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

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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.

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

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 or predict 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 September 7, 2019. We included quantitative and qualitative studies of HNHC patients (high healthcare use or cost), over the age of 18, and who received intervention services in a variety of settings.

Results. We included 94 studies (100 articles). Consistent with our best fit framework, characteristics associated with HNHC include patient chronic clinical conditions, several chronic disease rating scales, behavioral health factors including depression and substance use disorder, and social risk factors including homelessness and poverty. Prior healthcare use was also an important predictor. Only one study identified potentially preventable high use and found a correlation between higher than expected expenditures and potentially preventable healthcare events, which persisted across subsequent years. 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, community, and home-based care models result in reduced use of healthcare services (moderate to low strength of evidence [SOE]); ED, aICU, and primary care models result in reduced costs (moderate to low SOE); and system-level transformation and telephonic/mail models do not result in changes in costs (low SOE).

Conclusions. Patient characteristics available through electronic data sources 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 provide little information for determining why individual programs work, for whom, and when.

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Appendixes

Appendix A: Detailed Methods
Appendix B: Results

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

Main Points

- Patient data from claims and health records can identify characteristics associated with being high-need, high-cost (HNHC) 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.
- We developed program theories explaining context-mechanism-outcome relationships concerning HNHC patient recruitment, patient engagement, and provider engagement in HNHC interventions.
- Identifying and targeting HNHC patients require processes that capture patients' medical and social complexities. Engaging HNHC patients and care providers to build and maintain trusting, caring relationships underpins successful interventions that target HNHC patients. Both patients and care providers require emotional support and practical resources to foster an effective relationship.
- We found moderate to low strength of evidence (SOE) that emergency department (ED), primary care, community, and home-based care models are associated with reduced use of healthcare services; moderate to low SOE that ED, ambulatory intensive caring unit (aICU), and PCP models are associated with reduced costs; and low SOE that system-level transformation and telephonic/mail models are not associated with cost differences.

Background and Purpose

In the United States, payers, health systems, and providers have increasingly focused on the HNHC patient population. Although constituting a small percentage of the patient population, HNHC patients account for a disproportionally high level of healthcare utilization and cost. 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 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 in KQ 1, we used the best-fit framework synthesis approach; to examine the causal mechanisms and contexts leading to reductions in healthcare use and cost for KQ 2, we used realist review methodology; and to synthesize the effectiveness of interventions targeting HNHC patients for KQ 3, we used systematic review methodology. We searched multiple databases and the gray literature using publication dates from January 1, 2000, to September 7, 2019. We included quantitative and qualitative studies of adult HNHC patients (high healthcare use or cost) who received intervention services in a variety of settings. We describe our methods in the full report.

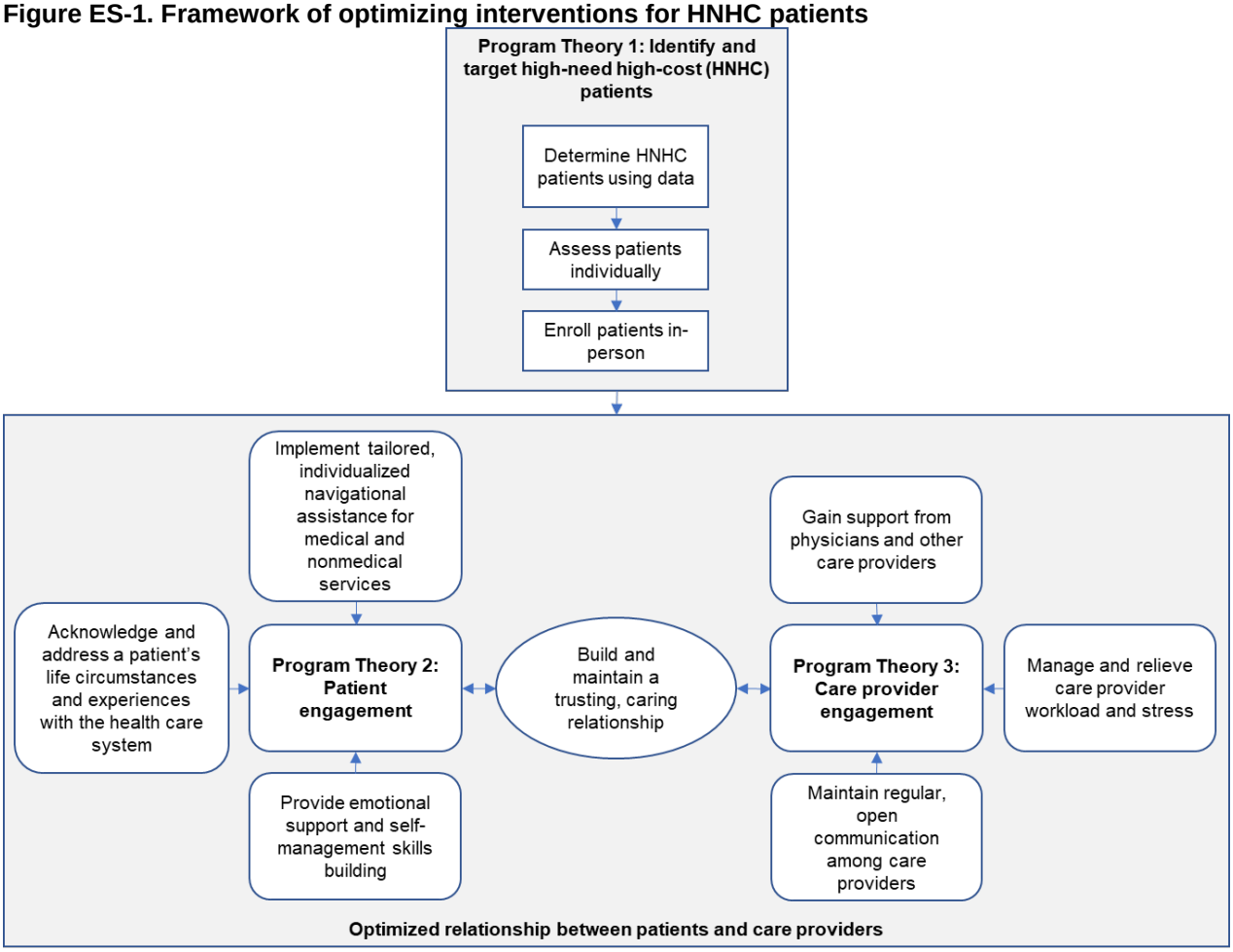
Results

We included 94 studies (100 articles) in our review. KQ 1 included 53 studies (55 articles). KQ 2 included 42 studies (45 articles; 14 articles were also evidence for KQ 1 and 22 articles for KQ 3). KQ 3 included 32 studies (36 articles) assessing intervention effectiveness.

KQ 1: Criteria that can be used to identify or predict HNHC patients. Consistent with a National Academy of Medicine framework, we found several characteristics were associated with being HNHC, including patient chronic conditions (e.g., diabetes); several health rating scales; behavioral health risk factors including depression and substance use disorder; and social risk factors including homelessness and poverty. Prior high use predicted future high use, generally, and by payer. A single study differentiated between potentially preventable high use and any high use. The study found an association between higher-than-expected expenditures and preventable health care events in subsequent years.

KQ 2: Contexts, mechanisms, and outcomes of interventions that lead to preventable or modifiable health care use among HNHC patients. We developed three realist program theories; Figure ES-1 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 patients are enrolled, engaging HNHC patients in interventions requires building a trusting relationship between the patient and care provider. Tailored, individualized assistance for medical and nonmedical needs and provision of emotional support and self-management education empowers 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 ES-1. 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, PCP, and home based).

ED-based models are associated with a reduction in ED visits and ED costs (moderate SOE) and a favorable increase in primary care visits (low SOE). aICU models (a separate clinic or team within a clinic) are associated with a reduction in costs (low SOE). Community-based models are also associated with a reduction in ED visits (low SOE). Primary care-based models are associated with a reduction in hospital admissions (moderate SOE) and ED visits and total costs (low SOE). Home-based care models are associated with a reduction in inpatient admissions for ambulatory care sensitive conditions (moderate SOE). System-level transformation and telephonic/mail models did not achieve lower costs (low SOE for the conclusion of no difference between the intervention and comparison groups). The studies identified virtually no harms. Studies reported few health and patient-reported and no social risk outcomes, so 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 interpreting the evidence identifying patient characteristics associated with being HNHC is inconsistent control for confounding across studies. As a result, the incremental effect of individual factors differed across studies. For the realist review, our analysis depended primarily on the effectiveness studies included in the systematic review, and many of the intervention effectiveness studies contained minimal evidence for constructing our program theories. This focus on the effectiveness literature may have limited our ability to fully explain the mechanisms associated with interventions targeting HNHC patients. For the systematic review, our method of grouping the studies directly affected what and how outcomes were graded. Given the complexity of the interventions, other researchers may group studies differently.

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 HNHC candidates for interventions is improved through individualized participant selection. Similarly, interventions themselves need to be individualized to address the complex needs of HNHC individuals. 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 increasingly 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 amount of healthcare utilization 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 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 utilization.[12, 13] Also, focusing on use and cost alone can obscure detecting 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. 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 include studies of high cost or use patients that meet our other inclusion criteria. Within this larger group of studies, we will highlight analyses

that more directly focus on patients whose use of healthcare services would be considered inappropriate and is potentially preventable or modifiable.

Description of the HNHC Population

A common approach to describing the magnitude of the HNHC population nationally is in relation to the concentration of healthcare costs or use that can be 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 similarly 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 age 65 years or older, 4.5 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 the total number of ED visits and 24 percent of ED charges. Further, a systematic review on frequent ED use across payers found that, across studies, approximately 4.5 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 population can also 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 persons with disability, each additional chronic condition was associated, on average, with an 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 (30.5%), 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 and extends upon a systematic review by Wammes et al. of characteristics associated with high-cost patients[27] and numerous reviews of interventions for these patients. The Wammes et al. review examined the characteristics of high-cost patients in high-income countries.[27] The review documented the variety of definitions of "high cost" and elucidated factors associated with high healthcare costs, organized according to Anderson's model of predisposing, enabling, and need characteristics. The authors 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.

The present review modifies the approach of the Wammes et al. review in several ways. The Wammes et al. review included studies from multiple countries while we limit our work to the United States so the findings are generalizable to the United States' healthcare coverage and

delivery systems.[27] We also examine HNHC patient characteristics associated with important categories of high utilization, in addition to cost. The categorization of diseases in the Wammes et al. review, by larger International Classification of Diseases (ICD) code groupings, meant that specificity was lost regarding specific diagnostic categories of interest (e.g., substance use and specific mental health disorders within the larger category of mental and behavioral disorders). These conditions are emerging in our understanding as being critical to HNHC. Also, the prior work did not include models of characteristics predicting use in a future period, only cross-sectional studies. Finally, instead of using the Anderson model, we group our predictor variables using the organizational framework developed by the National Academy of Medicine.[20]

Multiple reviews have attempted to synthesize the literature on interventions to decrease utilization or costs or to improve clinical outcomes among HNHC patients.[12-16, 27-32] Reviews describe interventions targeted to an entire HNHC population (e.g., a single ED's high utilization population)[12, 13, 28-31] or to a specific subgroup (e.g., persons with multiple chronic conditions).[14, 16, 32] Some reviews include any interventions that have the goal to reduce cost or utilization as the outcome,[12, 13, 28-30, 32] whereas others limit interventions to a specific type (e.g., case management).[14-16, 31] Broadly speaking, a number of reviews have found that interventions to reduce utilization and cost can be effective, specifically case management, care management, and disease management interventions.[12, 13, 28, 31, 32] Considerable overlap exists in the practices and processes of case management, care management, care coordination, and disease management.[33] Our review uses the AHRQ definition of care management where it is a team-based, patient-centered approach designed to help patients effectively manage their conditions.[34] This definition encompasses care coordination activities. While disease management is a population level approach and case management is a patient-centered approach, both approaches are disease-centric and generally administered by health plans.[34, 35]

Some of the limitations of earlier reviews of intervention studies are similarly 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, housing stability, and racial/ethnic demographics, is often missing. When systematic reviews include important social variables, analysis is 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 HNHC literature are challenged by the absence of a consensus in the field of a unifying classification schema or taxonomy organizing key intervention dimensions into meaningful distinctions for grouping and separating the components of complex interventions.[36] Intervention classification in recent systematic reviews regarding high utilizers differs 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

Interventions designed to target HNHC patients have been developed at multiple levels. The following 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 stratify 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 utilization by HNHC patients. A number of alternative models of health services delivery can support HNHC interventions. For example, accountable care organizations (ACOs) align financial incentives for care coordination and join financial and health outcome accountability among a large group of healthcare providers across the healthcare continuum (ambulatory outpatient, acute care, post-acute care, and home health settings). ACOs use a variety of strategies to accomplish these goals, including increasing physicians' access to a uniform source of complete information about patients' health service utilization and health status to support care coordination; using techniques such as population segmentation and risk stratification to focus resources on HNHC populations; and using approaches to increasing 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.[37] 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 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 interventions are organized at the health system and provider levels. Health system-level interventions are often designed to support changes at the population level by promoting a culture that furthers program goals and to organize intervention activities across intervention participants.[38] Rather than individual patients, system-level participants are generally lower levels of organizations or groups, such as clinics or practices, which in turn are often expected to implement provider and patient-level interventions. Provider-level interventions target care providers and attempt 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 use of data are ED alerts that 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.[39] Hotspotting typically includes multidisciplinary, coordinated care that treats the whole patient and attends to the nonmedical and social determinants that affect health, including housing, mental health, substance abuse, and emotional support. The underlying premise 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.[40]

Cross-Sector Interventions

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

Support services are intended to address common 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.[36]

Complex Interventions for HNHC patients

The interventions that target HNHC patients encompass all of the strategies discussed above. We modified the scheme proposed by Bodenheimer to group care management interventions for HNHC patients into seven categories based on the primary setting in which the intervention was delivered.[41] Most of the interventions designed to target the complex needs of HNHC patients are themselves complex and these interventions are often a hybrid of various models.

- 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 a high-risk team within a clinic;
- Primary care model: care is embedded in one or more primary care practices; and
- Home-based care model: care takes place in the patient's home.

Clinical and Policy Context

The most pressing aspect of the policy context for HNHC is that payers in the U.S. healthcare system, particularly Medicare and Medicaid, are incentivizing complex healthcare systems and their providers to move toward new structures of care, such as ACOs. At the same time, they are leveraging these healthcare systems to accept alternative payment models that include financial risk for healthcare systems.[6-9] Healthcare systems participating in these payment models

acknowledge that addressing the utilization and costs of HNHC patients is critical to their success.[10, 11]

A key question, however, in addressing utilization and costs of HNHC patients is how to equip health systems, individual providers, and patients to do so. Issues for health systems and providers include leadership support, changes in workflow, provider and staff skills development, adequate infrastructure and staffing, and realignment of financial incentives. Issues of patients may include various barriers related to 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 around providing care for HNHC patients. The intended audience of this review is broad given the wide range of stakeholders who are impacted by HNHC patients; the intended audience includes clinicians, healthcare systems, payers, and policymakers at local, state, and national levels. The first objective is to describe approaches to identifying and predicting HNHC populations. The second is to develop and refine a theory explaining why particular interventions, in various circumstances, are more likely to be successful in changing potentially preventable or modifiable healthcare use for HNHC patients. The third is to review the evidence supporting the overall effectiveness of these interventions.

Interventions to address the needs of HNHC patients are complex; that is, HNHC patients have interactions among components of the intervention, and important interactions between the intervention and the context, or mediators or moderators of the effects of the intervention.[42] Very little is understood about the individual components of these interventions (such as care management) and the extent that they independently or synergistically contribute to the intervention's outcomes. Sources of the 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).[42] For the purpose of this review, we will explore the nature of interactions between the interventions and the setting, and investigate 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.

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 health behaviors and sociodemographic characteristics (e.g., age, social risk factors, insurance status and source of coverage, and access to the healthcare system)?
c. How do criteria incorporate types, amount, duration, and patterns of healthcare use?
d. Do criteria differ at the payer, healthcare system, or provider level?
e. How can observed or predicted potentially preventable or modifiable high use of healthcare be differentiated from necessary and appropriate use?

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

a. What are the important contexts, such as the characteristics of the 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 harms of interventions for HNHC patients in reducing potentially preventable or modifiable healthcare use and costs, and in improving health outcomes?

Analytic Framework

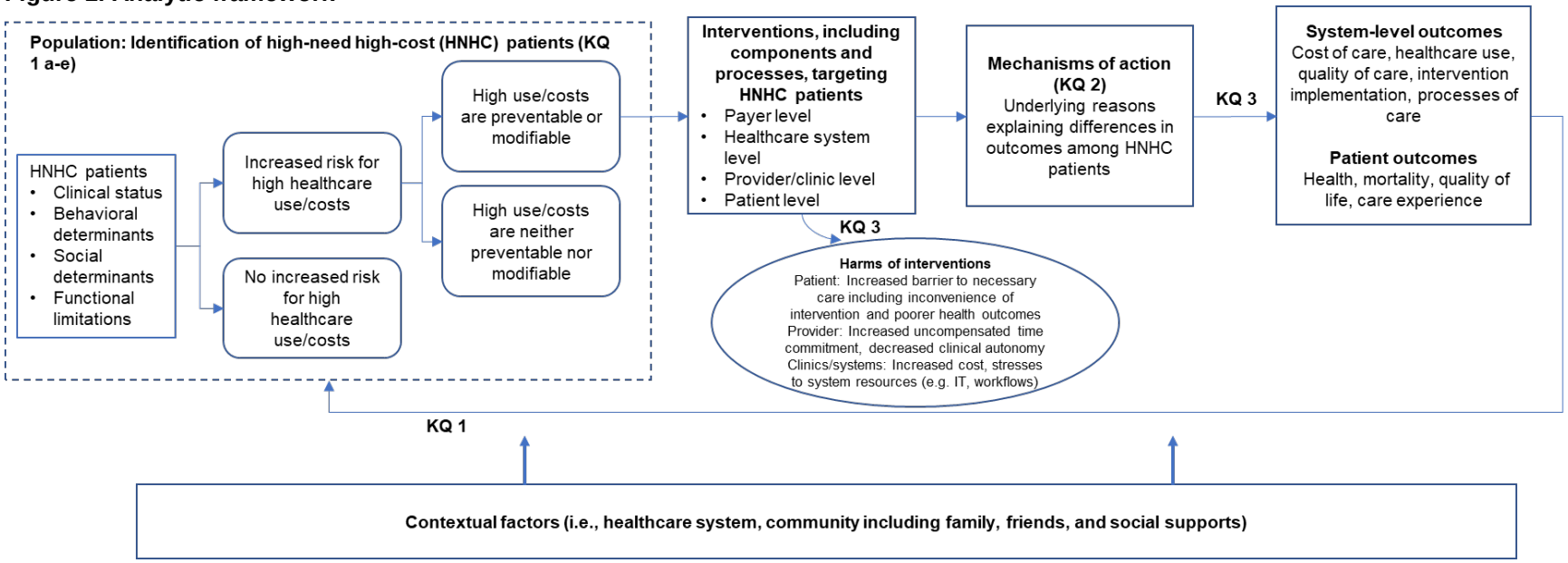
The framework in Figure 1 illustrates the relationships of the KQs, including the target population, interventions, contexts, mechanisms, and outcomes.

Review Approach

We tailored our approach for each KQ and used three methodologies to conduct our review. We used a “best fit” framework synthesis approach for KQ 1, a realist review approach for KQ 2, and systematic review methodology for KQ 3.

The topic of this report was developed by AHRQ in consultation with the Oregon Health Evidence Review Commission. We conferred with a Key Informant (KI) stakeholder panel to help ensure that the focus of the review would be relevant to potential end users. The KIs provided insights to design the project’s intervention taxonomy and guidance in appreciating important intervention features to inform the review.

Figure 1. Analytic framework



Abbreviations: HNHC = high-need high-cost; KQ = Key Question.

We used a "best fit" framework synthesis as an a priori framework to sort evidence into themes across included studies. See the Data Synthesis and Analysis section below for additional details.

The realist review approach is intended to explore and describe how complex HNHC interventions work, for whom, and in what particular contexts and settings through the synthesis of qualitative and quantitative evidence.[43] 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.[44] 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 HNHC interventions on specific outcomes of interest. The systematic review followed the Agency for Healthcare Research and Quality's (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.[45]

The topic of this report was developed by AHRQ in consultation with the Oregon Health Evidence Review Commission. Additionally, we conferred with a KI stakeholder panel to help ensure that the focus of the review would be relevant to potential end users. The KIs provided insights to design the project's intervention taxonomy and guidance in terms of understanding intervention features to inform the review. This discussion contributed to the determination 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.[46]

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) 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 healthcare, physicians' and health professionals' satisfaction with clinical practice, patient and health professional harms); (3) measured outcomes for 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 were any study design, except reviews or univariate descriptive studies. We required that all quantitative studies included for KQ 1 control for potential confounding. 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 credible and trustworthy).[47] Eligible KQ 3 studies were randomized controlled trials (RCTs), cluster randomized trials, cohort studies, case-control studies, and quasi-experimental designs that included a comparison group of any 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 (ED), 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, commonly supporting 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 included HNHC patients with 6 or more months of potentially preventable or modifiable high healthcare cost or use. For KQ 2 and KQ 3, we added a more stringent criteria, HNHC patients with 6 or more months of potentially preventable or modifiable 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 distinguish between these two populations in our analysis. Across all studies, we accepted the authors' definition of HNHC that met our other inclusion criteria (i.e., length of time, conducted in the United States etc.). In most included studies, high use or cost was measured without directly evaluating whether individual episodes of care were potentially preventable or modifiable.

Methods 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 September 7, 2019. We also conducted targeted searches for gray literature on the CMS and Commonwealth Fund website, 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 are provided in Methods Appendix A.

We will update searches while the draft report is under public review.

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 when applicable. A second investigator reviewed the information for completeness and accuracy.

KQ 2 data extraction was guided by 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 context-mechanism-outcomes (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 observational exposure studies (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.[48] In relation to the rigor of included quantitative studies, 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 (LCA), are statistical methods for identifying "hidden" or unobservable class membership (groupings) among subjects using observed variables.[49] 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.[46, 47, 50, 51] Data were appraised based on relevance, trustworthiness, plausibility of the argument underlying the theory, and rigor. We did not formally assess methodological rigor because all relevant data may be used to build and refine the program theories.[50] However, we globally assessed the data from the studies to determine whether the data were trustworthy and 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.[45] Two independent investigators assessed the risk of bias of each study, using predefined criteria established in the Cochrane ROBINS-I[52] tool for observational studies and the Cochrane RCT[53] tool for RCTs. We rated outcomes as low, some concerns, high, or unclear risk of bias for each study in KQ 3. Risk of bias was not assessed for KQ 1 or KQ 2 studies.

Data Synthesis and Analysis

Describing HNHC population (KQ 1): To achieve our aim of describing the approach to identifying the HNHC population, we conducted a "best fit" framework synthesis.[54] 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 (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 condition, 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.[44] 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.[44]

Once all papers were coded at the conceptual level, one investigator sorted excerpts across studies by concepts and developed initial, partial CMOs 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 HNHC interventions (KQ 3): To further support the goal of producing actionable information, we used traditional Evidence-based Practice (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, ED, ambulatory intensive caring unit [aICU], primary care, and home-based), loosely following the framework proposed by Bodenheimer to group care management interventions.[41]

Several studies assessed multiple HNHC cohorts, populations, or analyses. Some interventions included two separate and distinct cohorts that received the same intervention.[55-59] Other interventions looked at multiple HNHC subpopulations within a more general patient population; some patients might have been included in multiple populations constructed for separate studies.[60, 61, 62] Still other interventions conducted multiple analyses on different subsets of their HNHC population to answer different research questions.[63] We refer to each of these cohorts, populations, and analyses as "samples," and each sample is included as evidence from a separate study. Patients in the HNHC samples may have overlapped within two studies.[62, 63]

Because of the diversity of intervention designs and outcomes, we used a narrative synthesis approach to report most of our findings. We conducted a quantitative synthesis of results by calculating a pooled estimate when 3 or more samples with the same study design had similar treatment and comparison groups and reported 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.[64] 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 that are not clinically relevant.

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.

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 Results Appendix (Appendix B).

Literature Searches and Study Characteristics

The electronic search, gray literature, and reference mining identified 2,015 citations. After title and abstract screening, 621 studies were retrieved for full-text review. A total of 94 studies (100 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

		Total # of unique studies (Articles)	# KQ 1 studies (Articles)	# KQ 2 studies (Articles)	# KQ 3 studies (Articles)
Total		**94 (100)**	**53 (55)**	**42 (45)**	**32 (36)**
Study Design	RCT	14 (15)	0 (0)	10 (11)	14 (15)
	Intervention study: observational with comparison	20 (23)	0 (0)	12 (14)	18 (21)
	Exposure study: cluster analysis	7 (7)	7 (7)[a]	2 (2)	0 (0)
	Exposure study: multivariate cross-sectional	26 (26)	26 (26)[a]	0 (0)	0 (0)
	Exposure study: multivariate predictive	16 (18)	16 (18)	5 (6)	0 (0)
	Qualitative study: various designs	13 (13)	6 (6)	13 (13)	0 (0)
Healthcare coverage of study participants	Medicaid only	10 (14)	7 (9)	4 (6)	2 (4)[b]
	Medicare only or dual Medicare/Medicaid	26 (27)	10 (10)	13 (13)	16 (17)[b]
	Commercial only	8 (8)	8 (8)	1 (1)	0 (0)
	Mixed coverage across participants	40 (42)	27 (28)	19 (20)	4 (5)
	Uninsured	5 (6)	1 (1)	2 (2)	4 (5)
	Unknown	6 (6)	0 (0)	3 (3)	6 (6)

[a] Two studies included two types of analyses and are therefore counted twice; predictive and cluster[65] and predictive and cross-sectional.[66]
[b] One companion article was the evaluation report for multiple studies; this article was a companion article for two studies.

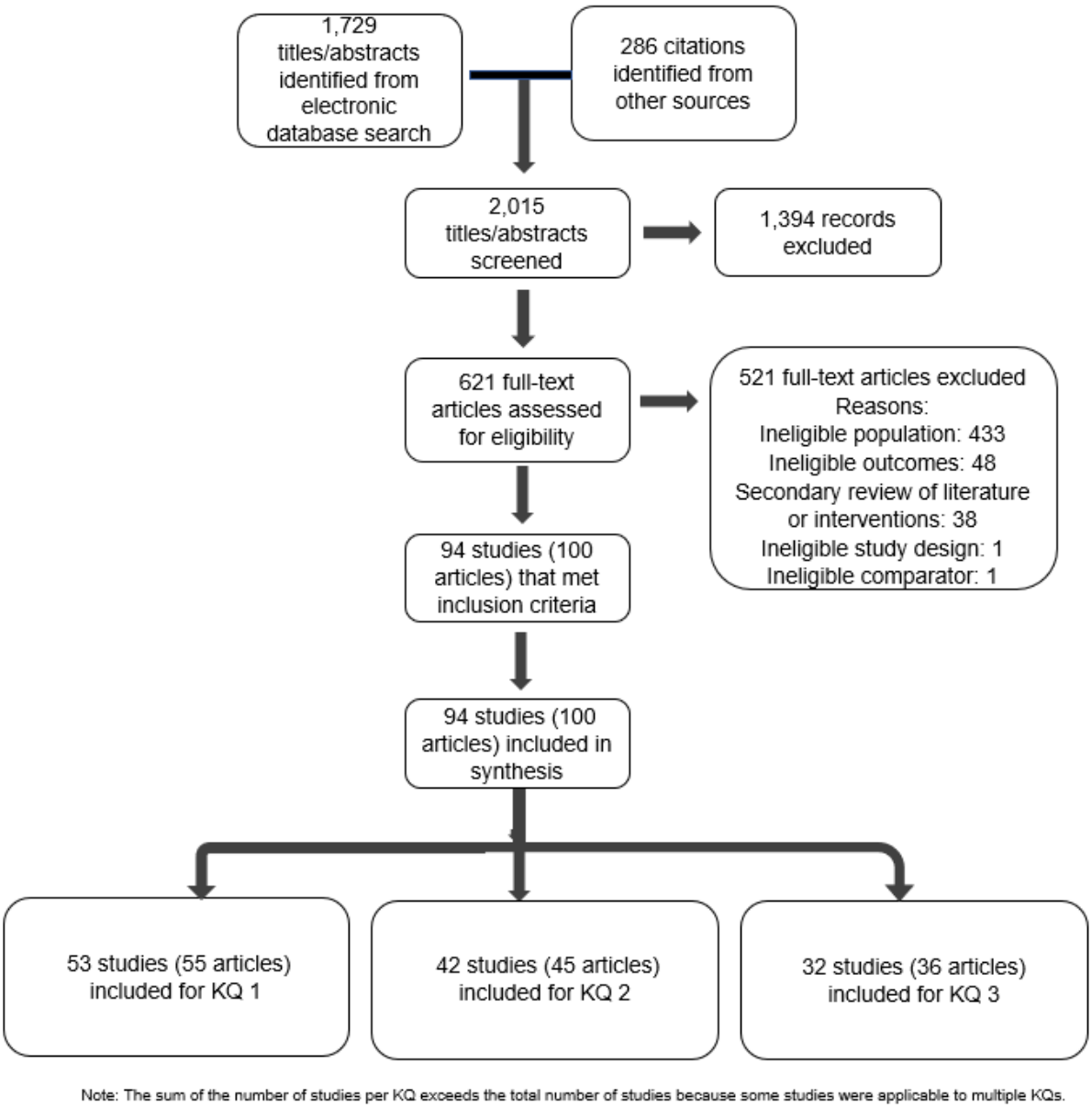
For KQ 1, we identified 53 studies reported in 55 articles, including 16 multivariate predictive studies,[65-82] 26 multivariate cross-sectional studies,[66, 83-107] 7 latent class studies,[65, 108-113]and 6 qualitative studies.[114-119]

For KQ 2, we identified 42 studies (45 articles).[20, 40, 55-60, 63, 67, 68, 71, 72, 78, 81, 111, 112, 114-141] Of these, 13 studies were also used to answer KQ1 (14 articles), 20 studies were also used to answer KQ 3 (22 articles) and nine studies were unique to KQ 2 (9 articles).[20, 120, 127, 129, 130, 137-140]

For KQ 3, we identified 32 studies, including14 RCTs and 18 observational studies (36 articles). Three RCT studies were rated as having low risk of bias,[40, 59, 142] 11 RCTs (12 articles) were rated as having some concerns for bias,[55-58, 121, 124, 126, 132, 134, 143-145] and none were high risk of bias. No observational studies were rated as having low risk of bias. Twelve observational studies (14 articles) were rated as having some concerns for bias,[60-63, 122, 123, 125, 128, 135, 146-150] and six observational studies (7 articles) were rated as having high risk of bias.[131, 133, 136, 141, 151-153]

Figure 2 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



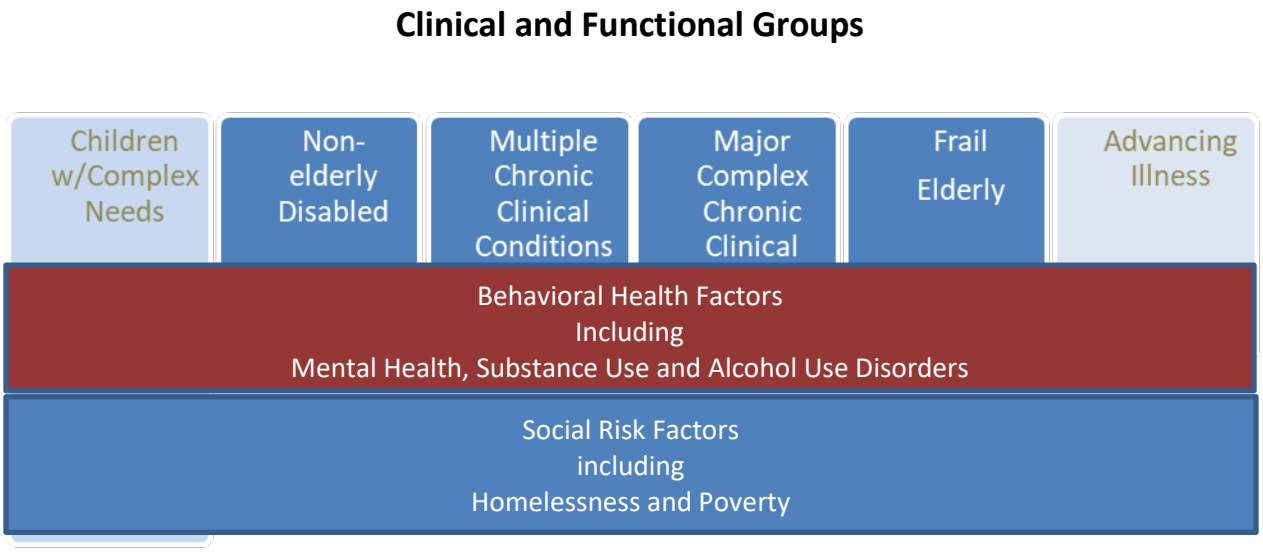
KQ = key question

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 prior work. We reviewed included studies to determine if the findings echoed 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*.[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 impacting healthcare utilization across clinical and functional groups.

Our review encompasses four of the six NAM taxonomy clinical and functional groups: nonelderly disabled, multiple chronic conditions, major complex chronic condition, and frail elderly. The number and combination of complex and noncomplex chronic medical conditions differentiate the multiple chronic conditions and complex chronic conditions groups. The multiple chronic condition group is defined as having one complex chronic condition and/or between one and five noncomplex chronic conditions. Examples of complex conditions include chronic kidney disease, congestive heart failure, dementia, diabetes and stroke. Examples of chronic conditions considered noncomplex include arthritis, immune disorders, hypertension and thyroid disease. The major complex chronic condition group is defined as including two or more complex chronic conditions or at least six noncomplex chronic conditions. We do not consider children with complex needs because our review is limited to adults. Our scope also does not include interventions for the advancing illness group because the characteristics and goals of interventions for end-of-life care are different than those focusing on chronic disease.

Figure 3. Best Fit Framework Synthesis: National Academy of Medicine HNHC Patient Characteristic Taxonomy



We identified 53 studies (reported in 55 articles) that examined characteristics of non-institutionalized HNHC patients, 18 years of age and older. We consider HNHC as having six months or more of potentially preventable or modifiable high health care use or cost. Studies differed in their definition of HNHC. Almost always, HNHC was defined solely as a measure of high use (most often ED or inpatient visits), or less often, high cost. In these studies, authors uniquely established criteria that they determined represented inappropriately high use or cost and examined the patient (and sometimes, healthcare system) characteristics significantly related meeting these criteria. Only several studies sought to more directly measure high use or cost that was potentially preventable or modifiable.

The evidence included to answer KQ 1 fall into four broad groups of methodological approaches. We present each included study in separate tables by analysis type: predictive (Table 2), cross-sectional (Table 3), latent class/cluster (Table 4), and qualitative (Table 5). For each study, we document study characteristics. For cross-sectional (Table 2) and predictive studies (Table 3), we also present outcomes and categories of predictors included in multivariate models. For latent class/cluster analyses (Table 4), we also present clusters identified in the analysis. For qualitative studies (Table 5), 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 1 a: Patient clinical conditions (corresponding to the NAM clinical and functional groups): 10 predictive, 17 cross-sectional, 6 cluster analysis, and 5 qualitative studies
- KQ 1 b: Patient demographic, behavioral health, and social risk factors (encompassing the NAM behavioral health and social risk factors): 15 predictive, 26 cross-sectional, 4 cluster analysis, and 6 qualitative studies
- KQ 1 c: Types, amount, duration, and patterns of use: 14 predictive, 25 cross-sectional, 2 cluster analysis and 4 qualitative studies
- KQ 1 d: Differences by payer, healthcare system, and provider-level: all studies, including 16 predictive, 25 cross-sectional, and 5 cluster analysis and 6 qualitative studies
- KQ 1 e: Potentially preventable and modifiable use: 2 predictive, 2 cross-sectional and 1 qualitative study

Most studies include HNHC patients across health conditions. Nine studies focused on subgroups of HNHC patients with specific chronic health conditions associated with high health care use (i.e., asthma,[95] chronic obstructive pulmonary disease,[94] acute heart failure syndrome,[93] migraine headache,[100] or specific mental health conditions.[66, 81, 88, 90]

Predictive Studies

Predictive analyses, deemed to be the most rigorous analytic approach, all used regression analysis suited to the functional form of the outcome (e.g., logistic, Poisson) or the intent of the analysis (e.g., stepwise, lasso linear) to identify possible predictors of HNHC healthcare use or cost in a subsequent period. One predictive study examined the results from regression analyses compared with using gradient boosting machine to accommodate a large number of interaction terms and recurrent neural networks in order to process sequential events [70]. 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 to 5 years. We identified 16 predictive studies, reported in 18 articles (Table 2).[66-82]

Several of the predictive studies developed, tested, or refined predictive tools or modeling techniques. For example, Billings and colleagues developed and tested an algorithm to identify Medicaid patients at high risk of rehospitalization and high costs within 12 months of an index hospitalization.[81] Raven and colleagues assessed the accuracy of the algorithm previously developed by Billings and colleagues to identify Medicaid patients at high risk of subsequent rehospitalization within 12 months, based on their diagnoses and prior service utilization.[80] In both studies, the algorithm calculated a rehospitalization positive predictive value of 0.67 among individuals with a risk score greater than 50 (on a scale ranging from 0-100). Chang and colleagues tested a previously validated algorithm, the Care Assessment Needs (CAN) score for predicting the persistence of risk of rehospitalization in the VA system for a period of 24

months.[79] Yang and colleagues assessed several methodological approaches to examining analytic model residuals to identify HNHC patients that have higher than expected healthcare expenditures from year to year with the goal of distinguishing potentially preventable from non-preventable healthcare utilization.[68, 78]

Table 2. Predictive studies with evidence for KQ 1 (N=16)

Author, N	HNHC Outcome Measured During the Follow-up 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[75]	ED visits (3+, 5+, 8+, 10+)	Medicaid: ED users in NYC, 2007	Number of chronic conditions, diagnosis, CCI rating scale	Age, Gender, Race	MI, SUD	Not measured	Prior utilization
Brannon et al., 2018 N=303,514[67]	ED visits (1+, 2+, 3+, 4+, 5+)	Patients in 3 health systems in 2 Michigan counties, 2015-2017	Number of chronic conditions	Age, race	Not measured	Zip code	Prior utilization
Chang, 2014[b] (N=863)[66]	ED visits (4+)	Patients with MH conditions, ED use across 4 hospitals in the Boston area, 2008-2009	Diagnoses	Age, gender	MI, SUD, AUD	Homeless-ness	Not measured Prior utilization
Colligan et al., 2016 N=9,820,215[72]	ED visits (4+)	Medicare: national 20% sample, 2009-2010	Diagnoses, HCC score	Age, gender, race	MI	Not measured	Medicaid, prior utilization
Hwang, 2014 N=161,707[76]	ED visits (4+; <4), hospitalizations	Hospital/ health system: urban, academic PCP-based research network, 2005-2012	Diagnoses	Gender, race	Depression, AUD	Not measured	Prior utilization
Kanzaria, 2017 (N=2,563,758)[71]	ED visits (4+), persistent over 2, 3, 6, and 11 years	California nonelderly adults, 2005-2015	Diagnosis	Race	Depression, SMI, MI, SUD, AUD	Income	Insurance type, prior utilization
Billing et al., 2007 (N=98,000)[81]	Inpatient admissions (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 Follow-up 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
Chang et al., 2019 (N=258,759)[79]	Probability of 90-day inpatient admission	VA population in top 5% risk of inpatient admission, 2012-2014	Diagnoses	Age, race, gender	MI, SUD	Zip code change, urban	Prior utilization
Hempsted, 2014 (N=291,147)[82]	Inpatient admissions (1+, 2, 3+ across hospitals)	Patients with ≥2 inpatient stays in a New Jersey hospital, 2007-2010	Number of chronic conditions, diagnosis	Age, race, gender	MI, SUD	Income	Insurance type, prior utilization
Leininger, 2014, 2015 (N=34,087)[73, 77]	Inpatient admissions (1+); ED (3+ visits); cost (top 10%)	Wisconsin new Medicaid enrollees, 2009- 2010	Self-reported rating scale	Age, gender, race	MI, SUD	Homeless-ness	Prior utilization
Leininger, 2015 (N = 6,725)[77]	Inpatient admissions (1+); ED (2+ visits); cost (top 10%)	Medicaid, participated in National Health Interview Survey; 1997-2008	Conditions, health-related quality of life	Age, gender, race	MI, SUD	Not measured	Prior utilization
Raven, 2008 (N=36,457)[80]	Inpatient admissions (1+ readmission)	NYC Medicaid public hospital users, 2001-2006	Chronic condition, self-rated health status	Not measured	MI, SUD	Homeless-ness, Social Isolation	Prior utilization
Meek, 2000 (N=4,210)[80]	All utilization (6+ visits in 6 months)	Midwest, commercial managed care enrollees, 1997	Self-reported rating scale	Age, race, gender	MI	Not measured	Prior utilization
Wherry, 2014 (N=6,725)[69]	All utilization (top decile)	Weighted sample of working age adults, 1997-2009	Self-reported rating scale	Not measured	MI	Not measured	Prior utilization
Yang et al., 2017, 2019 (N= between 464,572 and 535,422 in each of the years)[74, 77]	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)[68, 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[c] (N=6,047)[65]	Cost (top 25%, total costs)	Kaiser Permanente Colorado, newly enrolled ACA	Number of chronic conditions, condition that	Age, gender	Depression	Financial constraints	Prior insurance coverage, prior ED and IP use

Author, N	HNHC Outcome Measured During the Follow-up 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
		members, 2014	interferes with daily activity				

[a] High-need high-cost outcome in the next 12-month period unless otherwise specified.
[b] This study also includes a cross-sectional analysis.
[c] This study also includes a latent class analysis.

AUD = alcohol use disorder; ED = emergency department; HCC = hierarchical condition categories; HNHC = high-need, high-cost; KQ = Key Question; MCO = managed care organization; MI = mental illness; N = number; NYC = New York City; PCP = primary care practice; SMI = serious mental illness; SUD = substance use disorder; VA = Veterans Administration.

Cross-Sectional Studies

Cross-sectional studies (N=26) 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 controlled for potential confounding variables. Table 3 presents information regarding the cross-sectional studies.[83-107] Five cross-sectional studies pooled data across several years for analysis.[87, 92-94, 98, 99, 103]

Table 3. Cross-sectional studies with evidence for KQ 1 (N=26)

Study Citation Sample Size	Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
Doran et al., 2013 (N=5,531,379)[107]	ED visits (1, 2-4, 5-10, 11-25, >25)	VA population in 2010	Diagnoses, CSI	Gender, Age	Depression, SMI, MI, SUD, AUD	Homeless-ness, 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	Seriousness of need	Gender, race	MI, SUD	Employment, Consulted with family member prior	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	Homeless-ness	Insurance type
Chang, 2014[b] (N=863)[91]	ED visits (4+)	Patients with MI dx and ED use across 4 Boston area hospitals, 2008-2009	Diagnoses	Age, gender	MI, SUD, AUD	Housing status Homeless-ness	Prior utilization
Hasegawa et al., 2014 (N=412)[93]	ED visits (2+)	ED patients enrolled in homelessness	Diagnoses Rating scale	Age, gender, race	MI, SUD	, change in housing status	Utilization

Study Citation Sample Size	Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
		program with 1+ OP visit to Boston safety net hospital, 2011-2013					
Hasegawa et al., 2014 (N=294,678)[94]	ED visits (3+ for AHFS)	CA and FL ED patients with AHFS, 2010-2011	Selected diagnoses	Age, gender, race	Depression, SUD	Income	Insurance type
Hasegawa et al., 2014 (N=1,890)[95]	ED visits (3+ for acute exacerbation of COPD)	CA and FL ED patients with acute exacerbation of COPD, 2010-2011	Not measured	Age, gender, race	Not measured	Income	Insurance type
Doran et al., 2014 (N=965)[96]	ED visits for asthma (3+)	NYC public safety net hospital Patients with asthma at 48 EDs across 23 states, 2011-2012	Not measured	Age, gender, race	Not measured	Income for the zipcode area	Not measured
Liu, 2013 (N=965)[97]	ED visits (3+)	ED patients, 2007-2008	Overall health	Age, gender, race	MI, SUD, AUD	Employment,	Prior utilization, access, cost, quality of care
Liu, 2013 (N=65,201)[154]	ED visits (4+, 4-7, 8-18, 19+)	Urban academic hospital ED patients, 2010	Diagnoses	Gender, race	Not measured	Not measured	
Milbrett, 2009 (N=201)[98]	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)[101]	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)[102]	ED visits (5+)	Urban, academic hospital ED patients, 1993-1998	Not measured	Age, gender, race	Not measured	Homeless-ness	Insurance type
Vinton, 2014 (N=157,818)[92]	ED visits (4+, 10+)	National Health Interview Survey, 2004-2009	Diagnoses, rating scale	Age, gender, race	MI, AUD	Employment, income	Insurance type, prior ED use
Hunt, 2006 (N=59,725)[99]	ED visits (4+)	Community Tracking Study Household	Rating scale	Race	MI	Income	Insurance type, prior ED and outpatient

Study Citation Sample Size	Outcome[a]	Population	Clinical Health Conditions	Demographics	High-Impact Behavioral Variables	High-Impact Social Variables	Provider and Health System Variables
		Survey, 2000-2001					use, relationship with physician
Friedman, 2009 (N=59,725)[100]	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&1999	Rating scale, disability status	Race	Not measured	Income	Insurance type, Access to care
Bell, 2017 (N=494)[83]	Inpatient admissions (3+)	Atlanta, GA large safety-net hospital ED patients, 2011-2013	Number of chronic conditions	Age, gender, race	MI, SUD, AUD	Homeless-ness, income	Insurance type
Porter, 2019 (N=2,621)[105]	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
Levinson, 2005 (N=64)[88]	All utilization (3+ED; 2+ specialty clinic visits)[c]	VA, screened positive for depression or anxiety, dates of data collection: NR, Data period NS	Rating scale	Not measured	Not measured	Not measured	Not measured
Rohrer, 2008 (N=698)[85]	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)[104]	ED visits or acute hospitalizations (1+)	Partners Healthcare ACO members (12 practices), 2014-2015	Rating scale	Age, race, gender	MI	Not measured	Not measured
Reichard 2015 (N=53,586)[87]	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)[106]	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	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)[84]	Cost (top 10% total costs); ED utilization (3+)	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)[86]	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

[a] High-needs high-cost outcome in the next 12-month period unless otherwise specified.
[b] This study also includes a predictive analysis.
[c]Study outcome is defined as the Center for Epidemiological Articles Depression Scale (CES-D) score; however, high utilization is defined by ED and specialty clinic visits.

ACA = Affordable Care Act; ACO = accountable care organization; AHFS = acute heart failure syndrome; AUD = alcohol use disorder; CA = California; 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; HCC = hierarchical condition category; HMO = health maintenance organization; index; KQ = Key Question; MI = mental illness; N = number; NR = not reported; OP = outpatient, PCP = primary care physician; PTSD = post traumatic stress disorder; SMI = serious mental illness; SUD = substance use disorder; US = United States; VA = Veterans Administration.

Unlike the predictive analyses, the cross-sectional studies cover the same time period for the outcome and independent variables, making it sometimes 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 needs or high-cost utilization). Cross-sectional studies are also unable to provide insights about the persistence of being HNHC over time. For these reasons, we present predictive and cross-sectional results separately.

Cluster and Latent Class Analyses

We identified seven cluster or latent class analyses that examined characteristics of HNHC patients (Table 4).[108-113] Cluster analysis, and the associated technique latent class analysis (LCA), are statistical methods for identifying “hidden” or unobservable class membership (groupings) among subjects using observed variables.[49] These analyses group HNHC patients based on combinations of both modifiable and nonmodifiable characteristics, including healthcare utilization patterns, disease groups, demographic characteristics, and level of functioning.

Table 4. Latent class and cluster analysis studies with evidence for KQ 1 (N=7)

Study Citation Sample Size	Analytic Approach	Population	Cluster Types	Cluster Results
Yang, 2018 (N=1,734,896)[110]	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 Cluster 1 and 2
Bayliss et al., 2019 (N=9,617)[112]	Latent class analysis/ cluster analysis	Kaiser Permanente Colorado members, 65+ years of age, advanced illness, 2014-2017	14 clusters and 8 classes based on functioning and BH dx	Clusters identified as associated with high use: • Poor physical and MH, isolated/lonely • Poor physical and mental well-being and ADL limitations • Pain and physically inactive
Bayliss et al., 2016 (N= 1,512)[65]	Cluster analysis	Kaiser Permanente Colorado, newly enrolled ACA members, top 25% total costs, 2014	8 clusters based on self-reported functioning, health status and health care 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)[113]	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
Szymkowiak et al., 2017 (N=16,912)[108]	Latent class analysis	VA veterans with ≥ 1 hospital admission and/or ≥ 2 ED visits, during 5 quarters and experience of homeless-ness, 2014-20152017	7 clusters based on healthcare utilization	• ED only medical:13% had chronic medical conditions • Medical inpatient: oldest mean age, 88% had chronic medical condition • ED only MH/SU: approximately 2/3 with MH/SU diagnosis, 80% used ED for medical care • MH inpatient only: youngest mean age • SU inpatient only: 48% with trimorbid diagnoses (i.e., chronic health, MH, and SU disorder) • MH inpatient + ED: 32% with trimorbid diagnoses (i.e., chronic health, MH, and SU disorder), 30% had combat exposure; 50% had service- connected disability • SU inpatient + ED: 60% with trimorbid diagnoses (i.e., chronic health, MH, and SU disorder), highest mean ED use
Wong et al., 2018 (N=7,289)[111]	Latent class analysis	VA hospital inpatients during 1-week period, top 5% for	2 clusters based on risk of rehospitaliza tion over a	Baseline characteristics explained 23% of variation in group assignment Moderately high risk (65% of patients) • Greater decline in risk of hospitalization over time

Study Citation Sample Size	Analytic Approach	Population	Cluster Types	Cluster Results
		risk of future hospitaliza-tion, based on CAN score, November 2012	two year period	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 SU disorder
Prenovost, 2018 (N=68,400)[109]	Item response theory	VA CAN score in top 10%; predicted risk of hospitaliz-ation ≥ 25%, 2014	6 clusters based on chronic conditions, including BH	• SU and additional complexity because of presence of drug abuse, 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

ADL = activities of daily living; BH = behavioral health; CAD = coronary artery disease; CAN = Care Assessment Needs; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; dx = diagnosis; ED = emergency department; HMO = health maintenance organization; HNHC = high-need; high-cost; KQ = Key Question; MH = mental health; N = number; SU = substance use; VA = Veterans Administration.

Qualitative Studies

We identified six qualitative articles for answering KQ 1 (Table 5).[114-119] The studies relied on chart review as well as interviews with patients, providers, administrators and stakeholders. They largely discussed high impact patient clinical and demographic characteristics, as well as behavioral health and social risk factors, associated with high utilization. The studies also provided additional information characterizing HNHC patient and health system mismatch[114, 118] that may be relevant for developing successful care management strategies.

Table 5. Qualitative studies with evidence for KQ 1 (N=6)

Study Citation Sample Size	Definition of HNHC* Population/ Setting	Analytic Approach	Main findings
Ganguli, 2017[114] (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 behavioral health use seemed to have increased health care costs. Patient socioeconomic status, social network, activation, and trust in clinicians and the health system appeared to increase or decrease costs, with patient activation and trust appearing to mediate costs
Hardy et al., 2018[115] (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[116] (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 include forgetting to schedule regular health check-ups and having difficulty taking time away from daily responsibilities for necessary medical care.
Hasselman et al., 2013[117] (N=14 Summit participants)	Programs included a variety of definitions. Common characteristics include high ED use, inpatient admissions, readmissions, and poly-pharmacy. Medicaid	Expert panel testimony at "Super utilizer summit"; panel members included representatives from HNHC programs, states, CMS, health plans and other stakeholders	The panel identified strategies for targeting HNHC patient subgroups that are most likely to be impacted by complex care management • Use multiple data sources to identify 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 population is heterogenous; cluster analysis can be used to identify subpopulations. • Identify exclusions, including pregnancy, oncology, surgery for acute conditions, age 80 and older with dementia.

Study Citation Sample Size	Definition of HNHC* Population/ Setting	Analytic Approach	Main findings
			• HNHC patient Identification is an iterative process.
Chan et al., 2019[118] (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 patients	HNHC patient complexities are driven mainly by non-medical 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[119] (N=56; 11 health system leaders; 21 physicians; 21 patients and 3 caregivers)	One chronic condition and either 3+ ED visits or 2+ inpatient admissions Five 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 health care utilization: Unmet BH needs: inadequate access to MH and substance use disorder treatment, poor patient follow-up 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 health care 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

*HNHC definition includes utilization over a 12 month period unless otherwise stated.
ACO = accountable care organization; APM = alternative payment model; BH = behavioral health; CMS = Centers for Medicare and Medicaid Services; dx = diagnosis; ED = emergency department; EHR = electronic health record; Federally Qualified Health Centers = FQHCs; HNHC = high-need, high-cost; MH = mental health; N = number; PCCM = primary care case management

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

Key Points

- Most studies that included specific complex chronic conditions as independent variables in models (9 of 12 studies) (i.e., congestive heart failure, chronic obstructive pulmonary disease [COPD], cardiovascular disease, dementia, and diabetes) found positive associations with high use outcomes, including ED visits, inpatient admissions, total healthcare visits, and total cost.

- Both studies that used predictive and cross-sectional designs found a positive association between an increasing number of comorbid conditions and high use and 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 evidence for the HCC and CAN were population specific, Medicare beneficiaries and VA patients, respectively. The CAN was effective in identifying latent clusters among VA HNHC patients.
- Higher scores on patient self-assessment tools, including the Migraine Disability Assessment (MIDAS) questionnaire and global health scores, were associated with high utilization. The evidence was limited to cross-sectional studies.

Results of Studies

We present our findings describing chronic health conditions associated with high use or cost, separately by study design, in Tables 6 through 10. The clinical health conditions of HNHC patients are presented in three ways: specific diagnoses, number of chronic clinical conditions, and rating scales assessing condition severity. Additional study detail is included in Appendix Table B-1 and Appendix Table B-2.

Table 6. Number and results of studies examining the association between chronic health conditions and high ED use

	Number of Studies, Direction and Significance of Association	
Health Condition	**Predictive Studies**	**Cross-sectional Studies**
Diagnosis	-	-
Arthritis	1[+,*72]	2[+,*92, 102]
Asthma	-	1[98]
Cerebrovascular disease[c]	-	1[+,*92]
Congestive heart failure[c]	1[+,*72]	2[+,*94, 107]
COPD[c]	1[+,*72]	3[+,*93, 102, 107]
Cardiovascular disease[c]	-	2[+,*92, 94]
Dementia[c]	1[+,*72]	-
Diabetes[c]	1[+,*72]	3[+,*92-94]
Heart disease[c]	-	1[66]
Hepatitis C	-	1[+,*91]
Hepatobiliary disease	-	1[+,*59, 66]
HIV	-	1[91]
Hypertension	1[+,*72]	1[92]
Obesity	-	1[-94]
Pancreatic disease	-	1[66]
Renal disease	1[72]	3[+,*93, 102, 107]
Seizure	-	1[+,*102]
Sickle cell	-	1[+,*102]
Vascular disease[c]	-	1[66]
# of conditions	1[+,*67]	1[+,*87]
Rating Scales		
Charlson Comorbidity Index	1[+,*75]	1[+,*107]; 1[91]
Poorer global health rating	-	3[+,*92, 99, 103]
Hierarchic categorical condition score	1[+,* 72]	-
MIDAS disability score	-	1[+,*100]

Note: when the relationship in a study is not statistically significant, the direction of effect is not shown.
[+] Denotes positive association
[-] Denotes negative association.
[*] Denotes if the association, positive or negative, is statistically significant.

[c] Denotes complex chronic conditions as defined by the National Academy of Medicine. Psychiatric disease is presented separately under findings for KQ 1b.
- Denotes no studies.
COPD = chronic obstructive pulmonary disease; ED = emergency department; KQ = Key Question; MIDAS = Migraine Disability Assessment.

Table 7. Number and results of studies examining the association between chronic health conditions and high cost of care

	Number of Studies, Direction and Significance of Association	
Health Condition	**Predictive Studies**	**Cross-sectional Studies**
Cerebrovascular disease[c]	-	1[84]
Cardiovascular disease[c]	-	1[+,*84]
Diabetes[c]	1[+,*70]	1[*,-84]
Hypertension	1[+,*70]	-
Pulmonary circulation disorder	1[+,*70]	-
# of conditions	1[+,*65]	1[+,*87]
Rating Scales		
Charlson Cormorbidity Index–based rating	-	1[+,*84]
Global health rating	-	1[84] 1[+,*84]
Other rating scale	-	1[+,*65]

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

KQ = Key Question.

Table 8. Number and results of studies examining the association between chronic health conditions and high utilization of inpatient visits

	Number of Studies, Direction and Significance of Association	
Health Condition	**Predictive Studies**	**Cross-sectional Studies**
Arthritis	1[+,*79]	-
Chronic kidney disease[c]	1[+,*79]	-
Congestive heart failure[c]	1[+,*79]	-
Cardiovascular disease[c]	1[+,*79]	-
Diabetes[c]	1[+,*79]	-
Hypertension	1[+,*79]	-
# of conditions	1[+,*59, 82]	2[+,*83, 105]
Rating Scales		
Charlson Cormorbidity Index–based rating	-	1[+,*105]
Other rating scale	-	1[+,*105]

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

Table 9. Number and results of studies examining the association between chronic health conditions and high utilization, based on all health care visits

	Number of Studies, Direction and Significance of Association	
Health Condition	**Predictive Studies**	**Cross-sectional Studies**
COPD[c]	1[+,*69]	-
Diabetes[c]	1[+,*69]	-
Hypertension	1[69]	-
# of conditions	-	1[+87]
Rating Scales		
Charlson Cormorbidity Index–based rating	1[+,*74]	1[+85]
Global health rating	-	1[+,*104]
Other rating scale	-	1[+,*87]

Note: when the relationship in a study is not statistically significant, the direction of effect is not shown.
[+] Denotes positive association
[-] Denotes negative association.
[*] Denotes if the association, positive or negative, is statistically significant.
[c] Denotes complex chronic conditions as defined by the National Academy of Medicine. Psychiatric disease is presented separately under findings for KQ 1b.
- Denotes no studies.
COPD = chronic obstructive pulmonary disease; KQ = Key Question.

Table 10. Number of studies that identify chronic health conditions as characteristics defining high utilization clusters

Health Condition Diagnosis	**Number of studies, citations**
Cerebrovascular disease[c]	1[+ 113]
Chronic kidney disease[c]	1[+ 113]
Congestive heart failure[c]	2[+ 109, 111]
COPD[c]	2[+ 111, 113]
Cardiovascular disease[c]	2[+ 109, 113]
Dementia[c]	1[+ 113]
Diabetes[c]	2[+ 109, 113]
Heart disease[c]	1[+ 113]
Hepatitis	1[+ 109]
Hepatobiliary disease	1[+ 109]
Hypertension	2[+ 109, 111]
Obesity	1[+ 113]
Renal disease	2[+ 109, 111]
Rating Scales	
Global health rating	1[+ 112]
Other rating scale	1[+ 112]

[+] Denotes positive association
[-] Denotes negative association.
[c] Denotes complex chronic conditions as defined by the National Academy of Medicine. Psychiatric disease is presented separately under findings for KQ 1b.
COPD = chronic obstructive pulmonary disease.

Specific Diagnoses

Clinical diagnoses and counts of chronic conditions included in articles were based on International Classification of Diseases (ICD)-9 or ICD-10 codes, identified in electronic health records, claims data, or state or facility databases. A total of 12 predictive and cross-sectional articles examined the association between specific clinical conditions and high use, controlling for other factors.[66, 69, 70, 72, 79, 84, 92-94, 98, 102, 107] The specific conditions included both complex chronic (e.g., congestive heart failure, diabetes and stroke) and noncomplex chronic conditions

(e.g., arthritis, immune disorders and hypertension) consistent with those identified though the NAM framework.[155]

On the whole, studies did not assess specific combinations and numbers of complex and noncomplex conditions, making a direct comparison with the NAM framework difficult. Four studies focused on a group with a single chronic clinical condition; heart failure, COPD, acute asthma, and severe headache.[93-95, 100] An additional four studies focused on populations with chronic mental health conditions; depression, posttraumatic stress disorder, and serious mental illness (SMI).[66, 81, 84, 88] The association between HNHC and mental health factors is addressed under KQ1b.

Across nine predictive and cross-sectional studies, five complex chronic conditions (congestive heart failure, COPD, cardiovascular disease, dementia, and diabetes) had a positive significant association with high utilization outcomes, including ED visits, inpatient admissions, total healthcare visits, and cost.[69, 70, 72, 79, 92-94, 102, 107]

Two studies that did not find a significant association between chronic medical conditions and high utilization or cost focused on patients with mental health diagnoses.[66, 84] One cross-sectional study of patients with psychiatric conditions found their high ED use to be associated with hepatobiliary disease but not other complex chronic conditions, such as heart disease.[66] Another study found that high healthcare costs among patients with depression were not predicted by cerebrovascular disease or diabetes but were predicted by cardiovascular disease and obesity.[84]

Number of Chronic Conditions

The relationship between the number of chronic conditions and being HNHC was examined in four predictive studies[67, 72, 73, 77, 82] and three cross-sectional studies.[65, 83, 87, 90, 105, 107] Three of the four predictive studies reported a positive relationship between a larger number of chronic conditions and future high use or cost, with one study reporting on ED use,[67] one study reporting on inpatient admissions[73, 77, 82] and one study reporting on cost.[65] Cross-sectional studies supported predictive study results, findings a positive association between an increasing number of chronic conditions and high inpatient use[83, 105] and high cost and total utilization.[87]

In contrast, one cross-sectional study, conducted by Reichard and colleagues, explored the association between the number of chronic conditions and disability with high overall utilization. (Table 8).[87] They found that the number of chronic conditions alone was insufficient to predict high utilization because no matter where the bar was set, the resulting groups had diverse healthcare needs, leading to great variation in healthcare use and cost. In addition to the number of chronic conditions, functional disability and prior service utilization over the preceding year were required to predict high utilization.

Functional Limitations

Bayliss and colleagues developed a model predicting characteristics associated with patients being in the top 25 percent for healthcare costs. Their research supports Reichard's finding of the importance of functional disability, in addition to number of chronic conditions, as a predictor of HNHC.[65, 87] Bayliss and colleagues showed that self-reported health status, functional limitations, and a positive depression screen, as well as number of conditions and prior health use, were significant predictors of patients being in the top quartile for cost of care.

Rating Scales

Some analyses included rating scales or assessments, either conducted by a clinician or provided through self-report. Specific assessments included the CCI, the HCC, the CAN score, the health needs assessment (HNA), the MIDAS questionnaire, and global health scores. Three predictive studies [72, 74, 75, 77] and 11 cross-sectional studies[65, 84, 85, 87, 92, 99, 100, 103-105, 107, 154] 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.[156, 157] CCI encompasses 19 medical conditions that are weighted with 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.[158] The CCI, as well as its adaptations, such as the Quan-Charlson, have been validated in multiple studies.[159, 160]

The CCI 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.[74, 75, 77] Three cross-sectional studies reported positive associations between higher CCI scores and high ED utilization,[107, 154] high total healthcare visits[85] or cost.[84] These associations were found among veterans, patients served by hospitals in the state of Florida, and commercial health maintenance organizations (HMOs).

The HCC score is a risk adjustment approach created by the Centers for Medicare & Medicaid Services to calculate risk scores for Medicare. 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 HCC categories.[161] One predictive study by Colligan and colleagues found the HCC score to be positively related to future ED utilization in a Medicare population.[72]

The CAN score is a tool developed by the Veterans Administration to identify patients who are the highest risk of rehospitalization or mortality within a specific amount of time, such as 90 days or one year. The score estimates a patient's risk based on demographic characteristics, comorbid conditions, and healthcare use.[162]

The CAN score was used to identify clusters of HNHC patients in two studies of patients served by the Veterans Health Administration (VHA) (Table 10).[108, 109] One study used the CAN to identify seven clusters, which differed based on the degree to which high utilization patterns persisted over time. A group of HNHC patients with persistent service was characterized as having more mental health and substance use disorders (SUD).[108] The other study that used the CAN score revealed six distinct groupings of HNHC patients 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.[109] The analyses showed that the groups differed by demographic characteristics and utilization patterns, which underscored how each group was unique. The VHA sought to identify unique clusters of HNHC patients that could be used to develop tailored care management strategies for clinically distinct groups of patients and avoid applying "one-size-fits" all strategies.

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.[163] 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 utilization.[100]

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.[164-166] Four cross-sectional studies included a measure of self-reported health.[84, 92, 99, 103] Among these, three studies found a significant positive relationship between self-reported poor health and high ED utilization.[92, 99, 103] A fourth study did not find a significant relationship between self-reported poor health and high cost.[84]

KQ 1b: How do HNHC criteria incorporate patient demographic, behavioral health, and social risk factors, including access to healthcare?

To answer KQ 1b, we synthesize the evidence on the association between HNHC patient demographic characteristics, and consistent with the NAM framework, behavioral health factors and social risk factors. Tables 11 and 12 present an overview of our findings by HNHC outcome and study design. We discuss each of these factors in separate sections below. Additional detail concerning these factors can be found in Tables B-9 and B-10 in Appendix B.

Table 11. Number of multivariate studies examining demographic characteristics associated with high healthcare use or cost among HNHC populations, by direction and significance of effect

Outcome	Study Design	Male vs. Female	Black vs. White	Hispanic vs. White	Native American vs. White	Asian vs. White	Combined Minority Race vs. White
ED visits	Predictive		3[a71, 72, 92]	1[a71] 1[b72]	1[a72]	1[b72]	1[a67]
	Cross-sectional	5[a93-95, 98, 107] 2[b89, 92] 4[66, 90, 91, 102]	6[a89, 90, 92, 93, 102, 103]	1[a93] 3[b92, 94, 102] 1[103]	1[a102]	2[b92, 102] 1[103]	1[b98] 1[91]
IP admissions	Predictive	2[a79, 82]	2[b79, 82]	1[a79] 1[b82]	-	1[b82]	-
	Cross-sectional	-	1[83]	-	-	-	-
All Utilization	Predictive	1[b69]	-	-	-	-	-
	Cross-sectional	1[85]	-	-	-	-	-
Cost	Predictive	-	-	-	-	-	-
	Cross-sectional	1[b65] 1[84]	-	-	-	-	-

[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 symbol, then denotes non-significant. Blank cell denotes no reported sociodemographic, behavioral health, or social risk factors.
ED = emergency department; HNHC = high-need, high-cost; IP = inpatient; vs. = versus.
- Denotes no studies.

Table 12. Number of multivariate studies examining behavioral health and social risk factors associated with high healthcare use or cost among HNHC populations by direction and significance of effect

Outcome	Study Design	Depression	SMI	Other Mental Health Conditions	SUD	AUD	Home-less	Employed	Low Income or Poverty
ED visits	Predictive	1[a71]	1[b71]	2[a71, 72]	1[a71]	1[a71]	-	-	1[a100] 1[71]
	Cross-sectional	3[a93, 94, 107] 1[100]	2[a94, 107] 1[98]	5[a89, 92, 97, 99, 107] 1[91]	6[a66, 89, 93, 94, 97, 107] 2[90, 91]	4[a90, 97, 102, 107] 3[66, 91, 92]	4[a66, 90, 102, 107] 1[91]	3[b89, 92, 98,	5[a92-94, 99, 103] 1[95]
IP admissions	Predictive	-	1[a81]	3[a73, 77, 79, 82]	3[a73, 77, 79, 82]		1[b79]	-	1[a82]
	Cross-sectional	-	-	1[a105]	2[a83, 105]	1 [a 83]	1[a83]	-	1[83]
All Utilization	Predictive	-	-	2[69, 74]	-	-	-	-	-
	Cross-sectional	-	-	1[104]	-	-	-	-	-
Cost	Predictive	-	-	-	-	-	-	-	-
	Cross-sectional	1[a65] 1[86]		3[a84, 86, 106]	1[84]	1[84]		1[84]	

[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 symbol, then denotes non-significant. Blank cell denotes no reported sociodemographic, behavioral health, or social risk factors.
- Denotes no studies.
AUD = alcohol use disorder; ED = emergency department; HNHC = high-need, high-cost; IP = inpatient; SMI = serious mental illness; SUD = substance use disorder; vs. = versus.

Demographic Risk Factors

Key Points

- Older age was associated with high utilization in both predictive and cross-sectional analyses.
- The association between gender and high utilization was mixed.
- The association between race and ethnicity with healthcare use varied among groups. In comparison with white race, black race was associated with higher ED utilization, Asian race was associated with lower ED and inpatient utilization, and the results for Hispanic ethnicity were mixed.

Results of Studies

Demographic characteristics, including age, gender, and race, were included in the analyses in almost all studies. In some analyses, they were used solely as control variables in multivariate models and findings were not presented. Age was commonly reported in categories but groupings were not defined consistently across analyses.

Age

A total of 28 predictive and cross-sectional articles included age in modeling characteristics to identify HNHC patients. No latent class/cluster analysis included age as an indicator for creating clusters and no qualitative studies discussed age.

In exposure studies, older age was most commonly associated with higher healthcare use and cost, compared with younger age. Because of differences in the age range across studies and categories used to depict age in analyses, we did not have one metric that would be helpful in sorting our findings into a table. Therefore, we do not report findings by age in Table 9.

Five predictive studies reported a significant relationship between older age and high utilization outcomes in a subsequent period, including number of ED visits, inpatient admissions, and total healthcare visits.[67, 69, 72, 79, 82] Of these, three reported an association between high utilization and being middle-aged and older.[67, 69, 79]

One study found the direction of the effect of age followed a different pattern when the population included the elderly and younger people with disabilities. Colligan and colleagues noted a high probability of both frequent and persistent ED use among non-aged Medicare beneficiaries, compared with individuals 65 years or older.[72] Beneficiaries younger than 35 years old had the highest risk of frequent ED use (compared with those over 65 years)—even higher than other younger than 65 age groups. Because individuals younger than 65 years only qualify for Medicare because of disability, this study's findings are correlated with disability status to some extent and not simply related to age.

The majority of cross-sectional studies similarly found that older age predicted high utilization. This pattern held across different study populations and types of utilization. Only one study found the opposite relationship, that patients admitted to one family medicine inpatient service, who were older (older than 60 years of age) had lower odds of a "high frequency readmission" (3 or more inpatient readmissions in a given year) compared with younger patients.[105] The family medicine inpatient service consisted of a team of interns, residents and pharmacy students supervised by an attending physician. The role of this team is 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 physicians might not be as intuitively concerned about readmission for patients younger than 60 years and may not probe to ensure that this high-risk portion of the non-aged population have appropriate aftercare supports.

Gender

Gender was a predictor examined across patient populations and high utilization outcomes in 4 predictive and 15 cross-sectional analyses. We found no discernable pattern of differences by gender in relation to type of utilization across patient populations.[65, 66, 69, 76, 79, 82, 84, 85, 89-95, 98, 102, 107, 154]

One of the six latent class/cluster analysis articles included gender as an identifier for HNHC clusters. Within a VA population, Szymoniak and colleagues identified one high use cluster as consisting of females with trimorbid conditions who relied heavily on mental health inpatient and ED utilization, and a second, consisting of males with trimorbid conditions with high utilization of inpatient substance use services.[108] No qualitative study examined gender.

Race/Ethnicity

Racial groups and Hispanic ethnicity (compared to white race) were commonly included variables in studies. However, the interpretation of findings is complicated by possible mediating factors. Considerations such as poverty and environment have been known to have a complex relationship with race, particularly black race, and access to care. As a result, in some cases, race may be a proxy for some other patient characteristics, rather than an additional risk factor.[167-169]

The relationship between race and ethnicity and healthcare utilization patterns was examined in 27 predictive and cross-sectional studies. Race was not a characteristic of note in cluster analyses. In predictive studies, black race was associated with future higher ED utilization in two studies,[71, 72] and lower inpatient utilization in two other studies.[79, 82] In six cross-sectional studies, we also found black race to be significantly associated with higher ED utilization.[79, 82]Individuals who were Native American had higher ED utilization.[72] Asian race was associated with lower ED and inpatient utilization.[72, 82]The relationship between Hispanic ethnicity and utilization results were mixed across three predictive studies[72, 82, 170] and four cross sectional studies.[67, 71, 79, 82]

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 SMI are mixed.
- SUD is consistently associated with high use and high cost.
- Results for the association between AUD and high utilization is mixed.

Results of Studies

Twenty-five studies examined the association between behavioral health conditions (mental health concerns, SUDs and AUDs) and being HNHC.[65, 66, 69, 71-74, 77, 79, 81-84, 86, 89-94, 97, 99, 102, 105-107] Mental health concerns were further delineated as depression, SMI, and other mental health disorders.

Depression was significantly associated with ED use in one predictive study[71] and three cross-sectional studies.[93, 94, 107] In one other study, depression was associated with high cost.[65]

The findings for diagnoses reflective of SMI were nuanced. One predictive analysis examined patterns in high ED use over time. Schizophrenia was negatively associated with persistent high ED use (compared with nonpersistent high use) at 3 and 6 year follow-up but not significant by 11 years.[71] Instead, after 11 years, persistent high ED use was associated with having an anxiety disorder or having attempted suicide or intentionally self-inflicted injury. Another study indicated an increased risk of future hospital readmission and SMI, among Medicaid enrollees.[81]

Similarly, two cross-sectional studies revealed a positive association between SMI and high ED use. One study measured psychosis in a population with COPD,[94] and the second study measured diagnoses of schizophrenia, personality disorder and bi-polar disorder.[94, 107] A third study did not find an association.[94, 98, 107] However, the study measured psychiatric diagnosis, which is a broad term which could include different mental health diagnoses and does not isolate the effects of SMI.

Qualitative studies support the quantitative findings of association between SMI and high healthcare use.[118, 119] One 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.[119] Another qualitative study determined that patient-system mismatch, not patient diagnosis, contributed to high utilization.[118] This study clarified that high utilization results from patients' "behavioral issues interfering with care engagement, and lack of health system flexibility to address these barriers"[118, p. 497] in primary care, partially due to the limited time allowed to spend with each patient.

Other measures of mental health disorders were from global mental health assessments obtained by clinicians and self-report. Two predictive studies indicated a positive relationship between the presence of any mental health diagnosis and high ED utilization.[71, 72] Cross-sectional studies reached similar findings.[66, 89, 92, 97, 99, 107] Mental health conditions were also a predictor of future high inpatient utilization[73, 77, 79, 81, 82] with supporting evidence from cross-sectional articles.[105] Neither predictive[69, 74, 77] nor cross-sectional studies[104] found a significant relationship between mental health disorders and total healthcare utilization. However, three predictive articles found a positive association with high health care cost.[84, 86, 106]

SUDs were associated with high-use and high-cost care. SUD diagnosis was a predictor of both future high ED utilization[71] and inpatient admission.[73, 77, 79, 81, 82] Similarly, cross-sectional studies found SUD to be associated with ED utilization,[66, 89, 93, 94, 97, 107] and inpatient admission.[83, 105] Two additional cross-sectional studies found SUD to be associated with high cost. [83, 105]

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 utilization.[71] Cross-sectional results were mixed. Four cross-sectional studies showed a positive association,[90, 97, 102, 107] while three did not find a relationship.[66, 91, 92]

Five latent class/cluster analysis articles included behavioral health characteristics in HNHC clusters.[108, 109, 113, 171] Generally groups included a measure of poor mental health functioning or mental health diagnoses. (See Table 4)

Social Risk Factors

Key Points

- Studies conducted in hospital and health systems, including the VA, found homelessness to be associated with high ED utilization.
- Studies conducted in hospital and health systems and population-based survey data did not find a clear relationship between employment status and high healthcare utilization.
- Poverty, as defined by low income, is associated with high utilization.

Results of Studies

Twenty-two studies evaluated social risk factors (i.e., homelessness, unemployment, and poverty/low income).[66, 67, 71, 73, 76, 77, 79, 82, 83, 90, 92-95, 99, 100, 102, 103, 107]

Predictive studies' results were mixed regarding the association of homelessness and low income with high utilization.[71, 73, 76, 77, 79, 82] Four cross-sectional studies found a positive association between homelessness and high ED utilization.[66, 90, 102, 107] Ten cross-sectional studies addressed the relationship between poverty and high utilization: seven articles found low income or poverty was related to high utilization of healthcare,[76, 82, 92-94, 99, 100, 103] and three articles indicated no significant association.[71, 83, 95] However, the meaning of the effect in one of the studies that found no significant association between poverty and high healthcare utilization is unclear because the study also controlled for insurance status.[71]

The cross-sectional results for employment status were mixed. One study showed a positive association between employment and high utilization,[89] one study indicated a negative association,[98] and one study indicated no significant relationship.[89, 92, 98]

One latent class/cluster analysis study included an indicator for social risk factors.[108] Homelessness and combat exposure were noted as risk factors for VHA HNHC patients. One cluster consisted of veterans who were homeless and had high ED use for behavioral health and medical care. A second consisted of veterans with high combat exposure who had high use of mental health inpatient care. A third cluster was female veterans with high combat exposure who had high use of mental health inpatient care and ED visits.

KQ 1c: How do criteria to predict or explain which patients will be HNHC incorporate types, amount, duration, and patterns of healthcare use?

Key Points

- Regarding *types of healthcare use* that explain or predict high utilization, prior expenditures, ED use, hospitalizations, physician or outpatient visits, primary care and specialty visits, visits to mental healthcare, discharges against medical advice, and prior healthcare utilization as a whole were significant predictors of future high utilization (variously defined as use of all healthcare care services, ED use, and inpatient use).
- Regarding *amount or duration* of healthcare use that predicts or explains high utilization (e.g., 5 or more visits or within 6 months), studies were inconsistent in their use of thresholds, making interpretation challenging.

- Regarding patterns of healthcare use that predict or explain high utilization, both frequent and infrequent prior ED use predicted future high ED use. First or second hospitalization for a behavioral health diagnosis predicted fragmented hospital use, defined as multiple hospital episodes across different facilities.

Results of Studies

We found wide variation in both how high healthcare use or cost outcomes and predictors were defined. Table 13 presents outcomes across predictive and cross-sectional studies.

Twenty-six studies measured the outcome of high use of ED visits.[66, 67, 71-73, 75, 76, 77 , 89-103, 107, 110, 115, 116] No standard or consensus definition for frequent or persistent ED utilization 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 utilization affected which characteristics would be significantly associated with the outcome.

As with the wide variation in how high healthcare use or cost outcomes were defined, predictive studies varied substantially in how they incorporated prior healthcare use or cost as covariates in models. A few studies included algorithms that incorporated measures of prior healthcare use and reported on the algorithm's overall performance in effectively predicting high utilization and cost outcomes.[68, 78, 80, 81] Use and cost measures included across algorithms were frequency of and intervals between hospital admissions and ED visits, primary care provider and specialty care visits, and other services, including prescription drugs,[81] prior expenditures,[68, 78] and hospital admissions, ED use, and outpatient clinic visits.[80] However, the importance of each component of the algorithms is unclear. Because the reports on the algorithms are limited to their overall performance, we cannot determine the importance of prior use or cost relative to other algorithm components.

In contrast, and more commonly, studies directly incorporated measures of prior healthcare use in regression models. These studies reported that prior expenditures,[70, 75] ED use,[66, 67, 71-73, 75, 77, 79] hospitalizations,[69, 73, 77, 82] physician or outpatient visits,[69, 72] primary care and specialty visits,[75] visits to mental healthcare,[79] palliative care encounters[79] discharges against medical advice,[79] and prior overall healthcare use[74, 77] were significantly associated with predicting future high use (variously defined as use of all healthcare services,[74, 77] cost,[69] cost,[70] ED use,[66, 67, 71, 72, 75] and inpatient use[73, 77, 79, 82]).

A few studies specified minimal thresholds for the amount (e.g., 5 or more visits[72]) or duration of use (e.g., within 6 months[69]), but the lack of consistency across studies limits our ability to interpret these associations.

Few studies reported on the patterns of prior healthcare use. One study noted that both frequent and infrequent prior ED use predicted future high ED use.[72] A second study reported that hospitalization for a behavioral health diagnosis was the greatest predictor of fragmented hospital use, defined as multiple hospital episodes across different facilities.[82]

Table 13. Definitions of HNHC healthcare use or cost outcomes in predictive and cross-section studies

		ED Visits: Minimum Number								IP admissions		All Utiliza-tion	Top percentage			
		1	2	3	4	5	6	>6	Multiple Measures	1	More than 1	Top decile (≥75th)	10%	20%	25% +	Cost ratios
Medicaid	Predictive	-	-	2[75]	-	1[75]	-	-	1[75]	3[73, 77, 80, 81]	-	-	3[68, 70, 78]	-	-	-
Medicare	Predictive	-	-	-	1[72]	-	-	-	-	-	-	-	-	-	-	-
VA	Predictive	-	-	-	-	-	-	-	-	1[79]	-	-	-	-	-	-
	Cross-sectional	1[107]	1[a107]		-	1[b107]	-	1[107]	1[107]	-	-	1[88]	-	-	-	-
Hospital/ health system	Predictive	1[67]	1[67]	1[67]	3[66, 67, 76]	1[67]	-	-	1[67]	1[82]	-	-	-	-	-	-
	Cross-sectional	-	2[89, 91, 95, 101, 154]	5[89, 93-96, 154]	3[89, 90, 95, 97, 154]	3[89, 95, 97, 102]	2[97]	2[95, 97, 98, 101]	4[89, 95, 97, 101, 154]	-	2[83, 105]	2[85, 104]	-	-	-	-
Commercial (including HMO)	Predictive	-	-	-	-	-	-	-	-	-	-	1[69]	-	-	-	-
	Cross-sectional	-	-	-	-	-	-	-	-	-	-	-	1[84]	1[86]	1[65]	1[106]
Population based	Predictive	-	-	-	1[71]	-	-	-	-	-	-	1[74]	-	-	-	-
	Cross-sectional	-	-	-	3[92, 99, 100]	-	-	-	1[92, 99]	-	-	1[87]	-	-	-	-

[a] The outcome is 2-4 visits.
[b] The outcome is 5-10 visits
- Denotes no studies.
ED = emergency department; HMO = health maintenance organization; IP = inpatient; VA = Veterans Administration.

KQ 1d: Do criteria differ when HNHC is identified at the population, payer, healthcare system, or provider level?

Key Points

- Analyses across payers revealed that prior high healthcare utilization and behavioral health diagnoses are predictive of high ED utilization. Specifically, prior high health care utilization was predictive of high ED utilization among Medicaid, Medicare, Veteran's Administration, hospitals/health systems, and population-based populations. Behavioral health diagnoses were predictive of high ED utilization among Medicare, Veteran's Administration, and hospitals/health systems populations.
- Among multi-payer and population-based studies, having Medicare and Medicaid insurance coverage is predictive of high healthcare utilization.
- Only one study focused solely on the Medicare population. Predictors of frequent ED use were younger age, chronic medical or MH conditions, hierarchical categorical condition score, dual enrollment in Medicaid, and five or more physician visits.

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 14 provides a summary of the study population level by outcome.

Table 14. Number of studies by population level and criteria used to define HNHC

Level	ED Visits	IP Visits	All Utilization	Cost	Policy/Other
Population based	Predictive: 1[75] Cross-sectional: 7[92-95, 99, 100, 103]	-	Predictive: 1[73, 77, 80, 81] Cross-sectional: 1[87]	-	Qualitative: 1[117]
Payer: Medicaid	Predictive: 1[72] Latent class: 1[110]	Predictive: 3[73, 77, 80, 81]	-	Predictive: 2[68, 70, 78]	-
Payer: Medicare	-	Predictive: 1[107]	-	-	-
Health plans, including managed care organizations	-	-	Predictive: 1[82]	Cross-sectional: 4[83, 105] Latent class: 1[113]	-
Veterans Health Administration	Cross-sectional: 1[107]	Predictive: 1[79] Latent class: 2[109, 111]	Cross-sectional: 1[69] Latent class:1[108]	-	-
Population based	Predictive: 3[66, 67, 76] Cross-sectional: 7[89-91, 96-98, 101, 102] Qualitative: 2[115, 116]	Predictive:2[74] Cross-sectional: 2[83, 105] Qualitative: 1[118]	Cross-sectional: 2[85, 104]	Qualitative: 1[114]	Qualitative: 1[87]

- Denotes no studies.
ED = emergency department; HMO = health maintenance organization; HNHC = high-need, high-cost; IP = inpatient.

The largest group of the identified studies, 19 of 47 were conducted by single hospitals, multiple hospitals located in specific geographic areas such as states or counties, or health systems.[66, 67, 76, 82, 83, 85, 89-91, 93-98, 101, 102, 104, 105, 154] These studies were all multipayer analyses,

with many including payer and prior utilization in the particular health system as a predictor of HNHC patient use or cost.

Health System or Hospital Setting

Three hospital-based studies investigated predictors of high ED utilization.[66, 67, 76] Two of the studies focused on the general HNHC population, regardless of primary complaint. One found that the number of ED visits in the baseline period, age, zip code, and the number of days since the last ED and outpatient visits predicted higher future ED use.[67] Another study found that compared with nonpersistent ED high-utilizing patients, persistent ED high-utilizing patients, defined as visiting the ED four or more times within a year, over two consecutive periods were more medically and psychosocially complex and have a higher risk of future hospitalization, but not future ED visits.[76] A third 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, positive screen for cocaine use, homelessness, personality disorder, and hepatobiliary disease.[66] Four cross-sectional studies also evaluated multiple aspects associated with high ED utilization and found an association between Medicaid and/or Medicare coverage and high ED utilization.[89, 90, 94, 95, 102, 154]

Hospital- and health systems–based articles did not appear to support any discernable pattern in high inpatient utilization. One study analyzed predictors of fragmented high inpatient utilization (care in multiple hospitals) in a specific geographic area and found that fragmentation was more likely among men, the middle aged, and the privately insured.[82] Another cross-sectional study found that Medicaid and Medicare insurance coverage, a history of drug use, and being homeless contributed to significantly increased odds of being HNHC, measured as 3 or more readmissions in a calendar year.[105] This study also found that the population of patients who were considered to be high utilizers for hospital readmissions was dynamic and the composition of individual patients changed during the 3 consecutive years of the analysis.[105]

Two cross-sectional studies evaluated the feasibility of using rating scales to determine risk for increased healthcare use.[85, 104] One article tested the association of the Modified Charlson severity index with high utilization of medical visits in a primary care setting, finding the index to be accurate and practical in this setting.[85] One article described the feasibility of using a self-reported physical health measure to assess the risk for high healthcare utilization. The study determined that worse self-reported physical health, measured during routine healthcare visits, was associated with significantly higher rates of hospitalization and was not associated with increased rates of ED visits.[104]

Health Plans, Including Managed Care Organizations

Of the seven studies of health plan enrollees, including managed care organizations, six studies included high cost as the outcome of interest. One study, validating the predictive abilities of the Health Perceptions Assessment tool, a screener to predict a high number of healthcare encounters based on patient beliefs about their health and functioning, was the exception.[69]

Four cross-sectional studies focused on drivers of high healthcare cost. Behavioral health factors were significant independent variables across studies. One study, among a commercial HMO population, showed that the presence of behavioral health conditions, in addition to other characteristics was positively associated with being in the top 25 percent in total cost.[65] Another cross-sectional study also found that being in the highest cost group was significantly associated

with SUD and having a mental health condition.[84] One study of members of an HMO with post-traumatic stress disorder found that severity of the symptoms was associated with higher healthcare costs.[106] Another study 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, and witnessing domestic violence).[86]

Two cluster analyses were conducted in commercial HMO populations.[113, 171] In one cluster analysis, clusters were largely centered around different configurations of ADL limitations.[112] The other study included groupings of different chronic diseases with an overlay of comorbid conditions such as mental health condition, diabetes, and obesity.[113]

Veteran's Health Administration

Patients seeking services through the VHA were the population in six studies.[79, 88, 107-109, 111] Several of these studies focused on behavioral health and social risk factors as drivers of HNHC outcomes. One cross-sectional study of ED utilization found that the factors most strongly associated with multiple distinct levels of ED use, including 1, 2-4, 5 -10, 11- 25, and greater than 25 ED visits per year, were a diagnosis of schizophrenia, homelessness, opioid prescriptions, and heart failure.[107] Persistent risk of inpatient utilization was predicted by a variety of chronic diseases, zip code changes, urban address, nonadherence to medical care, and 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.[79]

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.[108, 109, 111]

Payer Level

Nine articles representing seven studies focused on the Medicaid population.[68, 70, 73, 75, 77, 78, 80, 81, 110] All were predictive studies analyzing claims data. One study used claims data to conduct analyses predicting high ED utilization, defined as three or more, five or more, eight or more or 10 or more visits.[75] Chronic conditions, past expenditures, and all types of prior utilization predicted high ED utilization. One study enriched claims data with patient interviews, providing a more nuanced understanding of patients' circumstances.[80] It determined that HNHC patients shared many risk factors for high inpatient utilization that have been challenging for providers to address. Patients interviewed cited homelessness, social isolation, substance use, depression, anxiety, and fragmented primary care as contributors.[80]

Only one study focused exclusively on the Medicare population.[72] This study found that frequent ED use in one year, defined as 4 or more ED visits (compared with no visits) was the strongest predictor of ED use in the subsequent year (RR = 35.2).

Population Level

Seven population-based studies addressed characteristics predictive of or associated with high healthcare utilization.[71, 74, 77, 87, 92, 99, 100, 103] One predictive study found that persistent frequent ED utilization at 3-, 6-, and 11-year intervals was positively associated with having public health insurance (Medicaid or Medicare) compared with commercial insurance. However,

the key finding (largest odds ratio) was that persistent frequent ED use is predicted by the intensity of ED use at baseline across the time interval, controlling for other factors.[71] Cross-sectional studies supported the findings regarding prior utilization and insurance status. One study found a positive association between having public insurance, a clinic or the ED as the usual source of care, and poor health with frequent ED use, as well as being more likely to be poor, heavy users of other outpatient care, and dissatisfied with their medical care.[99] Another cross-sectional population-based study found that being publicly versus privately insured and having had three or more outpatient visits but perceiving that you have unmet medical needs was associated with high ED use.[103] A population-based study of individuals with debilitating headaches partially supported findings about health insurance status and prior use. While controlling for disease severity, they found frequent ED use was associated with lower income and prior utilization of the ED for reasons other than headache; however, medical insurance was not protective against ED use.[100]

A predictive population-based study supported prior utilization, defined as at least one ED visit, one inpatient admission or at least 10 health professional office visits during the past 12 months, as a predictor of high inpatient hospital care.[74] 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.[74]

KQ 1e: How do studies differentiate potentially preventable or modifiable high use of healthcare 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 reports an alternative mechanism for identifying individuals at risk for potentially preventable healthcare use that relies 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 non-emergent 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 high users (e.g., 27 or more outpatient visits in 12 months[85] or top decile of all-cause total costs.[84] 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 four years of Medicaid data from Texas.[68, 78] 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 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. "[78, 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 one 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 emergency department 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.

Two studies surveyed patient population whose ED use may be preventable or modifiable, at least in part. Both studies focused on patients receiving care at an ED who were assigned an Emergency Severity Index score of 4 or 5, a classification of least urgent/non-emergent.[89, 96] In the first study,[89] the authors did not evaluate the severity score of these patients' earlier ED visits. Therefore, we cannot conclude if characteristics they found associated with high use across all ED visits are more likely to apply to patients whose ED use might be considered preventable or modifiable. The second study[96] 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), based on results from multivariate analyses, controlling for potential confounding.

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 42 studies (45 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 interventions.
- **Program Theory 1**. Identifying and targeting HNHC patients for interventions intended to reduce potentially preventable or modifiable healthcare use and costs requires capturing their complexity. HNHC patient complexity is based on consideration of a combination of factors. These are the patient's prior use of healthcare services, chronic

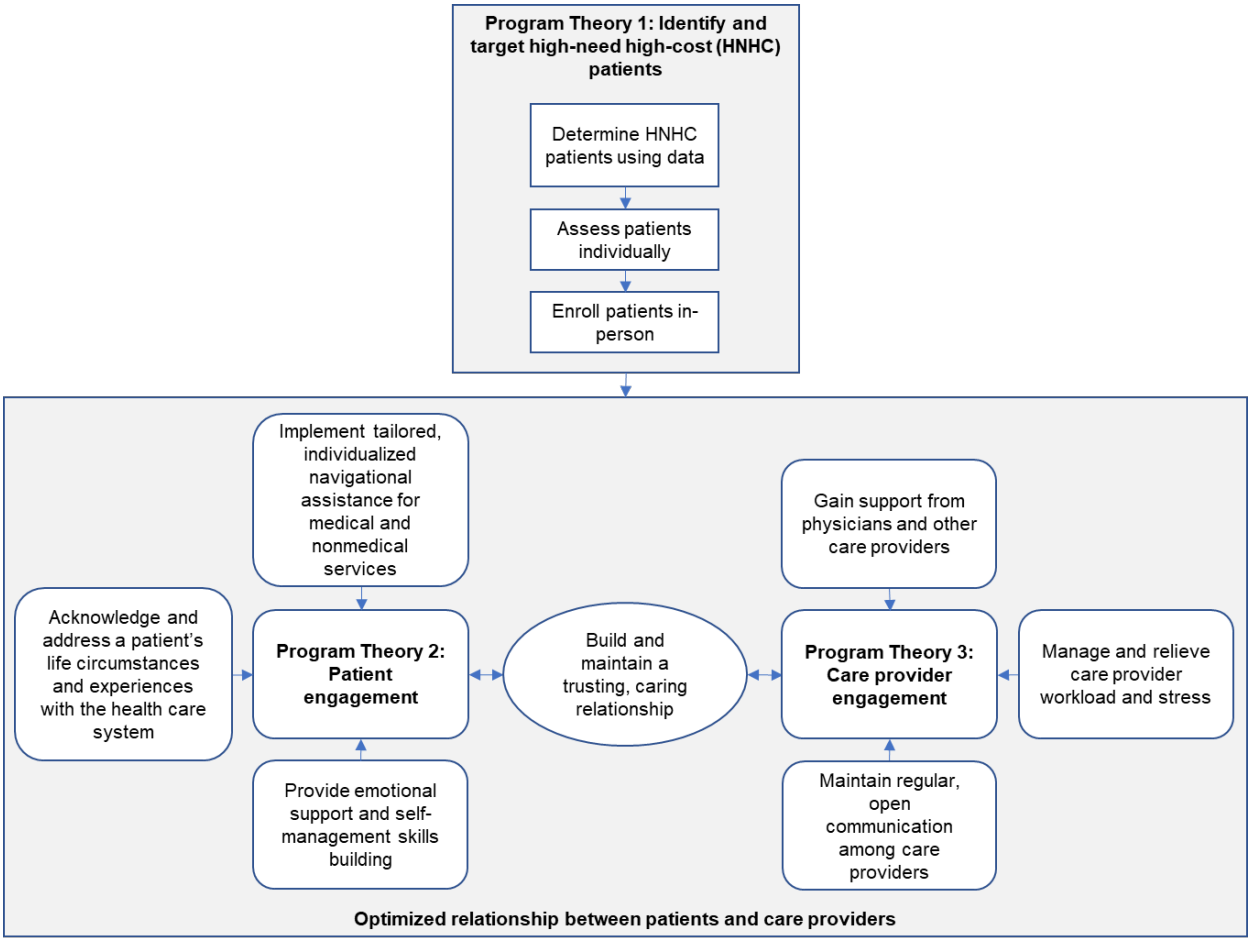
disease, nonmedical barriers to accessing care, experience with the healthcare system, clinician judgment, and willingness to participate in an intervention.

- **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 care 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, 42 studies (45 articles) were included in the realist review. Of the 45 articles, 14 were also used as evidence in KQ 1 and 22 articles were used as evidence in KQ 3. These studies were used to develop context-mechanism-outcome (CMO) configurations related to the implementation of interventions for HNHC patients. These CMOs were then used to iteratively refine three realist program theories (or our model of how and under what conditions an intervention is expected to work).

Program Theory 1 concerns the pathway for identifying and targeting patients for HNHC interventions. Once enrolled, building and maintaining trusting and caring relationships between patients and care providers underpin successful interventions. 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, and 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, 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.[67, 68, 71, 72, 78, 81, 111, 120, 121] However, while these data are generally considered necessary, they are not sufficient for identifying the population. The data 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[57, 117, 120] (see also KQ 1 findings). Regression to the mean can be a barrier to accurate projections (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).[55, 56, 81, 121]

The accuracy of data-based healthcare use and cost projections can be facilitated by refining current period specifications in several specific ways: (1) limiting data to healthcare use that would be the focus of an HNHC 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);[122] (2) including data across care settings and payers to capture the continuum of care;[120, 122] (3) focusing on use of services in "real time,"[58, 122] particularly, if possible, while a patient is still hospitalized, to identify the urgent need for an intervention;[56, 81] 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), because a cluster pattern has been found to be associated with HNHC ED service use.[115]

In addition to providing information on individuals' 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;[55] functional limitations;[20] and high scores on measures of clinical risk severity, such as the Chronic Condition Indicator (CCI)[55, 57-59, 123, 124] and concurrent hierarchical condition category (HCC).[58] 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 abuse diagnoses. Behavioral health diagnoses, comorbid with chronic medical conditions is associated with higher ED use and poorer disease management.[59, 81, 117, 119, 125] Also, 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.[115] 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.[115]

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 to further refine predictions of future modifiable high-cost care and use. Examples include the Medicare Health Risk Assessment, a tool that provides a patient's self-assessment of health status, psychosocial risks, depression, behavioral risks, pain, activities of daily living, and instrumental activities of daily living.[112, 126] Other simple assessments that can be administered directly to patients to determine 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 if they have been prescribed more than five medications.[124] 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.[137] Low health literacy scores are associated with poorer patient activation.[119]

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. Reliance on the ED system among HNHC patients is related to negative prior experiences with the traditional service delivery system not being designed for patients with complex healthcare needs.[118, 119] Resulting specific barriers to changing their behavior include distrust for providers and the larger healthcare system;[114, 123, 127] the time and expense of getting to a primary care provider's office, particularly if multiple visits and public transportation is required;[119] providers not accepting their insurance;[119] the cost of care being expensive;[119] long wait times to see a primary care provider; care after hours not being available;[119] and the belief that better quality of care is available in the ED than with the primary care provider/clinic.[116] Among HNHC individuals who are homeless or who have unstable housing, greater ED use is also associated with the ED providing shelter and respite.[119]

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.[122, 123, 127-130] The HNHC patient's current provider's judgment can add to the identification and selection of patients who are appropriate for the intervention.[128, 130] 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).[130] 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.[130, 131] 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.[130] Community health workers can help the care team understand the challenges and needs of these patients.[127] Excluding the patients who are more difficult to engage may reinforce and exacerbate disparities.[130]

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[56] 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.[40, 81, 125]

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 these patients that will facilitate behavior change. HNHC patients often come to interventions that are intended to help them manage their chronic diseases with a complex history of personal, social, and medical issues. Personal and current life circumstances often inhibit HNHC patients' ability to benefit from the interventions. The 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.[40, 59, 81, 123, 127, 138] Many of these 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 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.[123, 127, 133] 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 contributes to their not accepting and seeking all of the help and care they need.[123, 133, 138] Patients may have experienced disrespect by providers based on sex-, race-, or socioeconomic-based discriminations or feel uncared about, disengaged from maintaining self-care, or a lack of self-worth or deservingness of services.[127, 138] 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."[123, 127, 133, 138]

Building Relationships With Care Providers

Critical to engaging HNHC patients in an intervention and turning around insufficient disease self-management skills and a negative history with the healthcare system, patients need to trust the individuals providing the intervention services.[123] 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.[58-60, 131, 133, 139] 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 practice to affect diet and organizing medications.[123-125, 127, 131, 138-141]

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.[60] For example, patients appreciate when their care managers step in on their behalf and advocate for them when the patient is frustrated by their interactions with clinicians.[139] HNHC patients report feeling more supported, confident, and motivated in their efforts to change, with more frequent and longer visits with a care manager and, relatedly, having a greater opportunity to discuss both their clinical and psychosocial needs and receive feedback more often, especially after taking small steps on their own.[118, 123, 133, 138-140]

Patients are reassured knowing they have a care team to support them in managing their health and welfare.[59, 118, 123, 132, 138, 139] 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.[133, 138, 139] 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, the patient 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.[58, 123, 133, 138]

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 patients' needs and circumstances empowers providers to work with patients and their families to develop targeted interventions that reflect the patient's diverse needs.[118, 122, 123, 125, 127, 146] 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.[59, 81, 118, 123, 125] 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.[81, 118]

Interventions may teach patients how to connect to medical and non-medical cross-sector services that address their personal and system-level barriers to build patients' self-confidence.[40, 81, 124, 125, 133, 140, 141] 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.[123, 127]

Recognizing Barriers to Patient Change

Even after the establishment of 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.[132] 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.[63, 133] For HNHC interventions, patient-centered success may need to be redefined to be incremental goals, such as changes in the patients' self-care behaviors, interactions with the clinic, and relationships with providers, rather than changes in larger healthcare utilization or cost goals.[40, 118 132] However, gradual improvements in patients' experiences with their care providers may lead to long-term benefits in health behaviors and clinical outcomes.[132]

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.[40, 55, 56, 59, 124, 125, 132-135] 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 intervention can help smooth the path for implementing new processes into a care setting.[56, 59] Buy-in for the intervention is crucial across all care providers, and leadership support should be used to help attain staff support.[59] For example, visible organizational leadership assistance 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.[59]

When implementing interventions, health systems' use of targeted outreach to physicians supports securing their engagement, a necessary component for program success.[56, 59, 121] Garnering initial physician support and participation in an intervention is facilitated by outreach to physicians directly by a medical director[59] or nurse[121], or indirectly through practice staff and practice administrators by a nurse.[121] The outreach is more likely to be effective when it is practice specific, tailored, and face-to-face.[59, 121] Physicians' support for an HNHC patient intervention is increased if they believe the intervention will benefit their patients' care.[57, 59, 121] 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.[57] Recruiting physician champions can also facilitate support among fellow physicians,[56] as well as others among the practice staff.[59] 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.[59]

After initial physician support is obtained, it needs to be maintained and supported. Enough patients within a practice need to be participating in the intervention to justify the up-front work and cost to the practice.[56, 57] Financial incentives in the form of physician enrollment incentives, per-patient-per-month fees, counting of HNHC patients as more than one non-HNHC patient on physician panels, and other incentives that acknowledge the additional time needed to care for HNHC patients can be used to encourage physicians' continued support.[56, 59, 128]

Managing and Relieving Care Provider Workload and Stress

Acknowledging and managing care provider workload and stress is 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.[60, 136] The increase in stress can be explained by the increase in workload and responsibilities that many providers experience when participating in HNHC interventions[136] and by the emotional toll of working among sicker and frailer patients.[59]

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 to implement the intervention. This support may include providing training, supporting dedicated time to implement new processes, creating new positions, and hiring new staff to support care providers.[59, 60, 127, 136] HNHC interventions often organize providers into care teams to both provide more coordinated care for HNHC patients and provide mutual support for care providers.[59, 60, 63, 118, 123, 136] 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 required for managing HNHC patients (e.g., building trust, managing medication, referring community resources).[59, 60, 127] Other staff, such as community health workers, may add additional, nonclinical peer perspectives and insights into the needs of and challenges faced by HNHC patients that more traditional, health system–focused care team members may not have considered previously.[127] As the care team observes 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.[127] Care provider caseloads should 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.[60]

Finally, team members may gain additional emotional and technical support through peer counseling across offices and healthcare systems.[59, 60, 136] Providing regular opportunities for care team members to talk helps them cope with their frustrations from caring for HNHC patients by providing mutual support and assistance.[136] For example, a care manager network across health systems gives care managers opportunities to share best practices and provide emotional support for each other.[59, 60]

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 care teams with shared values and commitments[118] and coordinated care.[63] Tools to ensure regular communication among all care team members include regular newsletters, email feedback, intervention websites, and care team meetings.[56, 59, 136]

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.[63] Organization-wide meetings may be used to discuss broader performance and intervention goals and implications and topics for care, while practice-level meetings may be used to discuss practice-specific issues, including individual physician performance, protocol development, and provider trainings.[59, 63] At the care team level, small care team meetings or huddles that include all care team members give the team an opportunity to openly discuss specific patient cases.[59, 63, 127, 136] These open discussions foster a supportive environment for discussing positive and negative elements of patient care approaches[59] and performance on

quality metrics, outcomes, and other performance goals.[63] Physicians also receive practical, constructive feedback on approaches to care during care team meetings.[63, 136] To maximize the benefits of care team meetings, physicians and other care providers need sufficient time to attend care meetings and to act on patient care plans.[136]

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.[63] Being co-located in the same practice, or, even better, sitting next to each other, allows all team members to be heard, thus fostering strong working relationships, good team communication, and ultimately improves the coordination of patient care.[57, 63, 118] When introducing new positions such as care managers or care coordinators, having these individuals embedded in practices and physically part of the care team is particularly valuable because it encourages physicians and other existing practice staff to use their services.[57, 59, 60] Strong team communication and coordination related to patients' needs may ultimately help teams achieve long-term intervention goals (e.g., avoiding unnecessary readmissions, inpatient admissions, and ED visits).[63] 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 in other healthcare systems.[57, 121]

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

For the KQ 3 results, we describe the characteristics of included studies, organized by seven intervention model types based on the principal setting where the intervention took place: 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.) We also present outcomes rated as insufficient strength of evidence when two or more samples provided evidence. Outcomes for which only a single study was found were graded as insufficient and are not discussed in detail. 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

From the 32 studies included in KQ 3 (see the beginning of the chapter for a breakdown of the studies by study design and risk of bias), 40 samples were included in the analysis. As described in the Methods Section, multiple studies included in our review consisted of multiple cohorts, populations, or analyses that we included as "samples"; 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, study authors also required that

patients 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 (30% of samples) to six or more sites (40% of samples).

Table 15. Key characteristics for KQ 3 included samples (N=40)

Study Characteristics	Categories	Number of Samples	Percent of Samples
Risk of bias assessment by study design	RCT: Low risk-of-bias studies	4	10%
	RCT: Some concerns for risk-of-bias studies	15	38%
	Observational: Some concerns for risk-of-bias studies	15	38%
	Observational: High risk-of-bias studies	6	15%
Participant eligibility	High use only	20	50%
	High cost only	1	3%
	High use or cost and any chronic condition	19	48%
Participant Age Range	<65 only	2	5%
	65+ only	16	40%
	All adults	18	45%
	Not reported	4	10%
Participant Race	Majority white (>50%)	4	10%
	Majority nonwhite (≥50%)	11	28%
	Not reported	25	63%
Participant High Risk Conditions	Majority with mental health diagnosis (>50%)[a]	2	5%
	Majority with substance abuse (>50%)[b]	1	3%
	Majority with COPD diagnosis (>50%)	1	3%
	Majority with heart disease diagnosis (>50%)[‡]	2	5%
	Majority with social risk (>50%)[§]	1	3%
Participant Insurance Status	Medicare only or dual Medicare/ Medicaid	23	58%
	Medicaid	3	8%
	Mixed across participants	4	10%
	Uninsured or Medicaid	4	10%
	Unknown	6	15%
Sample size	<100	3	8%
	100 to <1,000	11	28%
	1,000 to <9,999	13	33%
	≥10,000	10	25%
	Not reported	3	8%
Comparison group	Usual care	39	98%
	Received education materials and an incentive	1	3%
Number of study sites	1	12	30%
	2 to 5	11	28%
	6+	16	40%
	Not reported	1	3%

[a] Mental health diagnoses include schizophrenia and other psychotic disorders, bipolar disorder, and major depression.
[b] Substance abuse includes alcohol or drug abuse.
[‡] Heart disease diagnoses include coronary artery/vascular disease, congestive heart failure, stroke/myocardial infarction, and cardiac arrest.
[§] Social risk factors include homelessness, low income, low education, and social isolation.

COPD = chronic obstructive pulmonary disease; HNHC = high-need, high-cost; KQ = Key Question; N = number; NA = not applicable; RCT = randomized controlled trial.

Table 16 provides strength-of-evidence findings on outcomes by intervention model type. (Appendix Table B-14 is a more detailed table with over 100 unique outcomes, by intervention model type). Among the 28 outcomes reported by two or more samples within a model type, we found moderate to low strength of evidence of benefit in utilization and cost from community, ED, aICU, primary care, and home-based care models. Studies were graded as low for no effect (i.e., total costs for system-level transformation interventions and for telephonic/mail interventions) if several large RCT samples reported no difference between the intervention and treatment groups. While much of the evidence was graded as insufficient, this assessment does not mean that the interventions had no impact on the outcome. Rather, the 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 study

Outcome (Subgroup)	System Level	Tele-phonic/ Mail	Community Based	ED Based	aICU	Primary Care	Home Based
Utilization outcomes							
ED visits, all-cause	I	I	L-B	M-B	-	L-B	I
ED visits, ACSC	I1	I	-	-	-	I	I
Inpatient admissions, all-cause	I	I	-	I1	I1	M-B	I
Inpatient admissions, any	-	I	I	-	-	M-B	I
Inpatient admissions, ACSC	I1	I	I1	-	-	I	L-B
Inpatient admissions, any ACSC	-	I	-	-	-	I	M-B
Inpatient days	-	-	I	-	-	I1	-
Outpatient visits	-	-	-	-	-	I	-
Primary care visits	I[a]	-	-	L-B[b]	I1	I	-
180-day readmission, count	-	-	I	-	-	-	-
Specialist visits	I	-	-	-	I1	-	-
FQHC visits	I	-	-	-	-	-	-
Cost outcomes							
Total costs	L-ND	L-ND	I	I1	L-B[c]	L-B	I
Inpatient costs	-	-	I1	I[b]	I1	-	-
ED costs	-	-	-	M-B	I1	-	-
Clinical and functional outcomes							
Mortality rate	I1	I	I1	-	I	I	I
Influenza vaccine	-	I	-	-	-	M-H	M-B
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	I
LDL test (Diabetes patients)	I	I	-	-	-	I	I
LDL test (IVD patients)	-	I	-	-	-	I	I
Eye exam (Diabetes patients)	I	I	-	-	-	-	-
Nephrology/nephropathy test (Diabetes patients)	I	I	-	-	-	-	-
Lipid test (IVD patients)	I	I	-	-	-	-	-
Oxygen saturation test (COPD patients)	-	-	-	-	-	-	I

I1: Insufficient, only one sample reporting on the outcome; I: Insufficient, 2+ samples reporting on the outcome within the model type; L-B: Low strength of evidence for benefit for the outcome; L-ND: Low strength of evidence for no difference for the

outcome; -: No eligible evidence; M-B: Moderate strength of evidence for benefit for the outcome; M-H: Moderate strength of evidence for harm for the outcome
[a] Defined as Evaluation and Management primary care visits by Kahn et al.[62]
[b] Shumway et al.[143] specified the outpatient and inpatient costs as medical outpatient costs and medical hospital costs.
[c] Durfee et al.[122] and Horn et al.[128] reported total charges.

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 cost, and 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 Model

Overview

- Four observational studies, including six samples, reported on system-level transformation models.
- We found that total costs were not greater among system-level transformation models, based on six observational samples (low strength of evidence for no difference between the intervention and usual care).
- The evidence on utilization, and clinical and functional outcomes comes from bodies of evidence of moderate study limitations, but the evidence is insufficient to judge any of these outcomes.
- We found insufficient evidence to judge all other reported outcomes because the evidence was limited to a single sample.

Detailed Results

Four studies, including six samples, reported on system-level transformation models in comparison to usual care (Appendix Table B-15).[60-63] This set of models were interventions that were designed and overseen by the Centers for Medicare & Medicaid Services (CMS) and implemented at practices or organizations. These models tested whether intervention practices or organizations were able to implement a diverse set of changes to their practice to alter how they deliver care, and whether those changes impacted the cost and quality of care that all of their patients received. All four were studies funded by CMS, 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.[62] 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.[62]

The second study focused on one component of CMS's 4-year Independence at Home (IAH) demonstration. IAH supported the provision of team-based primary care at home for fee-for-service (FFS) Medicare enrollees who were chronically ill and functionally limited by providing financial incentives to home-based primary care practices.[63] The IAH evaluation conducted two

analyses, using different study populations. The first analysis (included in this section) was to assess the effect of the IAH payment incentive to home-based primary care practices while the second was to assess the effect of receiving home-based primary care (discussed in the Home-Based Care Model section).[63] IAH practices earned a payment incentive if Medicare expenditures for their IAH patients were below a spending target and the practice met quality standards.[63] 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 home-based primary care.[63]

The other two system-level models, the Comprehensive Primary Care (CPC) initiative and the Comprehensive Primary Care Plus (CPC+) initiative, were multi-payer models that aimed to reform care delivery and payment in primary care practices. CPC's goal was to improve primary care delivery by offering primary care practices care management fees and shared savings to support improvements across five care delivery functions: access, chronic and preventive care, care management, patient and caregiver engagement, and care coordination.[60] The CPC study compared 4-year outcome differences between 497 intervention practices in eight regions with 908 matched comparison practices. CPC+ built on the CPC model requirements and required primary care practices to make more advanced care delivery changes and to target more complex patients.[61] In the first year of CPC+, primary care practices focused on improving their ability to identify patients who needed the most care and providing more intensive care management, hiring care managers, and integrating behavioral health services. The CPC+ study included two samples in 14 regions; the first sample compared 1,373 CPC+ practices with 5,247 matched comparison practices, upon completion of 1 year of the intervention, and the second sample compared 1,515 CPC+ practices with 3,784 comparison practices. Compared to the first sample, the second sample of practices were required to make more advanced care delivery changes to support their complex patients; these practices also received more financial payments to support their changes.

Intervention Characteristics

Across the four interventions, practices were provided 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 NCQA PCMH achievement, as well as utilization and expenditure measures.[62] Similar to the FQHC intervention, CPC and CPC+ provided financial support to practices, including care management fees to assist in practice reforms.[60, 61] CPC also offered shared savings, and CPC+ also offered prospective 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).[60, 61] Compared with CPC, CPC+ had more requirements related to care delivery, such as developing care plans, following-up with patients after ED or hospital discharge, and enhanced health information technology functionalities to support care delivery requirements such as empanelment and patient targeting.[61] The IAH model differed in that it used an incentive payment to motivate IAH practices to implement a variety of strategies to improve care and reduce unnecessary costs.[63] 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,[60] technical assistance, and data feedback reports.[62] 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 PCMH efforts, including technical assistance, and funding from the Health Resources and Service Administration, state Medicaid programs, and private managed care organizations (MCOs),[62] including 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.[63]

Implemented at the clinic, practice, or organization level, the interventions across the four studies included all patients. We present the findings specific to HNHC patients. The FQHC study reports 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.[62] The two FQHC samples may include overlapping patients. All IAH patients 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.[63] CPC reports on one HNHC sample, defined as two or more hospitalizations in the past 2 years, with at least 2 of 13 chronic conditions. CPC+ reports on two HNHC samples based on the two samples of practices; both samples are defined as one or more hospitalizations in the past year, with at least 2 of 12 frequently occurring chronic conditions.[61]

Intervention Outcomes

Utilization Outcomes

In relation to utilization, the IAH incentive payment intervention group found a favorable, significantly greater decrease in ED visits than its comparison group but neither of the two FQHC samples saw an effect (Appendix Table B-18). Due to the imprecise and inconsistent findings, we rated ED visits as insufficient strength of evidence (Table 15; full strength of evidence can be found in Appendix Table B-18). Neither of the two FQHC samples or the IAH incentive payment sample was superior to the comparison group in the use of inpatient admissions, primary care visits, specialist visits, and FQHC visits, and these outcomes were graded as insufficient strength of evidence.[62, 63] However, the IAH incentive payment sample also reported a greater reduction in the intervention group for inpatient admissions for acute care sensitive conditions (ACSC) and ED visits resulting in inpatient admission.[63]

Cost Outcomes

All four studies found no differences in changes in total costs among all samples of HNHC patients (Appendix Table B-19 and Appendix Table B-20);[60-63] the pooled effect size also showed no difference between the groups.[1] Since total costs were observed to not be greater

[1] The two samples in the FQHC study included potentially overlapping populations. The pooled estimate using the ED sample was -$50.21 (95% CI, -121.06 to 20.64; 3 observational samples, I2=0%) while the pooled estimate using the FQHC sample was -$112.06 (95% CI, -284.81 to 60.68; 3 observational samples, I2=36.5%).

across all 6 samples, we rated this outcome as low strength of evidence for no difference (Table 17).

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
Inpatient admissions, all-cause	HNHC patients	3 OBS[62, 63] (N=NR[b])	3 of 3 OBS samples found no difference	Insufficient
ED visits, all-cause	HNHC patients	3 OBS[62, 63] (N=NR[b])	3 of 3 OBS samples found no difference	Insufficient
Total cost	HNHC patients	6 OBS[60-63] (N=NR[b])	6 of 6 OBS samples found no difference	Low for no difference
Primary care visits[a]	HNHC patients	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
Specialist visits	HNHC patients	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
FQHC visits	HNHC patients	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
HbA1c test	HNHC patients, diabetes subgroup	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
LDL test	HNHC patients, diabetes subgroup	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
Eye exam	HNHC patients, diabetes subgroup	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
Nephropathy test	HNHC patients, diabetes subgroup	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient
Lipid test	HNHC patients, IVD subgroup	2 OBS[62] (N=NR[b])	2 of 2 OBS samples found no difference	Insufficient

[a] Defined as Evaluation and Management primary care visits by the study authors
[b] The Federally Qualified Health Center[62] and Comprehensive Primary Care[60] studies did not report sample sizes for their HNHC populations. The sample size was 42,132 for the Independence at Home study,[63] 269,0246 for Comprehensive Primary Care Plus Sample 1, and 254,458 for Comprehensive Primary Care Plus Sample 2.[61]
ED=emergency department, HbA1C = hemoglobin A1c, HNHC = high need, high cost, IVD = ischemic vascular disease, LDL = low-density lipoprotein, N = number, NR = not reported, OBS = observational study, RCT = randomized controlled trial.

Clinical and Functional Outcomes

In relation to clinical and functional outcomes, both FQHC samples found no difference from the comparison group in 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).[62] Differences in mortality rate between the intervention and comparison groups were not significant for the IAH incentive payment sample.[63] All clinical and functional outcomes were graded as insufficient strength of evidence because of inconsistent and imprecise findings (Table 17).

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 9 samples were included in the evidence.
- The evidence on telephonic/mail models comes from studies with moderate study limitations.
- We found the total cost was not greater among telephonic/mail studies based on evidence from seven RCT samples (low strength of evidence for no difference).
- The evidence is insufficient to judge the remaining utilization, cost, and clinical and functional outcomes.

Detailed Results

Six studies, analyzing 9 samples, reported on telephonic/mail models (Appendix Table B-23 and Appendix Table B-24).[55-57, 121, 126, 148] A telephonic/mail model is an intervention where most services are provided remotely, either telephonically or by mail. These interventions were generally operated directly by a health plan.

Intervention Characteristics

Five of the studies (with 8 samples) were RCTs.[55-57, 121, 126] All RCTs were rated as some concerns for risk of bias.

In one RCT, Kaiser Permanente of Ohio provided HNHC intervention group members 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.[126] Comparison HNHC members received baseline education materials and incentives, but did not receive personalized, followup materials.[126] Eligible members had 11 or more outpatient visits in the past 2 years and a diagnosis of one of three target conditions (arthritis, hypertension, diabetes).[126]

The other four RCTs were separate programs implemented as part of the Medicare Care Management for High Cost Beneficiaries (CMHCB) demonstration.[55-57, 121] The CMHCB programs were multifaceted interventions that tested a pay-for-performance contracting model and provided new care management or coordination interventions for high-cost or complex Medicare FFS patients. CMHCB models 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 a patient's needs. The CMHCB programs compared intervention-group patients with 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.[121] 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 back to patients' physicians.[121]

The second CMHCB RCT, the Health Buddy Consortium program, was a care management program for heart failure, diabetes, and chronic obstructive pulmonary disease (COPD) patients.[57] The intervention provided patients with a Health Buddy device, a home monitoring device set to 1 of 13 disease-specific programs, that allowed intervention 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.[57]

Both the TST and Health Buddy initiatives included a broader group of participants than the HNHC population. We present only the findings specific to the HNHC subgroup, defined by the study as those with $6,000 or more in Medicare costs in the previous year and a Hierarchical Condition Category (HCC) risk score of 1.7 or greater.[57, 121] 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.[55] In Phase II, Village Health expanded their patient focus to target patients with end-stage renal disease (ESRD) and extended their geographical territory to include five New York regions.[56]

Village Health nurse care managers provided support through the telephone or in person. This support was complemented by pharmacists, social workers, and dieticians and access to a 24-hour hotline.[55] 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.[56] Both Village Health RCTs included patients who had $5,000 or more in Medicare costs in the previous year and a CKD diagnosis.[55, 56]

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, and followed the samples for at least one year. Both samples received the same intervention.[55-57] 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.[55-57]

The remaining telephonic/mail model study is observational (rated some concerns for risk of bias) and was 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.[148] Eligible patients were predicted to be in the top 1 percent of healthcare utilization in the upcoming year.[148]

Intervention Outcomes

Utilization Outcomes

Four of the six studies (6 samples) reported on the effect of the intervention on healthcare utilization (Appendix Table B-25 and Appendix Table B-26). Most utilization outcomes were reported only in the two Village Health RCTs. Among the four Village Health RCT samples (original and refresh samples in Phase I and Phase II), differences between the intervention and comparison groups were not significantly different for all inpatient outcomes (both all-cause admissions and ACSC-related admissions).[55, 56] Pooled effect sizes for all-cause inpatient admissions (effect size [ES], 0.99; 95% CI, 0.92 to 1.06; 4 RCT samples, N=20,693, I^2=0%) and ACSC inpatient admissions (ES, 0.95; 95% CI, 0.85 to 1.06; 4 RCT samples, N=20,693, I^2=0%)

showed no difference between groups. Based on inconsistent and imprecise evidence, inpatient admissions outcomes were given a grade of insufficient strength of evidence (Table 18; full strength of evidence can be found in Appendix Table B-27).

ED visit outcomes were reported in the two Village Health studies (4 samples). In the four Village Health RCT samples, ED visits increased in both the intervention and comparison groups but the change was not significantly different between the two groups.[55, 56] Change in ACSC ED visits also were not found to be significantly different in these RCTs. Pooled effect sizes for all-cause ED visits (ES, 1.01; 95% CI, 0.94 to 1.08; 4 RCT samples, N=20,693, I^2=0%) and ACSC ED visits (ES, 0.99; 95% CI, 0.88 to 1.10; 4 RCT samples, N=20,693, I^2=0%) showed no difference between groups. The inconsistent and imprecise evidence led to a grade of insufficient strength of evidence for both all-cause and ACSC ED visits (Table 18).

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
Inpatient admissions, all-cause	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
Inpatient admissions, ACSC	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
Inpatient admissions, any	HNHC patients	2 RCTs[55] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[55] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
ED visits, all-cause	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
ED visits, ACSC	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
Total cost	HNHC patients	7 RCTs[55-57, 121] (N=25,000)	7 of 7 RCT samples found no difference	Low for no difference
Mortality rate	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
Influenza vaccine	HNHC patients	2 RCTs[55] (N=10,337)	2 of 2 RCT samples found no difference	Insufficient
Progression to ESRD	HNHC patients	4 RCTs[55, 56] (N=20,693)	4 of 4 RCT samples found no difference	Insufficient
Progression to ESRD	HNHC patients, CKD subgroup	2 RCTs[56] (N=4,822)	2 of 2 RCT samples found no difference	Insufficient
Graft or fistula prior to hemodialysis	HNHC patients, CKD subgroup	2 RCTs[56] (N=4,822)	1 of 2 RCT samples found benefit 1 of 2 RCT samples found no difference	Insufficient
Graft or fistula prior to hemodialysis	HNHC patients, ESRD subgroup	2 RCTs[55] (N=428)	2 of 2 RCT samples found no difference	Insufficient
HbA1c test	HNHC patients, diabetes subgroup	4 RCTs[55, 56] (N=7,931)	4 of 4 RCT samples found no difference	Insufficient
LDL test	HNHC patients, diabetes subgroup	4 RCTs[55, 56] (N=7,931)	4 of 4 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[55] (N=3,942)	2 of 2 RCT samples found no difference	Insufficient

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
Eye exam	HNHC patients, diabetes subgroup	2 RCTs[56] (N=7,931)	2 of 2 RCT samples found no difference	Insufficient
Nephrology test	HNHC patients, diabetes subgroup	2 RCTs[56] (N=7,931)	2 of 2 RCT samples found no difference	Insufficient
Lipid panel	HNHC patients, IVD subgroup	2 RCTs[56] (N=4,092)	1 of 1 RCT samples found benefit 1 of 1 RCT samples found no difference	Insufficient

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; N = number; RCT = randomized controlled trial.
[a] Comparison group participants for Dally et al. received baseline education materials and incentives.[126]

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).[126] 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.[148]

Cost Outcomes

Four of six studies reported on the impact of their interventions on costs (Appendix Table B-28). The seven samples from the four CMHCB programs[55-57, 121] all found no significant differences in changes in total cost between the study arms, and pooled effect size showed no difference between groups (ES, -$8.52; 95% CI, -130.02 to 112.98; 7 RCT samples, N=25,000, I^2=22.4%). But the direction of changes in costs over time was varied. The TST program observed reductions in costs for both intervention and comparison groups,[121] as did the two samples for the Health Buddy program.[57] The Phase I Village Health groups for both the original and refresh samples moved in tandem, with increased costs in all groups over time.[55] The original and refresh samples for Phase II Village Health moved in opposite directions: both the intervention and comparison groups increased over time in the original sample and both decreased over time in the refresh sample.[55] The evidence from several large RCTs 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 two Village Health RCTs (Appendix Table B-29 and Appendix Table B-30).[55, 56] We found no significant differences in mortality rates (ES, 0.34; 95% CI, -1.06 to 1.74, 4 RCT samples, N=20,693, I^2=0%) (insufficient strength of evidence) (Table 16). 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 clinical and functional outcomes as insufficient strength of evidence (Table 18).

The Village Health Phase I study surveyed original sample patients about their experience of care, self-management, and physical and mental functioning.[55] They found that intervention patients had fewer depression symptoms but felt that they had fewer treatment choices.

Social Risk Outcomes

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

Community-Based Models

Overview

- One RCT and six observational studies (seven samples) reported on community-based models, including three studies of the Camden Core Model.
- We found low strength of evidence that community-based models were associated with a reduction in ED use in interventions based on findings from four observational studies.
- The evidence on healthcare utilization among community-based intervention models is insufficient to judge inpatient admissions, inpatient days, readmissions, and healthcare cost.

Detailed Results

Seven studies in nine publications, analyzing seven samples, reported on community-based models (Appendix Table B-31).[40, 123, 125, 131, 141, 146, 149, 151, 153] 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.[41] All interventions were compared to usual care.

Three studies evaluated the Camden Core Model, an intensive, relationship-based "hotspotting" program that used real-time data to identify and recruit HNHC patients. One study was an RCT (rated low risk of bias) in which four local area hospital systems in Camden, NJ implemented the model.[40] Similarly, the Rutgers Center for State Health Policy (CSHP) evaluated the Camden model in a large observational study (rated some concerns for risk of bias) in provider groups in four states. While the model was implemented across payers, the CSHP study evaluated results only among Medicare FFS patients.[123, 149] Another observational study, Bridges to Care (B2C) (rated some concerns for risk of bias), also evaluated adoption of the Camden model.[125] B2C was one of the CSHP sites, so there is likely some overlap with the larger CSHP study. However, the B2C was not limited to Medicare FFS patients and primarily served Medicaid-eligible patients.

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.[146]

The other three observational studies (all did not control for potential confounding and were rated high risk of bias) intervened by helping low-income patients with their medical and social needs.[131, 141, 151, 153] 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.[141] 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.[131] Dallas Texas' 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.[151, 153]

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 criteria of 1 or more inpatient admissions in the past 6 months.[40] CSHP Camden, B2C and PACT focused on high use as the main eligibility criterion.[123, 125, 146, 149] In addition to meeting utilization criteria, PAD and CMP targeted HNHC uninsured patients,[141, 151, 153] while Familiar Faces targeted residents of the poorest zip codes in Memphis.[131]

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). Four interventions (Camden RCT, CSHP Camden, B2C, PAD) also provided patients with education and coaching related to their health, chronic conditions, self-care, and self-sufficiency.[40, 123, 125, 131, 149, 151, 153] All interventions except PACT also connected participants to community-based services through referrals or enrollment assistance.

Care team composition differed across programs. The Camden model was an intensive, face-to-face intervention. All three Camden 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.[40, 123, 125, 149] The other community-based interventions had smaller teams. In these interventions, the majority of services were provided by CHWs,[151, 153] social workers,[146] care managers,[141] or community navigators.[153]

Intervention Outcomes

Utilization Outcomes

All seven interventions reported on at least one healthcare utilization outcome (Appendix Table B-33 and Appendix Table B-34). The Camden RCT did not observe significant differences between groups in the two reported outcomes—180-day readmissions and inpatient days.[40] PACT, the only other study reporting 180-day readmissions, also did not observe a significant differences between groups.[146] 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 other three studies reporting inpatient days were all rated high risk of bias. CMP also reported no significant difference in inpatient days but PAD and Familiar Faces observed lower use of inpatient days in the intervention group compared with the comparison group.[131, 141, 151, 153]

Four studies reported ED visits at one year. CSHP did not find a significant difference but B2C reported a significantly greater reduction.[123, 125, 149] Both CMP and PAD observed fewer ED visits in the intervention group.[141, 151, 153] The consistent findings across three of four studies led to a grade of low strength of evidence for reductions in ED visits at 12 months (Table 19). B2C also reported a greater reduction in ED visits at 180 days among an intervention subgroup of patients with a comorbid mental health diagnosis.[125] Sevak et al. hypothesized that the difference between the CSHP and B2C findings 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.[123, 149]

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
180-day readmissions	HNHC patients	1 RCT[40] (N=800) 1 OBS[146] (N=1,158)	1 of 1 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient
ED visits, all cause	HNHC patients	4 OBS[123, 125, 141, 149, 151, 153] (N=5,913)	3 of 4 OBS samples found benefit 1 of 4 OBS samples found no difference	Low for benefit
Inpatient admissions, all-cause	HNHC patients	3 OBS[123, 125, 141, 149] (N=5,339)	1 of 3 OBS samples found benefit 2 of 3 OBS samples found no difference	Insufficient
Inpatient days	HNHC patients	1 RCT[40] (N=800) 3 OBS[131, 141, 151, 153] (N=1,271)	1 of 1 RCT samples found no difference 2 of 3 OBS samples found benefit 1 of 3 OBS samples found no difference	Insufficient
Total cost	HNHC patients	2 OBS[123, 131, 149] (N=1,271)	2 of 2 OBS samples found no difference	Insufficient

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

Among the three studies reporting inpatient admissions, we found a similar pattern as ED visits in the CSHP and B2C studies. CSHP again did not find a significant difference.[123, 149] 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.[125] Like CSHP, CMP did not observe a significant differences between groups.[141] The strength of evidence is insufficient for inpatient admissions because of inconsistent findings (Table 19).

B2C is the only community-based model to have examined primary care visits. As the study authors had hypothesized, primary care visits significantly increased in the intervention group while ED visits decreased. B2C reported this result for the intervention group overall and among those with a comorbid mental health diagnosis.[125]

Cost Outcomes

Four of seven studies reported the effect of the intervention on costs over 6 or more months of followup (Appendix Table B-36). The Camden RCT and CSHP observed no significant difference in hospital costs.[40] CSHP and Familiar Faces observed no significant difference in total costs,[123, 149] while PAD observed significantly greater reductions in the intervention group in ED costs.[131, 151, 153] We graded total costs as insufficient strength of evidence (Table 19).

Clinical and Functional Outcomes

Among the community-based studies, only the Camden RCT reported clinical and functional outcomes (Appendix Table B-37). The study observed no significant difference in 180-day mortality rate.[40]

Social Risk Outcomes

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 and General Assistance.[40]

Emergency Department-Based Models

Overview

- ED-based models were reported in four studies (four samples): one RCT examining clinical case management, one RCT and one observational study examining patient navigation, 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 two RCTs and one observational study rated moderate risk of bias (moderate strength of evidence for benefit).
- We found an increase in primary care visits, based on consistent and precise evidence from the one RCTs and one observational study rated moderate risk of bias (low strength of evidence for benefit).
- We found a greater reduction in ED costs, based on consistent and precise evidence from the two RCTs (moderate strength of evidence for benefit).
- The evidence is insufficient to judge all other outcomes because it was limited to single outcomes in single studies.

Detailed Results

Four studies in four publications, analyzing four samples, reported on ED-based models. All were evaluated in comparison to usual care (Appendix Table B-39).[143, 144, 147, 152] This type of model is described as one in which patients are recruited in the ED and an ED-affiliated team provides care.[41]

Two of the studies are RCTs conducted at urban EDs.[143, 144] Both RCTs were rated some concerns for risk of bias. One RCT assessed the effectiveness of clinical case management for frequent users of the ED.[143] 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 other RCT tested whether a trained patient navigator can reduce ED use and costs and increase primary care appointments and satisfaction among HNHC ED patients.[144]

The first 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 (three or more visits in the past year) who were enrolled in the UnitedHealthCare AARP Supplement Insurance Plan.[147] Through the ERDS program, nurse care managers, available via telephone, discussed treatment options and provided assistance making appointments and navigating health resources.[147]

The second observational study assessed an ED navigation program, conducted across nine EDs in one healthcare system. CHWs provided navigational services intended to promote appropriate primary care utilization and prevent or reduce primary care-related ED (PCR-ED) use among Medicaid and uninsured patients.[152] 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).This study was rated high risk of bias because the analyses did not control for potential confounding.[152]

Intervention Characteristics

HNHC patient eligibility for these interventions was primarily based on service use . In the two RCTs, high use was defined as five or more ED visits in the prior 12 months.[143, 144] The case management RCT further limited enrollment to patients with psychosocial problems that could be addressed with case management.[143] The observational study 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.[152]

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

In the 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 and conducted assertive community outreach.[143]

Among the ED patient navigator interventions, the navigators in the RCT interacted with patients at ED visits, subsequent to the initial visit, and followed up by telephone within 2 weeks, for 12 months. The navigators reviewed prescriptions and diagnoses with patients, arranged follow-up appointments, and identified relevant community resources.[144] The CHWs in the observational study 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.[152]

In the ERDS program, a nurse helped patient make connections with health resources and care coordination programs and make appointments with providers.[147]

Intervention Outcomes

Utilization Outcomes

All four studies reported at least one measure of healthcare utilization (Appendix Table B-41). All four found ED visits decreased in both the intervention and comparison groups but were significantly lower in the intervention groups.[143, 144, 147, 152] The two RCTs and the ERDS program found the reduction to be significant among patients with high ED use in the 12 months prior to the intervention. The precise, consistent, direct evidence among these three studies led to a grade of moderate strength of evidence for benefit (Table 20; full strength of evidence can be found in Appendix Table B-42). The observational patient navigation study found a significant difference in the percent of patients with an ED visit among patients with high use in the prior 24 months but did not find a difference among patients with high use in the prior 12 months.

Both RCTs and the ERDS study 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 appropriate care.[144] Similarly, the ERDS 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.[147] The consistent and precise evidence led to a grade of low strength of evidence for benefit (Table 20). The ERDS study also reported significantly greater reductions in inpatient admissions in the intervention group.[147] The case management RCT tested, but did not find, a difference between groups in outpatient visits.[143]

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
ED visits, all cause	HNHC patients	2 RCTs[143, 144] (N=556) 1 OBS[147] (N=14,140)	2 of 2 RCT samples found benefit 1 of 1 OBS samples found benefit	Moderate for benefit
Primary care visits	HNHC patients	1 RCT[144] (N=304) 1 OBS[147] (N=14,140)	1 of 1 RCT samples found benefit 1 of 1 OBS samples found benefit	Low for benefit
ED costs	HNHC patients	2 RCTs[143, 144] (N=556) 1 OBS[147] (N=14,140)	2 of 2 RCT samples found benefit 1 of 1 OBS samples found no difference	Moderate for benefit
Inpatient costs	HNHC patients	1 RCT[143] (N=252) 1 OBS[147] (N=14,140)	1 of 1 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient
Primary care visits	HNHC patients	1 RCT[143] (N=252) 1 OBS[147] (N=14,140)	1 of 1 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient

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

Cost Outcomes

The two RCTs and the ERDS study reported changes in cost (Appendix Table B-43). The two RCTs found that ED costs decreased in both intervention and comparison groups but were significantly lower in the intervention group.[143, 144] In the ERDS study, the greater reduction in ED utilization in the intervention group were reflected in greater reductions in ED costs but the reductions were not large enough to be significantly different from the comparison group.[147] The precise, consistent, and direct evidence led to a grade of moderate strength of evidence for benefit for ED costs (Table 20). The case management RCT and the ERDS study also tested but did not find a different between groups in inpatient costs and outpatients costs. Both inpatient costs and outpatient costs were graded as insufficient strength of evidence.

Clinical and Functional Outcomes

The case management RCT and the ED navigation RCT reported clinical and functional outcomes but no outcomes were reported across both studies. The case management RCT found

no differences in psychiatric symptom scores (Appendix Table B-44).[143] The ED navigation RCT reported no difference in patient satisfaction between groups.[144]

Social Risk Outcomes

Only the case management RCT reported social risk outcomes. The authors found several social risk outcomes such as homelessness and having social security income were significantly better in the intervention group (Appendix Table B-45).[143]

Ambulatory Intensive Caring Unit (aICU) Model

Overview

- One RCT and two observational studies with three samples reported on aICU models.
- aICU models were associated with a greater reduction in total costs, based on consistent evidence across three studies and precise evidence from two observational studies with moderate study limitations (low strength of evidence for benefit).
- Evidence from two studies were inconsistent in relation to the effect of aICU models on changes in mortality (insufficient strength of evidence).
- The evidence is insufficient to judge all other outcomes because each was limited to a single study.

Detailed Results

Three studies in four publications, analyzing three samples, reported on aICU models (Appendix Table B-46).[122, 124, 128, 132] This type of model is described as a separate clinic or a team within a clinic that provides care to a panel of complex HNHC patients.[41] One study was an RCT (rated some concerns for risk of bias) in which five Veterans Administration (VA) facilities compared an aICU intervention, the Patient Aligned Care Team (PACT)-Intensive Management (PIM) intervention, with usual care, the PACT PCMH.[124, 132] 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.[122] The second observational study compared an aICU model called Care One, implemented in one medical center, with usual care.[128]

Intervention Characteristics

HNHC patients were eligible for these interventions based on high inpatient service use in PIM (over a 6-month period)[124, 132] and IOC (over a 12-month period)[122] and by high cost in Care One (over a 12-month period).[128] 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 the array of care management and healthcare services (Appendix Table B-47). In all three interventions, service intensity varied 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.[122, 132] Both studies primarily attributed this to inefficiencies in targeting

participants who would be a good match for the program. Care One provided financial incentives to primary care physicians to accept Care One patients in their panels, in addition to participating in team-based intensive care management services.

Intervention Outcomes

Utilization Outcomes

Two of the three studies reported the effect of the intervention on changes in utilization but no outcomes were reported across both studies (Appendix Table B-48). The PIM RCT reported did not observe any differences between the intervention and comparison groups for inpatient and ED visits but reported significant favorable increases in several outpatient care visits, including primary care, care management and mental health. The observational IOC study reported a lower number of inpatient 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 significant. 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-41). The consistent evidence across the three studies and precise evidence from the two observational studies led to a grade of low strength of evidence for benefit for reduction in total costs (Table 21; full strength of evidence can be found in Appendix Table B-50).

The PIM RCT finding of no difference in changes in total costs was the result of a significantly greater increase in outpatient costs (primary care, care management, and mental healthcare) in the PIM group being offset by a larger, but not significantly different, reduction in inpatient costs.

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
Total costs	HNHC patients	1 RCT[124] (N=2,210) 2 OBS[122, 128] (N=5,183)	1 of 1 RCT samples found no difference 2 of 2 OBS samples found benefit	Low for benefit
Mortality rate	HNHC patients	1 RCT[124] (N=2,210) 1 OBS[122] (N=3,636)	1 of 1 RCT samples found no difference 1 of 1 OBS samples found benefit	Insufficient

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 based on inconsistent and imprecise findings) (Table 21).

The PIM RCT was the only one of the three studies that 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

- Four RCTs and three observational studies, representing eight samples, reported on primary care–based models.
- In relation to all-cause ED visits, evidence across four RCTs found that primary care–based interventions are associated with a greater reduction in ED visits than usual care (low strength of evidence for benefit)
- For all-cause inpatient admissions, consistent and precise evidence from three of five RCTs suggests that primary care–based interventions are associated with a greater reduction in the number of hospital admissions (moderate strength of evidence for benefit).
- In relation to the risk of any inpatient admissions, consistent and precise evidence from two RCTs suggest that primary care–based interventions are associated with a greater reduction in hospital admissions (moderate strength of evidence for benefit).
- The evidence is insufficient to judge the benefit for other utilization outcomes: ACSC ED visits, number of ACSC inpatient admissions, any ACSC inpatient admissions, primary care and outpatient visits.
- The evidence in three RCTs on the effect of primary care–based interventions on change in the healthcare total cost was consistent but imprecise from evidence with moderate study limitations. It suggests that these models are associated with a greater reduction in total cost (low strength of evidence for benefit).
- The evidence on clinical and functional outcomes among primary care–based interventions comes from bodies of evidence with moderate study limitations.
    - For influenza vaccines, evidence from two RCTs suggests that primary care–based interventions are associated with a greater reduction in influenza vaccines (moderate strength of evidence for harm).
    - The evidence is insufficient to judge the effect of these interventions on change in mortality rate.

Detailed Results

Seven studies, representing eight samples, in nine publications, reported on primary care–based interventions (Appendix Table B-52).[59, 133-136, 142, 145, 150] This type of model is described as one in which the intervention team is embedded in one or more primary care practice.[41] Usual care was the comparison in all analyses.

Four of the seven studies were RCTs.[59, 134, 142, 145] The first 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 heterogenous group of patients.[142] A second RCT, the Massachusetts General Hospital and Massachusetts General Physicians Organization

(MGH) Care Management Program (CMP) (rated low risk of bias), a CMHCB demonstration site, aimed to provide comprehensive, practice-based outpatient case management for high-risk patients.[59] This RCT included two intervention group samples, an original and a refresh sample.[59] 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.[145] The fourth RCT (rated some concerns for risk of bias) examined a depression management program (DMP) for patients with high utilization of outpatient visits.[134]

Three of the seven studies were observational designs.[63, 133, 135, 136, 150] The first (rated some concerns for risk of bias) compared enrollment in Hennepin Health (HH), a Medicaid risk-sharing, accountable care organization (ACO) with enrollment in other Medicaid MCOs.[135, 150] The 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 population.

The other two observational studies were rated high risk of bias because neither analysis controlled for potential confounding.[133, 136] 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.[133] 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.[136]

Intervention Characteristics

The levels of high use or cost required for inclusion varied across studies. Four of the studies used a high use criteria to identify eligible patients. Criteria included 2 or more hospitalizations in the past year the PIC RCT,[142] 4 or more ED visits or 2 or more hospitalizations for the HH ACO,[135] 6 or more ED visits in the past year for Bridges to Health,[133] and 8 or more clinic visits for the interdisciplinary pilot study.[136] Two studies required both high use diagnosis of a condition. The group visit RCT included patients with 11 or more outpatient visits in the past 18 months and at least 1 self-reported chronic condition[145] 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).[134] Finally, 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 scores ≥2.0 or costs of $1,000 or more and an HCC risk scores ≥3.0.[59]

The seven 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[145] and one observational study[133] tested the effectiveness of group visits, while two RCTs included home visits as needed.[59, 142] 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.[136, 145] 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 efficient, high-quality care.[59, 135, 150]

Intervention Outcomes

Utilization Outcomes

All seven studies reported one or more measures of healthcare utilization (Appendix Table B-54).[59, 133-136, 142, 145, 150] 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.[136]

Six samples from 5 studies reported on changes in the number of ED visits. Four analyses (the two MGH RCT samples and the two group visit studies, the group visits RCT, and the Bridges to Health observational study) reported significantly fewer ED visits in the intervention group compared with usual care.[59, 133, 145] In the MGH RCT original sample, the difference between the two groups was not statistically significant.[59] The PIC RCT and HH Medicaid ACO did not report any significant differences between the intervention and comparison groups.[135, 142, 150] The consistent effect for three RCT samples and one observational sample coupled with the imprecision in one RCT and two observations samples led to a grade of low strength of evidence in relation to reduction in ED use in the intervention compared with usual care (Table 20; 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).[59]

Significantly greater reductions in the number of inpatient admissions in the intervention group were observed in four analyses including both MGH RCT samples, the group-visit RCT[59, 145] and the HH ACO observational study.[135, 150] The PIC RCT and DMP RCT did not report significant differences in inpatient admissions.[134, 142] Consistent, precise, and direct evidence for three of the five RCT samples and one observational study and imprecise evidence for the remaining two RCT samples led to a grade of moderate strength of evidence for benefit for all-cause, inpatient admissions (Table 22).

Both MGH RCT samples also reported additional inpatient admissions findings. For any inpatient admissions, both samples reported a greater reduction of inpatient admissions in the intervention group compared with the comparison groups.[59] The consistent and precise evidence led to a rating of moderate strength of evidence for benefit for any inpatient admissions (Table 22).

ACSC inpatient admissions evidence was also limited to the two MGH RCT samples. Both analyses found no significant difference in the *number* of admissions between the intervention and comparison groups (insufficient strength of evidence).[59] In relation to *any* ACSC inpatient admissions, the original sample reported a greater reduction in the intervention group, while the refresh sample reported no difference.[59] We graded both measures of ACSC inpatient admissions as insufficient strength of evidence.

In addition to studies determining if HNHC patient interventions led to reductions in high-cost services like ED visits and inpatient admissions, studies also sought to determine if the interventions would increase patients' use of outpatient office visits. Favorable changes 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 to usual care across three studies, the PIC RCT, the group-visit RCT, and HH ACO.[135, 142, 145, 150] This imprecision led to a rating of insufficient strength of evidence for benefit (Table 22).

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

Outcome	Population	# Samples/Design (n Analyzed)	Findings	Strength of Evidence
Inpatient admissions, all cause	HNHC patients	5 RCTs[59, 134, 142, 145] (N=7,741) 2 OBS[135, 136, 150] (N=92,912)	3 of 5 RCT samples found benefit 2 of 5 RCT samples found no difference 1 of 2 OBS samples found benefit 1 of 2 OBS samples found no difference	Moderate for benefit
Inpatient admissions, any	HNHC patients	2 RCTs[59] (N=6,943)	2 of 2 RCT samples found benefit	Moderate for benefit
Inpatient admissions, ACSC	HNHC patients	2 RCTs[59] (N=6,943)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[59] (N=6,943)	1 of 2 RCT samples found benefit 1 of 2 RCT samples found no difference	Insufficient
ED visits, all cause	HNHC patients	4 RCTs[59, 142, 145] (N=7,334) 3 OBS[133, 135, 136, 150] (N=92,984)	2 of 4 RCT samples found benefit 2 of 4 RCT samples found no difference 1 of 3 OBS samples found benefit 2 of 3 OBS samples found no difference	Low for benefit
ED visits, ACSC	HNHC patients	2 RCTs[59] (N=6,943)	2 of 2 RCT samples found no difference	Insufficient
Primary care visits	HNHC patients	2 RCTs[142, 145] (N=391) 1 OBS[135, 150] (N=92,891)	2 of 2 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient
Outpatient visits	HNHC patients	1 RCT[134] (N=407) 1 OBS[136] (N=21)	1 of 1 RCT samples found benefit 1 of 1 OBS samples found no difference	Insufficient
Total cost	HNHC patients	3 RCTs[59, 142] (N=7,039)	2 of 3 RCT samples found benefit 1 of 3 RCT samples found no difference	Low for benefit
Mortality rate	HNHC patients	2 RCTs[59] (N=6,943)	1 of 2 RCT samples found benefit 1 of 2 RCT samples found no difference	Insufficient
Influenza vaccine	HNHC patients	2 RCTs[59] (N=6,943)	2 of 2 RCT samples found harm	Moderate for harms
HbA1c test	HNHC patients, Diabetes subgroup	2 RCTs[59] (N=1,959)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, Diabetes subgroup	2 RCTs[59] (N=1,959)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[59] (N=1,923)	2 of 2 RCT samples found no difference	Insufficient

ACSC = ambulatory care sensitive conditions; 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.

Consistent with the intervention's goal of providing primary care treatment for mental health patients, the DMP RCT reported favorable, increased use of outpatient visits; antidepressant

prescriptions; and specialty mental health visits among intervention patients.[134] The interdisciplinary care teams observational study also reported an effect estimate with information on precision for outpatient visits. Imprecision for the two studies led to a rating of insufficient.

Cost Outcomes

Cost outcomes were reported in two studies, representing three samples (Appendix Table B-56).[59, 142] 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.[59] In contrast, the PIC RCT reported no differences in total cost between the two groups.[142] The consistent and precise evidence from two RCT samples and the imprecision from one RCT led to a rating of low strength of evidence for benefit for the total cost (Table 22).

Clinical and Functional Outcomes

Clinical and functional outcomes were reported in three RCTs, representing four samples (Appendix Table B-57 and Appendix Table B-58).[59, 134, 142] However, only the two samples of the MGH RCT reported the same outcomes.

The MGH RCT measured several clinical and functional outcomes.[59] Two outcomes analyzed for the full original and refresh samples were mortality rate and receipt of an influenza vaccine, and nine other outcomes were assessed through a self-report survey yielding 590 responses. The MGH RCT refresh sample reported a lower mortality rate in the intervention group while the original sample did not observe any significant differences. This imprecise and inconsistent evidence between the two samples led to a rating of insufficient strength of evidence for mortality (Table 21). 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 explain that this inconsistent finding is likely due to the much higher baseline rate for the intervention group compared to the comparison group.[59] The consistent and precise evidence led to a rating of moderate strength of evidence for harm for likelihood of receiving an influenza vaccine (Table 22). Among the outcomes assessed through a survey, significantly better outcomes for the intervention group were found for discussion of treatment choices and communication with providers.

Two of the outcomes were analyzed for different subgroups within the MGH RCT refresh and original samples.[59] No differences were found between intervention and comparison group patients for the following tests: HbA1c tests among diabetics, LDL-C test among diabetics, and LDL-C test among IVD patients. Imprecise findings for these three outcomes and subgroups led to ratings of insufficient strength of evidence (Table 22).

The DMP RCT reported eight clinical outcomes.[134] Results for five of these outcomes were significantly better in the intervention group, one on general health, one on social functioning and three mental health measures, Three other clinical outcomes (physical functioning, role functioning, and pain perception) as well as patient satisfaction and physical and mental health function summary scores were not different between the groups.[142]

Social Risk Outcomes

Evidence on social risk outcomes was limited (Appendix Table B-59); no differences were found between intervention and comparison group patients in overall patient well-being in the interdisciplinary care team observational study.[136]

Home-Based Care Model

Overview

- One RCT with two samples and one observational study, representing three samples, reported on home-based care models. Both were rated as having moderate study limitations.
- Home-based care interventions were associated with a greater reduction in any ACSC inpatient admissions, based on consistent and precise evidence from two RCT samples (moderate strength of evidence of benefit).
- The evidence in three RCTs on the effect of home-based care model on the number of ACSC inpatient admissions was consistent but imprecise from evidence with moderate study limitations (low strength of evidence for benefit).
- The evidence for other utilization outcomes was considered insufficient to judge the benefit, including ED visits (all-cause and ACSC) and all-cause inpatient admissions.
- The evidence on healthcare cost outcomes was considered insufficient to judge whether there is a benefit from home-based care models on the total cost.
- In relation to clinical and functional outcomes, the evidence is insufficient to judge the benefit of home-based care models on mortality rate.
- For the healthcare delivery quality outcome of influenza vaccines, consistent and precise evidence from two RCT samples found home-based care interventions associated with a greater increase in influenza vaccines (moderate strength of evidence of benefit).
- Other improvements in quality measures through the home-based care intervention included receipt of the following tests: oxygen saturation tests among patients with COPD, HbA1c tests and LDL tests among patients with diabetes, and LDL tests among patients with IVD. The evidence is insufficient to judge the benefit of home-based care models on receipt of these tests.
- The evidence is insufficient to judge all other outcomes because it was limited to a single sample.

Detailed Results

Two studies with three samples in two publications reported on home-based care models implemented for Medicare populations (Appendix Table B-60).[58, 63] This type of model provides care in the home for patients who have difficulty leaving or who are unable to leave their homes.[41] 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, who had multiple chronic conditions, with physician home visits from a personal visiting physician that complemented care from their primary care practice.[58] CLM was part of the Medicare CMHCB Demonstration. Two study populations were assessed: an original sample and a refresh sample.[58]

The other study was observational (rated some concerns for risk of bias). As previously mentioned in the System-level Transformation Section, CMS's Independence at Home (IAH) demonstration provided 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.[63] 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 model (included in this section). In the home-based

care model sample, the IAH home-based primary care service delivery model was evaluated to determine if receipt of home-based primary care resulted in lower costs.[63] The analysis compared patients who newly received home-based primary care with patients who did not receive these services.[63]

Intervention Characteristics

HNHC patients were eligible for the CLM RCT and IAH home-based primary care services based on hospital use over a 1-year period.[58, 63] In the CLM RCT original sample, patient 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.[58] In the CLM RCT refresh sample, the eligibility criteria were simplified and patients were no longer required to have Medicare costs in the top 5 percent or to have a specific chronic condition diagnosis. Patients with select psychosocial problems were explicitly excluded from the refresh sample.[58]

The IAH home-based primary care analysis was expanded to included Medicare patients in the same region as IAH practices due to sample size concerns; these patients were not required to receive their home-based care from an IAH practice. For this review, we present only the home-based primary care findings for patients who received 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 have the majority of office visits take place at home or in an assisted living facility after the first home-based primary care visit.[63]

Across the studies, intervention components included an initial assessment, followed by face-to-face care management and medical care (Appendix Table B-60). 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.[58] The IAH study tested a team-based primary care model for delivering home-based care; clinicians made anywhere from 3 to 15 home visits per day overall, with the intensity of care per patient determined based on clinician judgment or patient risk stratification. Clinicians were also available at all hours and used electronic health information systems to further provide comprehensive care for patients.[63]

Intervention Outcomes

Utilization Outcomes

Each of the studies reported the effect of the intervention on changes in healthcare utilization (Appendix Table B-62). Neither of the two CLM RCT samples nor the IAH home-based care sample found a differences from a comparison group in the change in ED visits.[58, 63] These 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). No significant differences in ACSC ED visits were observed in any of the 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	Strength of Evidence
Inpatient admissions, all cause	HNHC patients	2 RCTs[58] (N=34,421) 1 OBS[63] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS samples found harm	Insufficient
Inpatient admissions, ACSC	HNHC patients	2 RCTs[58] (N=34,421) 1 OBS[63] (N=181,001)	2 of 2 RCT samples found benefit 1 of 1 OBS samples found no difference	Low for benefit
Inpatient admissions, any all cause	HNHC patients	2 RCTs[58] (N=34,421)	2 of 2 RCT samples found no difference	Insufficient
Inpatient admissions, any ACSC	HNHC patients	2 RCTs[58] (N=34,421)	2 of 2 RCT samples found benefit	Moderate for benefit
ED visits, all cause	HNHC patients	2 RCTs[58] (N=34,421) 1 OBS[63] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient
ED visits, ACSC	HNHC patients	2 RCTs[58] (N=34,421) 1 OBS[63] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS samples found no difference	Insufficient
Total cost	HNHC patients	2 RCTs[58] (N=34,421) 1 OBS[63] (N=181,001)	2 of 2 RCT samples found no difference 1 of 1 OBS samples found harm	Insufficient
Total cost	HNHC patients, high risk patient subgroup	2 RCTs[58] (N=15,400)	2 of 2 RCT samples found no difference	Insufficient
Total cost	HNHC patients, high cost only patient subgroup	2 RCTs[58] (N=5,758)	2 of 2 RCT samples found no difference	Insufficient
Mortality	HNHC patients	2 RCTs[58] (N=34,421)	2 of 2 RCT samples found no difference	Insufficient
Influenza vaccine	HNHC patients	2 RCTs[58] (N=34,421)	2 of 2 RCT samples found benefit	Moderate for benefit
Oxygen saturation test	HNHC patients, COPD subgroup	2 RCTs[58] (N=8,079)	2 of 2 RCT samples found no difference	Insufficient
HbA1c test	HNHC patients, Diabetes subgroup	2 RCTs[58] (N=10,452)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, Diabetes subgroup	2 RCTs[58] (N=10,452)	2 of 2 RCT samples found no difference	Insufficient
LDL test	HNHC patients, IVD subgroup	2 RCTs[58] (N=14,910)	2 of 2 RCT samples found no difference	Insufficient

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 their comparison groups for all-cause inpatient admissions.[58] In contrast, the IAH home-based care sample had an unfavorable, greater increase in all-cause inpatient admissions than the comparison group.[63] The strength of evidence was graded as insufficient because of inconsistent findings. None of the RCT samples found a difference from the comparison group in having any inpatient admissions (insufficient strength of evidence).

All samples reported ACSC inpatient admissions. The two analyses 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.[63] This consistent but imprecise evidence led to a rating of low strength of evidence for benefit for ACSC inpatient admissions (Table 23). Both samples of the RCT also reported significantly greater reductions in any ACSC admissions in the intervention group than the comparison group. This consistent and precise evidence led to a rating of moderate strength of evidence of benefit for any ACSC inpatient admissions (Table 23).

Cost Outcomes

All home-based studies reported on the effect of the intervention on cost (Appendix Table B-64 and Appendix Table B-65). The two RCT samples found that the home-based care interventions did not significantly change total costs.[58, 63] 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.[63] 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.[63] 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. Differences between the intervention and comparison groups were not significant (insufficient strength of evidence) (Appendix Table B-66 and Appendix Table B-67).[58] Several healthcare delivery 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 moderate strength of evidence (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.[58] No significant differences were found in relation to other measures.[58]

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 how patients may be selected for interventions that target HNHC patients. KQs 2 and 3 both examine 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 on HNHC patients as a subgroup of a larger initiative.

From the best-fit framework synthesis we conducted to answer KQ 1, we identified characteristics that are often available through electronic databases that can be used to help identify patients. We determined that in addition to patterns of healthcare use, chronic disease categories are more reliable predictors of HNHC when coupled with behavioral and social risk factors. From the realist review, we learned that identification and treatment for HNHC patients requires a recognition and ability to address the complexity of the medical and nonmedical issues that these patients often face. Finally, from the systematic review, we found limited evidence of interventions reducing use and cost among HNHC patients. Most of the evidence was insufficient for understanding which interventions could offer benefit. Largely, interventions did not report on the patient-centered outcomes that would allow us to assess the success of the interventions in changing how HNHC patients use healthcare services in managing their health (e.g., self-efficacy). Further, intervention studies reported limited information on why individual programs work (or do not work), for whom, and when.

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 may speak 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 does 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.

In relation to intervention studies, we drew data for the realist review primarily from and about KQ 3 included studies, to help us explain why these interventions were or were not effective. Our realist review analysis was constrained by the information in KQ 3 intervention effectiveness studies, which generally had limited information on intervention characteristics and other contextual information that could inform our understanding of how and why interventions worked. The outcomes reported in virtually all KQ 3 effectiveness studies were at the policy or health system level and were largely limited to healthcare use and cost outcomes. These outcomes are distal to the facilitators and barriers to enrollment and engagement at the clinic

level that were the focus for the realist review. Further, patient-centered outcomes, such as measures of engagement, quality and satisfaction with care, and health improvement were generally not reported. Because of these reporting limitations, we were unable to directly capture mediating factors that may be barriers between intervention mechanisms and ultimate intervention outcomes. Still, the KQ 2 findings concerning the relationships between context, mechanisms, and outcomes in these interventions helps us understand what is happening within the interventions that are the focus of the effectiveness review.

Below we present a separate discussion of our findings for each of the three KQs.

KQ 1: Identifying HNHC Patients

KQ 1 presents a synthesis of studies that examine characteristics of HNHC populations. We used the "best fit" framework synthesis approach to organize our findings.[54] The "best fit" framework is a method for testing and building on an existing model. We used the framework developed by the National Academy of Medicine, 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 conceptual model and taxonomy for identifying and serving HNHC patients. Clinical and functional categories include 1) children with complex needs, 2) nonelderly disabled, 3) multiple chronic, 4) major complex chronic, 5) frail elderly, and 6) advancing illness. As discussed in relation to applicability, children and individuals with advancing illness approaching the end of life, were out of scope for our review. We excluded those categories of the taxonomy from our analysis. 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 standalone categories in the NAM framework, but factors that span across all the clinical and functional categories.

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 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 their overuse of healthcare 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 highest level or cost of care. This approach assumes that individuals with high use or cost, above a particular threshold, are likely to be using care inappropriately. These studies differed considerably in the thresholds they used to identify high use or cost. Studies that used a 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 were unlikely to have been modifiable, such as services related to pregnancy, cancer, 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 had 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. The study also found a strong positive correlation between higher-than-expected costs and potentially preventable hospital readmissions and a positive but weaker correlation between higher costs and potentially preventable ED visits.[68, 172] We found no quantitative studies that sought to directly distinguish an individual's visits, those that were preventable or modifiable and those that were necessary.

We found support for much of the NAM framework as an approach for identifying HNHC patients. Consistent with the framework, we found strong support for the categories of nonelderly disabled and major complex chronic categories. However, we did not find studies that grouped conditions to examine multiple chronic conditions. Also, we found limited evidence focusing on the frail elderly, which may be because the scope of our review excluded institutionalized (e.g., nursing home) populations.

Most of the evidence for KQ 1 consisted of exposure studies that modeled patient characteristics associated with high use of healthcare. Using regression analyses, these studies examined associations between patient and health system characteristics and being HNHC, controlling for potential confounding variables. Although studies were inconsistent in the confounding variables that were controlled for in their respective analyses, we found patterns of support for some patient characteristics. Prior use was a consistent and strong predictor of high use. Specific complex chronic conditions, such as congestive heart failure, chronic obstructive pulmonary disease (COPD), cardiovascular disease, dementia, and diabetes were also positively 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 were positively associated with high use across analyses.

We also found strong support for identifying social risk factors. Housing insecurity and poverty were often significant predictors of HNHC. We found mixed results for the inclusion of unemployment as a characteristic for identifying HNHC patients. This may be because unemployment can be a poor proxy for poverty, given that unemployment can be transitional and unemployment status does not account for individual or family wealth. Among multipayer and population-based studies, Medicaid and Medicare coverage were predictive of high healthcare use compared with commercial coverage. Surprisingly, we found only one study that focused solely on Medicare beneficiaries.[72] The study found significant predictors of frequent ED use by Medicare beneficiaries to be prior use (ED visits and five or more physician visits), indicators of chronic disease or functional limitations (being younger than 65 years, having specific chronic conditions, a higher hierarchical categorical condition score), poverty (dual enrollment in Medicaid) and mental illness.

KQ 2: Understanding How and Why HNHC 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 these 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.

Overall, we found that individualization was a key theme, both in identifying HNHC participants for interventions and in developing the service mix of the interventions. Unlike disease management interventions that focus on one condition,[173] including patients with a heterogeneous mix of chronic diseases in HNHC interventions was not considered a barrier. Both providers and patients expressed that little of the complexity in serving this population was directly related to obtaining adequate treatment for their chronic conditions. Instead, interventions stressed building trusting relationships between patients and providers. Trusting relationships are considered key to being able to support and educate patients to gradually take on greater responsibility for self-managing their chronic disease conditions, as well as navigate other systems to address their behavioral health needs and social risk factors. The findings also suggest that patient changes require significant investments in time. Relationships require time to develop and care providers are unlikely to successfully modify patients' long time approaches to care, if the time allotted for the intervention is not relatively long. Evaluations measuring the impact of interventions may need to assess intermediate outcomes or extend their follow-up time.

Care providers cautioned that they can feel significant stress because of the greater time and resources needed to provide and coordinate the care of HNHC patients. While 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. Strategies include gaining provider buy-in, re-distributing 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 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 were of telephonic/mail models (N=9), followed by primary care–based models (N=8); community-based models (N=7); system-level transformation models (N=6); ED-based models (N=4); home-based models (N=3); and ambulatory intensive caring unit (aICU)–based models (N=3). We found low to moderate strength evidence to support intervention effectiveness in relation to a small number of outcomes in some settings (which we describe below). We found the evidence for most outcomes across settings to be insufficient. We either found no or limited evidence or results were inconsistent 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, subsequently, ED costs. We also found low strength of evidence that ED interventions shifted service use and resulted in increased primary care visits.

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[133, 145] while others included home visits[59, 142]). We found low to moderate strength of evidence that HNHC interventions set in primary care were associated

with reductions in ED visits and hospital admissions, and, in turn, costs. aICU models, interventions that provide care through a separate clinic or 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 moderate strength of evidence that home-based care was associated with a reduction in inpatient admissions for ambulatory care sensitive conditions (ACSC) and an increase in the uptake of influenza vaccinations. Because ACSC admissions are a quality indicator for preventable admissions,[174] 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, thus limiting our synthesis across studies. All 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. This set of models included three samples that tested the highly regarded Camden Core hotspotting model that used data to identify HNHC patients and provided them with intensive, relationship-based assistance.[40, 123, 125, 149] We found low strength of evidence that these interventions were associated with a reduction in ED use. We were unable to judge the benefit for nearly all 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. The evidence for these two model types was insufficient to judge all other outcomes.

All of the system-level transformation studies were funded by CMS and reflect the challenges of large-scale, innovative interventions successfully assisting HNHC patients, in addition to 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. Except for the Independence at Home (IAH) study that targeted HNHC patients, across system-level transformation study sites HNHC patients were not targeted for services. The uneven distribution of services to HNHC patients makes it unlikely that evaluations could detect an impact on HNHC patients.

In telephonic/mail models, the intervention was often instigated 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 embedding care team members in one location is an important context for the success of interventions for HNHC patients, a lack of adjunct, integrated services embedded in patients' site of care 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 HNHC interventions. However, in our KQ 3 review, virtually no studies reported on participant harms. We could not determine whether the

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.[59] 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.

As our KQ 1 findings suggest, many factors may be associated with being HNHC. This variation is reflected in the many methods of selecting eligible participants in the interventions. While all interventions used 6 to 12 months of data to identify high-use or high-cost patients per the inclusion criteria, some interventions used provider assessment to determine whether patients would be appropriate for the intervention and others identified eligible HNHC patients using electronic data alone. At least one study team[58] tried to improve their accuracy by using an algorithm to identify patients whom they believed would benefit from their services. However, as we reported in KQ 1, no algorithm has been found that can reliably predict future HNHC patients. Several interventions were also limited in their ability to identify HNHC patients in real time because of their use of claims data. For example, one commonly used data source, Medicare claims for inpatient admissions, has an approximate 4-month lag[175] presenting challenges for capturing real-time hospital use.

Strengths and Limitations

We used three methodological approaches to answer our three KQs. Each of these approaches bring unique strength and weaknesses to our findings.

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 within one specific time period are examined; 3) latent class or cluster analysis, which identified latent or hidden groupings among identified HNHC populations; and 4) qualitative studies. Across the HNHC criteria we reviewed, cross-sectional findings generally supported the predictive findings, even though regression to the mean at the individual level is a real concern. The latent class analysis studies also generally confirmed the predictive and cross-sectional findings. Similar chronic diseases, behavioral health, and social factors appeared as characteristics of latent class groupings as we found to be significant variables in predictive and cross-sectional studies. Qualitative studies found similar characteristics to be associated with this patient population.

The value of each KQ 1 methodology lies in its respective usage. Cross-sectional studies appear to be useful for exploratory purposes and for an initial identification of HNHC patients. Predictive analyses are useful for confirmation of the HNHC populations and HNHC screening and identification tools. Latent class analysis appears to be most useful after the broader HNHC population has been identified and a healthcare system or payer is designing targeted interventions for specific population groups. However, as we have previously noted, studies were inconsistent in the confounding variables controlled for in the models, so that results across studies could have differed based on the modeling approach alone. Also, studies did not have the power to separately examine many unique diseases in regression analyses. As a result, rarer complex chronic conditions that might be related to being HNHC may not have been identified.

To answer KQ 2, the how and why of complex interventions for HNHC patients by attempting to explain causal mechanisms, our analysis depends primarily on the effectiveness

studies that include descriptive information and/or mixed methods approaches. Many of the evaluations of the effectiveness of interventions were conducted at the system- or organization-level and included scant descriptions of contextual information outside of the intervention, such as family support, or assessments of patient-centered access or quality of care outcomes. Therefore, our realist review was unable to include evidence from all included HNHC interventions from KQ 3 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, in part, to time and resource limitations. In the realist review, additional studies might have furthered or modified our interpretation of the mechanisms associated with identified contexts and outcomes. 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.

Differences in how HNHC populations were identified for inclusion in complex interventions limited our ability to draw conclusions across studies. For comprehensiveness, this review did not pre-define HNHC further than study author 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. Similarly, by focusing on medical utilization and costs, our scope and inclusion criteria relied on the healthcare system. Identified interventions all included the healthcare system in some capacity. Different inclusion criteria may have identified useful nonmedical interventions, such as interventions that addressed homelessness or access to different aspects of the social services system.

Because we primarily identified complex interventions, determining how to meaningful classify and synthesize the literature was particularly challenging. While interventions may be described as care management, disease management, case management, or care coordination, these terms were used inconsistently. The components of these care delivery models overlap considerably. Although included studies provided a broad overview of their components, few described the exact intervention that patients received. Therefore, we followed a classification scheme developed by Bodenheimer, based on the principal site of the program.[41] We believed that categorizing the studies by primary setting would be the most useful for stakeholders, particularly health systems and others who are considering the site of care for proposed interventions. However, it should be borne in mind that many of the interventions we reviewed were large and complex; incorporated components used a variety of approaches; and, as a result, cut across primary settings. We found no comparative effectiveness studies that directly compared individual interventions or types of interventions.

We limited our effectiveness analyses to 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.

Weaknesses in identifying HNHC populations threaten the predictive ability of exposure studies and the internal validity of intervention studies. By targeting patients with the highest prior costs or utilization, the regression to the mean phenomenon can affect findings. 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. This phenomenon explains why we often see reductions in use and cost, regardless of participation in an intervention. Because of this, predicting which patients will be long-term chronic HNHC patients and which will be shorter-term is difficult.

Because of differences in outcomes reported across studies, a number of our strength of evidence grades were based on findings from one CMS demonstration.[55-59, 121] The evidence for several of the telephonic/mail, primary care, and home-based model outcomes were solely from the Medicare Care Management for High Cost Beneficiaries (CMHCB) demonstration program. All CMHCB interventions were evaluated by the same group and reported the same large set of outcomes. While 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, strength of evidence grades can be based on evidence from one study with multiple samples. For example, among home-based care models, the outcome of any ACSC inpatient admissions received a moderate strength of evidence grade for benefit (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.

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 diseases, individuals with major complex chronic diseases 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 a HNHC population of particular interest for this review, our information focusing on this group was limited to two latent class models 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 address care for children. A review of care for HNHC children with complex needs would need to account for differences in context. That review would likely require a greater emphasis on family caregivers *rather than* the patient and multiple child-serving agencies, as well as the child's age and developmental ability. We excluded 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 by HNHC adults.

We limited the included literature across KQs to studies conducted in the United States. 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 care management and navigational services may be similar across countries, the activities that are required to access healthcare services in the United States would often be different from those of 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 mental health and substance abuse disorders within this population. 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 such as housing before or concurrently to their chronic conditions.

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 multi-pronged strategy to identify HNHC patients could account for the complexity of their prior healthcare experiences, systemic barriers to access, clinician judgement, 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, and other 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 as after one year. Expectations of changing HNHC patient behaviors and resulting outcomes may need to take a longer view than was available through our included studies.

Implications for Research

Our review identified several 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.

More work is needed to support the direct chain of evidence between modifiable and targetable patient characteristics and preventable high use of healthcare. 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.

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

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 who do not trust the system and thus need to be intervene upon or to help identify areas that interventions need to address.

Similarly, intervention designers may want to specifically develop a component that focuses on 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 research describing the implementation process and the patient perspective. Better understanding 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.

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, or quality of and 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.[40, 132, 136, 142-144] 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 the more distal measures of healthcare utilization and cost. Furthermore, studies did not report whether patients were more satisfied or happier after participating in the intervention. 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.

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). We believe that the framework would be enhanced by including several additional considerations. Our findings differed by healthcare setting (e.g., ED, inpatient), signifying that the HNHC taxonomy might be improved by specifying the type of service use. We also found the pattern of prior use to be an important predictor of future behavior in some cases, signifying that the HNHC taxonomy could be enhanced by categorizing the temporal nature of the high use or cost, i.e., chronic over multiple periods or more short term groups of episodes or episodes of care.

We found strong support for including behavioral health conditions as an overarching contributor for identifying HNHC populations. 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 substance use disorders would be informative. Substance use disorders can encompass multiple conditions, including many different substances, polysubstance use, and alcohol use

disorder, with each substance potentially having a distinctly different impact on physical health over the life span.[176] For one, our review identified alcohol use disorder 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.[119]

Although we found black versus white race to be correlated with high use, studies did not consistently control for variables known to be confounded with race in relation to healthcare use, such as household income and geographic location. As a result, we were unable to disentangle black race as an independent risk factor.

The findings from the KQ1 analysis may yield support for polices 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 VA system were able to adequately integrate clinical, payment, and social risk data to identify the HNHC 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. Increased use of existing tools such as ICD-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, supports increased efforts for the integration of behavioral health and physical health services for this population. While the integration of behavioral healthcare is an aspect of some existing interventions, interventions that place 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 and primary-care based models in reducing unnecessary utilization and costs for HNHC patients suggest that interventions based in these sites may be more effective. However, it was clear that given the complexity of HNHC patient needs, interventions that target HNHC patients need a multi-pronged 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, patient and provider engagement, and patient-provider relationships. More detailed descriptions of interventions, patient-centered outcomes, and qualitative assessments would support further policy development of best practices.

Our system-level transformation and telephonic/mail findings of no difference in costs speak to the challenges that stakeholders can face in modifying healthcare use patterns of HNHC patients through larger patient population-based interventions. The current fee-for-service reimbursement model focuses on paying for services delivered instead of services appropriately

avoided. For HNHC interventions to succeed, a payment model should financially support care providers in their efforts to help HNHC patients reduce use of preventable or modifiable services. Many of the included system-level transformation and telephonic/mail interventions were able to make additional payments to practices for the extra services they provide to complex patients (often in the form of care management fees or incentive payments). Some healthcare systems are testing a delivery model that combines intensive medical and nonmedical service delivery with a full-risk capitation payments that pay care providers for each patient, regardless of the amount of care provided.[177-179] This model aims to incentivize care providers to provide HNHC patients with services that address social risk factors in hopes of preventing the use of more costly medical services. While early reports of these models are promising, 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 preventable or modifiable high use. 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 participants—some of which is likely to not be related to their medical conditions. 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 more distal policy outcomes.

References

1. Cohen S. The concentration of health care expenditures and related expenses for costly medical conditions, 2012. Statistical Brief #455. Rockville, MD: Agency for Healthcare Research and Quality; 2014. http://www.meps.ahrq.gov/mepsweb/data_files/publications/st455/stat455.pdf.

2. Cohen SB. The concentration and persistence in the level of health expenditures over time: estimates for the U.S. population, 2011–2012. Statistical Brief #449. Rockville, MD: Agency for Healthcare Research and Quality; September 2014. http://www.meps.ahrq.gov/mepsweb/data_files/publications/st449/stat449.shtml.

3. Cohen SB. The concentration of health care expenditures in the U.S. and predictions of future spending. J Econ Soc Meas. 2016;41:167–89.

4. Centers for Medicare & Medicaid Services. Medicare beneficiaries at a glance. Baltimore, MD: Centers for Medicare & Medicaid Services; 2019. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot.html. Accessed on February 27, 2019.

5. Centers for Medicare & Medicaid Services. All Medicare inpatient hospitals: utilization, program payments, and cost sharing for original medicare beneficiaries, by demographic characteristics and Medicare-Medicaid enrollment status, calendar year 2017. Baltimore, MD: Centers for Medicare & Medicaid Services; n.d. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2017/Downloads/UTIL/2017_CPS_MDCR_INPT_HOSP_2.PDF. Accessed on February 27, 2019.

6. Centers for Medicare & Medicaid Services. CMS proposes "pathways to success," an overhaul of Medicare's ACO program. Baltimore, MD: Centers for Medicare & Medicaid Service; 2018. https://www.cms.gov/newsroom/press-releases/cms-proposes-pathways-success-overhaul-medicares-aco-program?_ga=2.111400452.1093732935.1551231053-96630637.1551231053. Accessed on February 27, 2018.

7. Centers for Medicare & Medicaid Services. Medicare-Medicaid accountable care organization (ACO) model. Baltimore, MD: Centers for Medicare & Medicaid Services; 2016. https://www.cms.gov/newsroom/fact-sheets/medicare-medicaid-accountable-care-organization-aco-model. Accessed on February 27, 2019.

8. Centers for Medicare & Medicaid Services. Vermont all-payer ACO model. Baltimore, MD: Centers for Medicare & Medicaid Services; 2016. https://www.cms.gov/newsroom/fact-sheets/vermont-all-payer-aco-model. Accessed on February 27, 2019.

9. Centers for Medicare & Medicaid Services. CMS finalizes "pathways to success," an overhaul of Medicare's national ACO program. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. https://www.cms.gov/newsroom/press-releases/cms-finalizes-pathways-success-overhaul-medicares-national-aco-program. Accessed on February 27, 2019.

10. Brennan A, Gaus C. ACOs at a crossroads: costs, risk and MACRA. A NAACOS policy white paper. Washington, DC: National Association of ACOs,; 2016. https://www.naacos.com/acos-at-a-crossroads Accessed on February 27,, 2019.

11. Hagland M. NAACOS and ACO leaders express distress over just-announced MSSP application deadline. Sarasota, FL: Healthcare Innovation; 2019. https://www.hcinnovationgroup.com/population-health-management/article/13031036/naacos-and-aco-leaders-express-distress-over-justannounced-mssp-application-deadline. Accessed on February 27,, 2019.

12. Moe J, Kirkland SW, Rawe E, et al. Effectiveness of interventions to decrease emergency department visits by adult frequent users: a systematic review. Acad Emerg Med. 2017 Jan;24(1):40-52. doi: 10.1111/acem.13060. PMID: 27473387.

13. Soril LJ, Leggett LE, Lorenzetti DL, et al. Reducing frequent visits to the emergency department: a systematic review of interventions. PLoS One. 2015;10(4):e0123660. doi: 10.1371/journal.pone.0123660. PMID: 25874866.

14. 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.

15. Edwards ST, Peterson K, Chan B, et al. Effectiveness of intensive primary care interventions: a systematic review. J Gen Intern Med. 2017 Dec;32(12):1377-86. doi: 10.1007/s11606-017-4174-z. PMID: 28924747.

16. Smith SM, Wallace E, O'Dowd T, et al. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Cochrane Database Syst Rev. 2016 Mar 14;3:CD006560. doi: 10.1002/14651858.CD006560.pub3. PMID: 26976529.

17. Cohen S, Yu W. The concentration and persistence in the level of health expenditures over time: estimates for the U.S. population, 2008–2009. Statistical Brief #354. Rockville, MD: Agency for Healthcare Research and Quality; January 2012. http://www.meps.ahrq.gov/mepsweb/data_files/publications/st354/stat354.pdf.

18. Pearson SD, Katzelnick DJ, Simon GE, et al. Depression among high utilizers of medical care. J Gen Intern Med. 1999;14(8):461-8. doi: 10.1046/j.1525-1497.1999.06278.x.

19. Katon W, Von Korff M, Lin E, et al. Distressed high utilizers of medical care. DSM-III-R diagnoses and treatment needs. Gen Hosp Psychiatry. 1990;12(6):355-62. PMID: CN-00071507.

20. National Academy of Medicine. Effective care for high-need patients. Opportunities for improving outcomes, value, and health. Washington, DC: National Academy of Sciences; 2017.

21. Mitchell EM. Statistical brief #521: concentration of health expenditures and selected characteristics of high spenders, U.S. civilian noninstitutionalized population, 2016. Rockville, MD: AHRQ; 2019. https://meps.ahrq.gov/data_files/publications/st521/stat521.shtml. Accessed on September 22, 2020.

22. Ollove M. States focus on 'super-utilizers' to reduce Medicaid costs. Washington, DC: Pew Research Center; 2014. https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2014/12/5/states-focus-on-superutilizers-to-reduce-medicaid-costs. Accessed on September 22, 2020.

23. Jiang HJ, Weiss AJ, Barrett ML. Characteristics of emergency department visits for super-utilizers by payer, 2014. Washington, DC: AHRQ; 2017. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb221-Super-Utilizer-ED-Visits-Payer-2014.jsp. Accessed on September 22, 2020.

24. LaCalle E, Rabin E. Frequent users of emergency departments: the myths, the data, and the policy implications. Ann Emerg Med. 2010 Jul;56(1):42-8. doi: 10.1016/j.annemergmed.2010.01.032. PMID: 20346540.

25. Kronick RG, Bella M, Gilmer TP, et al. Faces of Medicaid II: recognizing the care needs of people with multiple chronic conditions. Hamilton, NJ: Center for Health Care Strategies, Inc.; 2007. https://www.chcs.org/resource/the-faces-of-medicaid-ii-recognizing-the-care-needs-of-people-with-multiple-chronic-conditions/. Accessed on September, 2020.

26. Lochner KA, Goodman RA, Posner S, et al. Multiple chronic conditions among Medicare beneficiaries: state-level variations in prevalence, utilization, and cost, 2011. Medicare Medicaid Res Rev. 2013;3(3). doi: 10.5600/mmrr.003.03.b02. PMID: 24753976.

27. Wammes JJG, van der Wees PJ, Tanke MAC, et al. Systematic review of high-cost patients' characteristics and healthcare utilisation. Family caregiving: a vision for the future. BMJ Open. 2018 Sep 8; Mar;8(9):e023113. doi: 10.1136/bmjopen-2018-023113; 10.1016/j.jagp.2017.06.023. PMID: 28774786.

28. 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.

29. Goodwin A, Henschen BL, O'Dwyer LC, et al. Interventions for frequently hospitalized patients and their effect on outcomes: a systematic review. J Hosp Med. 2018;13(12):853-9. doi: 10.12788/jhm.3090.

30. Iovan S, Lantz PM, Allan K, et al. Interventions to decrease use in prehospital and emergency care settings among super-utilizers in the United States: a systematic review. Med Care Res Rev. 2019 Apr 26:1077558719845722. doi: 10.1177/1077558719845722.

31. Kumar GS, Klein R. Effectiveness of case management strategies in reducing emergency department visits in frequent user patient populations: a systematic review. J Emerg Med. 2013 Mar;44(3):717-29. doi: 10.1016/j.jemermed.2012.08.035. PMID: WOS:000315946900033.

32. Bleich SN, Sherrod C, Chiang A, et al. Systematic review of programs treating high-need and high-cost people with multiple chronic diseases or disabilities in the United States, 2008-2014. Prev Chronic Dis. 2015 Nov 12;12:E197. doi: 10.5888/pcd12.150275.

33. Henderson TM, Wilhide SD. Care management and Medicaid: implications for family medicine. Washington, DC: AAFP State Government Relation; 2006. https://www.aafp.org/dam/AAFP/documents/advocacy/coverage/medicaid/ES-MedicaidCareManagement-022806.pdf. Accessed on November 13, 2020.

34. Agency for Healthcare Research and Quality. Care management: implications for medical practice, health policy, and health services research. Care management issue brief. Rockville, MD: AHRQ; 2015. https://www.ahrq.gov/ncepcr/care/coordination/mgmt.html.

35. Mantravadi S. Key components of the healthcare system: Disease management and case management. AJMC; 2016. https://www.ajmc.com/view/key-components-of-the-healthcare-system-disease-management-and-case-management. Accessed on November 13, 2020.

36. Guise JM, Chang C, Butler M, et al. AHRQ series on complex intervention systematic reviews-paper 1: an introduction to a series of articles that provide guidance and tools for reviews of complex interventions. J Clin Epidemiol. 2017 Oct;90:6-10. doi: 10.1016/j.jclinepi.2017.06.011. PMID: 28720511.

37. Association of American Medical Colleges. Hot spotting guide FAQ. Washington, DC: Association of American Medical Colleges; 2019. https://www.aamc.org/initiatives/hotspotter/faqs/372468/hotspottingguidefaq.html. Accessed on August 12, 2019.

38. Agency for Healthcare Research and Quality. Section 4: selecting care management interventions. Designing and implementing Medicaid disease and care management programs. Rockville, MD: Agency for Healthcare Research and Quality; 2014.

39. Brenner J. Healthcare hotspotting. A project of the Camden Coalition of Healthcare Providers. Princeton, NJ: Robert Wood Johnson Foundation, Nicholson Foundation, and Commonwealth Fund; n.d. https://hotspotting.camdenhealth.org/. Accessed on October 12, 2020.

40. Finkelstein A, Zhou A, Taubman S, et al. Health care hotspotting - a randomized, controlled trial. N Engl J Med. 2020 Jan 9;382(2):152-62. doi: 10.1056/NEJMsa1906848. PMID: 31914242.

41. Bodenheimer T. Strategies to reduce costs and improve care for high-utilizing Medicaid patients: reflections on pioneering programs. Center for Health Care Strategies. 2013 October.

42. Petticrew M, Rehfuess E, Noyes J, et al. Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute. J Clin Epidemiol. 2013;66(11):1230-43. doi: 10.1016/j.jclinepi.2013.06.005.

43. Pawson R, Greenhalgh T, Harvey G, et al. Realist synthesis: an introduction. Submitted to the ESRC Research Methods Programme. Working Paper Series. Southampton, UK: ESRC Research Methods Programme; 2004.

44. Pawson R, Greenhalgh T, Harvey G, et al. Realist review--a new method of systematic review designed for complex policy interventions. J Health Serv Res Policy. 2005 Jul;10(Suppl 1):21-34. doi: 10.1258/1355819054308530. PMID: 16053581.

45. Agency for Healthcare Research and Quality. Methods guide for effectiveness and comparative effectiveness reviews. AHRQ Publication No. 10(14)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality; January 2014. www.effectivehealthcare.ahrq.gov.

46. RAMESES Project. Quality standards for realist synthesis (for researchers and peer-reviewers). Oxford: Nuffield Department of Primary Care Health Sciences, University of Oxford; 2014. www.ramesesproject.org). Accessed on August 12, 2019.

47. Wong G, Greenhalgh T, Westhorp G, et al. RAMESES publication standards: realist syntheses. BMC Med. 2013 2013/01/29;11(1):21. doi: 10.1186/1741-7015-11-21.

48. Sterne J (2020, March 21). personal communication.

49. Andersen R, Hagenaars JA, McCutcheon AL. Applied latent class analysis. Can J Sociol. 2003;28(4). doi: 10.2307/3341848.

50. Wong G. Data gathering for realist reviews: looking for needles in haystacks. In: Emmel N, Greenhalgh J, Manzano A, Monaghan M, Dalkin S, eds. Doing realist research. London: Sage; 2018.

51. Berg RC, Nanavati J. Realist review: current practice and future prospects. J Res Pract. 2016;12(1).

52. Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016 Oct 12;355:i4919. doi: 10.1136/bmj.i4919. PMID: 27733354.

53. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. The Cochrane Collaboration; 2011. www.handbook.cochrane.org. Accessed on January 10, 2017.

54. Carroll C, Booth A, Leaviss J, et al. "Best fit" framework synthesis: refining the method. BMC Med Res Methodol. 2013 Mar 13;13:37. doi: 10.1186/1471-2288-13-37. PMID: 23497061.

55. Bott D, McCall N. Evaluation of Medicare care management for high cost beneficiaries (CMHCB) demonstration: VillageHealth's key to better health (KTBH) final report. Research Triangle Park, NC: RTI International 2010.

56. Urato C, McCall N, Cromwell J, et al. Evaluation of the extended medicare care management for high cost beneficiaries (CMHCB) demonstration: VillageHealth's key to better health (KTBH) final report. Research Triangle Park, NC: RTI International 2013.

57. McCall N. Evaluation of Medicare care management for high cost beneficiaries (CMHCB) demonstration: The Health Buddy® Consortium (HBC) revised final report. 2011.

58. RTI International. Evaluation of Medicare care management for high cost beneficiaries (CMHCB) demonstration: care level management (CLM). Atlanta, GA: Centers for Medicare & Medicaid Services; 2010.

59. RTI International. Evaluation of Medicare care management for high cost beneficiaries (CMHCB) demonstration: Massachusetts General Hospital and Massachusetts General Physicians Organization (MGH) final report. Atlanta, GA: Centers for Medicare & Medicaid Services; 2010.

60. Peikes D. Evaluation of the comprehensive primary care initiative fourth annual report Princeton, NJ: Mathematica Policy Research; 2018.

61. Anglin G. Independent evaluation of comprehensive primary care plus (CPC+) first annual report. Mathematica Policy Research. Princeton, NJ: April 2019 2019.

62. Kahn KL, Timbie JW, Friedberg MW, et al. Evaluation of CMS's federally qualified health center (FQHC) advanced primary care practice (APCP) demonstration. San Diego, CA: RAND Corporation.

63. Kimmey L. Evaluation of the independence at home demonstration: an examination of the first four years. Princeton, NJ: Mathematica Policy Research; 2019.

64. Berkman ND, Lohr KN, Ansari MT, et al. Grading the strength of a body of evidence when assessing health care interventions: an EPC update. J Clin Epidemiol. 2015 Nov;68(11):1312-24. doi: 10.1016/j.jclinepi.2014.11.023. PMID: 25721570.

65. Bayliss EA, Powers JD, Ellis JL, et al. Applying sequential analytic methods to self-reported information to anticipate care needs. EGEMS (Wash DC). 2016;4(1):1258. doi: 10.13063/2327-9214.1258. PMID: 27563684.

66. Chang G, Weiss AP, Orav EJ, et al. Predictors of frequent emergency department use among patients with psychiatric illness. Gen Hosp Psychiatry. 2014 Nov-Dec;36(6):716-20. doi: 10.1016/j.genhosppsych.2014.09.010. PMID: 24238312.

67. Brannon E, Wang T, Lapedis J, et al. Towards a learning health system to reduce emergency department visits at a population level. AMIA Symposium; 2018. Annual Symposium proceedings; 2018. pp. 295-304.

68. Yang C, Delcher C, Shenkman E, et al. Identifying high health care utilizers using post-regression residual analysis of health expenditures from a state Medicaid program. AMIA Annual Symposium; 2017. AMIA Symposium proceedings; 2017. pp. 1848-57.

69. Meek JA, Lyon BL, May FE, et al. Targeting high utilisers: predictive validity of a screening questionnaire. Disease Management and Health Outcomes. 2000;8(4):223-32. doi: 10.2165/00115677-200008040-00005.

70. Yang C, Delcher C, Shenkman E, et al. Machine learning approaches for predicting high cost high need patient expenditures in health care. Biomed Eng Online. 2018 Nov 20;17(Suppl 1):131. doi: 10.1186/s12938-018-0568-3. PMID: 30634955.

71. Kanzaria HK, Niedzwiecki MJ, Montoy JC, et al. Persistent frequent emergency department use: core group exhibits extreme levels of use for more than a decade. Health Aff (Millwood). 2017 Oct 1;36(10):1720-8. doi: 10.1377/hlthaff.2017.0658. PMID: 28445806.

72. Colligan EM, Pines JM, Colantuoni E, et al. Risk factors for persistent frequent emergency department use in Medicare beneficiaries. Ann Emerg Med. 2016 Jun;67(6):721-9. doi: 10.1016/j.annemergmed.2016.01.033. PMID: 26861026.

73. Leininger LJ, Friedsam D, Voskuil K, et al. Predicting high-need cases among new Medicaid enrollees. Am J Manag Care. 2014 Sep 1;20(9):e399-407. PMID: 23636712.

74. Wherry LR, Burns ME, Leininger LJ. Using self-reported health measures to predict high-need cases among Medicaid-eligible adults. Health Serv Res. 2014 Dec;49 Suppl 2:2147-72. doi: 10.1111/1475-6773.12222. PMID: 24925967.

75. Billings J, Raven MC. Dispelling an urban legend: frequent emergency department users have substantial burden of disease. Health Aff (Millwood). 2013 Dec;32(12):2099-108. doi: 10.1377/hlthaff.2012.1276. PMID: 24113687.

76. Hwang AS, Liu SW, Yelibi C, et al. Characteristics of persistent emergency department high utilizers in a large primary care practice-based research network. J Gen Intern Med. 2014 Apr;29:S47-S. PMID: WOS:000340996200116.

77. Leininger L, Avery K. The capacity of self-reported health measures to predict high-need Medicaid enrollees. Princeton, NJ: Robert Wood Johnson Foundation; 2015.

78. Yang C, Delcher C, Shenkman E, et al. Expenditure variations analysis using residuals for identifying high health care utilizers in a state Medicaid program. BMC Med Inform Decis Mak. 2019;19(1):N.PAG-N.PAG. doi: 10.1186/s12911-019-0870-4. PMID: 137452762.

79. Chang ET, Piegari R, Wong ES, et al. Which patients are persistently high-risk for hospitalization? Am J Manag Care. 2019 Sep 1;25(9):e274-e81. PMID: 31518099.

80. Raven MC, Billings JC, Goldfrank LR, et al. Medicaid patients at high risk for frequent hospital admission: real-time identification and remediable risks. J Urban Health. 2009 Mar;86(2):230-41. doi: 10.1007/s11524-008-9336-1. PMID: 19082899.

81. Billings J, Mijanovich T. Improving the management of care for high-cost Medicaid patients. Health Aff (Millwood). 2007 Nov-Dec;26(6):1643-54. doi: 10.1377/hlthaff.26.6.1643. PMID: 17978384.

82. Hempstead K, Delia D, Cantor JC, et al. The fragmentation of hospital use among a cohort of high utilizers: implications for emerging care coordination strategies for patients with multiple chronic conditions. Med Care. 2014 Mar;52 Suppl 3:S67-74. doi: 10.1097/mlr.0000000000000049. PMID: 24561761.

83. Bell J, Turbow S, George M, et al. Factors associated with high-utilization in a safety net setting. BMC Health Serv Res. 2017 Apr 14;17(1):273. doi: 10.1186/s12913-017-2209-0. PMID: 26516789.

84. Robinson RL, Grabner M, Palli SR, et al. Covariates of depression and high utilizers of healthcare: impact on resource use and costs. J Psychosom Res. 2016;85:35-43. doi: 10.1016/j.jpsychores.2016.04.002. PMID: 115438213.

85. Rohrer JE, Rasmussen N, Adamson SA. Illness severity and total visits in family medicine. J Eval Clin Pract. 2008;14(1):65-9. PMID: 105885067.

86. Sterling S, Chi F, Weisner C, et al. Association of behavioral health factors and social determinants of health with high and persistently high healthcare costs. Prev Med Rep. 2018;11:154-9. doi: 10.1016/j.pmedr.2018.06.017.

87. Reichard A, Gulley SP, Rasch EK, et al. Diagnosis isn't enough: understanding the connections between high health care utilization, chronic conditions and disabilities among U.S. working age adults. Disabil Health J. 2015;8(4):535-46. doi: 10.1016/j.dhjo.2015.04.006.

88. Levinson CM, Druss BG. Health beliefs and depression in a group of elderly high utilizers of medical services. Gen Hosp Psychiatry. 2005;27(2):97-9. doi: 10.1016/j.genhosppsych.2004.09.010.

89. Behr JG, Diaz R. Emergency department frequent utilization for non-emergent presentments: results from a regional urban trauma center study. PLoS One. 2016;11(1):e0147116. doi: 10.1371/journal.pone.0147116. PMID: 27031738.

90. Buhumaid R, Riley J, Sattarian M, et al. Characteristics of frequent users of the emergency department with psychiatric conditions. J Health Care Poor Underserved. 2015 Aug;26(3):941-50. doi: 10.1353/hpu.2015.0079. PMID: 26930236.

91. Thakarar K, Morgan JR, Gaeta JM, et al. Predictors of frequent emergency room visits among a homeless population. PLoS One. 2015;10(4):e0124552. doi: 10.1371/journal.pone.0124552. PMID: 25646745.

92. Vinton DT, Capp R, Rooks SP, et al. Frequent users of US emergency departments: characteristics and opportunities for intervention. Emerg Med J. 2014 Jul;31(7):526-32. doi: 10.1136/emermed-2013-202407. PMID: 24813059.

93. Hasegawa K, Tsugawa Y, Camargo CA, Jr., et al. Frequent utilization of the emergency department for acute heart failure syndrome: a population-based study. Circ Cardiovasc Qual Outcomes. 2014 Sep;7(5):735-42. doi: 10.1161/circoutcomes.114.000949. PMID: 24865472.

94. Hasegawa K, Tsugawa Y, Tsai CL, et al. Frequent utilization of the emergency department for acute exacerbation of chronic obstructive pulmonary disease. Respir Res. 2014 Apr 10;15:40. doi: 10.1186/1465-9921-15-40. PMID: 25130916.

95. Hasegawa K, Sullivan AF, Tovar Hirashima E, et al. A multicenter observational study of US adults with acute asthma: who are the frequent users of the emergency department? J Allergy Clin Immunol Pract. 2014 Nov-Dec;2(6):733-40. doi: 10.1016/j.jaip.2014.06.012. PMID: 25730349.

96. Doran KM, Colucci AC, Wall SP, et al. Reasons for emergency department use: do frequent users differ? Am J Manag Care. 2014 Nov 1;20(11):e506-14. PMID: 22563000.

97. Liu SW, Nagurney JT, Chang Y, et al. Frequent ED users: are most visits for mental health, alcohol, and drug-related complaints? Am J Emerg Med. 2013 Oct;31(10):1512-5. doi: 10.1016/j.ajem.2013.08.006. PMID: 23395105.

98. Milbrett P, Halm M. Characteristics and predictors of frequent utilization of emergency services. J Emerg Nurs. 2009 Jun;35(3):191-8; quiz 273. doi: 10.1016/j.jen.2008.04.032. PMID: 17115882.

99. Hunt KA, Weber EJ, Showstack JA, et al. Characteristics of frequent users of emergency departments. Ann Emerg Med. 2006 Jul;48(1):1-8. doi: 10.1016/j.annemergmed.2005.12.030. PMID: 18331577.

100. Friedman BW, Serrano D, Reed M, et al. Use of the emergency department for severe headache. A population-based study. Headache. 2009 Jan;49(1):21-30. doi: 10.1111/j.1526-4610.2008.01282.x. PMID: 17646191.

101. Ruger JP, Richter CJ, Spitznagel EL, et al. Analysis of costs, length of stay, and utilization of emergency department services by frequent users: implications for health policy. Acad Emerg Med. 2004 Dec;11(12):1311-7. doi: 10.1197/j.aem.2004.07.008. PMID: 12449550.

102. Mandelberg JH, Kuhn RE, Kohn MA. Epidemiologic analysis of an urban, public emergency department's frequent users. Acad Emerg Med. 2000 Jun;7(6):637-46. PMID: 14720612.

103. Zuckerman S, Shen YC. Characteristics of occasional and frequent emergency department users: do insurance coverage and access to care matter? Med Care. 2004 Feb;42(2):176-82. doi: 10.1097/01.mlr.0000108747.51198.41. PMID: 15890040.

104. Blumenthal KJ, Chang Y, Ferris TG, et al. Using a self-reported global health measure to identify patients at high risk for future healthcare utilization. J Gen Intern Med. 2017;32(8):877-82. doi: 10.1007/s11606-017-4041-y.

105. Porter M, Quillen D, Agana DF, et al. Are patients frequently readmitted to the hospital different from the other admitted patients? J Am Board Fam Med. 2019 Jan-Feb;32(1):58-64. doi: 10.3122/jabfm.2019.01.180052. PMID: WOS:000457274800010.

106. Walker EA, Katon W, Russo J, et al. Health care costs associated with posttraumatic stress disorder symptoms in women. Arch Gen Psychiatry. 2003 Apr;60(4):369-74. doi: 10.1001/archpsyc.60.4.369. PMID: WOS:000182096000006.

107. Doran KM, Raven MC, Rosenheck RA. What drives frequent emergency department use in an integrated health system? National data from the Veterans Health Administration. Ann Emerg Med. 2013 Aug;62(2):151-9. doi: 10.1016/j.annemergmed.2013.02.016. PMID: 23582617.

108. Szymkowiak D, Montgomery AE, Johnson EE, et al. Persistent super-utilization of acute care services among subgroups of veterans experiencing homelessness. Med Care. 2017 Oct;55(10):893-900. doi: 10.1097/mlr.0000000000000796. PMID: 26472609.

109. Prenovost KM, Fihn SD, Maciejewski ML, et al. Using item response theory with health system data to identify latent groups of patients with multiple health conditions. PLoS One. 2018;13(11):e0206915. doi: 10.1371/journal.pone.0206915. PMID: 30473764.

110. Yang C, Delcher C, Shenkman E, et al. Clustering inter-arrival time of health care encounters for high utilizers. 2018 IEEE 20th International Conference on e-Health Networking, Applications and Services, Healthcom 2018; 2018 September 17-20; Ostrava, Czech Republic. Curran Associates.

111. Wong ES, Yoon J, Piegari RI, et al. Identifying latent subgroups of high-risk patients using risk score trajectories. J Gen Intern Med. 2018 Dec;33(12):2120-6. doi: 10.1007/s11606-018-4653-x. PMID: 30225769.

112. 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.

113. Newcomer SR, Steiner JF, Bayliss EA. Identifying subgroups of complex patients with cluster analysis. Am J Manag Care. 2011 Aug 1;17(8):e324-32. PMID: 21851140.

114. Ganguli I, Thompson RW, Ferris TG. What can five high cost patients teach us about healthcare spending? Healthc (Amst). 2017 Dec;5(4):204-13. doi: 10.1016/j.hjdsi.2016.12.004. PMID: 28032213.

115. Hardy M, Cho A, Stavig A, et al. Understanding frequent emergency department use among primary care patients. Popul Health Manag. 2018 Feb;21(1):24-31. doi: 10.1089/pop.2017.0030. PMID: 28410614.

116. Birmingham LE, Cochran T, Frey JA, et al. Emergency department use and barriers to wellness: a survey of emergency department frequent users. BMC Emerg Med. 2017 May 10;17(1):16. doi: 10.1186/s12873-017-0126-5. PMID: 27604233.

117. Hasselman D. Super-utilizer summit: Common themes from innovative complex care management programs. Super-Utilizer Summit; 2013 Alexandria, VA. Center for Health Care Strategies Inc,.

118. Chan B, Hulen E, Edwards S, et al. "It's like riding out the chaos": caring for socially complex patients in an ambulatory intensive care unit (A-ICU). Ann Fam Med. 2019 Nov;17(6):495-501. doi: 10.1370/afm.2464. PMID: 31712287.

119. Das LT, Kaushal R, Garrison K, et al. Drivers of preventable high health care utilization: a qualitative study of patient, physician and health system leader perspectives. J Health Serv Res Policy. 2019 Sep 10:1355819619873685. doi: 10.1177/1355819619873685. PMID: 31505976.

120. Gross K, Brenner JC, Truchil A, et al. Building a citywide, all-payer, hospital claims database to improve health care delivery in a low-income, urban community. Popul Health Manag. 2013;16:S-20. doi: 10.1089/pop.2013.0037. PMID: 104229979.

121. Bott D, McCall N. Evaluation of Medicare care management for high cost beneficiaries (CMHCB) demonstration: Texas Senior Trails (TST) final report. Research Triangle Park, NC: RTI International 2010.

122. Durfee J, Johnson T, Batal H, et al. The impact of tailored intervention services on charges and mortality for adult super-utilizers. Healthc (Amst). 2018 Dec;6(4):253-8. doi: 10.1016/j.hjdsi.2017.08.004. PMID: 30938944.

123. Peterson G. Evaluation of health care innovation awards (HCIA): primary care redesign programs third annual report. Princeton, NJ: Mathematica Policy Research; 2017.

124. Yoon J, Chang E, Rubenstein LV, et al. Impact of primary care intensive management on high-risk veterans' costs and utilization. Ann Intern Med. 2018 Oct 2;169(7):515-6. doi: 10.7326/l18-0461. PMID: 30285201.

125. Capp R, Misky GJ, Lindrooth RC, et al. Coordination program reduced acute care use and increased primary care visits among frequent emergency care users. Health Aff (Millwood). 2017;36(10):1705-11. doi: 10.1377/hlthaff.2017.0612. PMID: 125553088.

126. Dally DL, Dahar W, Scott A, et al. The impact of a health education program targeting patients with high visit rates in a managed care organization. Am J Health Promot. 2002;17(2):101-11. doi: 10.4278/0890-1171-17.2.101. PMID: CN-00412072.

127. Roberts SR, Crigler J, Ramirez C, et al. Working with socially and medically complex patients: when care transitions are circular, overlapping, and continual rather than linear and finite. J Healthc Qual. 2015 Jul-Aug;37(4):245-65. doi: 10.1097/jhq.0000000000000006. PMID: 20604822.

128. Horn BP, Crandall C, Moffett M, et al. The economic impact of intensive care management for high-cost medically complex patients: an evaluation of New Mexico's care one program. Popul Health Manag. 2016 Dec;19(6):398-404. doi: 10.1089/pop.2015.0142. PMID: 27161849.

129. Wilber KH, Allen D, Shannon GR, et al. Partnering managed care and community-based services for frail elders: the care advocate program. J Am Geriatr Soc. 2003 Jun;51(6):807-12. doi: 10.1046/j.1365-2389.2003.51257.x. PMID: 12757567.

130. Fleming MD, Shim JK, Yen IH, et al. Patient engagement at the margins: health care providers' assessments of engagement and the structural determinants of health in the safety-net. Soc Sci Med. 2017 Jun;183:11-8. doi: 10.1016/j.socscimed.2017.04.028. PMID: 24813059.

131. Thompson MP, Podila PSB, Clay C, et al. Community navigators reduce hospital utilization in super-utilizers. Am J Manag Care. 2018 Feb;24(2):70-6. PMID: 29461853.

132. Zulman DM, Chang ET, Wong A, et al. Effects of intensive primary care on high-need patient experiences: survey findings from a Veterans Affairs randomized quality improvement trial. J Gen Intern Med. 2019 May;34(Suppl 1):75-81. doi: 10.1007/s11606-019-04965-0. PMID: 31098977.

133. Crane S, Collins L, Hall J, et al. Reducing utilization by uninsured frequent users of the emergency department: combining case management and drop-in group medical appointments. J Am Board Fam Med. 2012 Mar-Apr;25(2):184-91. doi: 10.3122/jabfm.2012.02.110156. PMID: 21415616.

134. Katzelnick DJ, Simon GE, Pearson SD, et al. Randomized trial of a depression management program in high utilizers of medical care. Arch Fam Med. 2000 Apr;9(4):345-51. doi: 10.1001/archfami.9.4.345. PMID: WOS:000086474400006.

135. Vickery KD, Shippee ND, Menk J, et al. Integrated, accountable care for Medicaid expansion enrollees: a comparative evaluation of Hennepin Health. Med Care Res Rev. 2018. doi: 10.1177/1077558718769481.

136. Adam P, Brandenburg DL, Bremer KL, et al. Effects of team care of frequent attenders on patients and physicians. Fam Syst Health. 2010 Sep;28(3):247-57. doi: 10.1037/a0020944. PMID: 21269012.

137. Hibbard JH, Greene J, Sacks R, et al. Adding a measure of patient self-management capability to risk assessment can improve prediction of high costs. Health Aff (Millwood). 2016 Mar;35(3):489-94. doi: 10.1377/hlthaff.2015.1031. PMID: 26953304.

138. Mautner DB, Pang HC, Brenner JC, et al. Generating hypotheses about care needs of high utilizers: lessons from patient interviews. Popul Health Manag. 2013 Oct;16:S26-S33. doi: 10.1089/pop.2013.0033. PMID: WOS:000324891700007.

139. Hudon C, Chouinard MC, Diadiou F, et al. Case management in primary care for frequent users of health care services with chronic diseases: a qualitative study of patient and family experience. Ann Fam Med. 2015 Nov;13(6):523-8. doi: 10.1370/afm.1867. PMID: 27074709.

140. Zulman DM, Ezeji-Okoye SC, Shaw JG, et al. Partnered research in healthcare delivery redesign for high-need, high-cost patients: development and feasibility of an Intensive Management Patient-Aligned Care Team (ImPACT). J Gen Intern Med. 2014 Dec;29 Suppl 4:861-9. doi: 10.1007/s11606-014-3022-7. PMID: 25364876.

141. Shah R, Chen C, O'Rourke S, et al. Evaluation of care management for the uninsured. Med Care. 2011 Feb;49(2):166-71. doi: 10.1097/MLR.0b013e3182028e81. PMID: 22317288.

142. Sledge WH, Brown KE, Levine JM, et al. A randomized trial of primary intensive care to reduce hospital admissions in patients with high utilization of inpatient services. Dis Manag. 2006;9(6):328-38. doi: 10.1089/dis.2006.9.328. PMID: CN-00576977.

143. Shumway M, Boccellari A, O'Brien K, et al. Cost-effectiveness of clinical case management for ED frequent users: results of a randomized trial. Am J Emerg Med. 2008 Feb;26(2):155-64. doi: 10.1016/j.ajem.2007.04.021. PMID: 16781915.

144. Seaberg D, Elseroad S, Dumas M, et al. Patient navigation for patients frequently visiting the emergency department: a randomized, controlled trial. Acad Emerg Med. 2017 Nov;24(11):1327-33. doi: 10.1111/acem.13280. PMID: 28834070.

145. Coleman EA, Eilertsen TB, Kramer AM, et al. Reducing emergency visits in older adults with chronic illness. A randomized, controlled trial of group visits. Eff Clin Pract. 2001 Mar-Apr;4(2):49-57. PMID: 12751871.

146. Weerahandi H, Basso Lipani M, Kalman J, et al. Effects of a psychosocial transitional care model on hospitalizations and cost of care for high utilizers. Soc Work Health Care. 2015;54(6):485-98. doi: 10.1080/00981389.2015.1040141. PMID: 109833750.

147. Navratil-Strawn JL, Hawkins K, Wells TS, et al. An emergency room decision-support program that increased physician office visits, decreased emergency room visits, and saved money. Popul Health Manag. 2014 Oct;17(5):257-64. doi: 10.1089/pop.2013.0117. PMID: 24148033.

148. Schickedanz A, Sharp A, Hu YR, et al. Impact of social needs navigation on utilization among high utilizers in a large integrated health system: a quasi-experimental study. J Gen Intern Med. 2019 Nov;34(11):2382-9. doi: 10.1007/s11606-019-05123-2. PMID: 31228054.

149. Sevak P, Stepanczuk CN, Bradley KWV, et al. Effects of a community-based care management model for super-utilizers. Am J Manag Care. 2018 Nov 1;24(11):e365-e70.

150. Sandberg SF, Erikson C, Owen R, et al. Hennepin Health: a safety-net accountable care organization for the expanded Medicaid population. Health Aff (Millwood). 2014 Nov;33(11):1975-84. doi: 10.1377/hlthaff.2014.0648. PMID: 25367993.

151. DeHaven M, Kitzman-Ulrich H, Gimpel N, et al. The effects of a community-based partnership, Project Access Dallas (PAD), on emergency department utilization and costs among the uninsured. J Public Health (Oxf). 2012 Dec;34(4):577-83. doi: 10.1093/pubmed/fds027. PMID: 21862145.

152. Enard KR, Ganelin DM. Reducing preventable emergency department utilization and costs by using community health workers as patient navigators. J Healthc Manag. 2013 Nov-Dec;58(6):412-27; discussion 28. PMID: 24400457.

153. Gimpel N, Marcee A, Kennedy K, et al. Patient perceptions of a community-based care coordination system. Health Promot Pract. 2010 Mar;11(2):173-81. doi: 10.1177/1524839908320360. PMID: 19131540.

154. Chukmaitov AS, Tang A, Carretta HJ, et al. Characteristics of all, occasional, and frequent emergency department visits due to ambulatory care-sensitive conditions in Florida. J Ambul Care Manage. 2012 Apr-Jun;35(2):149-58. doi: 10.1097/JAC.0b013e318244d222. PMID: 23091842.

155. Long P, Abrams M, Milstein A, et al., eds. Effective care for high-need patients: opportunities for improving outcomes, value, and health. Washington, DC: National Academy of Medicine; 2017.

156. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40(5):373-83. doi: 10.1016/0021-9681(87)90171-8. PMID: 3558716.

157. Austin SR, Wong YN, Uzzo RG, et al. Why summary comorbidity measures such as the Charlson Comorbidity Index and Elixhauser Score Work. Med Care. 2015 Sep;53(9):e65-72. doi: 10.1097/MLR.0b013e318297429c. PMID: 23703645.

158. Hall WH, Ramachandran R, Narayan S, et al. An electronic application for rapidly calculating Charlson comorbidity score. BMC Cancer. 2004 Dec 20;4:94. doi: 10.1186/1471-2407-4-94. PMID: 15610554.

159. Sharabiani MT, Aylin P, Bottle A. Systematic review of comorbidity indices for administrative data. Med Care. 2012 Dec;50(12):1109-18. doi: 10.1097/MLR.0b013e31825f64d0. PMID: 22929993.

160. Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Med Care. 2005;43(11):1130-1.

161. Centers for Medicare & Medicaid Services. Report to Congress: risk adjustment in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf. Accessed on August 24, 2020.

162. U.S. Department of Veterans Affairs. Organizational excellence. Care assessment needs. Washington, DC: U.S. Department of Veterans Affairs; 2019. https://www.va.gov/HEALTHCAREEXCELLENCE/about/organization/examples/care-assessment-needs.asp. Accessed on August 24, 2020.

163. Stewart WF, Lipton RB, Kolodner KB, et al. Validity of the Migraine Disability Assessment (MIDAS) score in comparison to a diary-based measure in a population sample of migraine sufferers. Pain. 2000;88(1):41-52. doi: 10.1016/s0304-3959(00)00305-5.

164. Benjamins MR, Hummer RA, Eberstein IW, et al. Self-reported health and adult mortality risk: an analysis of cause-specific mortality. Soc Sci Med. 2004 Sep;59(6):1297-306. doi: 10.1016/j.socscimed.2003.01.001. PMID: 15210100.

165. Idler EL, Angel RJ. Self-rated health and mortality in the NHANES-I Epidemiologic Follow-up Study. Am J Public Health. 1990 Apr;80(4):446-52. doi: 10.2105/ajph.80.4.446. PMID: 2316767.

166. Wu S, Wang R, Zhao Y, et al. The relationship between self-rated health and objective health status: a population-based study. BMC Public Health. 2013 Apr 9;13:320. doi: 10.1186/1471-2458-13-320. PMID: 23570559.

167. Gaskin DJ, Thorpe RJ, Jr., McGinty EE, et al. Disparities in diabetes: The nexus of race, poverty, and place. Am J Public Health. 2014 Nov;104(11):2147-55. doi: 10.2105/AJPH.2013.301420. PMID: 24228660.

168. Noonan AS, Velasco-Mondragon HE, Wagner FA. Improving the health of African Americans in the USA: an overdue opportunity for social justice. Public Health Rev. 2016;37:12. doi: 10.1186/s40985-016-0025-4. PMID: 29450054.

169. Neal K. Not by proxy: Arguments for improving the use of race in biomedical research. Am J Bioeth. 2017;17.9:52-4.

170. Osborn R, Doty MM, Moulds D, et al. Older Americans Were Sicker And Faced More Financial Barriers To Health Care Than Counterparts In Other Countries. Health Aff (Millwood). 2017 Dec;36(12):2123-32. doi: 10.1377/hlthaff.2017.1048. PMID: 27564725.

171. Takeshita T, Yamamoto-Ibusuki M, Yamamoto Y, et al. PTIP associated protein 1, PA1, is an independent prognostic factor for lymphnode negative breast cancer. PLoS One. 2013;8(11):e80552. doi: 10.1371/journal.pone.0080552. PMID: 27272030.

172. Rideout J. “Hot Spots” Face Scrutiny in Next Cost & Quality Atlas. CHCF Blog. Oakland, CA: California Health Care Foundation; 2017.

173. Kastner M. Underlying mechanisms of complex interventions addressing the care of older adults with multimorbidity: a realist review. BMJ open. 2019 2019;9(4). doi: 10.1136/bmjopen-2018-025009.

174. NCQA. Hospitalization for potentially preventable complications (HPC). Washington, DC: NCQA; 2020. https://www.ncqa.org/hedis/measures/hospitalization-for-potentially-preventable-complications/. Accessed on August 26, 2020.

175. Research Data Assistance Center (ResDAC). RIF Medicare quarterly data. Minneapolis, MN: University of Minnesota; 2016. Accessed on September 28, 2020.

176. Schulte MT, Hser YI. Substance use and associated health conditions throughout the lifespan. Public Health Rev. 2014;35.

177. Myers G, Price G, Pykosz M. Caring for older adults in a value-based model. NEJM Catalyst. 2016.

178. Myers G, Lee TH. Rebuilding health care as it should be: personal, equitable, and accountable. NEJM Catalyst. 2018.

179. Ghany R, Tamariz L, Chen G, et al. High-touch care leads to better outcomes and lower costs in a senior population. Am J Manag Care. 2018 Sep 1;24(9):e300-e4. PMID: 30222926.