergency department; RCT = randomized controlled trial; vs. = versus.

Table B-42. Strength of evidence for ED-based care models versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	ED visits	ED-PN RCT: greater reduction in G1 than G2: DiD=-1.37 (95% CI, -2.40 to -0.34)[110] CHW RCT: between-group difference: -35% (p=0.10)[111] Case management RCT: lower use in G1 than G2 (p<0.01);[116] Navigation RCT: greater reduction in G1 than G2 (p<0.0001);[118] ERDS: greater reduction in G1 than G2: DiD=-178 (p=0.033)[120] ED and housing: greater reduction in G1 than G2: DiD (prospective controls): -12.1 (95% CI, -22.1 to -2.0); DiD (retrospective controls): -12.8 (95% CI, -26.1 to 0.6)[129]	4 RCTs, N=728 2 OBSs, N=14,200	Moderate study limitations (2 high RoB OBS studies),[129] consistent, precise, direct	Moderate (Favorable)
HNHC patients	Inpatient admissions, all cause	ED-PN RCT: greater reduction in G1 than G2: DiD=-0.97 (95% CI, -1.56 to -0.38) (p=0.001)[110] ERDS: greater reduction in G1 than G2: DiD=-53 (p=0.002)[120]	1 RCT, N=100 1 OBS, N=14,140	Moderate study limitations, consistent, precise, direct	Low (Favorable)
HNHC patients	Primary care visits	Navigation RCT: greater use in G1 than G2 (p=0.001)[118] ERDS: smaller reduction in G1 than G2: DiD=897 (p<0.001)[120]	1 RCT, N=304 1 OBS, N=14,140	Moderate study limitations, consistent, precise, direct	Low (Favorable)
HNHC patients	Outpatient visits	ED-PN RCT: DiD: 0.60 (95% CI, -0.43 to 1.63) (p=0.25)[110] Case management RCT: G1 vs. G2 (p=NS)[116]	2 RCTs, N=352	Moderate study limitations, inconsistent, imprecise, direct	Insufficient (Mixed findings)
HNHC patients	ED costs	CHW RCT: between-group difference=-15% (p=0.20)[111] Case management RCT: lower in G1 than G2[a] (p<0.01)[116] Navigation RCT: greater reduction in G1 than G2 (p<0.0001)[118] ERDS: DiD=-21 (p=0.140)[120]	3 RCTs, N=628 1 OBS, N=14,140	Moderate study limitations; consistent, precise, direct	Low (Favorable)
HNHC patients	Inpatient costs	CHW RCT: between-group difference=-8% (p=0.10)[111] Case management RCT: G1 vs. G2 (p=NS)[116] ERDS: DiD=-59 (p=0.080)[120]	2 RCTs, N=324 1 OBS, N=14,140	Moderate study limitations, inconsistent, imprecise, direct	Low (No difference)
HNHC patients	Hospital costs of care	ED-PN RCT: DiD=-10,202 (95% CI, -22,464 to 2,062)[110] Case management RCT: G1 vs. G2 (p=NS)[116]	2 RCTs, N=352	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients	Outpatient costs	Case management RCT: G1 vs. G2 (p=NS)[116] ERDS: DiD=10 (p=0.828)[120]	1 RCT, N=252 1 OBS, N=14,140	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

CHW = community health worker; CI = confidence interval: DiD = difference-in differences; ED = emergency department; ED-PN = ED-initiated Patient Navigation; ERDS = Emergency Room Decision-Support; G = group; HNHC = high-need, high-cost; N = number; NS = not significant; OBS = observational study;; RCT = randomized controlled trial; RoB = risk of bias; vs. = versus.

Table B-43. Cost outcomes for ED-based care model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
ED costs	RCT	NR	NR	Between-group difference (G1-G2) =-15% (p=0.20)[111]
	RCT	⬇	⬇	Lower in G1 than G2[a] (p<0.01)[116]
	RCT	⬇	⬇	Greater reduction in G1 than G2 (p<0.0001)[118]
	Observational	⇩	⇩	DiD=-21 (p=0.140)[120]
Inpatient costs	RCT	⇩	⇩	G1 vs. G2[a,b] (p=NS)[116]
	RCT	NR	NR	Between group difference (G1-G2) =-8% (p=0.10)[111]
	Observational	⇩	⇩	DiD=-59 (p=0.080)[120]
Medicaid cost (payment)	RCT	⇩	⇧	DiD=-5,765 (95% CI, -15,883 to 4,353) (p=0.26)[110]
Psychiatric emergency costs	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Psychiatric hospital costs	RCT	⇩	⇧	G1 vs. G2[a] (p=NS)[116]
Hospital costs of care	RCT	⇩	⇧	DiD=-10,202 (95% CI, -22,464 to 2,062) (p=0.10)[110]
	RCT	⇩	⇩	G1 vs. G2[a,c] (p=NS)[116]
All non-ED case management costs	RCT	⇩	⇩	G1 vs. G2[a] (p=NS)[116]
Total costs ($)	Observational	⇩	⇩	DiD=-40 (p=0.502)[120]
Outpatient costs	RCT	⇩	--	G1 vs. G2[a,b] (p=NS)[116]
	Observational	⇩	⇩	DiD=10 (p=0.828)[120]
Prescription costs ($)	Observational	⇧	⇧	DiD=9 (p=0.201)[120]

[a] Interaction between level of prior ED use (5 to 11 or ≥12 visits in prior 12 months) and group: p=NS.
[b] Shumway et al. specified the outpatient and inpatient costs as medical outpatient costs and medical hospital costs.[116]
[c] Shumway et al. included the costs for the ED case management intervention in all hospital costs.[116]

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

CI = confidence interval; DiD = difference-in differences; ED = emergency department; G = group; NR = not reported; NS = not statistically significant; RCT = randomized controlled trial; vs. = versus.

Table B-44. Clinical and functional outcomes for ED-based care model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality	RCT	G1: 0/20 vs. prospective G2: 2/20 and retrospective G2: 7/20 (p=NR)[129]
Satisfaction (4-point Likert scale)	RCT	G1 vs. G2 (p=NS)[118]
Psychiatric symptoms (total BSI)	RCT	G1 vs. G2[a] (p=NS)[116]

[a] Interaction between level of prior ED use (5 to 11 or ≥12 visits in prior 12 months) and group: p=NS.

BSI = brief symptom inventory; ED = emergency department; G = group; NR = not reported; NS = not statistically significant; RCT = randomized controlled trial; vs. = versus.

Table B-45. Social risk outcomes for ED-based care model studies

Social Risk Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Housed	RCT	G1: 18/20 vs. prospective G2: 0/20 and retrospective G2: 0/20 (p=NR)[129]
Problem alcohol use (%)	RCT	Lower in G1 than G2[a] (p=0.04)[116]
Homelessness (%)	RCT	Lower in G1 than G2[a] (p<0.01)[116]
No health insurance (%)	RCT	Lower in G1 than G2[a] (p=0.02)[116]
No social security income (%)	RCT	Lower in G1 than G2[a] (p<0.01)[116]
Basic financial needs unmet	RCT	Lower in G1 than G2[a] (p=0.04)[116]

ED = emergency department; G = group; NR = not reported; RCT = randomized controlled trial; vs. = versus.

Table B-46. Study characteristics of aICU (ambulatory intensive caring unit) interventions

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other
Yoon et al., 2019[87]; Zalman, 2019[97] GA, OH, WI, NC, CA: 5 sites	(N=2,210) Intervention (N=1,105) Comparison (N=1,105) (N=1,527) Intervention (N=759) Comparison (N=768)	RCT (RoB: some concerns)	Veterans whose risk of 90-day hospitalization was ≥ 90th percentile based on the VA's Care Assessment Need (CAN) score and who had experienced a hospitalization or ED visit in past 6 months	NA	Intensive management teams at each site reviewed patient charts to determine whether participants would benefit from intensive services
Durfee et al., 2018[83] CO: 1 site	(N=3,636) Intervention (N=1,749) Comparison (N=1,887)	Observational study (RoB: some concerns)	IP admission (analysis index admission) and at least 2 other admissions OR at least one other admission with a serious mental health diagnosis in past 1 year	NA	Age: 19+
Horn et al., 2016[92] Albuquerque, NM: 1 academic medical center	(N=1547) Intervention (N=753) Comparison (N=794)	Observational study (RoB: some concerns)	High cost (top 1%) in past 1 year	Medically complex patients with a chronic medical condition and at high risk for future hospitalization	Participant selection guided by the likelihood of recurrent illness and response to care management, and patient willingness to participate in the program and be monitored and contacted

aICU = ambulatory intensive caring unit; CA = California; CAN = care assessment need; CO = Colorado; ED = emergency department; GA = Georgia; IP = inpatient; N = number; NA = not applicable; NC = North Carolina; NM = New Mexico; OH = Ohio; RCT = randomized controlled trial; RoB = risk of bias; VA = Department of Veterans Affairs; WI = Wisconsin.

Table B-47. Intervention characteristics of aICU (ambulatory intensive caring unit) interventions

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Yoon et al., 2019[87, 97] GA, OH, WI, NC, CA: 5 sites	Augmenting the VA's PCMH PACT with a PACT-PIM intervention for highest cost patients; locally tailored by site	Up to 15 months	Initial assessment: record review, followed by comprehensive in-person assessment for medical, MH, and social needs; goals assessment; health coaching for patient and caregivers, pharmacist medication reconciliation and adherence monitoring	Care coordination; transitional care management post IP discharge; feedback to PCP, assistance with navigating healthcare services	NR: VA provides many support services in-house	Interdisciplinary team: physician or nurse practitioner, a nurse, pharmacist, rehabilitation therapists, MH and addiction support	Outpatient, home, and phone	Limited: 1-2 encounters or referral to PCP; Full: goal was 3+ encounters in person or by phone from PIM team; received by 44% of participants. Tailored to individual needs. Full-intervention participants received mean of 14 encounters (range: 3-116)	Patient Aligned Care Team (PACT) only
Durfee et al., 2018[83] CO: 1 sites	IOC in integrated delivery system	NR	In-depth intake assessment included determining medical barriers to improving health, taking into account BH needs, social determinants of health, and patient-identified priorities	Sought to develop comprehensive care plans. More nursing support allowed for medical interventions to be done within the clinic instead of the ED or hospital	NR	Eight existing family practice and internal medicine teams composed of a PCP, medical assistant, and shared nursing and social work resources. Supported by clinical pharmacists, patient navigators, BH clinicians	Additional staffing to existing PCPs and developed IOCs (new, specialized primary care clinics). Face-to-face with care team; navigators and pharmacists primarily by phone	IOC had higher staff-patient ratio than regular PCP clinic, longer visits, walk-in availability. Mean number of encounters per patient: NR	Usual care: historic comparison group who received care prior to implementing the IOC

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Horn et al., 2016[92] Albuquerque, NM: 1 academic medical center	Care One, an intensive chronic care, primary care-oriented program designed to target HNHC patients	NR	Assessment of whether amenable to care management based on interview and medical record review	Provided access to specialty care consultations, assistance from nurse coordinators and social workers, and assistance with unanticipated problems related to access or quality	Assistance with social services, such as transportation to clinical appointments, food stamp applications, etc.	A physician, social worker/case manager, patient care coordinator, and MH therapist. A pharmacist assists with medication management for patients with complex comorbidities	Primary care	NR	Usual care

aICU = ambulatory intensive caring unit; BH = behavioral health; CA = California; CO = Colorado; ED = emergency department; GA = Georgia; HNHC = high-need, high-cost; IOC = intensive outpatient clinic; IP = inpatient; MH = mental health; NC = North Carolina; NM = New Mexico; NR = not reported; OH = Ohio; PACT = patient aligned care team; PCMH = Patient-Centered Medical Homes; PCP = primary care provider; PIM = PACT-intensive management; VA = Department of Veterans Affairs; WI = Wisconsin.

Table B-48. Healthcare utilization outcomes for aICU (ambulatory intensive caring unit) model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Acute medical/ surgery inpatient stays	RCT	NR	NR	DiD: 1.13 (95% CI, 0.92 to 1.38)[87]
Other inpatient stays[a]	RCT	NR	NR	DiD: 1.04 (95% CI, 0.66 to 1.65)[87]
Inpatient admissions	Observational	⬇	⬇	DiD: lower reduction in G1 than G2 (negative finding) ($p<0.01$)[83]
ED visits	RCT	NR	NR	DiD: 1.02 (95% CI, 0.93 to 1.13)[87]
Primary care visits	RCT	NR	NR	Greater use in G1: DiD: 1.40 (95% CI, 1.30 to 1.50)[87]
Care management visits	RCT	NR	NR	Greater use in G1: DiD: 2.70 (95% CI, 1.77 to 4.12)[87]
Specialty care visits	RCT	NR	NR	DiD: 1.03 (95% CI, 0.96 to 1.10)[87]
Mental healthcare visits	RCT	NR	NR	Greater use in G1: DiD: 1.33 (95% CI, 1.17 to 1.52)[87]
Homeless care visits	RCT	NR	NR	DiD: 1.11 (95% CI, 0.86 to 1.44)[87]

[a] Other inpatient stays included psychiatric, substance use disorders, and rehabilitation stays.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

Table B-49. Cost outcomes for aICU (ambulatory intensive caring unit) model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Outpatient costs	RCT	⬆	⬇	DiD: greater increase in G1 than G2: 2636 (95% CI, 524 to 4748)[87]
Inpatient costs	RCT	⇩	⇧	DiD: −2,164 (95% CI, -7,916 to 3,587)[87]
ED costs	RCT	⇩	⇩	DiD:−20 (95% CI,−277 to 237)[87]
Total costs/ charges	RCT	⇩	⇩	DiD: 471 (95% CI,−6,347 to 7,290)[87]
	Observational	⬇	⬇	DiD: greater reduction in G1 than G2 ($p<0.04$)[83]
	Observational	⬇	⬇	DiD: greater reduction in G1 than G2: -$44,504 ($p<0.01$)[92]

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

CI = confidence interval; DiD = difference-in-difference; ED = emergency department; G = group; RCT = randomized controlled trial.

Table B-50. Strength of evidence for aICU models versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Total costs	PIM: DiD: 471 (95% CI,-6,347 to 7,290)[87] IOC: DiD: greater reduction in G1 than G2 (p<0.04);[83] Care One DiD: -$44,504 (p<0.01)[92]	1 RCT, N=2,210 2 OBSs, N=5,183	Moderate study limitations, consistent, precise, direct	Low (Favorable)
HNHC patients	Mortality 1-year post-randomization	PIM: (p=0.93)[87] IOC: Lower in G1 than G2: (p<0.01)[83]	1 RCT, N=2,210 1 OBS, N=3,636	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

aICU = ambulatory intensive caring unit; CI = confidence interval; DiD = difference-in- difference; G = group; HNHC = high need, high cost; IOC: Intensive Outpatient Clinic; N = number; OBS = observational study; PIM: Patient Aligned Care Team (PACT)-Intensive Management; RCT = randomized controlled trial; vs. = versus.

Appendix Table B-51. Clinical and functional outcomes for aICU (ambulatory intensive caring unit) model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality, 1-year post-randomization	RCT	(p=0.93)[87]
	Observational	Lower in G1 than G2: (p<0.01)[83]
Patient-centered care coordination	RCT	AOR for all 6 measured dimensions past 6 months[a] (p=NS)[97]
Access to care	RCT	AOR for all 3 measured dimensions[b] (p=NS)[97]
Patient satisfaction with care	RCT	AOR for all 4 measured dimensions[c] (p=NS)[97]
Relationships with Providers: trusted provider	RCT	Greater in G1 than G2: AOR=1.30 (95% CI, 1.04 to 1.62)[97]
Relationships with Providers: feel respected by provider	RCT	(p=NS)[97]
Healthcare hassles summary score (challenges in getting care)	RCT	(p=0.61)[97]
Patient assessment of chronic illness care (PACIC) summary score (receipt of care for chronic illness)	RCT	Greater in G1 than G2: (p=0.022)[97]

[a] Goals assessed: barriers, medications reviewed, between-visit reminders, primary care informed about specialty care, VA healthcare provider helps coordinate care from different doctors and services, someone talked to them about their health goals, report 10 out of 10 satisfaction with primary care, patient assessment of chronic illness care based on PACIC scale, not significant for medications reviewed in past 6 months, between-visit reminders in past 6 months, primary care informed about specialty care in past 6 months.

[b] Dimensions included access to needed services, access to provider when questions about care arise, and received needed services.

[c] Dimensions included satisfaction with overall care at VA facility, social services, mental healthcare services, and primary care services.

AOR = adjusted odds ratio; CI = confidence interval; G = group; NS = not statistically significant; PACIC = patient assessment of chronic illness care; RCT = randomized controlled trial; VA = Department of Veterans Affairs.

Table B-52. Study characteristics of primary care-based interventions

First Author, Year, Site(s)	Type of Intervention; Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
McCall et al., 2010[86] 5 MA counties (Norfolk, Suffolk, Middlesex, Essex, and Plymouth)	Primary care model includes home visits pay-for-performance APM (Original N=5,374) Intervention (N=2,619) Comparison (N=2,755)	RCT (RoB: some concerns)	Beneficiaries with HCC risk scores ≥2.0 and annual costs of ≥$2,000 or HCC risk scores ≥3.0 and ≥$1,000 annual medical costs in past 1 year	HCC risk scores ≥2.0	Medicare FFS beneficiaries; at least 2 visits to MA General Hospital physicians for a selected group of outpatient and ED procedures	Nonwhite: 13.4% Medicaid: 5.3%
McCall et al., 2010[86] 5 MA counties (Norfolk, Suffolk, Middlesex, Essex, and Plymouth)	Primary care model includes home visits pay-for-performance APM (Refresh N=1,569) Intervention (N=785) Comparison (N=784)	RCT (RoB: some concerns)	Beneficiaries with HCC risk scores ≥2.0 and annual costs of ≥$2,000 or HCC risk scores ≥3.0 and ≥$1,000 annual medical costs in past 1 year	HCC risk scores ≥2.0	Medicare FFS beneficiaries; at least 2 visits to MA General Hospital physicians for a selected group of outpatient and ED procedures	Nonwhite: 12.8% Medicaid: 5.4%
Sledge et al., 2006[115] Northeastern U.S.: 1 site	Primary care model (N=96) Intervention (N=47) Comparison (N=49)	RCT (RoB: low)	2+ medical or surgical hospital admissions per year, excluded highest cost outliers in 12-18 month period	NA	Age: 18+	Nonwhite: 62.5% Medicare/Medicaid: 93% Major depression: 34% 6th grade or lower reading level: 32% of those who spoke English (n=91)
Coleman et al., 2001[117] Denver, CO: 19 physician-nurse teams in 8 PCP practices	Primary care model: (Group visits) (N=295) Intervention (N=146) Comparison (N=149)	RCT (RoB: some concerns)	11+ outpatient visits in past 18 months	1+ self-reported chronic condition	Age: 60+	NA

First Author, Year, Site(s)	Type of Intervention; Sample size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Katzelnick et al., 2000[99] WI, WA, MA: 163 physician practices affiliated with 1 of 3 included HMOs	Primary care model (N=407) Intervention (N=218) Comparison (N=189)	RCT (RoB: some concerns)	Ambulatory visit counts above the 85th percentile (including PCP, medical specialty, and walk-in clinic visits—not MH provider visits) in previous 2 years	Screened positive for current major depression or major depression in partial remission (HAM-D score of 15 or more)	Age: 25-63	Female: 77%
Powers et al., 2020[108] Memphis, TN: 1 site	Primary care model (N=253) Intervention (N=93) Comparison (N=160)	RCT (RoB: some concerns)	Top 5% of total medical expenditures in past year and 2+ inpatient admissions or 3+ ED visits in past year	Top 5% chronic Illness Intensity Index (CI3) score and 2+ chronic conditions	NA	Mean age: 45 Nonwhite: NR Medicaid: 100% Medicare: NR
Crane et al., 2012[98] Hendersonville, NC: 1 site	Primary care model: Group Visits (N=72) Intervention (N=36) Comparison (N=36)	Observational study (RoB: high)	6+ ED visits in past 1 year	NA	Below 200% FPL; uninsured	Median age: 32 The following were only reported in intervention group Chronic pain: 75% Uninsured: 100% Substance abuse: 47% Depression: 36%
Adam et al., 2010[102] MN: 1 residency clinic	Primary care model (N=21) Intervention (N=13) Comparison (N=8)	Observational study (RoB: high)	8+ clinic visits in past 1 year	NA	Age: 18+	Psychiatric diagnosis: 85% Nonwhite: 28% Female: 65% Median age: 49.5
Vickery et al., 2018[100, 125] MN: 1 site	Primary care model (N=NR of 92,891) Intervention (N=NR of 19,433) Comparison (N=NR of 73,458)	Observational study (RoB: some concerns)	HNHC patient subgroup: More than 4 ED visits or 2 inpatient hospital visits in past 1 year	NA	Whole study population: Adults with 1+ months of enrollment under early Medicaid expansion	NR

First Author, Year, Site(s)	Type of Intervention; Sample size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Harrison et al., 2020[130] Philadelphia, PA: 12 sites	Primary care model (N=3,048) CBCM enrollee (N=896) Comparison (N=2,152)	Observational (ROB: some concerns)	Top 10% of total costs for the Medicaid MCO in past year	NA	Received primary care at 1 of 12 participating clinical practices, 18+ years, enrolled in Medicaid	Percentage in age range (years): 18-39: 27% 40-59: 60% ≥60: 12% Nonwhite: 88% Medicaid 2+ years: 82% Medicare: NR

APM = advanced alternative payment model; CBCM = Community-Based Care Management; CO = Colorado; ED = emergency department; FFS = fee-for-service; FPL = federal poverty line; HAM-D = Hamilton Depression Rating Scale; HCC = hierarchical condition category; HNHC = high-need, high-cost; MA = Massachusetts; MCO = managed care organization; MH = mental health; MN = Minnesota; N = number; NA = not applicable; NC = North Carolina; NR = not reported; PA = Pennsylvania; PCP = primary care provider; RCT = randomized controlled trial; RoB = risk of bias; TN = Tennessee; U.S. = United States; WA = Washington; WI = Wisconsin.

Table B-53. Intervention characteristics of primary care-based interventions

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
McCall et al., 2010[86] 5 MA counties (Norfolk, Suffolk, Middlesex, Essex, and Plymouth)	Provider-based care management program	Up to 36 months for original population, up to 24 months for refresh population	Conducted comprehensive assessment to evaluate the unique needs of each patient; educated patients about resources available and lifestyle changes that could help to prevent exacerbations of disease, to prevent or delay hospitalization and about the purpose of their medications and other treatment interventions; reviewed self-management activities	The role of the case manager is to provide support across patients' continuum of care	Connect patients to resources to meet medical and psychosocial needs	Nurse case managers supported by case management program project manager, an administrative assistant, a community resource specialist, and a patient financial counselor as well as social workers to help with mental health program and pharmacists	In person at primary care offices, hospitals, and home visits as needed and via telephone	Among the original population, 97% of the intervention group received at least 1 contact. The mean number of contacts per patient was 8. A higher proportion of patients in the HCC risk score group received 10 or more calls during the 36-month period compared with the low HCC risk score group (27% compared to 17%), with 10% of patients in the high HCC risk score group receiving 20+ phone calls compared with 4% in the low HHC risk score group. In the refresh group, 87% received at least 1 contact, and the mean number of contacts was 4	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Sledge et al., 2006[115] Northeastern U.S.: 1 site	Primary Intensive Care (PIC)	1 year	Comprehensive interdisciplinary medical and psychosocial assessment, used a patient-centered approach to improve self-care patterns and coping skills, aimed to track and facilitate completion of recommendations made to the PCP based on the assessment	A report and recommendations for care were presented to PCP and subspecialty providers; the recommendations were intended to optimize chronic illness management; case manager used patient-centered approach to improve coordination of care	Offered assistance with referrals and appointments	Psychiatric nurse and team including social worker, psychiatrist, and general internist	In person and via telephone; home visits when necessary	Varied based on patient needs; at minimum included a monthly telephone call; patients were defined by 3 levels of contact: minimum contact, biweekly contact, and weekly or greater contact	Usual care (psychiatric consultation provided only if requested by PCP)

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Coleman et al., 2001[117] Denver, CO: 19 physician-nurse teams in 8 PCP practices	Patient group visits model of care	2 years	Education on general and specific health topics, medication management, exercise, and nutrition; assessments included health promotion activities such as blood pressure measurement and need for and delivery of immunizations and medication refills and ongoing chronic disease management and evaluation of acute conditions in 1:1 sessions	Provided active care coordination within the primary care team and between other providers and care settings; promoted continuity of care with the health team	NR	Primary care physician, nurse, pharmacist. Periodic ancillary providers: dietitian, social worker, physical therapist	In person	Group visits were held monthly for 24 months, 120 minutes per session, with an average attendance of 8 to 12 participants per group	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Katzelnick et al., 2000[99] WI, WA, MA: 163 physician practices affiliated with 1 of 3 included HMOs	Depression management program (DMP)	1 year	Assessed patients to confirm diagnosis and appropriateness for medication; patients and PCPs received education about depression; periodic followup with PCP to monitor patient status and telephone monitoring by coordinators	PC was supported by coordinators who reviewed patient prescription refills and office visits and monitored treatment adherence, response, and adverse effects	Study psychiatrists had ongoing contact with PCPs via periodic case reviews and as-needed telephone consultation; psychiatric consultations were encouraged for patients not responding to treatment by 10 weeks and those with more complicated depression	PCPs, psychiatrists, and treatment coordinators with some clinical mental health experience	In person and via telephone	Coordinators made telephone contact at 2 weeks, 10 weeks, 18 weeks, and 30 weeks and have an average of 2.7 contacts per patient; followup visits with the PCP were prescheduled at 1, 3, 6, and 10 weeks, subsequent visits occurred approximately every 10 weeks	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Powers et al., 2020[108] Memphis, TN: 1 site	Complex care management program	12 months	In-person intake visit to assess patient's medical, behavioral, and social risk factors. The patient and care team co-developed a tailored care plan that outlined interventions, roles, and responsibilities. CHW called patients at least weekly to assess progress and troubleshoot barriers	CHW responsible for patient outreach, engagement, activation, and accompaniment while the social worker was responsible for coordinating referrals to social service agencies and other medical providers and the PCP was responsible for proving comprehensive care for acute and chronic conditions and for coordinating with specialist and inpatient providers	CHW accompanied patients to specialist, social service, and other appointments as needed. Social worker responsible for counseling and brief interventions for patients with behavioral health needs and for coordinating referrals to social service agencies.	Community health worker, a social worker, and a primary care provider	Telephone or face-to-face at the PCP office	Weekly phone call from CHW and monthly in person followup visit to review and revise the care plan	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Crane et al., 2012[98] Hendersonville, NC: 1 site	Care management and drop-in group medical appointments (DIGMAs)	1 year	Small-group sessions emphasized life skills; group and individual sessions addressed health and behavioral issues identified by the patient	For patients with a PCP, care other than emotional or group support provided in the program was reported to or coordinated with the PCP. All care was documented in an electronic medical record, including all phone calls. These records could be accessed by physicians in the ED as needed.	Program was based at a county free clinic that provided office space for case manager, room for DIGMA, and variety of wrap-around services to intervention group including free prescriptions at onsite pharmacy	The care team consisted of a family physician, 2 behavioral health providers, and a nurse care manager	In person in clinic or via telephone	DIGMA visits were scheduled twice a week for 1 hour; small group sessions with care manager, scheduled twice a week for 1 hour; direct telephone access to RN care manager available Monday-Friday, 8 AM to 5 PM; median number of visits per month per patient was 2 and median number of patient contacts per month was 3.5	Usual care
Adam et al., 2010[102] MN: 1 residency clinic	Family medicine care team	6 months	Care team met to review the healthcare status of a case patient and develop a care plan based on discussions with the patient's primary physician. A member of the team called the patient to schedule a free visit to review the care plan	The team was interdisciplinary; providing joint care with consultants was encouraged when indicated, as was engaging family members or other stakeholders in the patient's care	Care plans included referrals as needed to care such as mental health treatment or medications	Faculty physician, 4 resident physicians, the clinic psychologist, pharmacist, triage nurse, certified medical assistant, and front desk manager	In person at family medicine residency clinic	Care team met 1 time per week to discuss the care and status of a patient	

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Vickery et al., 2018[100] MN: 1 site	Hennepin Health Accountable Care Organization (HH ACO)	24 months	Developing patient-specific plans based on need, patient education and goal setting	Connected patients to primary care and other necessary services, increased access to care for mental illness and substance use (behavioral health) including integration within primary care, care coordination and disease management service intensity based on risk	Integrated county services for social and behavioral needs (housing, vocational, social services) with health care, increased access to services to meet social needs, improved access to dental services, high-risk patient referred to a Coordinated Care Center	Care coordination team: RN care coordinators embedded in primary care clinics, clinical social workers, CHW Coordinated care center team: physician, NP or PA, care coordinator, social worker, psychologist, pharmacists, licensed chemical dependency counselors, and a part-time addiction psychiatrist support	Patients received care at various care settings, program managed by county	NR; based on patient risk	Usual care: enrolled in non-Hennepin Health managed care in Hennepin or Ramsey County

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(s)	Intensity	Comparison
Harrison et al., 2020[130] Philadelphia, PA: 12 sites	MCO-led Community-Based Care Management (CBCM)	12 months	NR	Coordinated care and managed medications	Identified social needs and connected patients to local community resources and partnered with a nonprofit to provide health and substance abuse services for Philadelphia County Medicaid recipients	Community health workers hired by practices and nurse case managers hired by the MCO	NR	Varied by practice site	Usual care

CBCM = Community-Based Care Management; CHW = community health worker; CO = Colorado; DIGMA = drop-in group medical appointments; DMP = depression management program; ED = emergency department; HCC = hierarchical condition category; HH ACO = Hennepin Health Accountable Care Organization; MA = Massachusetts; MCO = managed care organization; MN = Minnesota; NC = North Carolina; NP = nurse practitioner; NR = not reported; PA = Pennsylvania; PC = primary care; PCP = primary care provider; PIC = primary intensive care; RN = registered nurse; TN = Tennessee; U.S. = United States; WA = Washington; WI = Wisconsin.

Table B-54. Healthcare utilization outcomes for primary care–based model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
ED visits, all cause	RCT	⇩	⇩	Difference in change over time, G1 vs. G2: (p=0.9)[115]
	RCT	⇧	⇧	Original sample: IRR=0.94 (95% CI, 0.81 to 1.09)[86]
	RCT	⬆	⬆	Refresh sample: Lower increase in G1 than G2: IRR=0.75 (95% CI, 0.57 to 0.99)[86]
	RCT	NR	NR	Lower use in G1 than G2: aMD=-0.42 (95% CI, -0.13 to -0.72)[117]
	RCT	NR	NR	aMD=-0.02 (95% CI, -0.51 to 0.47) (p=1.00)[108]
	Observational	NR	NR	Greater use in G1 than G2: aMD=0.18 (95% CI, 0.01 to 0.37)[130]
	Observational	NR	NR	G1 vs. G2: aMD=34.22 (95% CI, -10.9 to 79.3)[100, 125]
	Observational	⬇	⬇	Greater reduction in G1 than G2: (p=0.005)[98]
	Observational	⇧	⇩	Difference=0.5 (p=NR)[102]
ED, any (%)	RCT	NR	NR	Lower use in G1 than G2: aRR=0.64 (95% CI, 0.44 to 0.86)[117]
ED visits, ACSC	RCT	⇧	⇧	Original sample: IRR=0.90 (95% CI, 0.70 to 1.16)[86]
	RCT	⇧	⇧	Refresh sample: IRR=0.80 (95% CI, 0.51 to 1.25)[86]
Inpatient admissions, all cause	RCT	⇩	⇩	Difference in change over time, G1 vs. G2: (p=0.55)[115]
	RCT	⬆	⬆	Original sample: lower increase in G1 than G2: IRR=0.81 (95% CI, 0.70 to 0.94)[86]
	RCT	⬆	⬆	Refresh sample: lower increase in G1 than G2: IRR: 0.76 (95% CI, 0.58 to 0.99)[86]
	RCT	NR	NR	Lower use in G1 than G2 (mean # of admissions): 0.44 vs. 0.81 (p=0.04)[117]
	RCT	⇧	⇩	G1 vs. G2: (p=0.09)[99]
	RCT	NR	NR	Greater reduction in G1 than G2: aMD=-0.32 (95% CI, -0.54 to -0.11) (p=0.014)[108]
	Observational	NR	NR	Greater use in G1 than G2: aMD=0.10 (95% CI, 0.03 to 0.16)[130]
	Observational	NR	NR	Lower use in G1 vs. G2: aMD=-26.11 (95% CI, -35.9 to -16.3)[100, 125]
	Observational	--	--	Difference=0 (p=NR)[102]
Inpatient admissions, any (%)	RCT	⬆	⬆	Original sample: lower increase in G1 than G2, OR=0.65 (95% CI, 0.55 to 0.78}[86]
	RCT	⬇	⬆	Refresh sample: greater reduction in G1 than G2, OR=0.66 (95% CI, 0.48 to 0.90)[86]

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Inpatient admissions, ACSC	RCT	⇧	⇧	Original sample: IRR=0.87 (95% CI, 0.66 to 1.14)[86]
	RCT	⇧	⇧	Refresh sample: IRR=0.78 (95% CI, 0.49 to 1.24)[86]
Inpatient admissions, any ACSC (%)	RCT	⬆	⬆	Original sample: lower increase in G1 than G2, OR=0.73 (95 %CI, 0.57 to 0.95)[86]
	RCT	⇧	⇧	Refresh sample: OR=0.79 (95% CI, 0.51 to 1.21)[86]
Inpatient days	RCT	NR	NR	Greater reduction in G1 vs. G2: aMD=-3.46 (95% CI, -4.04 to -2.89) (p<0.001)[108]
	Observational	NR	NR	G1 vs. G2: aMD=-219.7 (95% CI, -826 to 386.6)[100, 125]
Primary care visits	RCT	⇧	⇩	Difference in change over time, G1 vs. G2: (p=0.055)[115]
	RCT	NR	NR	G1 vs. G2: (p=0.20)[117]
	Observational	NR	NR	Less use in G1 than G2: aMD=-1.83 (95% CI, -2.10 to -1.55)[130]
	Observational	NR	NR	G1 vs. G2: aMD=6.0 (95% CI: -39.3 to 51.4)[100, 125]
Outpatient visits	RCT	⬆	⬇	Greater increase in G1 than G2: (p=0.02)[99]
	Observational	⇩	⇧	Difference=4.5 (p=NR)[102]
Care center visits	RCT	NR	NR	aMD: 0.47 (95% CI, -0.16 to 1.11) (p=0.576)[108]
Specialist visits	RCT	NR	NR	Greater reduction in G1 vs. G2: aMD: -1.35 (95% CI, -1.98 to -0.73) (p<0.001)[108]
Total visits	Observational	NR	NR	Less use in G1 than G2: aMD: -1.55 (95% CI, -1.93 to -1.21)[130]
Filled ≥3 antidepressant prescriptions in first 6 months	RCT	NR	NR	Greater use in G1 than G2: (p<0.001)[99]
Specialty mental health visit in first 6 months	RCT	NR	NR	Greater use in G1 than G2: (p=0.03)[99]
Cancelled visits and/or no shows	Observational	⇧	⇩	Difference=3.5 (p=NR)[102]
Intensive care unit visits	Observational	NR	NR	G1 vs. G2: aMD=0.1 (95% CI: -0.7 to 0.9)[100, 125]
Dental visits	Observational	NR	NR	Greater reduction in G1 vs. G2: aMD=-30.7 (95% CI, -41.0 to -20.3)[100, 125]

[a] Outpatient visits were defined as primary care visits and group intervention visits for the intervention group and as primary care visits only for the comparison group.

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

ACSC = ambulatory care sensitive conditions; aMD = adjusted mean difference; aRR = adjusted risk ratio; CI = confidence interval; ED = emergency department; G = group; IRR = incidence rate ratio; NR = not reported; OR = odds ratio; RCT = randomized controlled trial; vs. = versus.

Table B-55. Strength of evidence for primary care–based models versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	ED visits, all cause	PIC RCT: Diff in change over time (p=0.9)[115] MGH CMP original sample: IRR=0.94 (95% CI, 0.81 to 1.09)[86] MGH CMP refresh sample: IRR=0.75 (95% CI, 0.57 to 0.99)[86] Group visit RCT: aMD=-0.42 (95% CI, -0.13 to -0.72)[117] CCM RCT: aMD=-0.02 (95% CI, -0.51 to 0.47)[108] CBCM: Greater use in G1 than G2: aMD=0.18 (95% CI, 0.01 to 0.37)[130] HH ACO: diff=34.22 (95% CI, -10.9 to 79.3)[100, 125] Bridges to Health: Greater reduction in G1 than G2: (p=0.005)[98] Interdisciplinary pilot: Diff=0.5 (p=NR)[102]	5 RCTs, N=7,587 4 OBSs, N=NR[a]	Moderate study limitations (2 high RoB OBS studies),[98, 102] inconsistent, imprecise, direct	Insufficient (Mixed findings)
HNHC patients	ED visits, ACSC	MGH CMP original sample: IRR=0.90 (95% CI, 0.70 to 1.16)[86] MGH CMP refresh sample: IRR=0.80 (95% CI, 0.51 to 1.25)[86]	2 RCTs, N=6,943	Moderate study limitations, consistent imprecise, direct	Insufficient
HNHC patients	Inpatient admissions, all cause	PIC RCT: diff in change over time: (p=0.55)[115] MGH CMP original sample: IRR=0.81 (95% CI, 0.70 to 0.94)[86] MGH CMP refresh sample: IRR: 0.76 (95% CI, 0.58 to 0.99)[86] Group visit RCT: less use in G1 than G2: 0.44 vs. 0.81, (p=0.04)[117] DMP RCT: G1 vs. G2: (p=0.09)[99] CCM RCT: Greater reduction in G1 than G2: aMD=-0.32 (95% CI, -0.54 to -0.11) [108] CBCM: Greater use in G1 than G2=aMD: 0.10 (95% CI, 0.03 to 0.16)[130] HH ACO: G1 vs. G2: Diff=-26.11 (95% CI, -35.9 to -16.3)[100, 125] Interdisciplinary Pilot: diff=0 (p=NR)[102]	6 RCTs, N=7,994 3 OBS, N=NR[a]	Moderate study limitations (one high RoB OBS studies),[102] consistent, precise, direct	Insufficient (Mixed findings)

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Inpatient admissions, any (%)	MGH CMP: original sample: OR=0.65 (95% CI, 0.55 to 0.78)[86] MGH CMP refresh sample: OR=0.66 (95% CI, 0.48 to 0.90)[86]	2 RCTs, N=6,943	Moderate study limitations, consistent, precise, direct	Low (Favorable)
HNHC patients	Inpatient admissions, ACSC	MGH CMP original sample: IRR=0.87 (95% CI, 0.66 to 1.14)[86] MGH CMP refresh sample: IRR=0.78 (95% CI, 0.49 to 1.24)[86]	2 RCTs, N=6,943	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	Inpatient admissions, any ACSC (%)	MGH CMP original sample: OR=0.73 (95% CI, 0.57 to 0.95)[86] MGH CMP refresh sample: OR=0.79 (95% CI, 0.51 to 1.21)[86]	2 RCTs, N=6,943	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	Inpatient days	CCM RCT: Greater reduction in G1 vs. G2: aMD=-3.46 (95% CI, -4.04 to -2.89)[108] HH ACO: G1 vs. G2: aMD=-219.7 (95% CI, -826 to 386.6)[100, 125]	1 RCT, N=253 1 OBS, N=NR[a]	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	Primary care visits	PIC RCT: diff in change over time: (p=0.055);[115] RCT group visits: G1 vs. G2: (p=0.20);[117] CBCM: Less use in G1 than G2: aMD=-1.83 (95% CI, -2.10 to -1.55);[130] HH ACO: G1 vs. G2: Diff=6.0 (95% CI: -39.3 to 51.4)[100, 125]	2 RCTs, N=391 2 OBSs, N=NR[a]	Moderate study limitations, inconsistent imprecise, direct	Insufficient (Mixed findings)
HNHC patients	Outpatient visits	DMP: greater use in G1 than G2: (p=0.02)[99] Interdisciplinary pilot: diff=4.5 (p=NR)[102]	1 RCT, N=407 1 OBS, N=21	High study limitations (one high RoB OBS studies)[102] imprecise, inconsistent, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Total cost	PIC RCT: diff in change over time, G1 vs. G2: (p=0.82)[115] MGH CMP: original sample DiD: -288 (p<0.01)[86] MGH CMP: refresh sample DiD: -355 (p<0.05)[86] CCM RCT: Greater reduction in G1 vs. G2: aMD=-7,732 (95% CI, -14,914 to -550)[108] CBCM: aMD=829 (95% CI, -1,279 to 3,098)[130] Pooled mean difference: -$3,848.43 (95% CI, -5,514.24 to -2,182.61); 3 RCT samples, N=7,196, I^2=0.0%	4 RCTs, N=7,292 1 OBS, N=3,048	Moderate study limitations, consistent, imprecise, direct	Low (Favorable)
HNHC patients	Mortality rate	MGH CMP: original sample diff: G1 vs. G2, -1.63 (p=0.19)[86] MGH CMP: refresh sample diff: G1 vs. G2: -3.97 (p=0.04)[86]	2 RCTs, N=6,943	Moderate study limitations, imprecise, inconsistent, direct	Insufficient
HNHC patients	Influenza vaccine	MGH CMP: original sample DiD OR=0.79 (95% CI, 0.66 to 0.95)[86] MGH CMP refresh sample DiD: OR=0.64 (95% CI, 0.46 to 0.87)[86]	2 RCTs, N=6,943	Moderate study limitations, consistent, precise, direct	Low (Unfavorable)
HNHC patients Diabetes subgroup	HbA1c test	MGH CMP, original sample: DiD OR=0.99 (95% CI, 0.56 to 1.76)[86] MGH CMP refresh sample: DiD OR=0.70 (95% CI, 0.27 to 1.84)[86]	2 RCTs, N=1,959	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients Diabetes subgroup	LDL-C test	MGH CMP original sample: DiD OR=0.85 (95% CI, 0.58 to 1.24)[86] MGH CMP refresh sample: DiD OR=1.72 (95% CI, 0.86 to 3.42)[86]	2 RCTs, N=1,959	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients IVD subgroup	LDL-C test	MGH CMP original sample: DiD OR=0.92 (95% CI, 0.63 to 1.33)[86] MGH refresh sample: DiD OR=1.40 (95% CI, 0.76 to 2.58)[86]	2 RCTs, N=1,923	Moderate study limitations, inconsistent, imprecise, direct	Insufficient

[a] The HH ACO[100, 125] study did not report sample sizes for their HNHC populations; the total sample size for the study was 92,891. The sample size for CBCM[130] was 3,048, 21 for the interdisciplinary pilot,[102] and 72 for Bridges to Health.[98]

ACSC = ambulatory care sensitive conditions; aMD = adjusted mean difference; CBCM = Community-Based Care Management; CCM = complex care management; CI = confidence interval; DiD = difference-in-difference; DMP = depression management program; ED = emergency department; G = group; HbA1c = hemoglobin A1c; HH ACO = Hennepin Health Accountable Care Organization; HNHC = high-need, high-cost; IRR = incidence rate ratio; IVD = ischemic vascular disease; LDL-C = low-density lipoprotein cholesterol; MGH CMP = Massachusetts General Hospital, Care Management Program, N = number; NR = not reported; OBS = observational study; OR = odds ratio; PIC = Primary Intensive Care; RCT = randomized controlled trial; RoB = risk of bias; vs. = versus.

Table B-56. Cost outcomes for primary care–based model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost	RCT	⇩	⇩	Difference in change over time, G1 vs. G2: (p=0.82)[115]
	RCT	⬆	⬆	Original sample DiD: Lower increase in G1 than G2: -288 (82.1), (p<0.01)[86]
	RCT	⬆	⬆	Refresh sample DiD: Lower increase in G1 than G2: -355 (157.6), p<0.05[86]
	RCT	NR	NR	Greater reduction in G1 vs. G2: aMD=-7,732 (95% CI, -14,914 to -550) (p=0.036)[108]
	Observational	NR	NR	aMD=829 (95% CI, -1,279 to 3,098)[130]
Inpatient costs	Observational	NR	NR	aMD=297 (95% CI, -1,150 to 1,729)[130]
Pharmacy costs	Observational	NR	NR	aMD=110 (95% CI, -875 to 1,109)[130]
Outpatient costs	Observational	NR	NR	aMD=10 (95% CI, -439 to 492)[130]
Postacute costs	Observational	NR	NR	aMD=362 (95% CI, 150 to 569)[130]
ED costs	Observational	NR	NR	aMD=5 (95% CI, -155 to 171)[130]
Other costs	Observational	NR	NR	aMD=45 (95% CI, -159 to 262)[130]

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

aMD = adjusted mean difference; CI = confidence interval; DiD = difference-in-difference; Ed = emergency department; G = group; NR = not reported; RCT = randomized controlled trial; vs. = versus.

Table B-57. Clinical and functional outcomes for primary care–based model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality rate	RCT	Original sample difference: G1 vs. G2, -1.63 (p=0.19)[86]
	RCT	Refresh sample difference: lower in G1 than G2: -3.97 (p=0.04)[86]
Influenza vaccine	RCT	Original sample DiD: increased less in G1 than G2: OR=0.79 (95% CI, 0.66 to 0.95)[86]
	RCT	Refresh sample DiD: increased less in G1 than G2: OR=0.64 (95% CI, 0.46 to 0.87)[86]
PHC score	RCT	Better in G1 than G2: ANCOVA-adjusted intervention effect=2.3, p<0.01[86]
MHC score	RCT	ANCOVA-adjusted intervention effect=1.1, p>0.05[86]
PQH-2 score (depression 0 to 6)	RCT	ANCOVA-adjusted intervention effect=-0.03, p>0.05[86]
Number of ADLs difficult to do (0 to 6)	RCT	ANCOVA-adjusted intervention effect=-0.28, p>0.05[86]
Number ADLs receiving help (0 to 6)	RCT	ANCOVA-adjusted intervention effect=-0.21, p>0.05[86]
Patient satisfaction	RCT	Difference in change over time, G1 vs. G2: p=0.30[115]
SF-36 Summary Score	RCT	Difference in change over time, G1 vs. G2: p=0.32[115]
SF-36 Mental Health Function Score	RCT	Difference in change over time, G1 vs. G2: p=0.6[115]
Change in HAM-D score	RCT	Greater decrease in G1 than G2: p<0.001[99]
In remission (HAM-D <7)	RCT	Higher proportion in G1 than G2: p<0.001[99]
SF-20 subscale: Social Functioning	RCT	Better in G1 than G2: p<0.05 (data NR)[99]
SF-20 subscale: Mental Health	RCT	Better in G1 than G2: p<0.05 (data NR)[99]
SF-20 subscale: General Health	RCT	Better in G1 than G2: p<0.05 (data NR)[99]
SF-20 subscale: Physical Functioning	RCT	G1 vs. G2: p=NS (data NR)[99]
SF-20 subscale: Role Functioning	RCT	G1 vs. G2: p=NS (data NR)[99]
SF-20 subscale: Pain Perception	RCT	G1 vs. G2: p=NS (data NR)[99]
Helping to cope with a chronic condition (1 to 5)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=0.16, p>0.05[86]
Number of helpful discussion topics (0 to 5)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=-0.02, p>0.05[86]
Discussing treatment choices (1 to 4)	RCT	Better score in G1 than G2: ANCOVA-adjusted intervention effect=0.26, p<0.01[86]
Communicating with providers (0 to 100)	RCT	Better score in G1 than G2: ANCOVA-adjusted intervention effect=4.5, p<0.05[86]
Getting answers to questions quickly (0 to 100)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=5.0, p>0.05[86]
Multimorbidity Hassles score (0 to 24)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=-0.27, p>0.05[86]
Percentage receiving help setting goals	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=-5.6, p>0.05[86]
Percentage receiving help making a care plan	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=2.3, p>0.05[86]
Self-efficacy: Take all medications (1 to 5)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=0.05, p>0.05[86]
Self-efficacy: Plan meals and snacks (1 to 5)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=0.01, p>0.05[86]
Self-efficacy: Exercise 2 or 3 times weekly (1 to 5)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=0.11, p>0.05[86]

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Self-care activities: Prescribed medications taken (mean # of days)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=-0.10, p>0.05[86]
Self-care activities: Followed healthy eating plan (mean # of days)	RCT	G1 vs. G2 (N=590), ANCOVA-adjusted intervention effect=-0.16, p>0.05
Self-care activities: 30 minutes of continuous physical activity (mean # of days)	RCT	G1 vs. G2 (N=590): ANCOVA-adjusted intervention effect=-0.05, p>0.05[86]

ADL = activities of daily living; ANCOVA = analysis of covariance; CI = confidence interval; DiD = difference-in-difference; G = group; HAM-D = Hamilton Depression Rating Scale; G = group; MHC = mental health composite; NR = not reported; NS = not statistically significant; OR = odds ratio; PHC = physical health composite; PHQ-2 = Patient Health Questionnaire-2; RCT = randomized controlled trial; SF = short form; vs. = versus.

Table B-58. Clinical and functional outcomes for primary care–based model studies: Subgroup outcomes

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
HbA1c test	RCT	Original sample diabetes subgroup: DiD OR=0.99 (95% CI, 0.56 to 1.76)[86]
	RCT	Refresh sample diabetes subgroup: DiD OR=0.70 (95% CI, 0.27 to 1.84)[86]
LDL-C test	RCT	Original sample diabetes subgroup: DiD OR=0.85 (95% CI, 0.58 to 1.24)[86]
	RCT	Refresh sample diabetes subgroup: DiD OR=1.72 (95% CI, 0.86 to 3.42)[86]
	RCT	Original sample IVD subgroup: DiD OR=0.92 (95% CI, 0.63 to 1.33)[86]
	RCT	Refresh sample IVD subgroup: DiD OR=1.40 (95% CI, 0.76 to 2.58)[86]

CI = confidence interval; DiD = difference-in-difference; HbA1c = hemoglobin A1c; IVD = ischemic vascular disease LDL-C = low density lipoprotein cholesterol; OR = odds ratio; RCT = randomized controlled trial.

Table B-59. Social risk outcomes for primary care–based model studies

Social Risk Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Overall well-being	Observational	G1 vs. G2: p=NR[102]

G = group; NR = not reported; vs. = versus.

Table B-60. Study characteristics for home-based care interventions

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
McCall et al., 2010[84] CA, FL, TX	(Original N=16,077) Intervention (N=11,516) Comparison (N=4,561) (COPD subgroup N=3,344) Intervention (N=2,384) Comparison (N=960) (Diabetes subgroup N=4,502) Intervention (N=3,223) Comparison (N=1,279) (IVD subgroup N=7,356) Intervention (N=5,223) Comparison (N=2,133) (High-cost-only PBPM subgroup N=4,344) Intervention (N=3,105) Comparison (N=1,239) (High-cost and high-risk PBPM subgroup N=6,802) Intervention (N=4,845) Comparison (N=1,957)	RCT (RoB: some concerns)	High costs with top 5% of costs and 2+ hospitalizations in past 1 year	1+ diagnosis from a list, such as heart failure; HCC score was ≥2.75 OR if had an HCC score <2.75, had a diagnosis of selected clinical conditions including peripheral vascular disease, ischemic heart disease, hypertensive heart and/or kidney disease, heart failure, chronic obstructive pulmonary disease (COPD), and asthma	Medicare FFS beneficiaries	Nonwhite: 27% Mean HCC: 2.8

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
McCall et al., 2010[84] CA, FL, TX	(Refresh N=18,344) Intervention (N=13,104) Comparison (N=5,240) (COPD subgroup N=4,735) Intervention (N=3,393) Comparison (N=1,342) (Diabetes subgroup N=5,950) Intervention (N=4,199) Comparison (N=1,751) (IVD subgroup N=7,554) Intervention (N=5,384) Comparison (N=2,170) (High-cost-only PBPM subgroup N=1,414) Intervention (N=1,027) Comparison (N=387) (High-cost and high-risk PBPM subgroup N=8,598) Intervention (N=6,142) Comparison (N=2,456)	RCT (RoB: some concerns)	2+ hospitalizations in past 1 year	HCC score was >2.749	Medicare FFS beneficiaries; excluded beneficiaries with drug/alcohol psychosis or dependence, major depressive, bipolar, and paranoid disorders; institutionalized in last 3 months of previous year; had a hospital claims where discharge date was equal to admission date	Nonwhite: 40% Mean HCC: 3.8

First Author, Year, Site(s)	Sample Size	Study Design (Risk of Bias Assessment)	Patient Selection: High Healthcare Use or Cost; Time Period	Patient Selection: Chronic Conditions	Patient Selection: Other	Additional Selected Patient Characteristics
Kimmy et al., 2019[103] National: 14 practices	(Home-based care N=181,001) Intervention (N=30,324) Comparison (N=150,677)	Observational study (RoB: some concerns)	Hospitalization and use of acute or subacute rehabilitation services; and 1+ home visit from the IAH practice in past 1 year	2+ chronic conditions 2+ ADLs that require human assistance, new to home-based primary care (2+ E&M visits from a primary care clinician in the home or an assisted living facility during the 6-month period starting with the first home visit), majority of E&M visits from a primary care clinician during the same period must have taken place in the home or assisted living facility	Medicare FFS beneficiaries, new patients receiving home-based primary care who were IAH eligible and lived in an area served by an IAH practice	Mean HCC : 3.686 Chronically critically ill/medically complex: 29.1% Depression: 31.9%
Valluru et al., 2019[131] Philadelphia, PA; Richmond, VA; Washington, D.C.: 3 sites	(N=1,376) IAH patients at 3 sites (N=721) Comparison with home-based care (N=82) Comparison without home-based care (N=573)	Observational study (ROB: high)	Nonelective hospitalization and post-acute care use, either skilled home care or skilled nursing facility, in past year	2+ chronic conditions	Enrollment in 1 of 3 sites, FFS Medicare, score of 6+ in JEN Frailty Index	Percentage in age range: <75: 31% 75-84: 30% ≥85: 39% African American: 62% Medicaid: NR Medicare: 100% Mean HCC: 3.58

ADL = activities of daily living; CA = California; COPD = chronic obstructive pulmonary disease; E&M = evaluation and management; FFS = fee-for-service; FL = Florida; HCC = hierarchical condition category; IAH = Independence at Home; IVD = ischemic vascular disease; N = number; NR = not reported; OR = odds ratio; PA = Pennsylvania; PBPM = per beneficiary per month; RCT = randomized controlled trial; RoB = risk of bias; TX = Texas, VA = Virginia.

Table B-61. Intervention characteristics for home-based models

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(S)	Intensity	Comparison
McCall et al., 2010[84] CA, FL, TX	Evaluation of Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration: Care Level Management (CLM) home-based primary care for patients with multiple chronic conditions	Up to 29 months for original population, up to 18 months for refresh population	Assessment tool on patient acuity: number of admissions and emergency room visits within the last 6 months, presence of unmet social and emotional needs, expected number of PVP visits needed in the next 30 days, and presence of compliance, psychiatric, or ongoing home health issues	Provided home-based care and 24/7 access to a PVP to patients; care management addressed adherence to treatment regimens, coordination of care services, end-of-life planning, home safety, socioeconomic issues, psychosocial issues, and medication management	Helped selected beneficiaries receive services from community-based ancillary services as needed	PVPs, NPs to support PVPs, nurse care managers as patient advocates and care coordinators (PVPs were adjuncts to patients' PCP)	Face-to-face and by phone	12% had no contact, 75% of beneficiaries had one or more physician visits, 22% had 10 or more visits, and 14% had 20 or more visits. 88% of beneficiaries received a telephone call from a nurse or physician, while 24% received 10 or more calls, and 39% of beneficiaries received 20 or more calls	Usual care

First Author, Year, Site(s)	Intervention: Brief Description	Intervention Duration	Assessment, Education, Skills, Monitoring	Coordination and Continuity of Care	Referral to/Linkages to Community-Based Support Services	Providers	Mode of Delivery Setting(S)	Intensity	Comparison
Kimmy et al., 2019[103] Effect of home-based primary care National: 14 practices	Practices may earn an additional payment if their chronically ill, functionally limited patients' Medicare expenditures are below an estimated spending target and if the practice meets required standards for a set of quality measures	Up to 4 years	Clinicians are available at all hours of the day; carry out individualized care plans; and use electronic health information systems, remote monitoring, and mobile diagnostic technology	Report on other measures, including fall risk assessments and depression screenings, to promote the provision of such care	Some practices added social workers or other staff to coordinate care for their patients with other organizations	Physicians or nurse practitioners; team may have also included physician assistants, clinical staff, and other health and social services staff	Face-to-face	Clinicians made 3-15 home visits per day, varied by site	Usual care: Patients who did not receive primary care in the home during the 6 months after their index date
Valluru et al., 2019[131] Philadelphia, PA; Richmond, VA; Washington, DC: 3 sites	Home-based primary care integrated with long-term service supports (LTSS)	36 months	NR	Integrated care coordination with community supports including adult day healthcare and home health aide-provided personal care services	Assistance with meals and transportation and social workers who collaborate with various community LTSS resources	Care managers, case managers, or social workers depending on the site	Face-to-face in patient home	NR	Usual care: Home-based care without long-term services and supports or no home-based care

CA = California; CLM = care level management; CMHCB = Care Management for High Cost Beneficiaries; DC = District of Columbia; FL = Florida; LTSS = long-term services and supports NP = nurse practitioner; NR = not reported; PA = Pennsylvania; PCP = primary care provider; PVP = personal visiting physician; TX = Texas; VA = Virginia.

Table B-62. Healthcare utilization outcomes for home-based care model studies

Utilization Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Inpatient admissions, all cause	RCT	⇩	⇩	Original sample DiD: IRR=0.94 (95% CI, 0.87 to 1.01)[84]
	RCT	⇩	⇩	Refresh sample DiD: IRR=0.94 (95% CI, 0.88 to 1.00)[84]
	Observational	NR	NR	Lower reduction in G1 than G2: home-based care DiD=0.05 (90% CI, 0.01 to 0.09)[103]
Inpatient admissions, any all cause (%)	RCT	⇩	⇩	Original sample DiD: OR=1.05 (95% CI, 0.93 to 1.18)[84]
	RCT	⇩	⇩	Refresh sample DiD: OR=.93 (95% CI, 0.85 to 1.03)[84]
Inpatient admissions, ACSC	RCT	⬇	⬆	Greater reduction in G1 than G2: original sample DiD: IRR=0.86 (95% CI, 0.76 to 0.97)[84]
	RCT	⬇	⬆	Greater reduction in G1 than G2: refresh sample DiD: IRR=0.89 (95% CI, 0.81 to 0.99)[84]
	Observational	NR	NR	Home-based care sample DiD=0.00 (90% CI, -0.02 to 0.02)[103]
Inpatient admissions, any ACSC (%)	RCT	⬇	⬇	Greater reduction in G1 than G2: original sample DiD: OR=0.87 (95% CI, 0.77 to 0.99)[84]
	RCT	⬇	⬇	Greater reduction in G1 than G2: refresh sample DiD: OR=.90 (95% CI, 0.81 to 1.00)[84]
ED visits, all cause	RCT	⇩	⇩	Original sample DiD: IRR=0.88 (95% CI, 0.69 to 1.12)[84]
	RCT	⇧	⇧	Refresh sample DiD: IRR=0.95 (95% CI, 0.85 to 1.07)[84]
	Observational	NR	NR	Home-based care DiD=0.00 (90% CI, -0.04 to 0.05) (p>0.10)[103]
ED visits, ACSC	RCT	⇩	⇩	Original sample DiD: IRR=0.89 (95% CI, 0.66 to 1.18)[84]
	RCT	⇧	⇧	Refresh sample DiD: IRR=1.06 (95% CI, 0.87 to 1.30)[84]
	Observational	NR	NR	Home-based care DiD=0.00 (90% CI, -0.02 to 0.01) (p>0.10)[103]
Long-term institutionalization rate	Observational	NR	NR	G1: 8.1%, G2 with home-based care: 17.7%, G2 without home-based care: 16.4%: p<0.05[131]

⬆ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⬇ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was statistically significant.

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

ACSC = ambulatory care sensitive conditions; CI = confidence interval; DiD = difference-in-difference; ED = emergency department; G = group; IRR = incidence rate ratio; NR = not reported; OR = odds ratio; RCT = randomized controlled trial.

Table B-63. Strength of evidence for home-based care models versus usual-care outcomes

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	ED visits, all cause	CLM original sample DiD: IRR=0.88 (95% CI, 0.69 to 1.12)[84] CLM refresh sample DiD: IRR=0.95 (95% CI, 0.85 to 1.07)[84] IAH home-based care: higher use in G1 than G2: DiD=0.00 (90% CI, -0.04 to 0.05), (p>0.10)[103]	2 RCTs, N=34,421 1 OBS, N=181,246	Moderate study limitations, imprecise, inconsistent, direct	Insufficient
HNHC patients	ED visits, ACSC	CLM original sample DiD: IRR=0.89 (95% CI, 0.66 to 1.18)[84] CLM refresh sample DiD: IRR=1.06 (95% CI, 0.87 to 1.30)[84] IAH home-based care sample DiD=0.00 (90% CI, -0.02 to 0.01, p>0.10)[103]	2 RCTs, N=34,421 1 OBS, N=181,246	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients	Inpatient admissions, all cause	CLM original sample: IRR=0.94 (95% CI, 0.87 to 1.01)[84] CLM refresh sample: IRR=0.94 (95% CI, 0.88 to 1.00);[84] IAH home-based care: lower reduction in G1 than G2: DiD=0.05 (90% CI, 0.01 to 0.09)[103]	2 RCTs, N=34,421 1 OBS, N=181,246	Moderate study limitations, imprecise, inconsistent, direct	Insufficient
HNHC patients	Inpatient admissions, ACSC	CLM original sample: DiD: IRR=0.86 (95% CI, 0.76 to 0.97)[84] CLM refresh sample: DiD: IRR=0.89 (95% CI, 0.81 to 0.99)[84] IAH home-based care sample: DiD=0.00 (90% CI, -0.02 to 0.02)[103]	2 RCTs, N=34,421 1 OBS, N=181,246	Moderate study limitations, imprecise, consistent, direct	Low (Favorable)
HNHC patients	Inpatient admissions, any all cause (%)	CLM original sample: DiD: OR=1.05 (95% CI, 0.93 to 1.18)[84] CLM refresh sample: DiD: OR=0.93 (95% CI, 0.85 to 1.03)[84]	2 RCTs, N=34,421	Moderate study limitations, imprecise, inconsistent, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
HNHC patients	Inpatient admissions, any ACSC (%)	CLM original sample: DiD: OR=0.87 (95% CI, 0.77 to 0.99)[84] CLM refresh sample: DiD: OR=0.90 (95% CI, 0.81 to 1.00)[84]	2 RCTs, N=34,421	Moderate study limitations; precise, consistent, direct	Low (Favorable)
HNHC patients	Total cost	CLM original sample DiD=41 ($p>0.05$);[84] CLM refresh sample DiD=-29 ($p>0.05$)[84] IAH home-based care sample DiD=451 (90% CI, 342.4 to 559.6, $p<0.10$)[103]	2 RCTs, N=34,421 1 OBS, N=181,246	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
High-cost, high risk patient subgroup	Total cost	CLM original sample: DiD=107 ($p>0.05$)[84] CLM refresh sample DiD=-21 ($p>0.05$)[84]	2 RCTs, N=15,400	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
High-cost only patient subgroup	Total cost	CLM original sample DiD=-170 ($p>0.05$)[84] CLM refresh sample: DiD=-236 ($p>0.05$)[84]	2 RCTs, N=5,758	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients	Mortality rate	CLM original sample: diff in mean rate=0.4, ($p=0.63$)[84] CLM refresh sample: Diff in mean rate=0.1 ($p=0.88$)[84] IAH LTSS: G1 vs. G2 with HBC and G2 without HBC=NR ($p>0.05$)[131]	2 RCTs, N=34,421 1 OBS, N=1,376	Moderate study limitations, consistent, imprecise, direct	Low (No difference)
HNHC patients	Influenza vaccine	CLM original sample: DiD OR=1.15 (95% CI, 1.02 to 1.30)[84] CLM refresh sample: DiD OR=1.15 (95% CI, 1.03 to 1.27)[84]	2 RCTs, N=34,421	Moderate study limitations, consistent, precise, direct	Low (Favorable)
HNHC patients COPD subgroup	Oxygen saturation test	CLM original sample: DiD OR=1.02 (95% CI, 0.77 to 1.34)[84] CLM refresh sample: DiD OR=0.97 (95% CI, 0.77 to 1.22)[84]	2 RCTs, N=8,079	Moderate study limitations, inconsistent, imprecise, direct	Insufficient
HNHC patients Diabetes subgroup	HbA1c test	CLM original sample: DiD OR=0.91 (95% CI, 0.74 to 1.13)[84] CLM refresh: DiD OR=0.98 (95% CI, 0.82 to 1.18)[84]	2 RCTs, N=10,452	Moderate study limitations, consistent, imprecise, direct	Insufficient
HNHC patients Diabetes subgroup	LDL-C test	CLM original sample: DiD OR=0.92 (95% CI, 0.75 to 1.12)[84] CLM refresh sample: DiD OR=0.97 (95% CI, 0.77 to 1.22)[84]	2 RCTs, N=10,452	Moderate study limitations, consistent, imprecise, direct	Insufficient

Population	Outcome	Results	Study Design and Sample Size	Strength of Evidence Domains	Overall Evidence Strength (Direction of Effect)
IVD patient Subgroup	LDL-C test	CLM original sample: DiD OR=0.89 (95% CI, 0.76 to 1.05)[84] CLM refresh sample: DiD OR=0.95 (95% CI, 0.81 to 1.11)[84]	2 RCTs, N=14,910	Moderate study limitations, consistent, imprecise, direct	Insufficient

ACSC = ambulatory care sensitive conditions; CI = confidence interval; CLM = care level management; COPD = chronic obstructive pulmonary disease; DiD = difference-in-difference; ED = emergency department; G = group; HbA1c = hemoglobin A1c; HBC = home-based care; HNHC = high-need, high-cost; IAH = Independence at Home; IRR = incidence rate ratio; IVD = ischemic vascular disease; LDL-C = low-density lipoprotein cholesterol; LTSS = long-term services and supports; N = number; NR = not reported; OBS = observational study; OR = odds ratio; RCT = randomized controlled trial; vs. = versus.

Table B-64. Cost outcomes for home-based care model studies

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost	RCT	⇩	⇩	Original sample DiD=41 (SE: 67.9) (p>0.05)[84]
	RCT	⇧	⇧	Refresh sample DiD=-29 (SE: 73.1) (p>0.05)[84]
	Observational	NR	NR	Greater increase in G1 than G2: home-based care DiD=$451 (SE: 66) (90% CI, 342.4 to 559.6)[103]

⇧ = Increase in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

CI = confidence interval; DiD = difference in difference; G = group; NR = not reported; NS = not statistically significant; RCT = randomized controlled trial; SE = standard error.

Table B-65. Cost outcomes for home-based care model studies: Subgroup outcomes

Cost Measures	Study Design	Direction of Change in Intervention Group (G1)	Direction of Change in Comparison Group (G2)	Difference
Total cost	RCT	⇩	⇩	Original sample high-cost, high-risk subgroup DiD=107 (SE: 127.6) (p>0.05)[84]
	RCT	⇩	⇩	Refresh sample high-cost, high-risk subgroup DiD=-21 (SE: 121.3) (p>0.05)[84]
	RCT	⇩	⇩	Original sample high-cost-only subgroup DiD=-170 (SE: 104.0) (p>0.05)[84]
	RCT	⇩	⇩	Refresh sample high-cost-only subgroup DiD=-236 (SE: 197.5) (p>0.05)[84]

⇩ = Reduction in the outcome between the intervention period and the baseline period; the difference between the intervention and comparison groups was not statistically significant.

DiD = difference-in-difference; G = group; RCT = randomized controlled trial; SE = standard error.

Table B-66. Clinical and functional outcomes for home-based care model studies

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Mortality rate	RCT	Original sample: difference in mean rates=0.4, (p=0.63)[84]
	RCT	Refresh sample: difference in mean rates=0.1 (p=0.88)[84]
	OBS	G1: 35.8%, G2 with home-based care: 24.9%, G2 without home-based care: 26.9%: p>0.05[131]
Influenza vaccine	RCT	DiD greater in G1 than G2: original sample: DiD OR=1.15 (95% CI, 1.02 to 1.30)[84]
	RCT	DiD greater in G1 than G2: refresh sample: DiD OR=1.15 (95% CI, 1.03 to 1.27)[84]
PHC score (physical health)	RCT	Greater in G1 than G2: ANCOVA-adjusted IE=2.1 (p<0.05[84])
MHC score (mental health)	RCT	ANCOVA-adjusted IE=1.7 (p>0.05[84])
PHQ-2 score (depression)	RCT	ANCOVA-adjusted IE=0.26 (p>0.05[84])
Number of activities of daily living (ADLs) difficult to do	RCT	ANCOVA-adjusted IE=0.03 (p>0.05[84])
Number ADLs receiving help	RCT	ANCOVA-adjusted IE=0.00 (p>0.05[84])
Helping to cope with a chronic condition	RCT	ANCOVA-adjusted IE=0.19 (p>0.05[84])
Number of helpful discussion topics	RCT	ANCOVA-adjusted IE=0.20 (p>0.05[84])
Discussing treatment choices	RCT	Greater in G1 than G2: ANCOVA-adjusted IE=0.23 (p<0.05[84])
Communicating with providers	RCT	Greater in G1 than G2: ANCOVA-adjusted IE=6.55 (p<0.01[84])
Getting answers to questions quickly	RCT	ANCOVA-adjusted IE=4.90 (p>0.05[84])
Multimorbidity Hassles score	RCT	ANCOVA-adjusted IE=-0.44 (p>0.05[84])
Percentage receiving help setting goals	RCT	ANCOVA-adjusted IE=6.1 (p>0.05[84])
Percentage receiving help making a care plan	RCT	ANCOVA-adjusted IE=3.9 (p>0.05[84])
Self-efficacy: Take all medications	RCT	ANCOVA-adjusted IE=0.20 (p>0.05[84])
Self-efficacy: Plan meals and snacks	RCT	ANCOVA-adjusted IE=0.15 (p>0.05[84])
Self-efficacy: Exercise 2 or 3 times weekly	RCT	ANCOVA-adjusted IE=0.20 (p>0.05[84])
Self-care activities: Prescribed medications taken	RCT	ANCOVA-adjusted IE=0.06 (p>0.05[84])
Self-care activities: Followed healthy eating plan	RCT	ANCOVA-adjusted IE=-0.03 (p>0.05[84])
Self-care activities: 30 minutes of continuous physical activity	RCT	Greater in G1 than G2: ANCOVA-adjusted IE=0.63 (p<0.05[84])

ADL = activities of daily living; ANCOVA = analysis of covariance; CI = confidence interval; DiD = difference-in-difference; G = group; IE = intervention effect; MHC = mental health composite; OR = odds ratio; PHC = physical health composite; PHQ-2 = patient health questionnaire-2; RCT = randomized controlled trial.

Table B-67. Clinical and functional outcomes for home-based care model studies: Subgroup outcomes

Clinical and Functional Outcomes	Study Design	Difference Between Intervention Group (G1) and Comparison Group (G2)
Oxygen saturation test	RCT	Original sample COPD subgroup: DiD OR=1.02 (95% CI, 0.77 to 1.34)[84]
	RCT	Refresh sample COPD subgroup: DiD OR=0.97 (95% CI, 0.77 to 1.22)[84]
HbA1c test	RCT	Original sample diabetes subgroup: DiD OR=0.91 (95% CI, 0.74 to 1.13)[84]
	RCT	Refresh sample diabetes subgroup: DiD OR=0.98 (95% CI, 0.82 to 1.18)[84]
LDL-C test	RCT	Original sample diabetes subgroup: DiD OR=0.92 (95% CI, 0.75 to 1.12)[84]
	RCT	Refresh sample diabetes subgroup: DiD OR=0.97 (95% CI, 0.77 to 1.22)[84]
	RCT	Original sample IVD subgroup: DiD OR=0.89 (95% CI, 0.76 to 1.05)[84]
	RCT	Refresh sample IVD subgroup: DiD OR=0.95 (95% CI, 0.81 to 1.11)[84]

CI = confidence interval; COPD = chronic obstructive pulmonary disease; DiD = difference-in-difference; HbA1c = hemoglobin A1c; IVD = ischemic vascular disease; LDL-C = low-density lipoprotein-cholesterol; OR = odds ratio; RCT = randomized controlled trial.

Appendix B Figures

Figure B-2. System-level transformation models versus usual care, total cost

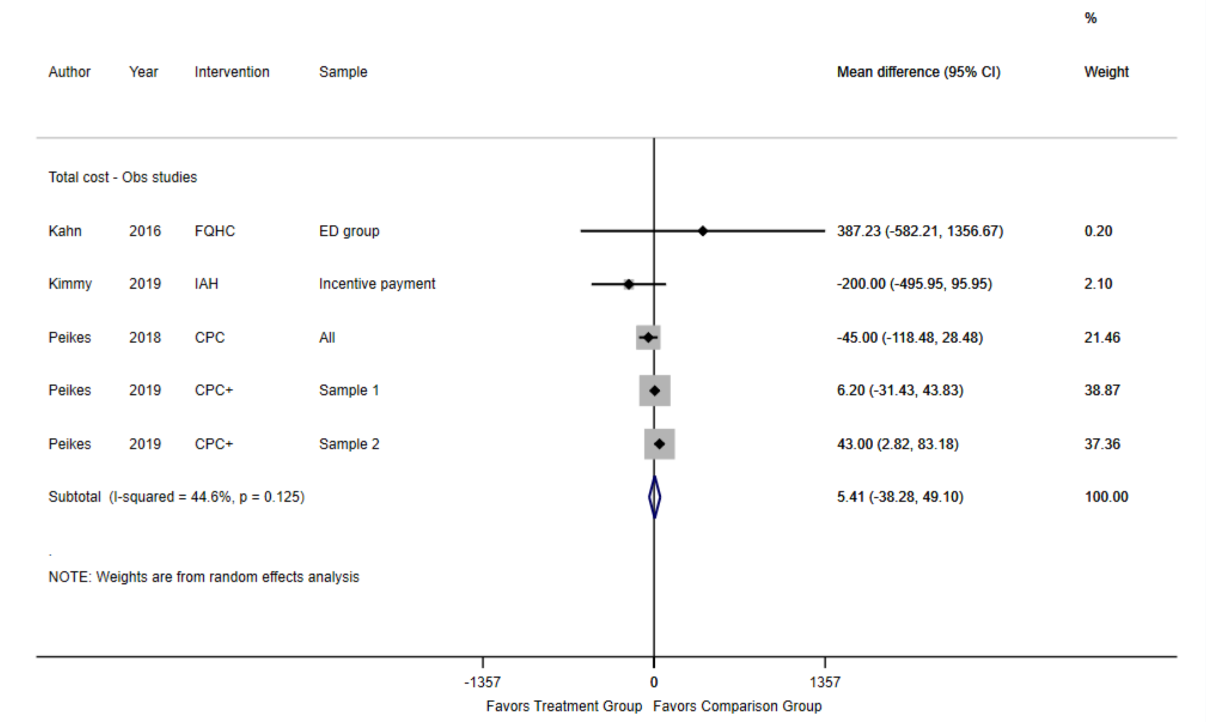


Figure B-3. Telephonic/mail models versus usual care, all-cause ED visits

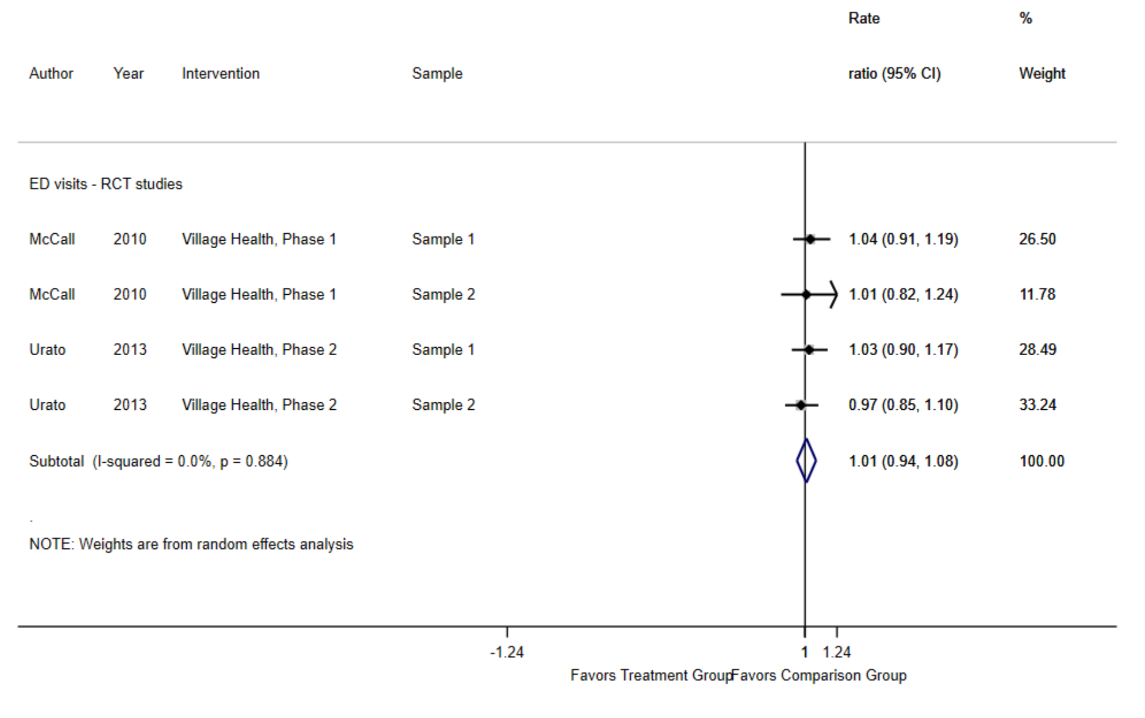
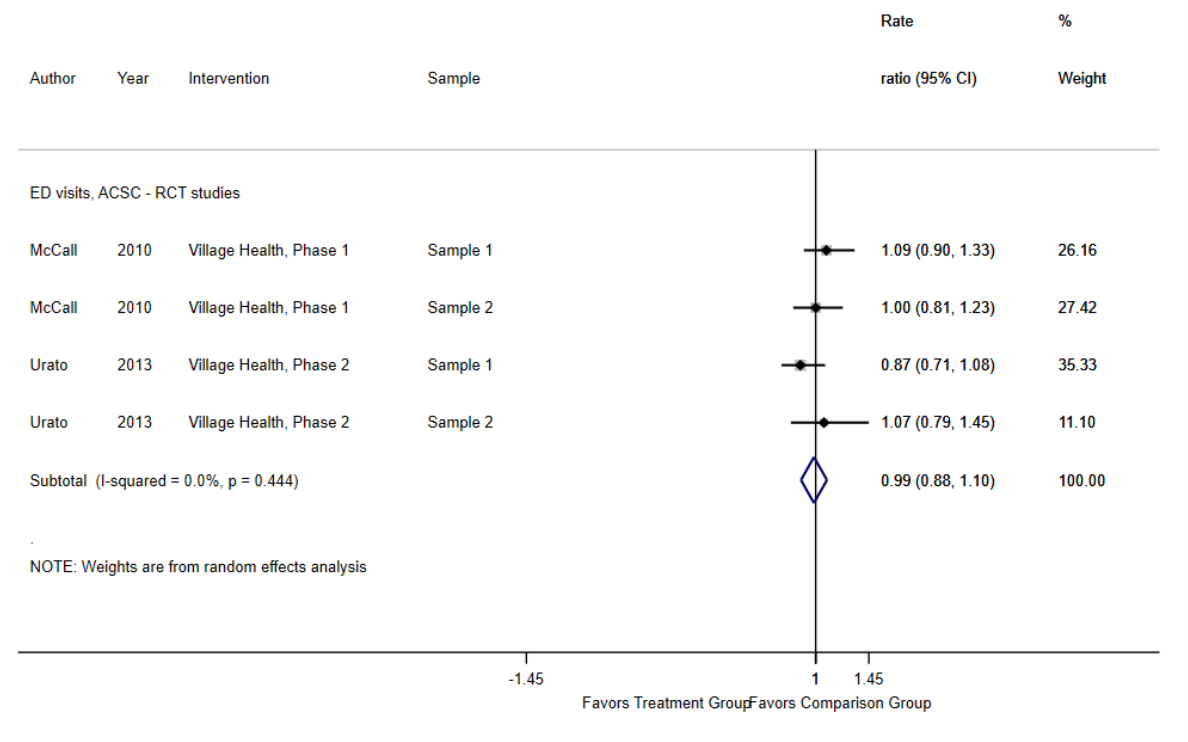


Figure B-4. Telephonic/mail models versus usual care, ACSC ED visits

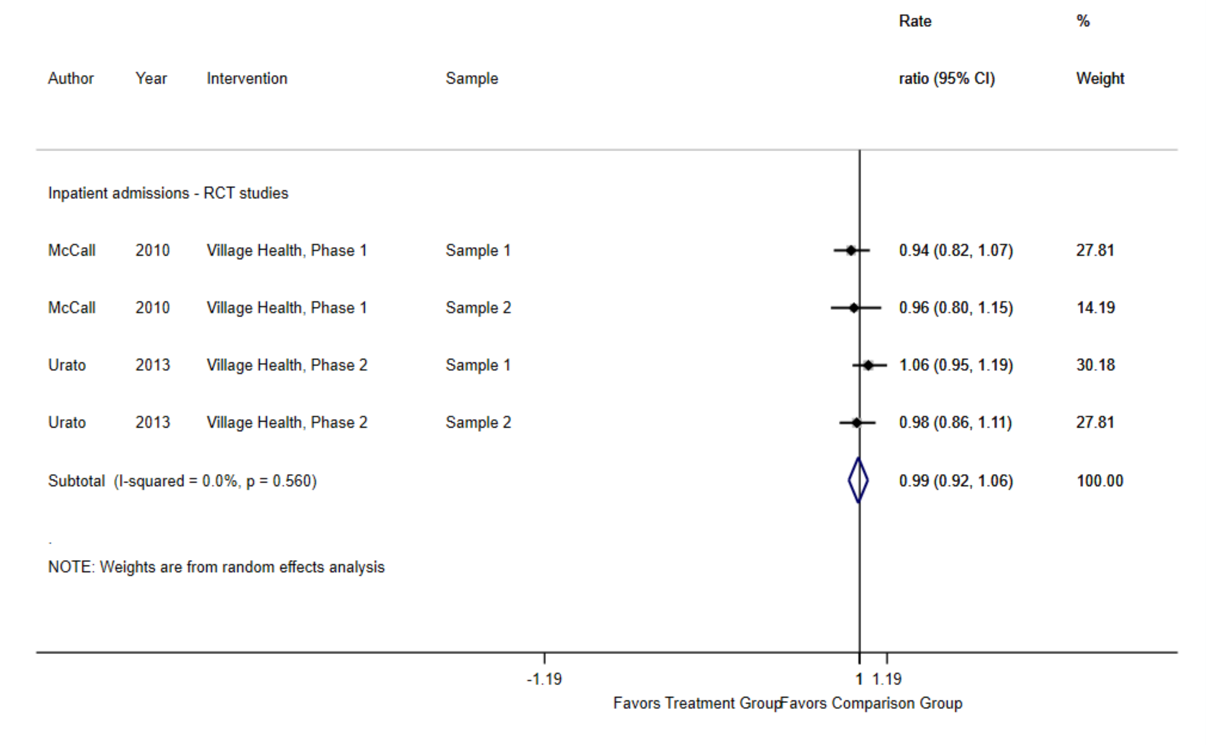


Author	Year	Intervention	Sample	Rate ratio (95% CI)	% Weight
ED visits, ACSC - RCT studies					
McCall	2010	Village Health, Phase 1	Sample 1	1.09 (0.90, 1.33)	26.16
McCall	2010	Village Health, Phase 1	Sample 2	1.00 (0.81, 1.23)	27.42
Urato	2013	Village Health, Phase 2	Sample 1	0.87 (0.71, 1.08)	35.33
Urato	2013	Village Health, Phase 2	Sample 2	1.07 (0.79, 1.45)	11.10
Subtotal (I-squared = 0.0%, p = 0.444)				0.99 (0.88, 1.10)	100.00

.

NOTE: Weights are from random effects analysis

Figure B-5. Telephonic/mail models versus usual care, all-cause inpatient admissions

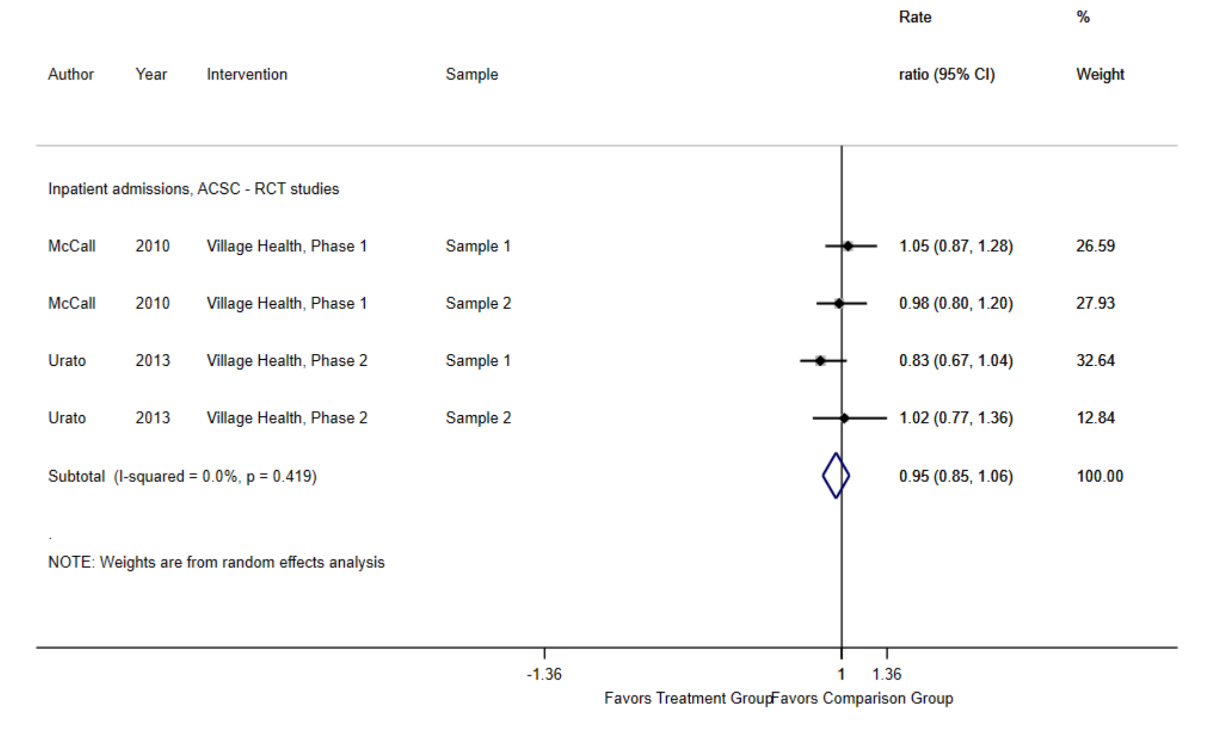


Author	Year	Intervention	Sample	Rate ratio (95% CI)	% Weight
Inpatient admissions - RCT studies					
McCall	2010	Village Health, Phase 1	Sample 1	0.94 (0.82, 1.07)	27.81
McCall	2010	Village Health, Phase 1	Sample 2	0.96 (0.80, 1.15)	14.19
Urato	2013	Village Health, Phase 2	Sample 1	1.06 (0.95, 1.19)	30.18
Urato	2013	Village Health, Phase 2	Sample 2	0.98 (0.86, 1.11)	27.81
Subtotal (I-squared = 0.0%, p = 0.560)				0.99 (0.92, 1.06)	100.00

.

NOTE: Weights are from random effects analysis

Figure B-6. Telephonic/mail models versus usual care, ACSC inpatient admissions



Author	Year	Intervention	Sample	Rate ratio (95% CI)	% Weight
Inpatient admissions, ACSC - RCT studies					
McCall	2010	Village Health, Phase 1	Sample 1	1.05 (0.87, 1.28)	26.59
McCall	2010	Village Health, Phase 1	Sample 2	0.98 (0.80, 1.20)	27.93
Urato	2013	Village Health, Phase 2	Sample 1	0.83 (0.67, 1.04)	32.64
Urato	2013	Village Health, Phase 2	Sample 2	1.02 (0.77, 1.36)	12.84
Subtotal (I-squared = 0.0%, p = 0.419)				0.95 (0.85, 1.06)	100.00

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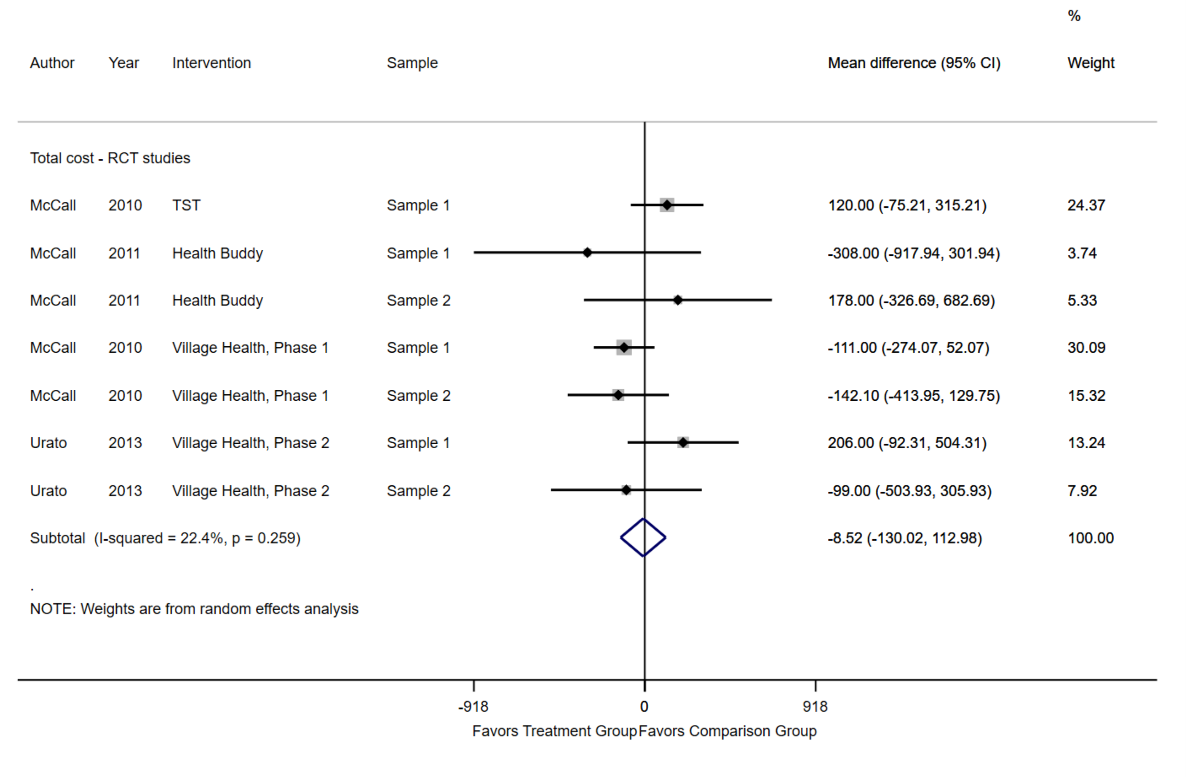
NOTE: Weights are from random effects analysis

Figure B-7. Telephonic/mail models versus usual care, total cost



Author	Year	Intervention	Sample	Mean difference (95% CI)	% Weight
Total cost - RCT studies					
McCall	2010	TST	Sample 1	120.00 (-75.21, 315.21)	24.37
McCall	2011	Health Buddy	Sample 1	-308.00 (-917.94, 301.94)	3.74
McCall	2011	Health Buddy	Sample 2	178.00 (-326.69, 682.69)	5.33
McCall	2010	Village Health, Phase 1	Sample 1	-111.00 (-274.07, 52.07)	30.09
McCall	2010	Village Health, Phase 1	Sample 2	-142.10 (-413.95, 129.75)	15.32
Urato	2013	Village Health, Phase 2	Sample 1	206.00 (-92.31, 504.31)	13.24
Urato	2013	Village Health, Phase 2	Sample 2	-99.00 (-503.93, 305.93)	7.92
Subtotal (I-squared = 22.4%, p = 0.259)				-8.52 (-130.02, 112.98)	100.00

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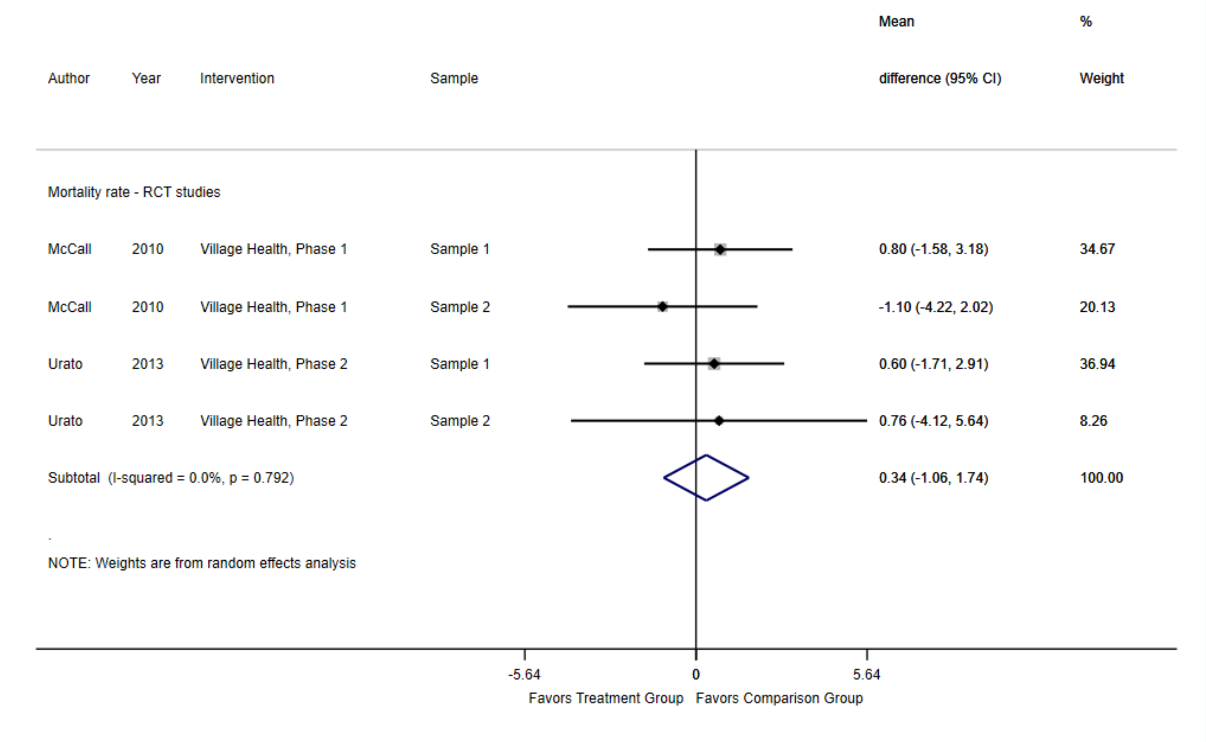
NOTE: Weights are from random effects analysis

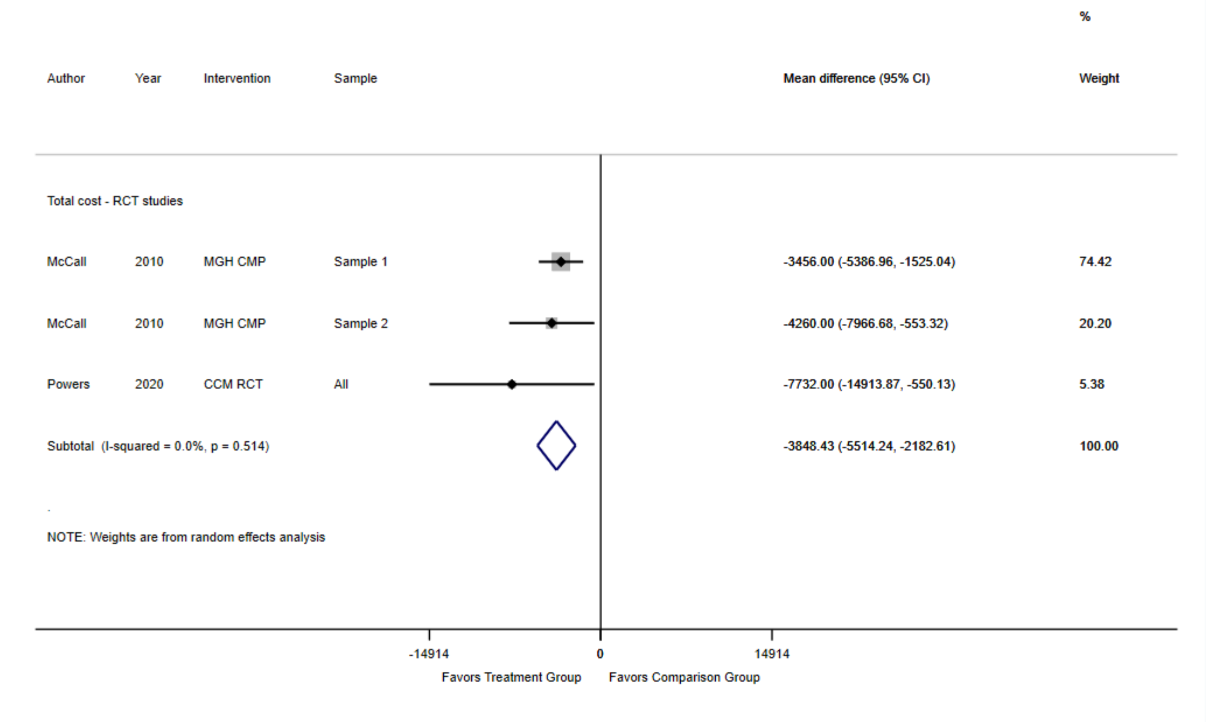
Figure B-8. Telephonic/mail models versus usual care, mortality rate



Author	Year	Intervention	Sample	Mean difference (95% CI)	% Weight
Mortality rate - RCT studies					
McCall	2010	Village Health, Phase 1	Sample 1	0.80 (-1.58, 3.18)	34.67
McCall	2010	Village Health, Phase 1	Sample 2	-1.10 (-4.22, 2.02)	20.13
Urato	2013	Village Health, Phase 2	Sample 1	0.60 (-1.71, 2.91)	36.94
Urato	2013	Village Health, Phase 2	Sample 2	0.76 (-4.12, 5.64)	8.26
Subtotal (I-squared = 0.0%, p = 0.792)				0.34 (-1.06, 1.74)	100.00

NOTE: Weights are from random effects analysis

Figure B-9. Primary care models versus usual care, total cost



Author	Year	Intervention	Sample	Mean difference (95% CI)	% Weight
Total cost - RCT studies					
McCall	2010	MGH CMP	Sample 1	-3456.00 (-5386.96, -1525.04)	74.42
McCall	2010	MGH CMP	Sample 2	-4260.00 (-7966.68, -553.32)	20.20
Powers	2020	CCM RCT	All	-7732.00 (-14913.87, -550.13)	5.38
Subtotal (I-squared = 0.0%, p = 0.514)				-3848.43 (-5514.24, -2182.61)	100.00

NOTE: Weights are from random effects analysis

Appendix C. Appendix References

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