REVIEWS Interventions to Improve Outcomes for High-Need, High-Cost Patients: A Systematic Review and Meta-Analysis

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BACKGROUND: Chronic disease patients who are the greatest users of healthcare services are often referred to as high-need, high-cost (HNHC). Payers, providers, and policymakers in the United States are interested in identifying interventions that can modify or reduce preventable healthcare use among these patients, without adversely impacting their quality of care and health. We systematically reviewed the evidence on the effectiveness of complex interventions designed to change the healthcare of HNHC patients, modifying cost and utilization, as well as clinical/functional, and social risk factor outcomes.

METHODS: We searched 8 electronic databases (January 2000 to March 2021) and selected non-profit organization and government agency websites for randomized controlled trials and observational studies with comparison groups that targeted HNHC patients. Two investigators independently screened each study and abstracted data into structured forms. Study quality was assessed using standard risk of bias tools. Random-effects meta-analysis was conducted for outcomes reported by at least 3 comparable samples.

RESULTS: Forty studies met our inclusion criteria. Interventions were heterogenous and classified into 7 categories, reflecting the predominant service location/modality (home, primary care, ambulatory intensive caring unit [aICU], emergency department [ED], community, telephonic/mail, and system-level). Home-, primary care-, and ED-based interventions resulted in reductions in high-cost healthcare services (ED and hospital use). ED-based interventions also resulted in greater use of primary care. Primary care- and ED-based interventions reduced costs. System-level transformation interventions did not reduce costs.

DISCUSSION: We found limited evidence of intervention effectiveness in relation to cost and use, and additional evidence is needed to strengthen our confidence in the findings. Few studies reported patient clinical/functional or social risk factor outcomes (e.g., homeless-

Prior Presentations Findings from an early draft of these results were presented at the 2020 AcademyHealth Annual Research Meeting. The results using all included studies can be found in the full AHRQ evidence report, available at https://doi.org/10.23970/AHRQEPCCER246.

Received February 8, 2022 Accepted September 13, 2022 Published online October 11, 2022 ness) or sufficient details for determining why individual interventions work, for whom, and when. Future evaluations could provide additional insights, by including intermediate process outcomes and patients' experiences, in assessing the impact of these complex interventions. **PROSPERO REGISTRATION NUMBER:** CRD42020161179

KEY WORDS: high-need high-cost patients; complex interventions; systematic review; healthcare utilization; healthcare costs.

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INTRODUCTION

Patients referred to as high-need, high-cost (HNHC) constitute a small percentage of all US patients but account for a disproportionally high level of healthcare use and cost.¹ Often these patients have multiple chronic conditions, and their care may be complicated by functional limitations, behavioral health concerns, and social risk factors (e.g., homelessness).¹ HNHC patients often use higher levels of high-cost care, particularly emergency department (ED) visits or hospitalizations. Some of this care is believed to be potentially preventable or modifiable through better management of chronic conditions in primary care or other ambulatory care settings.²

Finding effective interventions to address HNHC patient needs is a pressing concern for the US healthcare system. One 2014 US-focused systematic review of HNHC patient interventions found that care and case management models improved patient satisfaction, clinical outcomes, and healthcare use and spending.³ Other prior reviews have been limited to specific settings (e.g., ED),^{4–10} included studies conducted outside the USA,^{4–7,9} or included study designs that may lead to biased results (e.g., no comparison groups).^{7,11,12} In contrast, this review focuses on more rigorous evaluations to understand the effectiveness of a broad set of HNHC interventions, tested across US healthcare system settings.

The objective of this review was to evaluate the effectiveness of interventions targeting HNHC patients that intend to improve the quality of care while reducing potentially preventable or modifiable healthcare use and cost. This work is particularly timely as US payers, particularly the Centers for Medicare & Medicaid Services (CMS), increasingly require payment through alternative payment models that incorporate financial risk. Health systems and providers recognize that their success in these models can depend on their effectiveness in addressing the care and costs of HNHC patients.

METHODS

This systematic review was developed through a larger project conducted by the RTI-University of North Carolina Evidence-Based Practice Center for the Agency for Healthcare Research and Quality (AHRQ). We adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.¹³ This review followed an a priori protocol¹⁴ and is registered with PROSPERO (CRD42020161179). The full report provides additional details on the methods and results.¹⁵

Search Strategy and Study Selection

We searched PubMed, the Cochrane Library, CINAHL, Embase, PsycINFO, Web of Science, Academic Search Premier, and Scopus for English-language articles published from January 1, 2000, to March 4, 2021, using relevant medical subject headings (MeSH) and keywords associated with HNHC patients and interventions (full search strategy provided in Appendix 1). We also searched for gray literature from selected websites (e.g., CMS). Reference lists of pertinent articles were hand-searched to identify additional studies.

Two reviewers independently screened titles and abstracts and reviewed full-text articles. Disagreements were resolved by consensus or a third reviewer.

The detailed eligibility criteria are in Appendix 2. Briefly, any approach to a HNHC patient intervention was included if it was conducted in a noninstitutional setting; initial contact could be before hospital discharge. The overall goal across these interventions was to improve the healthcare use and outcomes of HNHC patients. Studies were eligible if they presented intervention findings on noninstitutionalized, US adults identified as HNHC based on having high healthcare use or cost, measured over ≥ 6 months. High use or cost was defined by study authors. Study designs included randomized controlled trials (RCTs) and observational studies. Studies had to compare intervention participant results with those of a comparison group.

Data Extraction and Quality Assessment

We abstracted data on study characteristics, including design, participants, intervention, and outcome measures (changes in healthcare utilization, cost, clinical and functional outcomes, and social risk factors). Abstracted outcomes are listed in Appendix 3. One reviewer abstracted data into a structured evidence table and a second reviewer checked for completeness and accuracy. Two independent reviewers assessed the risk of bias (RoB) for each study as low, some concerns, or high using the Cochrane RoB 2.0 tool¹⁶ for RCTs and the ROBINS-I tool¹⁷ for observational studies. Discrepancies in ratings between reviewers were resolved through discussion.

Data Synthesis and Analysis

Given the diversity of HNHC interventions, we adapted Bodenheimer's scheme to group care management models by predominant service location/modality to classify each study into one intervention category for synthesis.¹⁸ Included studies were categorized as follows: home-based care; primary care; ambulatory intensive caring unit (aICU); ED; community; telephonic/mail; or system-level transformation. The predominant service location for interventions that incorporated multiple locations/modalities was determined through consensus. Some studies included multiple distinct intervention cohorts. We refer to each cohort-comparison group pair as a "sample." For broader interventions (e.g., practice-wide interventions), only HNHC patient findings were included.

We synthesized study outcomes narratively or, when possible, quantitatively. When an outcome was reported in \geq 3 samples in an intervention category and study design, we conducted a random-effects meta-analyses, using the Sidik-Jonkman model with Knapp-Hartung standard errors in Stata 16.¹⁹

The strength of evidence (SoE) of outcomes was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach,²⁰ as modified by the AHRQ Evidence-based Practice Center Program.²¹ Assessing study limitations, directness, consistency, precision, and reporting bias, each outcome reported by \geq 2 studies within an intervention category was assigned a grade of high, moderate, low, or insufficient (Appendix 4 defines these levels).²² Two senior reviewers independently graded each relevant outcome. Disagreements were resolved through discussion. High RoB studies were solely used to qualitatively consider their impact on SoE grades.¹⁷

RESULTS

A total of 40 studies (reported in 46 articles) met eligibility criteria. Figure 1 depicts the article flowchart. We identified 19 RCTs and 21 observational studies. We rated 4 RCT studies as low RoB²³⁻²⁶ and 15 RCTs as some concerns.²⁷⁻⁴² We rated 12 observational studies as some concerns for RoB.⁴³⁻⁵⁸ Nine observational studies⁵⁹⁻⁶⁸ were rated as high RoB because of critical flaws in \geq 1 category. Of these, 7 high RoB studies^{59,61-} ^{66,68} inadequately controlled for confounding: 4^{59,63,64,66} did not control for confounding at all, 2^{61,62,65} were unclear about the variables included in models, and 1⁶⁸ did not control for important baseline characteristics that differed in the treatment and control groups. Two studies^{64,67} inadequately controlled for potential selection bias, and one⁶⁰ for potential bias due to

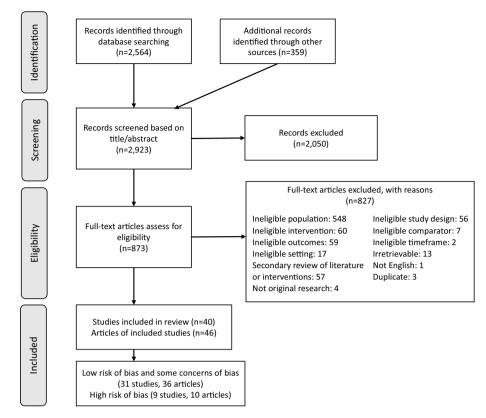


Figure 1 Flowchart of study selection.

missing data. Appendix 5 shows the study-specific RoB ratings.

Our analysis included 31 studies reporting on 38 samples (Table 1). Most samples focused on adults of all ages (n=33). Samples mostly included participants with Medicare coverage (n=19) or a mix of insurance types (n=10). Most samples were conducted in multiple study sites (n=29). Only 2 samples had fewer than 100 participants (minimum: 72). All but one sample²⁷ was compared with usual care.

Participant eligibility varied widely across studies and was based on study author established minimum thresholds that they considered represented high cost and/or utilization. Some samples also used diagnoses and/or risk scores. Criteria for high use ranged from ≥ 1 hospitalization to ≥ 11 outpatient visits. Criteria for high cost included thresholds by dollar values (e.g., \geq \$5000) and percentiles (e.g., top 10% of expenditures). Samples were mostly based on high use alone (*n*=13) or high cost or use with ≥ 1 chronic condition (*n*=15).

Intervention Effectiveness by Intervention Category

We present the results for outcomes with a grade of low SoE or better, organized by intervention category (Table 2). Although samples reported over 100 unique outcomes, only 25 outcomes were reported by ≥ 2 samples within an intervention category. Only a limited number of clinical and functional outcomes and no social risk factor outcomes were graded. No outcomes were graded as high SoE. Sensitivity analyses including the 9 high RoB, observational studies did not impact final SOE grades. All study and intervention characteristics and SoE grades are available in Appendix 6.

Home-Based Care Interventions. One RCT (2 samples)³⁷ and one observational study⁵⁶ evaluated interventions providing in-home care for patients who had difficulty leaving their homes. The RCT³⁷ assessed in-home care management through a visiting physician as part of the larger Medicare's Care Management for High Cost Beneficiaries (CMHCB) demonstration, which tested various pay-for-performance and care management/coordination approaches among high-cost complex Medicare patients. The observational study, Independence at Home (IAH)⁵⁶, evaluated the effectiveness of providing home-based primary care to Medicare patients with multiple chronic conditions and functional limitations.

Home-based care interventions resulted in reductions in hospitalizations for ambulatory care sensitive conditions (ACSC) (a quality indicator for preventable utilization)⁶⁹, increases in receipt of influenza vaccinations (a quality measure), and no change in mortality (all findings low SoE).

Primary Care–Based Interventions. Five RCTs (6 samples)^{23,29,30,38,40} and 1 observational study⁵⁸ evaluated interventions embedded in primary care practices. Three RCTs^{23,38,40} tested team-based care or case management interventions. One²³ of the RCTs examined providing psychiatric

Study characteristics	No. of	No. of	
	studies (%)	samples (%)	
Total	31	38	
Intervention category [†]			
Home-based	2 (6)	3 (8)	
Primary care-based	6 (19)	7 (18)	
aICU-based	3 (10)	3 (8)	
ED-based	5 (16)	5 (13)	
Community-based	6 (19)	6 (16)	
Telephonic/mail	6 (19)	9 (24)	
System-level transformation	4 (13)	5 (13)	
Participant age range			
Non-elderly adults	4 (13)	4 (11)	
Elderly adults	1 (3)	1 (3)	
Adults of all ages	26 (84)	33 (87)	
Participant race			
Majority white (≥51%)	8 (26)	12 (32)	
Majority nonwhite ($\geq 51\%$)	12 (39)	12 (32)	
Not reported	11 (35)	14 (37)	
Participant primary insurer			
Medicare	12 (39)	19 (50)	
Medicaid	5 (16)	5 (13)	
Commercial	3 (10)	3 (8)	
Mixed coverage	10 (32)	10 (26)	
Not reported	1 (3)	1 (3)	
Participant eligibility‡			
High cost alone	1 (3)	1 (3)	
High use alone	13 (42)	13 (34)	
High cost or use and high-risk score	4 (13)	5 (13)	
High cost or use and ≥ 1 chronic	11 (35)	15 (39)	
condition			
High cost or use, ≥ 1 chronic	3 (10)	4 (11)	
condition, and high-risk score			
Sample size			
<100	2 (6)	2 (5)	
100 to <1000	10 (32)	11 (29)	
1000 to <10,000	11 (35)	14 (37)	
≥10,000	4 (13)	6 (16)	
Not reported	4 (13)	5 (13)	
Number of study sites	0 (20)	0 (01)	
1	9 (29)	9 (24)	
≥ 2	22 (71)	29 (76)	
Comparison group	20 (07)	25 (05)	
Usual care	30 (97)	37 (97)	
Other§	1 (3)	1 (3)	
Risk-of-bias assessment by study			
design	4 (12)	4 (11)	
RCT: Low risk-of-bias studies	4 (13)	4 (11)	
RCT: Some concerns for risk-of-bias	15 (48)	20 (53)	
studies	12 (20)	14 (27)	
Observational: Some concerns for	12 (39)	14 (37)	
risk-of-bias studies			

* The 9 observational studies identified as high risk of bias are not included in the analysis or in this table $^{59-68}$

† One study⁵⁶ included 2 different analyses in 2 samples. One analysis using data from 1 of the samples was classified as home-based care and the second analysis based on data from a second sample was classified as system-level

[‡] One study³⁷ included 2 samples with different participant eligibility criteria for each sample (high cost or use and ≥ 1 chronic condition, high cost or use and high risk score)

§ The comparison group received baseline education materials and an incentive to fill out the end-of-study questionnaire²⁷

aICU ambulatory intensive caring unit; ED emergency department; RCT randomized controlled trial

nurse-led case management to high-using patients. Another³⁸ (2 samples), a Medicare CMHCB intervention, tested embedding comprehensive nurse-led case management, and a third⁴⁰ tested community health worker (CHW)–led complex care management for Medicaid patients. A fourth RCT³⁰, conducted in a health maintenance organization (HMO), examined providing depression management to high outpatient users, while an observational study⁵⁸ tested providing care coordination and disease management to Medicaid managed care organization patients. A fifth RCT²⁹ tested providing group visits to older adults to support them in managing their chronic conditions.

Primary care–based interventions resulted in reductions in hospitalizations and total costs (-\$4,119 [95% CI, -7,935 to -302] (Fig. 2)) (both low SoE). However, based on evidence from the 2 CMHCB independent samples, these interventions also resulted in a reduction in receipt of influenza vaccinations (low SoE for unfavorable findings).

Ambulatory Intensive Caring Unit–Based Interventions. aICUs are a separate clinic or a separate team within a clinic providing enhanced care. One RCT^{31,32} and 2 observational studies^{45,50,51} evaluated aICU interventions for HNHC patients. The RCT^{31,32} compared a Veterans Affairs intensive care management and coordination initiative to its ongoing patient-centered medical home (PCMH) model. One observational study⁴⁵ evaluated intensive chronic care management from a specialized team in a university healthcare system. A second observational study^{50,51} evaluated a multidisciplinary team providing care coordination and referral to intensive primary care in a Medicaid accountable care organization. All outcomes received an SoE grade of insufficient evidence, primarily because of inconsistent findings.

Emergency Department–Based Interventions. Four RCTs^{25,28,39,42} and 1 observational study⁴⁷ evaluated interventions for high-ED use patients recruited in the ED and providing care by an ED-affiliated team. All interventions provided care/case management to coordinate clinical care and support services and promoted increasing the receipt of care in ambulatory settings. Two RCTs provided patient navigation; one²⁵ for Medicaid patients at an ED in Connecticut and a second³⁹ at multiple EDs in Tennessee. Another RCT²⁸ evaluated case management, conducted by psychiatric social workers, that included assistance with psychosocial problems (e.g., homelessness). A fourth RCT⁴² provided ED-based clinical care planning followed by CHW-led care coordination. The observational study⁴⁷ telephonically provided nurse-led decision support to elderly ED patients.

ED-based interventions resulted in reductions in ED visits (moderate SoE) and ED costs (low SoE). Further, greater use of primary care visits (low SoE) suggested a shift to lower-cost care. ED-based interventions resulted in reductions in hospitalizations but no difference in hospital costs (both low SoE).

Community-Based Interventions. Community-based interventions, where the care team provides services primarily at community sites convenient to their HNHC patients, were evaluated in three RCTs^{24,26,41} and 3 observational studies^{43,44,46,49}. The Camden model identifies

Outcome type	Outcome	# Samples/design (n analyzed)	Summary of findings†	Overall evidence strength (direction of effect)
Home-based care interventions High-cost utilization	Hospitalizations, ACSC	2 RCT ³⁷ (N=34,421)	2 of 2 RCT samples had favorable findings	Low (favorable)
0		1 OBS $\frac{56}{2}$ (N =181,001)	1 of 1 OBS sample found no difference	
Clinical/functional	Hospitalizations, any ACSC	$\begin{array}{c} 2 \text{ RCT}^{3} (N = 34,421) \\ 2 \text{ BCT}^{37} (N = -34,421) \end{array}$	2 of 2 RCT samples had favorable findings	Low (favorable) Low (no difference)
CIIIILCAP IMILCUORA	Influenza vaccine	$2 \text{ RCT}^{37} (N = 34, 421)$	2 of 2 RCT samples had favorable findings	Low (favorable)
Primary care-based interventions High-cost utilization H	ns Hospitalizations, all cause	$6 \ \underline{RCT}^{23,29,30,38,40}_{50} (N = 7994)$	4 of 6 RCT samples had favorable findings	Low (favorable)
		$1 \text{ OBS}^{3} (N = 3048)$	2 of 6 RCT samples found no difference 1 of 1 OBS sample had unfavorable findings	
Cost	Hospitalizations, any all cause Total costs	2 RCT ³⁸ (<i>N</i> =6943) 4 RCT ^{23,38,40} (<i>N</i> =7292) 1 OBS ⁵⁸ (<i>N</i> =3048)	2 of 2 RCT samples had favorable findings 3 of 4 RCT samples had favorable findings 1 of 4 RCT samples found no difference	Low (favorable) Low (favorable)
			1 of 1 OBS sample found no difference MA pooled mean difference 54,119 (95% CI,	
Clinical/ functional	Influenza vaccine	2 RCT ³⁸ (N =6943)	- (,955 to -502); 5 RC1 samples; $N = 7,196$; $\Gamma = 29\%$ 2 of 2 RCT samples had unfavorable findings	Low (unfavorable)
ED-based interventions High-cost utilization	ED visits, all cause	4 RCT ^{25,28,39,42} (<i>N</i> =728) 1 OBS ^{47,67} (<i>N</i> =13,140)	3 of 4 RCT samples had favorable findings 1 of 4 RCT samples found no difference	Moderate (favorable)
	Hospitalizations, all cause	$1 \text{ RCT}^{25}_{47} (N = 100)$		Low (favorable)
Low-cost utilization	Primary care visits	$1 OBS (N = 14, 140)$ $1 RCT^{39} (N = 304)$ $1 OBC47 (N = 304)$		Low (favorable)
Cost	ED costs	$\begin{array}{c} 1 \text{ OBS} \overset{(N)}{=} \begin{smallmatrix} (N = 14, 140) \\ 3 \text{ RCT}^{28,39,42} \begin{smallmatrix} (N = 628) \\ 1 \text{ OBS}^{47} \begin{smallmatrix} (N = 14, 140) \\ \end{smallmatrix} \end{array}$	1 of 1 UBS sample had favorable findings 2 of 3 RCT samples had favorable findings 1 of 3 RCT samples found no difference	Low (favorable)
	Hospitalization costs	$\begin{array}{c} 2 \ \mathrm{RCT}^{28,42} \ \mathrm{(N=324)} \\ 1 \ \mathrm{OBS}^{47} \ \mathrm{(N=14\ 140)} \end{array}$	1 of 1 OBS sample found no difference 2 of 2 RCT samples found no difference	Low (no difference)
Community-based interventions Clinical/ functional	s Mortality	$3 \text{ RCT}^{24,26,41} (N = 2.343)$		Low (no difference)
System-level transformation interventions Cost	terventions Total costs	5 OBS ^{\$2-57} (N=NR‡)	4 of 5 OBS samples found no difference 1 of 5 OBS samples had unfavorable findings MA pooled mean difference: -513 (95% CI, -132 to 106); 5 observational samples, $P^2=91\%$	Low (no difference)
§ All outcomes graded as insu can be found in Appendix 6 (1 * The 9 observational studies	§ All outcomes graded as insufficient are omitted from this table, including all c can be found in Appendix 6 (Tables 6-3, 6-9, 6-9, 6-12, 6-15, 6-18, and 6-21) * The 9 observational studies identified as high risk of bias are not included i	§ All outcomes graded as insufficient are omitted from this table, including all aICU and telephonic/mail outcomes can be found in Appendix 6 (Tables 6-3, 6-9, 6-9, 6-12, 6-13, 6-18, and 6-21) * The 9 observational studies identified as high risk of bias are not included in the analysis or in this table ^{39–68}	all alCU and telephonic/mail outcomes. A comprehensive presentation of all SoE grades, including outcomes graded as insufficient 5-21) ded in the analysis or in this table ^{59–68}	outcomes graded as insufficient

Table 2 Summary of Low and Moderate Strength of Evidence Findings by Intervention Category^{§*}

care, a greater increase in the use of ED visits among intervention group patients compared with comparison group patients would be unfovorable, while an increase in primary care visits would be favorable \ddagger Four samples²⁻⁵⁴ reported the total sample size but not the sample size specific to their HNHC patient populations; the total sample size for the Federally Qualified Health Center Advanced Primary Care Practice (FQHC APCP)⁵² verse)^{53, 1730,958} for Comprehensive Primary Care (CPC)^{53, 5}, 5,163,969 for Comprehensive Primary Care Plus (CPC+)⁵⁴ Track 1 practices sample, and 4,804,265 for CPC+⁵⁴ Track 2 practices sample. The sample size was 42,132 for the Independence at Home (IAH) study ⁵⁶ Group remary care versitive conditions; alCU ambulatory intensive caring unit; ED emergency department; HNHC high-cost; N number; NR not reported; MA meta-analytic; OBS Findings were determined to be favorable or unfavorable based on the intervention and the outcome. For example, in studies that intended to reduce ED visits and shift service use to primary

observational study(ies); RCT randomized controlled trial(s)

HNHC patients in real time and uses multidisciplinary relationship-based care management to address medical and psychosocial concerns. This model was evaluated in three studies, one RCT²⁴ and 2 observational study replications (one^{46,49} among Medicare patients and another⁴⁴ among most-ly Medicaid-eligible patients). Another RCT²⁶ provided nurse-led care management to disabled, Medicaid patients with behavioral health problems. A third RCT⁴¹ examined a housing intervention with case management and other supportive services for chronically homeless adults. One observational study⁴³ evaluated social worker-led, post-hospital discharge care transitions tailored to patients' care coordination needs.

Evidence from three samples found no difference in mortality (low SoE). All cost and use outcomes were graded as insufficient.

Telephonic/Mail Interventions. Five RCTs^{27,33–36} (8 samples) and 1 observational study⁴⁸ evaluated interventions where most services were provided remotely by telephone, mail, or a device. Four of the RCTs^{33–36} examined Medicare CMHCB interventions. One³⁴ provided multidisciplinary care management telephonically or in writing and one³⁵ (2 samples) provided home monitoring devices to support health monitoring and communication with nurse care managers. Two other studies were HMO-based. One RCT²⁷ mailed personalized health promotion materials to high-use members with arthritis, hypertension, or diabetes. An observational study⁴⁸ telephonically provided social needs screening and navigation to members predicted to be high users. All outcomes received an SoE grade of insufficient evidence.

Two of the CMHCB RCTs^{33,36} (4 samples) tested disease and care management delivered telephonically to chronic kidney disease patients. This evidence was graded separately because, unlike other studies in the review, it focuses on patients with one condition. The evidence is summarized in Appendix 7.

System-Level Transformation Interventions. Four large, observational studies^{52–57} (5 samples), testing care delivery and payment innovations to lower cost and improve quality of care across *all* Medicare patients at a practice, separately measured outcomes for HNHC patient subgroups. Comprehensive Primary Care (CPC)⁵³ and CPC Plus (2 samples)^{54,55} aimed to reform care delivery in primary care practices using care management fees to support improvements, while the Federally Qualified Health Center Advanced Primary Care Practice (FQHC APCP) initiative⁵² aimed to help FQHCs transform into APCPs through PCMH recognition. The IAH study^{56,57} (one sample discussed in the "Home-Based Care Interventions" section) assessed, in a separate sample, the effect of providing global incentive payments to home-based primary care practices.

The pooled estimate of changes in annual costs, using data from all 5 samples, showed no difference between treatment

and control HNHC patients (-\$13 [95% CI, -132 to 106] (Fig. 2)) (low SoE for no difference).

DISCUSSION

In this review, we sought to inform policy and clinical practice by identifying intervention categories that have been effective in reducing HNHC patients' preventable healthcare use or modifying high-cost to lower-cost services, while maintaining or improving clinical outcomes. To our knowledge, this is the most comprehensive and rigorous systematic review of the effectiveness of interventions for HNHC patients across multiple US healthcare settings. Because we identified a diverse group of interventions, we sorted samples into 7 categories. As a result, some intervention categories were limited to a small number of samples, especially home-based and aICU-based care.

Despite considerable interest and investment in improving care and reducing costs for HNHC patients, studies demonstrated limited effectiveness. Most outcomes across intervention categories were graded as insufficient because of limited evidence or inconsistent results across samples. Future research providing additional data on the effectiveness of interventions for HNHC patients is essential.

Our review found limited evidence that some HNHC intervention categories reduce costs and use of high-cost services. ED- and primary care-based interventions were associated with reductions in cost. ED-, primary care-, and home-based interventions were associated with reductions in hospitalizations. ED-based interventions were also associated with reductions in ED use. Samples reported few intermediate or clinical, functional, and social risk factor outcomes. Home-based care and community-based interventions were associated with no difference in mortality. Evidence was too limited to assess any social risk factor outcomes.

ED-based interventions identified HNHC patients based on high ED use and changed their ED services through care/case management. Similarly, a previous systematic review found ED-based case management interventions were effective for reducing frequent ED use among high-risk, US. patients.¹⁰ We also found that ED-based interventions were successful at reducing hospitalizations and increasing primary care visits. While increases in primary care use suggest that these interventions may change where patients receive care, future studies directly measuring the pathway of individual patient replacement of higher cost ED care with lower cost primary care is needed.

Primary care-based interventions used multidisciplinary care teams to support and coordinate care. Otherwise, these interventions were heterogenous in their approach and team composition. Consistent with a prior review,⁷⁰ we found these interventions to be associated with reductions in hospitalizations. Our further finding of overall reductions in costs suggests that reductions in hospitalizations outweighed increases

Study	HNHC sample size			ence Cl
Primary Care-based Interventions: RCT				
CMHCB with comprehensive case management (Original sample) ³⁸	5374		-3456 [-5387,	-1525]
CMHCB with comprehensive case management (Refresh sample) ³⁸	1569		-4260 [-7967,	-553]
CHW-led complex care management (full sample) ⁴⁰	253		-7732 [-14914,	-550]
Heterogeneity: 1 ² = 29%		-	-4119 [-7935,	-302]
System-level Transformation Interventions: OBS				
FQHC APCP (high ED use sample) ⁵²	NR	-	387 [-582,	1357]
IAH (incentive payment sample) ^{56,57}	42132		-200 [-496,	96]
CPC (HNHC sample) ⁵³	NR	+	-45 [-118,	28]
CPC+ (Track 1 practices HNHC sample) ^{54,55}	NR	+	6[-31,	44]
CPC+ (Track 2 practices HNHC sample) ^{54,55}	NR	+	43 [3,	83]
Heterogeneity: $I^2 = 91\%$			-13 [-132,	106]
Telephonic/Mail Interventions: RCT				
CMHCB with multidisciplinary care management (Original HNHC sample) ³⁴	3955		1440 [-903,	3783]
CMHCB with home monitoring device (Original HNHC sample) ³⁵	125		-3420 [-10307,	3467]
CMHCB with home monitoring device $(Refresh HNHC sample)^{35}$	227		— 4620 [- 3798,	13038]
Heterogeneity: $I^2 = 46\%$			837 [-7428,	9101]
	Favors In	tervention Group Favors Co	omparison Group	
	-20000	0 -10000 0 100	000	
Random-effects Sidik- Jonkman model				

Random-effects Sidik-Jonkman model Knapp-Hartung standard errors

Figure 2 Forest plot of annual total costs for primary care-based, telephonic/mail, and system-level transformation interventions for HNHC patients. The size of the squares reflects the study's relative weight and horizontal lines represent 95% CIs of the estimates. Diamonds represent the pooled mean with the points of the diamonds representing 95% CIs. Studies with multiple listed entries included multiple, non-overlapping samples. Four system-level transformation samples^{52–54} reported the total sample size but not the sample size specific to their HNHC patient population; the total sample size for the FQHC APCP⁵² was 730,353; 1,730,958 for CPC⁵³; 5,163,969 for CPC⁴⁵⁴ Track 1 practices sample, and 4,804,265 for CPC⁴⁵⁴ Track 2 practices sample. Abbreviations: CHW, community health worker; CI, confidence intervals; CMHCB, Medicare Care Management for High Cost Beneficiaries Demonstration; CPC, Comprehensive Primary Care initiative; CPC+, Comprehensive Primary Care Plus initiative; ED, emergency department; FQHC APCP, Federally Qualified Health Center Advanced Primary Care Practice; HNHC, high-need, high-cost; IAH, Independence at Home; NR, not reported; OBS, observational study; RCT, randomized controlled trial.

in other care. Further investigations of how care was modified and its effect on health outcomes are needed.

Home-based care was the only category with evidence to assess changes in ACSC hospitalizations, a direct measure of preventable utilization. These interventions resulted in reductions in ACSC hospitalizations among infirm patients with prior hospitalizations whose conditions could be managed in ambulatory settings.⁶⁹ However, the evidence was insufficient to determine if at-home care also reduced total costs.

Changes in receipt of influenza vaccinations were found to be favorable in home-based care but unfavorable in primary care-based interventions. Study authors of the primary care evaluation explained the unexpected finding as due to a higher baseline rate in intervention patients that limited the intervention's ability to show improvement.³⁸

Community-based interventions largely delivered services outside the healthcare system. Besides supporting improved self-care and access to medical and mental health services, these interventions assumed the additional challenge of addressing HNHC participants' social risk factors by helping them navigate access to community resources and social services. Interventions included the Camden model that identified HNHC patients in real time and provided them with intensive, relationship-based assistance.^{24,44,46,49} Communitybased interventions were associated with no difference in mortality and findings related to healthcare use and costs were inconclusive. However, this body of complex interventions generally lacked reporting on intermediate outcomes, like changes in access to social services. Therefore, we cannot know if these ambitious interventions were on a path to eventual success that needed more time to be realized.

System-level transformation interventions that sought to change practice-wide care delivery did not decrease costs among HNHC subgroups. These interventions may have been too distal or limited in intensity to effectively change HNHC patient behaviors. The lack of success in these larger-scope interventions reflects the challenges that stakeholders are likely to continue to face in implementing alternative payment models if required savings goals are contingent on changing HNHC patients' healthcare services use.

Finally, the evidence was insufficient to reach a conclusion across all outcomes assessed for telephonic/mail and aICU- based interventions. Telephonic care management was shown previously to be unsuccessful among elderly patients with chronic diseases.⁷¹ Future studies assessing telemedicine may test whether adding video can facilitate HNHC patient-provider relationships to improve outcomes. While some authors propose using specialized clinics like aICU-based interventions for HNHC patients to provide individualized attention using multidisciplinary teams and high patient-staff ratios,^{72,73} the limited number of samples and insufficient evidence to reach conclusions suggest that additional studies are needed to determine if aICU interventions can improve care.

Our review highlights the dual need for evaluations to report a standard and larger set of outcomes. Few comparable outcomes were reported by multiple samples within an intervention category. Notably, health and social risk factor outcomes were rarely measured, despite the goal of many interventions of addressing these needs. While healthcare use and cost are key outcomes for healthcare systems, these measures do not necessarily reflect changes in patients' experience in managing their health. Similarly, many interventions acknowledge that social risk factors can impact access to healthcare services and health; measuring changes in these outcomes may provide insights into their role in mediating clinical outcomes. Future research evaluating these outcomes may help us understand what interventions are accomplishing and why many have not achieved their ultimate healthcare use and cost goals.

Strengths and Limitations

This systematic review was strengthened by its ability to identify relevant studies through the inclusion of gray literature evaluations of federally funded interventions and a broad definition of HNHC patients. This review focused on the most rigorous evidence by only including samples with comparison groups. Many samples had large, representative sample sizes which increase the generalizability of findings for the US healthcare system. We also included a range of interventions, settings, and patients with various chronic conditions.

Our review has several limitations. First, findings were limited by both the small numbers and inconsistent reporting of outcomes across samples. Second, no standard definition of HNHC patients exists and samples varied considerably in their eligibility criteria. Thus, we cannot be sure if differences in success across samples were related to differences in sample populations. Third, system-level samples included in the metaanalysis measuring total cost had high heterogeneity (i.e., $I^2 \ge 75\%$) and may reflect the variability and complexity among these interventions. Fourth, we grouped samples based on the intervention's predominant service location/modality. SoE conclusions may be sensitive to these classifications. An alternative approach would be to group samples based on their key components (e.g., care management).³ However, interventions were complex and multi-faceted; study descriptions were often broad overviews of their multiple and overlapping components. We concluded that categorizing samples would be the most useful for stakeholders considering implementing interventions in particular settings.

Finally, an unachieved goal of the review was to distinguish changes in care that was potentially preventable or modifiable. Because of the focus on populations with high needs as well as high costs, some reductions in high-cost care will likely need to be replaced by ambulatory care. However, no studies defined or tracked changes in an individual patient's preventable or modifiable care separately from unavoidable care. Also, no studies directly evaluated the success of interventions, shifting needed care from high-cost to lower-cost settings or reducing need through better management of chronic conditions.

Conclusions

We found limited evidence of effectiveness in relation to use and cost, particularly among ED- and primary care–based interventions. Intervention studies provided little information for determining why individual programs work, for whom, and within what contexts. Intermediate process outcomes and patient-centered experience outcomes may provide upstream results that can help explain and improve the likelihood of positive clinical and more distal policy outcomes.

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Data Availability The datasets generated during and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations:

Conflicts of Interest: The authors declare that they do not have a conflict of interest.

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