



# Effective Health Care Program

## Transitional Care Interventions To Prevent Readmissions for People With Heart Failure

### Executive Summary

#### Background

Heart failure (HF) is a major public health problem and a leading cause of hospitalization and health care costs in the United States. It is the most common principal discharge diagnosis among Medicare beneficiaries and the third highest for hospital reimbursements, according to 2005 data from the Centers for Medicare & Medicaid Services (CMS).<sup>1</sup> Up to 25 percent of patients hospitalized with HF are readmitted within 30 days.<sup>2-5</sup>

In an effort to reduce the frequency of rehospitalization of Medicare patients, in October 2012 CMS began lowering reimbursements to hospitals with excessive risk-standardized readmission rates as part of the Hospital Readmissions Reduction Program authorized by the Affordable Care Act.<sup>6</sup> This policy provides incentives for hospitals to develop effective transition programs to reduce readmission rates for people with HF.

In 2010, nearly 7 million Americans 18 years of age and older had an HF diagnosis; by 2030, an additional 3 million Americans will have the condition.<sup>7,8</sup> The incidence of HF increases with age; it affects 1 of every 100 people 65 years of age and older.<sup>9</sup> Coronary disease and

#### Effective Health Care Program

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

The full report and this summary are available at [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).



uncontrolled hypertension are the two highest population-attributable risks for HF.<sup>10</sup> Survival after HF diagnosis has improved over time, as shown by data from the Framingham Heart Study.<sup>11,12</sup> However, the death rate remains high: 50 percent of people diagnosed with HF die within 5 years after diagnosis.<sup>11,12</sup> Among Medicare beneficiaries, more than 30 percent of patients with HF die within 1 year after hospitalization.<sup>13</sup> National data show no evidence that readmission rates for HF patients have fallen during the past two decades, despite the observation that HF hospitalizations in the United States have declined by almost 30 percent during the past decade. Readmission rates vary by both geographic location and insurance coverage.<sup>14,15</sup>

In 2007, the Medicare Payment Advisory Commission called for hospital-specific public reporting of readmission rates, identifying HF as a priority condition. The Commission stated that readmissions for HF were common, costly, and often preventable.<sup>16</sup> An estimated 12.5 percent of readmissions for HF were potentially preventable.<sup>17</sup>

Readmissions following an index hospitalization for HF are related to various conditions. An analysis of Medicare claims data for 2007–09 reported that 35.2 percent of readmissions within 30 days were for HF; the remainder of readmissions were for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia or shock).<sup>5</sup>

The relationship between readmission rates and other important outcomes (e.g., mortality, emergency room [ER] visits) is unclear. Some data suggest that hospitals with the lowest mortality rates among patients with HF tend to have higher readmission rates.<sup>18</sup> Some predict that interventions aimed at reducing readmissions may increase use of other health care services, such as ER observational visits.<sup>19</sup>

### **Transitional Care Interventions for People With Heart Failure**

Interventions designed to prevent readmission among patients with HF are often referred to as “transitional care interventions.”<sup>20,21</sup> Naylor and colleagues defined transitional care as “a broad range of time-limited services designed to ensure health care continuity, avoid preventable poor outcomes among at-risk populations, and promote the safe and timely transfer of patients from one level of care to another or from one type of setting to another” (p. 747).<sup>20</sup> Transitional care interventions overlap other forms of care (primary care, care coordination,

discharge planning, disease management, and case management); however, they aim specifically to avoid poor clinical outcomes arising from uncoordinated care.<sup>22</sup>

No clear set of intervention components defines transitional care interventions. They tend to focus on the following: patient or caregiver education (including education on self-care—e.g., self-titrating diuretics), medication reconciliation, coordination with outpatient providers, arrangements for future care (e.g., home health, outpatient followup), and symptom monitoring or reinforcement of education during the transition (e.g., home visits, telephone support, or additional outpatient visits).

No clear consensus exists about when the transition period ends. Although evaluating 30-day readmissions is important for certain stakeholders (hospitals, payers, quality improvement organizations, health care providers), outcomes beyond this period are clinically important and may benefit from overall improvements in care. Outcomes far away from the index hospitalization probably reflect the natural history of HF or an unrelated illness, whereas a higher proportion of earlier readmissions are thought to be preventable.

### **Existing Guidance**

The 2013 American Heart Association/American College of Cardiology (AHA/ACC) Heart Failure guidelines addressed postdischarge HF interventions.<sup>23</sup> These guidelines focus on the importance of optimizing HF pharmacotherapy before discharge, providing HF education before discharge (including education on self-care), and addressing barriers to care. Specifically, the following components were noted as reasonable postdischarge care options: a followup visit within 7 to 14 days of discharge, a telephone followup within 3 days of discharge, or both.<sup>24</sup> The AHA/ACC guidelines also recommend initiating multidisciplinary (MDS)-HF disease management programs for patients at high risk for readmission. The 2010 Heart Failure Society of America guidelines are similar; their guidance emphasizes particular components of discharge planning.<sup>25,26</sup> No specific guidance is given on the optimal components of transitional care interventions aimed at preventing readmissions for patients with HF.

Several national performance measures pertain to the standard of care for hospital discharge of HF patients. The Joint Commission performance measures mandate that all patients with HF receive comprehensive written discharge instructions or other educational materials

that address activity level, diet, discharge medications, followup appointment, weight monitoring, and planned actions to take should symptoms worsen.<sup>27</sup> These measures are publicly reported by hospitals. In 2011, the ACC/AHA/AMA (American Medical Association) Performance Consortium added a documented postdischarge appointment to the list of recommended HF performance measures.<sup>28</sup> Required documentation includes location, date, and time for a followup office visit or home health care visit.

## Scope and Key Questions

An assessment of the efficacy, comparative effectiveness, and harms of transitional care interventions is needed to support evidence-based policy and clinical decisionmaking. Despite advances in the quality of acute and chronic HF disease management, gaps remain in knowledge about effective interventions to support the transition of care for patients with HF. To address these issues, we conducted a systematic review and meta-analysis of investigations of transitional care interventions for adults with HF.

Our report focuses mainly on transitional care interventions that aim to reduce 30-day readmission and mortality rates for patients hospitalized with HF. We also include readmissions measured over 3 to 6 months because these are common, costly, and potentially preventable. We examine several related issues, including other health care use (e.g., ER visits), quality of life, and potential harms such as increased caregiver burden. We include these outcomes because they may provide information on the unintended consequences of interventions aimed at preventing readmissions. Specifically, we address the following five Key Questions (KQs):

KQ 1: Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health care utilization rates?

- a. Readmission rates
- b. Emergency room visits
- c. Acute care visits
- d. Hospital days (of subsequent readmissions)

KQ 2: Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health and social outcomes?

- a. Mortality rate
- b. Functional status
- c. Quality of life
- d. Caregiver burden
- e. Self-care burden

KQ 3: This question has three parts:

- a. What are the components of effective interventions?
- b. Among effective interventions, are particular components necessary?
- c. Among multicomponent interventions, do particular components add benefit?

KQ 4: This question has three parts:

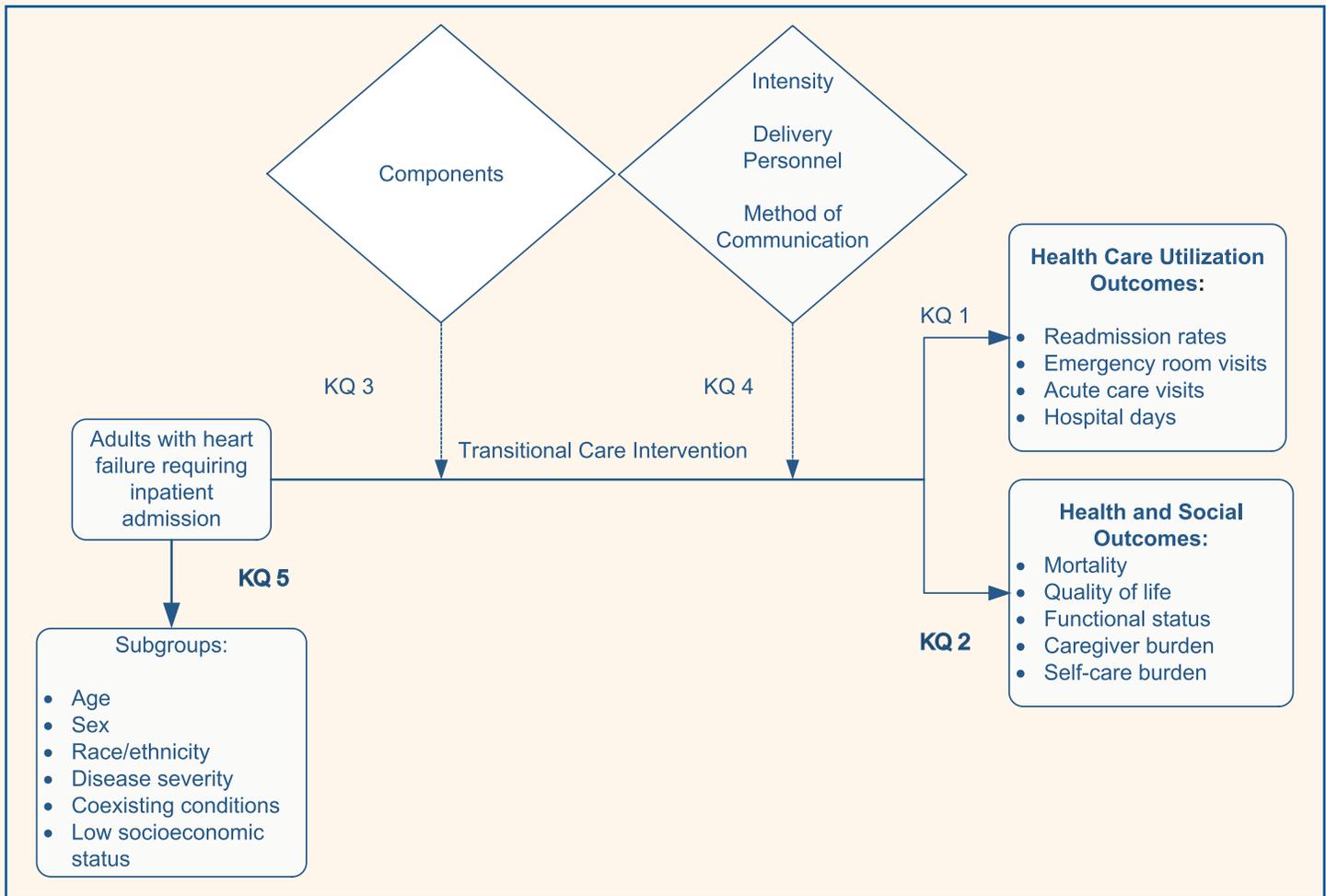
- a. Does the effectiveness of interventions differ based on intensity (e.g., duration, frequency, or periodicity) of the interventions?
- b. Does the effectiveness of interventions differ based on delivery personnel (e.g., nurse, pharmacist)?
- c. Does the effectiveness of interventions differ based on method of communication (e.g., face-to-face, telephone, Internet)?

KQ 5: Do transitional care interventions differ in effectiveness or harms for subgroups of patients based on age, sex, race, ethnicity, disease severity (left ventricular ejection fraction or New York Heart Association classification), coexisting conditions, or socioeconomic status?

## Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure A).

**Figure A. Analytic framework for transitional care interventions to prevent readmissions in people with heart failure**



KQ = Key Question.

## Methods

### Literature Search Strategy

We searched MEDLINE®, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL)® for English-language and human-only studies published from July 1, 2007, to May 9, 2013, and used a previous Agency for Healthcare Research and Quality (AHRQ) Technology Assessment on a similar topic to identify randomized controlled trials (RCTs) published before July 1, 2007.<sup>29</sup> We also searched the same electronic databases for relevant nonrandomized trials or prospective cohort studies from 1990 to May 5, 2013, that measured caregiver or self-care burden. We updated the database searches through October 29, 2013, while the report was

undergoing peer review. An experienced Evidence-based Practice Center (EPC) librarian conducted the searches and another EPC librarian peer-reviewed them.

We also manually searched reference lists of pertinent reviews, included trials, and background articles on this topic to look for any relevant citations that our searches might have missed. We searched for unpublished studies relevant to this review using ClinicalTrials.gov and the World Health Organization’s International Clinical Trials Registry Platform. We updated these searches through February 5, 2014.

### Eligibility Criteria

We developed inclusion and exclusion criteria with respect to populations, interventions, comparators, outcomes,

timing, and setting (PICOTS) and study designs. Briefly, we included studies of adults with HF requiring inpatient admission that recruited subjects during or immediately following (i.e., within 1 week) the index hospitalization. We ultimately included one trial (after verification with trial investigators) that enrolled most participants during an inpatient admission but allowed enrollment up to 2 weeks following an inpatient admission.<sup>30</sup>

We required studies to compare a transitional care intervention aimed at reducing readmissions with another transitional care intervention or with usual care (i.e., routine care or standard care, as defined by the primary studies). We required that transitional care interventions include one or more of the following components: education to patient, caregiver, or both delivered pre-discharge, post-discharge, or both; discharge planning; appointment scheduling before discharge; increased planned or scheduled outpatient clinic visits (primary care, MDS-HF); home visits; telemonitoring (including remote clinical visits); telephone support; transition coach or case management; or interventions to increase provider continuity.

This review focuses on the primary outcomes of readmission rates and mortality. Specifically, we included the following primary outcomes: all-cause readmission, HF-specific readmission, composite all-cause readmission or death, and all-cause mortality. We also evaluated the following outcomes when studies assessing readmission rates or mortality reported them: ER visits, acute care visits, hospital days (of subsequent readmissions), quality of life, functional status, and caregiver or self-care burden. We required a length of followup of at least 30 days, and we included outcomes occurring no more than 6 months from the index hospitalization. We included only studies that assessed interventions applicable to patients who were discharged to home (and not another health care facility).

RCTs were eligible for all KQs. For caregiver burden and self-care burden outcomes, nonrandomized controlled trials or prospective cohort studies with an eligible comparison group were also eligible.

## Study Selection

Two members of the research team independently reviewed each title and abstract (identified through searches) to determine eligibility. Studies marked for possible inclusion by either reviewer and those that lacked adequate information to determine eligibility underwent a full-text review. Two members of the team independently reviewed each full-text article to determine eligibility. If the

reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a senior member of the team.

## Data Extraction

We designed and used structured data extraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions, comparators, study designs, methods, and results. One investigator extracted the relevant data from each included article; a second member of the team reviewed all data abstractions for completeness and accuracy.

## Risk-of-Bias Assessment of Individual Studies

To assess the risk of bias (internal validity) of studies, we used predefined criteria based on the AHRQ “Methods Guide for Effectiveness and Comparative Effectiveness Reviews” (Methods Guide).<sup>31</sup> We assessed selection bias, confounding, performance bias, detection bias, and attrition bias. We included questions about adequacy of randomization, allocation concealment, similarity of groups at baseline, masking, attrition, use of intention-to-treat (ITT) analysis, methods of handling missing data, reliability and validity of outcome measures, and treatment fidelity. When assessing measurement bias related to readmission ascertainment, we considered whether studies had access to all potential readmission data as opposed to readmissions collected only from a single institution’s database. We rated the studies as low, medium, high, or unclear risk of bias.<sup>31</sup> Two independent reviewers assessed the risk of bias for each study. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team.

## Categorization of Interventions

We grouped studies of similar interventions for our evidence synthesis. We categorized intervention types based primarily on the mode and environment of delivery (Table A). We believed that this method of categorization would best address the needs of multiple stakeholders who may be interested in interventions that could be implemented in specific health care settings. One investigator categorized the intervention, and a second team member reviewed the categorization. Disagreements were resolved by consensus. Most of the studies included components delivered both during hospitalization and after discharge.

**Table A. Categories and definitions of transitional care interventions**

Category	Definition
<b>Home-visiting programs</b>	Home visits by clinicians, such as nurses or pharmacists, who deliver education, reinforce self-care instructions, perform physical examinations, or provide other care (e.g., physical therapy, medication reconciliation). These interventions are often referred to as nurse case-management interventions, but they also can include home visits by a pharmacist or multidisciplinary team.
<b>Structured telephone support</b>	Monitoring, education, and/or self-care management (or various combinations) using simple telephone technology after discharge in a structured format (e.g., series of scheduled calls with a specific goal, structured questioning, or use of decision support software).
<b>Telemonitoring</b>	Remote monitoring of physiological data (e.g., electrocardiogram, blood pressure, weight, pulse oximetry, respiratory rate) with digital, broadband, satellite, wireless, or Bluetooth transmission to a monitoring center, with or without remote clinical visits (e.g., video monitoring).
<b>Outpatient clinic-based interventions</b>	Services provided in one of several different types of outpatient clinics—multidisciplinary-HF, nurse-led HF, or primary care clinic. The clinic-based intervention can be managed by a nurse or other provider and may also offer unstructured telephone support (e.g., patient hotline) outside clinic hours.
<b>Primarily educational interventions</b>	Patient education (and self-care training) delivered before discharge or upon discharge by various delivery personnel or modes of delivery: in person, interactive CD-ROM, video education. Interventions in this category do not feature telemonitoring, home visiting, or structured telephone support. They are not delivered primarily through a clinic-based intervention (described above). Followup telephone calls may occur to ascertain outcomes (e.g., readmission rates) but not to monitor patients' physiological data.
<b>Other</b>	Unique interventions or interventions that did not fit into any of the other categories (e.g., individual peer support for HF patients).

CD-ROM = compact disc read-only memory; HF = heart failure.

## Data Synthesis

We conducted meta-analyses using random-effects models to estimate pooled effects. For binary outcomes, we calculated relative risks (RRs) and 95% confidence intervals (CIs). For continuous outcomes (e.g., scales of quality of life or functional status) measured with the same scale, we report the weighted mean difference between intervention and control subjects. When we combined multiple scales in one meta-analysis, we used the standardized mean difference, Cohen's *d*. A Cohen's *d* of zero means that the intervention and control groups have equivalent effects; a small effect size is 0.20, medium effect size is 0.50, and large effect size is 0.80.<sup>32</sup> For readmission rates, we conducted meta-analyses of studies that reported the number of people readmitted in each group (and not the total number of readmissions per group). We stratified analyses for each intervention category by timing; specifically, we separated rates reported at 30 days from those beyond 30 days, including combining rates reported over 3 to 6 months. We did not include studies rated as high or unclear risk of bias in our main analyses, but we included them in sensitivity analyses for KQ 1 and KQ 2. We calculated the chi-squared statistic and the I<sup>2</sup> statistic (the proportion of variation in study estimates attributable to heterogeneity) to assess statistical

heterogeneity in effects between studies.<sup>33,34</sup> When quantitative synthesis was not appropriate (e.g., because of clinical heterogeneity, insufficient numbers of similar studies, or insufficiency or variation in outcome reporting), we synthesized the data qualitatively.

In addition, we calculated the number needed to treat (NNT) for readmission and mortality outcomes. We derived the NNTs from the RRs and the median usual care event rates reported in included trials, using the methods described in the Cochrane Handbook.<sup>35</sup>

The aim of KQ 3 was to describe the components of effective interventions; KQ 3 is intended as a descriptive question to provide information about the interventions that work to providers, health systems, and others who may want to implement transitional care interventions. For KQ 3, we synthesized the evidence qualitatively by first extracting detailed information on intervention components, content, and processes and then describing common components and combinations of components that were effective in reducing all-cause readmissions or mortality. KQ 3 asks primarily: "What are the components of effective interventions?" and "Are particular components necessary?" We considered "necessary" to mean that a particular component (e.g., inpatient

education) was included in every effective intervention but was not necessarily sufficient (i.e., the component could be included in some interventions that were not efficacious). We defined effective interventions as: (1) intervention categories (defined in Table A, above) that reduced all-cause readmissions (from our meta-analyses for KQ 1) or the composite endpoint; (2) intervention categories that reduced mortality in our meta-analyses; (3) individual trials in other categories that were efficacious for reducing all-cause readmissions, mortality, or the composite endpoint.

For KQ 4, we assessed whether the efficacy of interventions differed based on intensity, delivery personnel, and method of communication both across intervention categories and within categories of interventions. We conducted meta-analyses stratified by intensity, delivery personnel, and method of communication within each intervention category when appropriate (e.g., when these factors varied).

Given the heterogeneity of included interventions, we were unable to develop a single measure of intensity to apply to all interventions. We categorized the intensity of each intervention as low, medium, or high using the duration, frequency, and periodicity of patient contact. We also considered resource use as a dimension of intensity, such as the total number of intervention components. We reserved the low-intensity category for interventions that included one episode of patient contact or that required few resources (e.g., no additional components, such as time spent coordinating care).

We considered the majority of interventions to be medium or high intensity; most were multicomponent and included repeated patient contacts. For KQ 4, we included only studies rated as low or medium risk of bias.

### **Strength of the Body of Evidence**

We graded the strength of evidence (SOE) to answer KQs using the guidance established for the EPC program.<sup>36</sup> We graded the SOE for the following outcomes: all-cause readmissions, HF-specific readmissions, a composite endpoint (all-cause readmission or mortality), mortality, ER visits, length of hospital stay (for all-cause readmissions), quality of life, and functional status.

Developed to grade the overall strength of a body of evidence, the approach incorporates four key domains: risk of bias (including study design and aggregate quality), consistency, directness, and precision of the evidence.<sup>36</sup> It also considers optional domains. Two reviewers assessed each domain for each key outcome and determined an overall SOE grade based on domain ratings. In the event

of disagreements on the domain rating or overall grade, we resolved differences by discussion or by consulting a third investigator.

SOE grades are specified as high, moderate, low, or insufficient to convey the confidence we have that the effect estimates reported lie close to the true effect of an intervention. “Insufficient” indicates that evidence is unavailable, does not permit estimation of an effect, or does not permit us to draw a conclusion with at least a low level of confidence.

### **Applicability**

We assessed applicability of the evidence following guidance from the Methods Guide.<sup>37</sup> We used the PICOTS framework to explore factors that affect applicability.

### **Results**

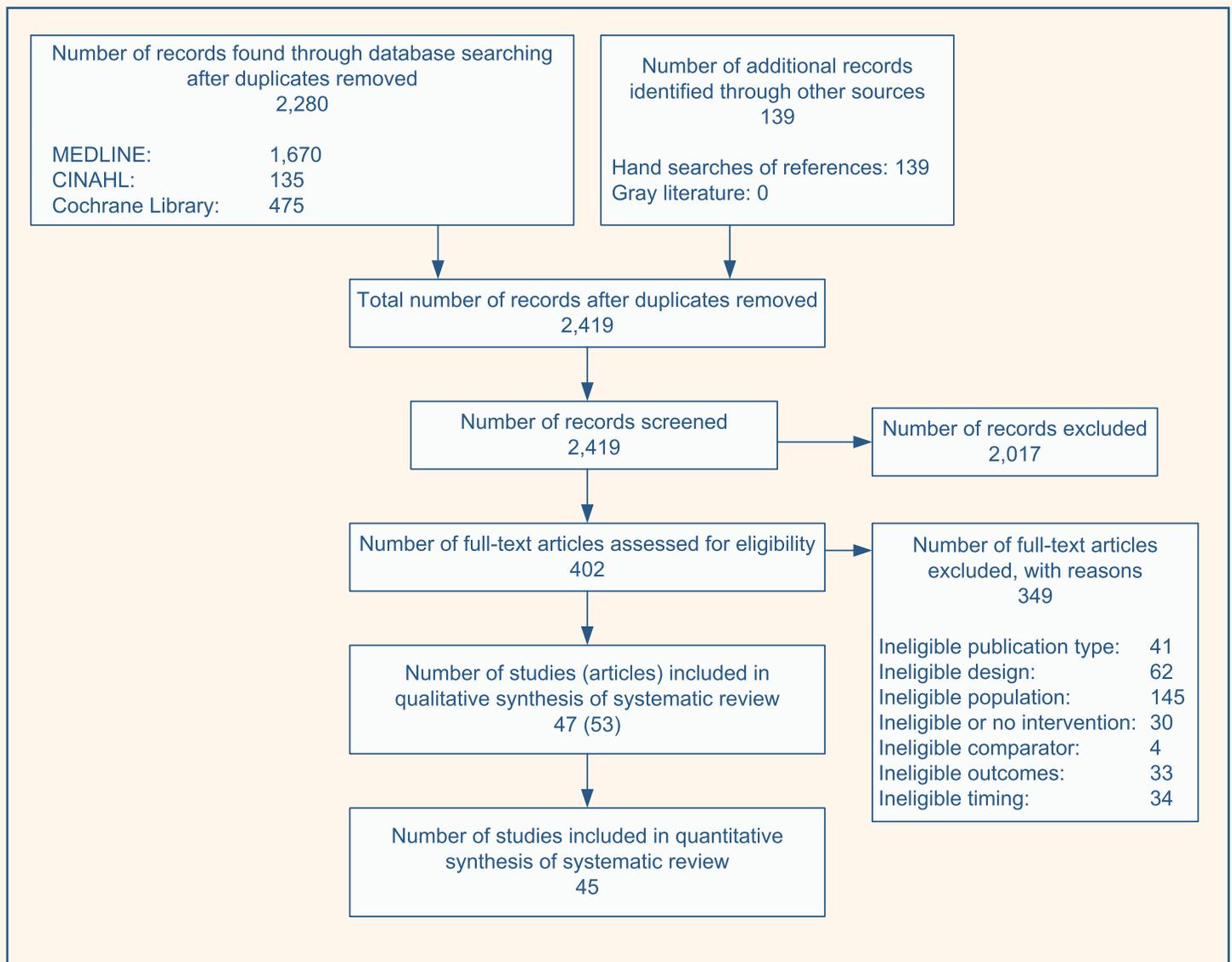
We included 53 published articles reporting on 47 studies; all were RCTs (Figure B).

We grouped trials of similar interventions based primarily on the mode and environment of delivery (Table A): home-visiting programs (15 RCTs), structured telephone support (STS) (13 trials), telemonitoring (8 trials), outpatient clinic-based interventions (7 trials), and primarily educational interventions (4 trials). We also included two unique interventions in an “other” category; one featured “individual peer support” and one emphasized cognitive training for patients with coexisting mild cognitive impairment.

Most trials compared a transitional care intervention with usual care; only two trials (both rated high risk of bias) directly compared more than one transitional care intervention. Usual care was somewhat heterogeneous across trials and often not well described.

In general, trials included adults with moderate to severe HF. The mean age of subjects was generally in the 70s; very few trials enrolled patients who were, on average, younger or older. Across most included trials, the majority of patients were prescribed an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) (when information was reported). However, the percentages of patients across trials who were prescribed beta-blockers at discharge varied widely. Included trials were conducted in a mix of settings, including academic medical centers, Department of Veterans Affairs (VA) hospital settings, and community hospitals.

**Figure B. Disposition of articles about transitional care interventions for patients hospitalized for heart failure**



## Efficacy for Reducing Readmissions and Mortality

Table B summarizes our key findings by intervention category, main outcomes (readmission rates, mortality rate, or the composite of all-cause readmissions or death), and timing of measurement of outcomes (30 days, 3–6 months). It documents our results when data met the following three criteria: (1) sufficient evidence to grade the SOE and to draw a conclusion that evidence either

supports benefit (+) or does not (-); (2) insufficient (I) evidence to make a determination (e.g., only one trial reporting an outcome of interest); or (3) no included trials that reported an outcome (NR).

Table C presents more detailed results, including RRs and 95% CIs as well as NNTs (when applicable) for comparisons that included at least one trial reporting an outcome of interest.

**Table B. Summary of key findings and strength of evidence, by outcome and intervention category**

Intervention Category	All-Cause Readmissions		HF Readmissions		Composite Endpoint		Mortality	
	30 Days	3 to 6 Months	30 Days	3 to 6 Months	30 Days	3 to 6 Months	30 Days	3 to 6 Months
Home-visiting programs	+ low <sup>a</sup>	+ high	NR	+ mod	+ low	+ mod	I	+ mod
Structured telephone support	I	- mod	I	+ high	NR	- low	NR	+ mod
Telemonitoring	I	- mod	NR	- mod	NR	NR	NR	- low
MDS-HF clinic interventions	NR	+ high	NR	I	NR	- mod	NR	+ mod
Nurse-led clinic interventions	NR	- low	NR	I	NR	I	NR	- low
Primary care clinic interventions	NR	I	NR	NR	NR	NR	NR	I
Primarily educational interventions	NR	I	NR	I	NR	- low	NR	- low
Other interventions	I	NR	NR	NR	NR	NR	I	NR

<sup>a</sup>Two home-visiting programs reported all-cause readmission at 30 days. The intervention studied by Naylor and colleagues<sup>38</sup> was of higher intensity and showed efficacy. The lower intensity intervention studied by Jaarsma and colleagues<sup>39</sup> did not show efficacy at 30 days (low SOE). The “+” here refers to high intensity home-visiting programs.

**Note:** Low, mod, high, and I represent our strength-of-evidence grades: mod = moderate, I = insufficient; + indicates that we found benefit (i.e., statistically significant reduction in readmission rate or mortality compared with usual care), - indicates that we found no benefit (i.e., no statistically significant reduction in the outcome). HF = heart failure; MDS = multidisciplinary; NR = not reported (no trials in this category reported an eligible outcome at this timepoint).

**Table C. Summary of key findings and strength of evidence for transitional care interventions: readmission rates and mortality**

<b>Intervention Category</b>	<b>Outcome</b>	<b>Outcome Timing</b>	<b>N Trials; N Subjects</b>	<b>Relative Risk (95% CI)<sup>a</sup></b>	<b>Numbers Needed To Treat</b>	<b>Strength of Evidence</b>
Home-visiting programs	All-cause readmission	30 days	2; 418	High intensity (1 study): 0.34 (0.19 to 0.62) Lower intensity (1 study): 0.89 (0.43 to 1.85)	6 for high intensity NA <sup>b</sup> for lower intensity programs	Low <sup>c</sup> for benefit
	All-cause readmission	3 to 6 months	9; 1,563	0.75 (0.68 to 0.86)	9	High for benefit
	HF-specific readmission	3 to 6 months	1; 282	0.51 (0.31 to 0.82)	7	Moderate <sup>d</sup> for benefit
	Composite endpoint <sup>e</sup>	30 days	1; 239	Hazard ratio (SE): 0.869 (0.033) vs. 0.737 (0.041)	NA	Low <sup>f</sup> for benefit
	Composite endpoint	3 to 6 months	4; 824	Hazard ratio (SE): 0.071 (0.045) vs. 0.558 (0.047) 0.78 (0.65 to 0.94)	10	Moderate <sup>g</sup> for benefit
	Mortality	30 days	1; 239	1.03 (0.15 to 7.16)	NA	Insufficient
	Mortality	3 to 6 months	8; 1,693	0.77 (0.60 to 0.997)	33	Moderate for benefit
Structured telephone support	All-cause readmission	30 days	1; 134	0.80 (0.38 to 1.65)	NA	Insufficient
	All-cause readmission	3 to 6 months	8; 2,166	0.92 (0.77 to 1.10)	NA	Moderate for no benefit
	HF-specific readmission	30 days	1; 134	0.63 (0.24 to 1.87)	NA	Insufficient
	HF-specific readmission	3 to 6 months	7; 1,790	0.74 (0.61 to 0.90)	14	High for benefit
	Composite endpoint	3 to 6 months	3; 977	0.81 (0.58 to 1.12)	NA	Low for no benefit
	Mortality	3 to 6 months	7; 2,011	0.74 (0.56 to 0.97)	27	Moderate for benefit
Telemonitoring	All-cause readmission	30 days	1; 168	1.02 (0.64 to 1.63)	NA	Insufficient
	All-cause readmission	3 to 6 months	3; 434	1.11 (0.87 to 1.42)	NA	Moderate <sup>h</sup> for no benefit
	HF-specific readmission	3 to 6 months	1; 182	1.70 (0.82 to 3.51)	NA	Moderate <sup>h</sup> for no benefit
	Mortality	3 to 6 months	3; 564	0.93 (0.25 to 3.48)	NA	Low for no benefit

**Table C. Summary of key findings and strength of evidence for transitional care interventions: readmission rates and mortality (continued)**

<b>Intervention Category</b>	<b>Outcome</b>	<b>Outcome Timing</b>	<b>N Trials; N Subjects</b>	<b>Relative Risk (95% CI)<sup>a</sup></b>	<b>Numbers Needed To Treat</b>	<b>Strength of Evidence</b>
MDS-HF clinic	All-cause readmission	3 to 6 months	2; 336	0.70 (0.55 to 0.89)	8	High for benefit
	HF-specific readmission	3 to 6 months	1; 106	0.70 (0.29 to 1.70)	NA	Insufficient
	Composite endpoint	3 to 6 months	2; 306	0.80 (0.43 to 1.01)	NA	Moderate for no benefit
	Mortality	3 to 6 months	3; 536	0.56 (0.34 to 0.92)	18	Moderate for benefit
Nurse-led clinic	All-cause readmission	3 to 6 months	2; 264	0.88 (0.57 to 1.37)	NA	Low for no benefit
	HF-specific readmission	3 to 6 months	1; 158	0.95 (0.68 to 1.32)	NA	Insufficient
	Composite endpoint	3 to 6 months	1; 106	0.66 (0.43 to 1.01)	NA	Insufficient
	Mortality	3 to 6 months	2; 264	0.59 (0.12 to 3.03)	NA	Low for no benefit
Primary care clinic intervention	All-cause readmission	3 to 6 months	1; 443	1.27 (1.05 to 1.54)	NA	Insufficient
	Mortality	3 to 6 months	1; 443	1.52 (0.88 to 2.63)	NA	Insufficient
Primarily educational interventions	All-cause readmission	3 to 6 months	1; 200	1.14 (0.84 to 1.54)	NA	Insufficient
	HF-specific readmission	3 to 6 months	1; 223	0.53 (0.31 to 0.90)	NA	Insufficient
	Composite endpoint	3 to 6 months	2; 423	0.92 (0.58 to 1.47)	NA	Low
	Mortality	3 to 6 months	2; 423	1.20 (0.52 to 2.76)	NA	Low
Other (cognitive training)	All-cause readmission	30 days	1; 125	1.15 (0.71 to 2.28)	NA	Insufficient
	Mortality	30 days	1; 125	0.07 (0.00 to 1.12)	NA	Insufficient

<sup>a</sup>Entries in this column are RRs from our meta-analyses or RR calculations unless otherwise specified. RRs less than 1 favor interventions over controls.

<sup>b</sup>NA entry for NNT indicates that the relative risk (95% CI) was not statistically significant, so we did not calculate an NNT. NA for hazard ratios indicates that we could not calculate an NNT with the data provided by the investigators

<sup>c</sup>Two home-visiting programs reported all-cause readmission at 30 days; the higher intensity intervention showed efficacy but the lower intensity intervention did not.

<sup>d</sup>Although only 1 trial reported total number of people readmitted per group, we considered the findings consistent because 1 other trial reported on the number of readmissions per group and found a similar effect.

<sup>e</sup>The composite endpoint comprises all-cause readmission or death.

<sup>f</sup> Although only a single trial reported the number of people alive and not readmitted at 30 days and 3 months, we considered the consistency of similar programs reducing 3-month readmission rates when grading the SOE for this intervention at 30 days.

<sup>g</sup> Although evidence was limited to 1 trial, consistency for the 30-day outcome was unknown, and evidence was imprecise, we upgraded the SOE because this intervention category demonstrated no effect on mortality at 3 or 6 months, thus increasing our confidence in the results of this single trial.

<sup>h</sup> Although only a single trial reported on the number of people readmitted, we considered this finding consistent given that 4 other telemonitoring trials reported the total number of readmissions per group (rather than the number of people readmitted); all-cause readmissions did not differ between people receiving telemonitoring and those receiving usual care at 30 days, 3 months, or 6 months.

CI = confidence level; MDS-HF = multidisciplinary heart failure; N = number; NA = not applicable; NNT = number needed to treat; RR = relative risk; SE = standard error; SOE = strength of evidence.

We found very little evidence on whether interventions reduce 30-day readmissions. Most trials reported rates over 3 to 6 months. A high-intensity home-visiting program reduced all-cause readmission and the composite endpoint (all-cause readmission or death) at 30 days (low SOE).<sup>38</sup> Despite having only a single trial of home visiting that reported rates at 30 days, we took into consideration, when grading the SOE, that similar interventions in this category consistently reduced readmission rates over 3 to 6 months. Evidence was insufficient to determine whether the following intervention types reduced 30-day all-cause readmissions (1 trial each, unknown consistency; none showed efficacy): STS, telemonitoring, and cognitive training. We found no eligible trials of other types of interventions that reported 30-day all-cause readmission rates.

For outcomes measured over 3 to 6 months, we found strong evidence of efficacy for improving at least one of our primary outcomes for home-visiting programs, STS, and MDS-HF clinic interventions. Specifically, we found that home-visiting programs and MDS-HF clinic interventions reduced all-cause readmission rates (high SOE for both). Home-visiting programs also reduced HF-specific readmission rates and the composite endpoint (moderate SOE for both outcomes). STS reduced HF-specific readmission rates (high SOE) but not all-cause readmission (moderate SOE). Three interventions produced a mortality benefit (all moderate SOE): home-visiting programs, MDS-HF clinic interventions, and STS.

For all-cause readmission over 3 to 6 months, NNTs were 9 for home-visiting programs and 8 for MDS-HF clinic interventions (Table C). For example, an NNT of 9 signifies that nine people with HF would need to receive a home-visiting program following discharge (rather than usual care) to prevent one additional person from being readmitted over 3 to 6 months. For mortality, NNTs were 33, 27, and 18, respectively, for home-visiting programs, STS, and MDS-HF clinic interventions.

Our meta-analyses found that telemonitoring and primarily educational interventions were not efficacious for any primary outcomes. In addition, home-visiting programs were not efficacious for reducing mortality at 30 days (low SOE). STS interventions were not efficacious for reducing all-cause readmissions (low SOE). Evidence was insufficient to determine the efficacy of the following interventions in reducing readmission rates: most primarily educational interventions, nurse-led HF clinic interventions, primary care clinic interventions, peer support interventions, and cognitive training interventions (for people with HF and coexisting mild cognitive impairment).

Some experts have cautioned that inappropriate focus on reduction of readmission rates could negatively affect patient care and perhaps increase mortality. We found no evidence of such an effect—i.e., no interventions that reduced readmission rates but increased mortality.

### **Other Utilization Outcomes**

Few trials reported on ER visits or hospital days of subsequent readmissions; when these were reported, few trials reported measures in the same manner or at similar timepoints. No trial reported the number of acute outpatient (non-ER) visits.

We generally found insufficient evidence to determine whether transitional care interventions increased or decreased ER visits. The one exception was that STS interventions had no effect on the rate of ER visits over 3 to 6 months (low SOE).

Two intervention types significantly reduced the total number of all-cause hospital days (of subsequent readmissions) over 3 to 6 months: STS (moderate SOE) and home-visiting programs (low SOE). Evidence was generally insufficient to determine whether other transitional care interventions increased or decreased hospital days of subsequent readmissions.

## Quality of Life

Few trials measured quality of life or function using the same measures at similar timepoints. We found that improvement in HF-specific quality of life (as measured by the Minnesota Living With Heart Failure questionnaire) was greater for home-visiting programs than usual care over 3 months (low SOE) but not at 6 months (low SOE). STS interventions did not improve HF-specific quality of life at 3 or 6 months. Evidence was insufficient to determine whether other intervention categories improved quality of life.

## Components of Effective Interventions

The two categories of interventions that reduced all-cause readmissions and the composite outcome—namely, home-visiting programs and MDS-HF clinic interventions—are multicomponent complex interventions. We found no single-component intervention that reduced all-cause readmissions. As a whole, these two categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.
- HF pharmacotherapy emphasizing patient education about medications, promotion of adherence to medication regimens, and promotion of evidence-based HF pharmacotherapy before discharge, during followup, or both.
- Face-to-face contact following discharge via home-visiting personnel, MDS-HF clinic personnel, or both. In most cases, this contact occurred within 7 days of discharge.
- Streamlined mechanisms to contact care delivery personnel (clinic personnel or visiting nurses or pharmacists) outside of scheduled visits (e.g., patient hotline).
- Mechanisms for postdischarge medication adjustment. In most cases, home-visiting personnel either directly recommended medication adjustment or assisted with coordination of care (e.g., with primary care provider or cardiologist) to facilitate timely medication adjustment based on a patient's needs (rather than advising patients to call for help themselves).

Three categories of interventions reduced mortality rates over 3 to 6 months: home-visiting programs, STS, and MDS-HF clinic interventions. All are multicomponent complex interventions. As a whole, these three categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.
- A series of scheduled structured visits (via telephone or clinic followup) that focused on reinforcing education and monitoring for HF symptoms.
- A mechanism to contact providers easily outside of scheduled visits (e.g., patient hotline).

Separating out individual components from the overall categories (or “bundles”) of interventions that showed efficacy was not possible.

## Intensity, Delivery Personnel, and Mode of Delivery

In general, intervention categories that included higher intensity interventions (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality, whereas categories with lower intensity interventions (i.e., primarily educational interventions, nurse-led HF clinic interventions) did not. Within most categories, evidence was insufficient to draw definitive conclusions about whether higher or lower intensity interventions were more or less efficacious in reducing all-cause readmissions or mortality. The one exception was home-visiting programs: a high-intensity program was efficacious in reducing all-cause readmission at 30 days, whereas a low-intensity program was not. Subgroup analyses found no significant difference in efficacy based on intensity for home-visiting programs or STS over 3 to 6 months. Subgroup analyses were not possible for other categories of interventions because of either lack of variation or too few trials reporting outcomes at similar timepoints.

The two categories of interventions that reduced all-cause readmissions and mortality (home-visiting programs and MDS-HF clinic interventions) were more likely to include teams of providers delivering the intervention (e.g., home visits that a nurse and pharmacist conducted together) than interventions that did not show efficacy (e.g., telemonitoring, primarily educational interventions). STS interventions (delivered primarily by nurses and pharmacists) were efficacious in reducing mortality but did not reduce all-cause readmissions. Within categories, evidence was insufficient to draw definitive conclusions about whether specific delivery personnel were more or less efficacious for reducing all-cause readmissions or mortality.

Across intervention categories, interventions were primarily delivered face to face or via technology (telephone, telemonitoring, video visits). The two categories of interventions delivered primarily face to face (i.e., home-visiting programs and MDS-HF clinic interventions) reduced all-cause readmission. For these two categories, method of delivery did not vary within each category. STS reduced mortality; some of these interventions included a face-to-face component (e.g., pre-discharge educational intervention). In general, interventions primarily delivered remotely (i.e., telemonitoring, STS) did not reduce all-cause readmissions. Only STS interventions varied in the method of communication; our subgroup analyses for reduction in all-cause readmissions and mortality found no statistically significant difference by method of communication at any outcome timepoint.

## Discussion

We found very little evidence on whether interventions reduced 30-day readmissions; most trials reported rates over 3 to 6 months. One home-visiting trial showed efficacy in reducing both 30-day all-cause readmission and the 30-day composite outcome.<sup>38</sup> For improving all-cause readmission rates over 3 to 6 months, we found strong evidence of efficacy for home-visiting programs and MDS-HF clinic interventions. Three categories of interventions were efficacious in reducing mortality rates over 3 to 6 months (moderate SOE for each category): home-visiting programs, STS interventions, and MDS-HF clinic interventions.

The two categories of interventions that reduced all-cause readmissions and the composite outcome (home-visiting programs and MDS-clinic interventions) are multicomponent complex interventions. We could not separate out individual components from the overall bundle of interventions that showed efficacy; we found no single-component intervention that reduced all-cause readmissions. Few trials reported on whether transitional care interventions increased or decreased ER visits. Furthermore, few trials measured quality of life at the same timepoint with the same scale. No trial assessed whether transitional care interventions increased or decreased caregiver or self-care burden.

Whether certain interventions that reduce readmissions at 3 and 6 months would also be effective in reducing earlier readmissions remains uncertain. Data based on Medicare claims suggest that 35 percent of 30-day readmissions are for HF; the remainder are for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia

or shock).<sup>5</sup> We found strong evidence for interventions that provided relatively frequent in-person monitoring following discharge—specifically, home-visiting programs and MDS-HF clinic interventions. Interventions that did not show efficacy for all-cause readmissions tended to focus on HF self-care promotion alone (e.g., STS, primarily educational interventions). For reducing all-cause readmissions, focusing on HF disease management alone does not appear sufficient.

Current clinical practice in the care of adults with HF after hospitalization varies greatly; readmissions vary by geography and insurance coverage.<sup>14</sup> A recent telephone survey of 100 U.S. hospitals found wide variation in education, discharge processes, care transition, and quality improvement methods for patients hospitalized with HF.<sup>15</sup>

Our findings provide some guidance to quality improvement efforts, especially those that aim to reduce readmissions for people with HF. Specifically, systems or providers aiming to implement interventions to improve transitional care for patients with HF may be uncertain about what type of intervention to implement. Strong evidence supports the use of home-visiting programs and MDS-HF clinic interventions for reducing all-cause readmissions and mortality, and STS for reducing HF-specific readmissions and mortality. These interventions should receive the greatest consideration by systems or providers seeking to implement transitional care interventions for people with HF.

## Applicability

Most trials included adults with moderate to severe HF. The mean age of subjects was generally in the 70s; very few trials enrolled patients who were, on average, either younger or older. We did not find evidence to confirm or refute whether transitional care interventions are more or less efficacious for many other subgroups, including groups defined by sex, racial or ethnic minorities, people with higher severity of HF, and those with certain coexisting conditions. Included trials commonly excluded patients who had end-stage renal disease or severe or unstable cardiovascular disease (e.g., recent myocardial infarction). The interventions included are applicable only to patients who are discharged to home; whether interventions would benefit patients who are discharged to another institution (e.g., assisted living facility) remains unclear. Most included trials did not use a readmission risk-prediction tool to determine inclusion eligibility.

All included trials enrolled patients with HF, but some degree of population heterogeneity across intervention categories would affect our findings (e.g., variation in HF severity, etiology, or number of coexisting conditions). The majority of trials included patients with moderate to severe HF based on the New York Heart Association classification and enrolled patients with both preserved and reduced ejection fraction.

One of three trials assessing MDS-HF clinics was conducted in the United States; the other two were conducted in Taiwan and Canada. Whether results reflect differences in populations or health care systems is unclear. Approximately one-half of the home-visiting programs were conducted in the United States; the others were conducted in Australia, the United Kingdom, and various European countries. Across most included trials, the majority of patients were prescribed an ACEI or ARB (when information was reported); however, the percentages of patients across trials who were prescribed beta-blockers at discharge varied widely across trials.

Whether “usual care” in trials published during the early 1990s is comparable to current practice is questionable. In general, trials did not report on details of usual care, including whether followup was scheduled soon after discharge or whether patients were receiving additional services such as home health care. However, rates of readmission in the usual-care arms of included trials are similar to recent rates of readmission in Medicare populations.<sup>2</sup> Included trials were conducted in a mix of settings; these settings included academic medical centers, VA hospital settings, and community hospitals.

We did not prespecify a magnitude of effect (i.e., a specific reduction in RR) that should be considered a meaningful change in readmission rates from a clinical or policy perspective. The percentage of readmissions that are preventable may differ across settings and patient populations.

## **Limitations of the Comparative Effectiveness Review Process**

The interventions in the included trials were quite diverse; they probably could be categorized using a variety of classification schemes or conceptual models. As explained previously, we classified them in a manner that we believe is both descriptive and informative; it accords with how numerous experts conceptualize these highly varied programs. Nonetheless, we acknowledge that other approaches to categorization could lead analysts to different conclusions. Other reviews have highlighted the difficulty in classifying trials into distinct categories.

For example, we classified one trial by Rainville et al.<sup>40</sup> as STS, as did a 2011 Cochrane review,<sup>41</sup> but a 2012 Cochrane review classified the same trial as case management, grouping it with trials that assessed home-visiting programs.<sup>42</sup>

We use the term “transitional care” broadly; generally we were guided by Coleman’s definition of “a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location” (p. 30).<sup>22</sup> The included interventions are diverse in terms of whether they aimed to coordinate care at the provider level or focused more on strategies to transfer care back to the patient (e.g., through self-care promotion for managing HF). We did not include or exclude trials based on any specific set of components; for that reason, included trials assess diverse interventions. We chose to cast a broad net to be able to examine a comprehensive set of strategies to reduce readmissions, lower mortality, improve quality of life, or influence other patient-centered outcomes, on the grounds that doing so would be useful to stakeholders in different settings (hospitals, outpatient clinics, or others).

Our inclusion and exclusion criteria specified that included trials had to enroll patients during or soon after a hospitalization for HF and also had to measure a readmission rate at or before 6 months. We did not include readmission rates or mortality rates measured beyond 6 months; interventions that we did not find efficacious may or may not be beneficial in long-term disease management in patients with HF (e.g., perhaps for reducing 12-month readmission rates).

Finally, publication bias and selective reporting are potential limitations. Although we searched for unpublished trials and unpublished outcomes, we did not find direct evidence of either of these biases. Many of the included trials were published before trial registries (e.g., [clinicaltrials.gov](http://clinicaltrials.gov)) became available; had we been able to consult such registries, we would have had greater certainty about the potential for either type of bias.

## **Limitations of the Evidence Base**

The evidence base was inadequate to draw conclusions for some of our questions or subquestions of interest. In particular, as described above, direct evidence was insufficient to permit us to draw conclusions on comparative effectiveness of transitional care interventions. In addition, evidence was quite limited for some outcomes (e.g., readmissions within 30 days, other utilization outcomes such as ER visits, and quality of life). Evidence was insufficient to draw any definitive conclusions about

whether any transitional care interventions are more or less efficacious in reducing readmissions or mortality based on patient subgroups defined by age, sex, race, ethnicity, socioeconomic status, disease severity, or coexisting conditions. Only two eligible trials reported information on different subgroups. We identified little evidence on the potential harms of transitional care interventions. No trial measured caregiver burden.

Many trials had methodological limitations introducing some risk of bias. Some trials did not clearly describe methods used for assessing utilization outcomes (e.g., readmissions, ER visits). Methods of handling missing data varied; some trials did nothing to address missing data (i.e., analyzed only completers). However, many trials conducted true ITT analyses and used appropriate methods of handling missing data.

Limitations also included inadequate sample size and heterogeneity of outcome measures across trials (specifically, types of readmission rates). Reporting use of health services other than for the primary outcomes, such as ER visits, was variable across the included trials.

Sometimes usual care and certain aspects of treatment interventions were not adequately described. Specifically, descriptions of whether (and how) interventions addressed medication management were often unsatisfactory. Categories of interventions that showed efficacy (e.g., MDS-HF clinic interventions and home-visiting programs) often included frequent visits with clinicians. Separating out individual components that are necessary from the overall type of interventions that showed efficacy was not possible. Moreover, some confounding components that were not described may be associated with efficacy as well (e.g., addressing social needs, optimizing HF pharmacotherapy).

### Research Gaps

We identified important gaps in the evidence that future research could address; many are highlighted above. Of note, these gaps relate only to the KQs this report addresses, and they should not eliminate a wide range of potentially important research that falls outside the specified scope of this review. Table D summarizes the gaps and offers examples of potential future research that could address the gaps.

**Table D. Evidence gaps for future research, by Key Question**

KQ	Evidence Gap	Potential Future Research and Improved Methods
1	Few trials measured 30-day all-cause readmission outcomes (including those rated as high or unclear risk of bias); we found low SOE for home-visiting programs in reducing all-cause readmission and the composite outcome (all-cause readmission or death). Evidence was insufficient to determine the efficacy of other intervention categories in reducing 30-day readmission rates.	If 30-day readmission rates remain an important metric for policy, reimbursement, and quality, then future studies should evaluate whether interventions that show efficacy in reducing 3- and 6-month readmission rates (e.g., care in an MDS-HF clinic following discharge) are also effective in reducing 30-day readmission rates. Future trials should ensure that the sample sizes and methods of ascertaining readmission outcomes are adequate to determine the effect of transitional care interventions on 30-day readmission rates. Future research could also include methods such as meta-analysis of individual patient data to ascertain whether other intervention categories reduce 30-day readmission rates.
1, 2	Only one trial evaluated one intervention that was based in a primary care clinic; this intervention primarily aimed to increase access. Evidence was insufficient to determine the efficacy of this intervention in reducing readmissions or mortality.	Given that many patients do not have access to specialty care (e.g., in rural settings) or may prefer to receive care following an HF admission in primary care clinics, future studies should evaluate the efficacy of transitional care interventions based in primary care clinics. Such experimental programs could include features such as home visits or a series of clinic-based visits following discharge. In addition, future research could examine the features of patients receiving services in primary care clinics versus those of patients in cardiology-run HF clinics; these variables might include severity of HF or coexisting conditions.

**Table D. Evidence gaps for future research, by Key Question (continued)**

<b>KQ</b>	<b>Evidence Gap</b>	<b>Potential Future Research and Improved Methods</b>
1, 3, 4	Key intervention components (content and process) were inconsistently described across trials. Some trials provided great detail, others very little. Researchers who aim to assess whether interventions reduce readmissions for the included timepoints (30 days to 6 months) do not use a common conceptual framework.	Future research of transitional care interventions could rely on guidance from the AHA statement offering a taxonomy for disease management for investigators to categorize and compare such programs. <sup>43</sup> Alternatively, the AHA or others might amend this taxonomy to include more specific guidance on categorizing transitional care-type interventions; for instance, incorporating subdomains in the “environment” domain that are more specific to the transition period might be helpful.
1	Evidence was insufficient to determine the comparative effectiveness of transitional care interventions. Nearly all trials examined a particular program against “usual care” of various sorts. No trial tested a single complex intervention with and without a particular component thought to be critical to the intervention.	Future RCTs should address whether certain types of interventions are more efficacious than others. Examples of head-to-head trials include: (1) home-visiting programs that are higher vs. lower intensity or that differ in specific components; and (2) MDS-HF clinic followup compared with home visits that provide similar periodicity of followup and content (e.g., education on self-care and medication reconciliation).
1	Telemonitoring interventions did not reduce readmissions over 6 months; whether this can be attributed to lack of care coordination or other factors remains unclear.	Future RCTs of telemonitoring interventions should include additional components that appear to be necessary for efficacy (based on our results for KQs 1-3). For example, conventional telemonitoring might be combined with one (or more) of three key components: (1) starts immediately after discharge, (2) is combined with initial in-person visits (in the clinic or in the home), and (3) is integrated with the patient’s established outpatient care.
2	Evidence was insufficient to determine whether transitional care interventions can reduce 30-day mortality.	Future trials and observational studies should evaluate whether interventions that reduce 30-day readmission rates increase or decrease mortality rates over the same period. There remains a concern about the relationship between reductions in 30-day readmission rates and mortality, especially for vulnerable populations.
2	The literature did not adequately address the effect of interventions on burdens placed on either patients themselves or their caregivers. It also did not adequately examine the effect of interventions on health-related quality of life or physical functioning, beyond measuring changes in disease-specific outcomes (with the MLWHFQ).	Future research should include validated measures of caregiver burden, patient-reported measures of the self-care burden, or both.
2	The literature did not adequately examine the effect of interventions on health-related quality of life or physical functioning, beyond measuring changes in disease-specific outcomes (with the MLWHFQ).	Health-related quality of life (in the form of PROs) is a crucial variable for many patients, families, professional societies, and research groups. Investigators could continue to use an HF-specific instrument (such as the MLWHFQ, the Kansas City Cardiomyopathy Questionnaire, or the Chronic Heart Failure Assessment tool). For broader quality of life outcomes, researchers should also consider use of reliable and valid PRO instruments; widely administered ones include the Medical Outcomes Study Short Forms and the EURO-QOL.

**Table D. Evidence gaps for future research, by Key Question (continued)**

KQ	Evidence Gap	Potential Future Research and Improved Methods
5	Evidence was insufficient to determine whether certain subgroups of patients benefit from transitional care interventions.	Future research should assess whether readmission rates or other key outcomes differ by sex, racial or ethnic minority status, disease severity, literacy level, income, or socioeconomic status.

AHA = American Heart Association; EURO-QOL = European Quality of Life questionnaire; HF = heart failure; KQ = Key Question; MDS-HF = multidisciplinary heart failure; MLWHFQ = Minnesota Living With Heart Failure Questionnaire; PRO = patient-reported outcome; RCT = randomized controlled trial; SOE = strength of evidence.

We also identified several methodological issues that increased the risk of bias for trials measuring readmission rates; these issues should be addressed in future research. Often trials inadequately described the method of ascertaining use of health care services (e.g., readmissions, ER visits)—specifically, whether measurements were based on patient report, chart review, or some combination of measurements. Masking outcome assessments also raised concerns; for example, in some trials personnel delivering the intervention also appeared to be primarily responsible for measuring health care use. Future studies should consider methods (such as blinded outcome assessments) that guard against measurement bias.

## Conclusions

Few trials evaluating transitional care interventions for adults with HF reported 30-day readmission rates; we identified one home-visiting trial that reduced all-cause readmission and the composite endpoint (low SOE). For outcomes measured over 3 to 6 months, home-visiting programs and MDS-HF clinic interventions reduced all-cause readmissions and mortality; STS reduced HF-specific readmissions and mortality. The SOE for these conclusions was high for the readmission measures and moderate for mortality. Based on current evidence, telemonitoring interventions and primarily educational interventions are not efficacious for reducing readmissions or mortality. Direct evidence was insufficient to conclude whether one type of intervention was more efficacious than any other type. Evidence was generally insufficient to determine whether the efficacy of interventions differed for subgroups of patients. We found no evidence on potential harms of transitional care interventions, such as caregiver burden.

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## Full Report

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