

**Hospital-based Quality Improvement Interventions for Patients with Heart
Failure:
A Systematic Review**

by

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Thesis submitted in partial fulfillment of
the requirements for the degree of
Master of Science in the Duke Global Health Institute
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ABSTRACT

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ABSTRACT

Importance: Quality improvement initiatives have been developed to improve clinical outcomes in patients with heart failure (HF), but data from randomized trials of these initiatives have not previously been synthesized.

Objective: To estimate the direction and magnitude of effect and quality of evidence for hospital-based HF quality improvement interventions on process of care measures and clinical outcomes among patients with acute HF.

Evidence Review: We performed a structured search to identify relevant randomized trials through February 2017. Studies were independently reviewed in duplicate for key characteristics, outcomes were summarized, and a qualitative synthesis was performed due to substantial heterogeneity.

Findings: From 3,615 records, 14 randomized controlled trials were identified for inclusion with multi-faceted interventions. The mean in-hospital mortality rate reported in three trials (n = 75,164 participants) ranged from 3.4% to 5.6% in the intervention compared to 3.4% to 15.4% in the comparator. There was a trend towards higher in-hospital use of angiotensin converting enzyme inhibitors (ACE-I; 57.9% versus 40.0%) and beta-blockers (BB; 46.7% versus 10.2%) in the intervention than the comparator in one trial (n = 429 participants). Five trials (n = 78,727 participants) demonstrated no effect of the quality improvement intervention on use of ACE-I or angiotensin receptor blocker (ARB) at discharge; whereas, one trial (n = 17,544 participants) demonstrated an increase in ACE-I or ARB use at discharge (86.1% to 92.4%, absolute difference 5.9%; 95% CI 1.0, 10.7; P = 0.02). Three trials (n = 89,660 participants) reported no effect on use of

BB at discharge, and one trial (n = 71,829 participants) reported no effect on use of aldosterone antagonist at discharge. Two trials (n = 419 participants) demonstrated a trend towards lower hospital readmission up to 90 days after discharge. There was no consistent effect of the quality improvement intervention on 30-day all-cause mortality, hospital length of stay, and patient-level health-related quality of life.

Conclusions and Relevance: Randomized trials of hospital-based HF quality improvement interventions do not show a consistent effect on most process of care measures and clinical outcomes. The overall quality of evidence for these outcomes is very low to moderate, suggesting that future research will likely influence these estimates.

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1. INTRODUCTION

Heart failure (HF) often is an end-stage manifestation of cardiovascular disease and a growing cause of global cardiovascular morbidity and mortality.^{1,2} HF affects an estimated 26 million people worldwide and is estimated to have cost \$108 billion globally in 2012.³ At 40 years of age, the lifetime risk of developing HF is 1 in 4 in the United States and even higher in some race/ethnic sub-groups.⁴ The prevalence of HF in the United States is expected to increase 46% from 2012 to 2030 leading to greater than 8 million patients with HF, and approximately 50% of patients diagnosed with HF will die within 5 years.^{5,6}

Given the high mortality and morbidity rates of patients with HF and disparities in the use of guideline-recommended therapy,^{7,8} quality improvement initiatives have been developed to improve clinical outcomes. These quality improvement initiatives have largely targeted inpatient HF management to improve process of care measures and re-admission rates. For example, the American Heart Association's Get With the Guidelines program has been associated with improvements in processes of care and lower 30-day readmission rates.⁹ Large scale, hospital-based registries with associated quality improvement tools, such as the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) and the Acute Decompensated Heart Failure National Registry (ADHERE), have also demonstrated the use of inpatient process-of-care improvement tools are associated with better quality of care as defined by use of guideline-recommended therapy, adherence to performance measures, and shorter length

of hospitalization.^{7,10} However, whether or not these relationships are causal or are driven by patient-, provider-, or institutional-level confounders is less certain but appears possible.

To understand which components of these multi-faceted quality improvement interventions are effective, several research teams have led randomized trials evaluating the effect of HF quality improvement interventions to overcome the potential confounding and bias inherent in non-randomized studies. Most hospital-based quality improvement interventions include admission and discharge checklists, personalized site performance feedback, and patient education.¹¹ These interventions may be particularly useful in low- and middle-income countries where the quality of HF care remains poor,¹² and adherence to guideline-recommended therapy is suboptimal.¹³ The objective of this systematic review is to estimate the direction and magnitude of effect and quality of evidence for randomized trials of hospital-based HF quality improvement interventions on process of care measures and clinical outcomes among patients with acute HF.

2. METHODS

2.1 Literature Search and Study Selection

This review evaluated the effect of in-hospital heart failure quality improvement interventions in hospitalized patients with heart failure compared to usual care on the primary outcomes of in-hospital mortality, in-hospital and discharge medical therapy, and hospital readmissions up to 90 days after discharge (**Appendix 1**). This review followed guidelines published by the Cochrane Collaboration to synthesize the effects of multiple interventions,¹⁴ and the pre-specified protocol was prospectively registered.¹⁵

We searched the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA), MEDLINE, EMBASE, CINAHL, and Conference Proceedings Citation Index—Science (Web of Science), for published literature from the date of inception in each database to February 6, 2017. We also searched ClinicalTrials.gov for records of ongoing trials and unpublished studies on February 13, 2017. An experienced information specialist (MAB) performed all searches. We contacted study authors of included trials when necessary to identify additional information we might have missed. We used the reference section of published trials that met our inclusion criteria as an added resource to identify other trials. Details of the search methods are provided in **Appendix 2**.

2.2 Eligibility Criteria

We included randomized trials of HF quality improvement interventions. We sought to include quasi-randomized (e.g., interrupted time series), but there were none identified in our search. We excluded general, hospital-based quality improvement interventions. We included trials that tested the effect of a variety of individual or combined interventions including, but not limited to: audit and feedback reporting systems, admission and discharge checklists, chart case management, patient educational or behavioral change materials, health care quality training that was directed at the hospital system, doctors, nurses, or allied health professionals, or information management systems with the goal of being inclusive in the type and target of intervention. We included trials evaluating the effect of these interventions among individuals admitted to hospitals for the management of HF, which is a common definition for acute HF.

2.3 Data Extraction

Three authors (AA, EB, SGKY) independently screened abstracts, titles, and full texts of retrieved studies in duplicate to identify studies to be assessed further. Two authors (AA, SGKY) independently extracted key data using a structured data extraction form and assessed risk of bias using the Cochrane Risk of Bias Tool in duplicate across the domains of selection, performance, detection, attrition, reporting, and other biases. Discrepancies in risk of bias assessment were resolved through consensus or through review with a third review author (MDH).

2.4 Outcomes

We included a combination of process of care measures and clinical outcomes. The primary outcomes included: 1) rate of in-hospital mortality, 2) rates of in-hospital and discharge medical therapy (combined and separate), and 3) rate of hospital readmission up to 90 days after discharge. The secondary outcomes included: 1) rates of 30- and 90-day all-cause mortality, 2) hospital length of stay, 3) uptake of quality improvement intervention components, 4) rate of cardiac rehabilitation referral, 5) rate of implantable cardioverter defibrillator (ICD) placement to prevent sudden death in eligible patients, 6) patient-level health-related quality of life using a validated instrument, and 7) patient-related direct costs. We created a Summary of Findings table reporting the effects of the intervention and the quality of evidence related to the primary and key secondary outcomes.

2.5 Quality Assessment

Two authors (AA, SGKY) independently evaluated the quality of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework, which takes into account issues related to internal validity (risk of bias, inconsistency, imprecision, publication bias) and to external validity, such as directness of results.¹⁶ Discrepancies were resolved through consensus or through review with a third review author (MDH).

2.6 Data Synthesis

We planned to perform a meta-analysis, but there was substantial, unexplained heterogeneity across the studies, as well as differences in their presentation of intervention effects that precluded pooling and reporting of summary effect estimates. Thus, we present a narrative, qualitative synthesis.

3. RESULTS

3.1 Search Results

The initial search identified 3,615 records after merging data from independent searches and removing duplicates (**Figure 1**). After title and abstract screening, we evaluated 69 full-text articles and identified 14 studies for inclusion in the review.^{11,17-29} Details regarding studies that were excluded are reported in **Appendix 3**, and details regarding ongoing studies are reported in **Appendix 4**.

3.2 Characteristics of the Included Studies

A description of the 14 included studies is provided in **Table 1**, and detailed characteristics of the included studies are provided in **Appendix 5** in the Supplement. We identified six cluster randomized control trials (RCTs) in which the unit of randomization was the hospital^{11,18,24-26,29} and eight RCTs in which the unit of randomization was the individual participant.^{17,19-23,27,28} Eight studies were conducted in a single academic center.^{17,19-23,27,28} Ten studies were conducted in the United States,^{11,18-20,22-24,26-28} and the other four studies were conducted in Sweden,¹⁷ Japan,²¹ Italy,²⁵ and Canada.²⁹ Two large cluster RCTs contributed the greatest number of participants (DeVore 2015: 71,829 participants;¹¹ Tu 2009: 17,544 participants²⁹), and three RCTs were small with less than 200 participants.^{17,21,28} The participants were hospitalized patients with HF, and type or cause of HF was generally not reported. Two studies also included outpatients with HF, and disaggregated data specifically for hospitalized patients with HF

were not available.^{19,20} The mean age of participants ranged from 63.0 to 80.7 years, and the proportion of females in each study ranged from 1% to 63%. Two trials did not report age nor sex.^{18,24}

Trial-specific risk of bias assessment is presented in **Figure 2**, and detailed risk of bias assessment across the domains of selection, performance, detection, attrition, reporting, and other bias is presented in **Appendix 5**. Thirteen trials had low risk of selection bias based on reported methods of random sequence generation,^{11,17,19-29} but only four trials had low risk of selection bias based on reported methods of allocation concealment.^{19,20,22,27} All others had an unclear risk of selection bias based on reported methods of allocation concealment.^{11,17,18,21,23-26,28,29} Most trials (n = 12) did not blind study personnel and participants given the nature of the quality improvement intervention and were at high risk of performance bias.^{11,17,18,21-29} One trial had high risk of detection bias from lack of blinding of outcome assessors,²³ four trials had low risk of detection bias,^{17,18,20,28} and the remainder had an unclear risk of detection bias from reported methods of outcome assessment.^{11,19,21,22,24-27,29} Five trials had high risk of attrition bias from incomplete outcome data.^{19-21,23,24} Two trials had high risk of reporting bias from selective reporting based on previously published protocols,^{20,29} two trials had low risk of reporting bias,^{11,25} and 10 trials had unclear risk of reporting bias.^{17-19,21-24,26-28}

3.3 Interventions

The in-hospital heart failure quality improvement interventions varied across trials. Five trials tested multi-faceted quality improvement interventions that included various combinations of HF-specific patient education, HF guideline clinical staff education, admission order sets, in-hospital guideline-recommended medication reminders, discharge checklists, case management coordination of care, performance reports, and post-discharge telephone calls.^{18,23-26} Interventions in five trials emphasized HF-specific patient education on medication management including self-management of diuretics, maintaining a symptom diary, diet, and tobacco and alcohol cessation.^{17,21,22,27,28} Two large cluster RCTs evaluated the specific effect of audit and feedback by sharing personalized quality improvement reports highlighting performance measures to each hospital site¹¹ or via a publicly released report card.²⁹ Two studies at the same academic medical center evaluated the effect of automated guideline-recommended medication reminders attached to echocardiography reports.^{19,20}

3.4 Primary Outcomes

The primary outcomes included rate of in-hospital mortality, rates of in-hospital and discharge medical therapy (combined and separate), and rate of hospital readmission up to 90 days after discharge (**Table 2**). Overall, mean rate of in-hospital mortality presented in three trials (n = 75,164 participants) ranged from 3.4% to 5.6% in the intervention group compared to 3.4% to 15.4% in the comparator group.^{11,25,26} Two trials revealed no effect of the quality improvement intervention on in-hospital mortality. The smallest of the three trials reporting in-

hospital mortality demonstrated a decrease from 15.4% (33 events/215 participants) in the comparator group to 5.6% (12 events/214 participants) in the intervention group.²⁵ One trial (n = 429 participants) measured rates of in-hospital medical therapy. In-hospital use of angiotensin converting enzyme inhibitors (ACE-I) increased from 40.0% in the comparator group to 57.9% in the intervention group, and in-hospital use of beta-blockers (BB) increased from 10.2% in the comparator group to 46.7% in the intervention group.²⁵ No difference in the use of in-hospital diuretics was observed. Six trials (n = 96,271 participants) measured rates of discharge medical therapy.^{11,18,23,25,26,29} Five out of the six trials demonstrated no effect of the quality improvement intervention on use of ACE-I or angiotensin receptor blocker (ARB) at discharge. In the largest cluster RCT (n = 71,829 participants), the estimated treatment effect (95% CI) of the intervention on ACE-I or ARB at discharge was 0.8% (-2.7%, 4.2%; P = 0.67) between the intervention and control groups.¹¹ The second largest cluster RCT (n = 17,544 participants) revealed the absolute difference (95% CI) for intervention versus control on ACE-I or ARB at discharge for participants with left ventricular systolic dysfunction was 5.9% (1.0%, 10.7%; P = 0.02) higher in the intervention group.²⁹ Three trials reported no effect of the quality improvement intervention on use of BB at discharge,^{11,23,29} and one trial reported no effect of the intervention on use of aldosterone antagonist at discharge.¹¹ Of the three small trials reporting hospital readmissions up to 90 days after discharge (n = 706 participants), two demonstrated an effect of the intervention on reducing hospital

readmissions from 67% and 19% in the comparator to 37% and 7%, respectively.^{23,27,28}

3.5 Secondary Outcomes

The secondary outcomes included rates of 30- and 90-day all-cause mortality, hospital length of stay, uptake of quality improvement intervention components, rate of cardiac rehabilitation referral, rate of ICD placement to prevent sudden death in eligible patients, patient-level health-related quality of life using a validated instrument, and patient-related direct costs (**Table 2**). Pre-specified outcomes that were not reported by any of the included trials include: uptake of quality improvement intervention components, rate of cardiac rehabilitation referral, rate of ICD placement to prevent sudden death in eligible patients, and patient-related direct costs. Two studies (n = 17,681 participants) demonstrated no effect of the quality improvement intervention on 30-day all-cause mortality with the outcome ranging from 7.5% to 10.6% in the comparator to 7.1% to 9.6% in the intervention, respectively (P = 1.00, P = 0.26).^{28,29} Of the two studies reporting hospital length of stay (n = 3,335 participants), the smaller trial showed a decrease in the mean (95% CI) hospital length of stay by one day in the intervention group from 11.4 (10.5, 12.3) days to 10.4 (9.6, 11.0; P = 0.03) days in the comparator group.^{25,26} Three trials (n = 3,411 participants) assessed patient-level health-related quality of life using validated questionnaires.^{22,26,27} Only one trial demonstrated an improvement in patient-level health-related quality of life as assessed by the Chronic Heart Failure Questionnaire with mean

(SD) score improving from 11.3 (16.4) in the comparator to 22.1 (20.8) in the intervention,²⁷ but the other two trials demonstrated no difference.

3.6 Study Quality Assessment

Outcome-specific assessment of the quality of included studies using the GRADE framework is presented in **Table 3**. The quality of evidence for the primary outcomes of in-hospital mortality and in-hospital medical therapy is low, and both outcomes were downgraded for inconsistency and imprecision.¹⁶ The quality of evidence for the primary outcome of discharge medical therapy is moderate, downgraded for inconsistency as the direction of effect is inconsistent and point estimates vary across studies. The quality of evidence is low for the secondary outcome of hospital readmission up to 90 days after discharge, downgraded for inconsistency and imprecision. The quality of evidence is low for the secondary outcomes of 30-day all-cause mortality and hospital length of stay. For the secondary outcome of patient-level health-related quality of life, the quality of evidence is very low, downgraded for inconsistency, imprecision, and study limitations.

4. DISCUSSION

Randomized trials of hospital-based HF quality improvement interventions do not show a consistent effect on process of care measures nor clinical outcomes including in-hospital mortality, discharge medical therapy, 30-day all-cause mortality, hospital length of stay and patient-level health-related quality of life. These interventions appear to increase utilization of in-hospital ACE-I and BB and may reduce hospital admission up to 90 days after discharge. To our knowledge, this is the first systematic review of randomized trials to evaluate the effect of in-hospital HF quality improvement interventions compared to usual care on a range of outcomes of importance in hospitalized patients with HF.

The interventions studied in these RCTs have more modest effects on process of care measures than non-randomized studies suggest. For example, during the two year OPTIMIZE-HF observational quality improvement registry with 259 participating US hospitals, the prescription rates of BB at discharge increased from 76.3% to 86.4% ($P < 0.001$).¹⁰ However, in the large cluster RCT of 147 hospitals participating in the Get With The Guidelines-Heart Failure quality improvement program, there was no change in the already high rates of BB at discharge (96.8% in the intervention group versus 95.5% in the comparator group; estimated treatment effect 1.05, 95% CI -1.17, 3.27, $P = 0.36$) as a result of personalized performance feedback.¹¹ Further, median rates of use of ACE-I in participants with left ventricular systolic dysfunction in the ADHERE registry were 72.0%, revealing a gap in adherence to established quality-of-care indicators during the period of data collection (July 1, 2002 to December 31, 2003).⁷

However, both subsequent observational HF registry and RCT data demonstrate little effect of quality improvement interventions on treatment rates of ACE-I or ARB at discharge for eligible participants,^{10,11,18,23,25,26} which may be driven by favorable temporal trends in medication use in the comparator groups.

It can be challenging to assess which elements of multi-component interventions, including audit and feedback on performance metrics, standardized HF checklists for admission and discharge, clinical pathways, and patient education, influence heterogeneous process of care measures and clinical outcomes. Two large cluster RCTs demonstrated no effect of release of performance indicators either via personalized feedback to the hospital or publicly-released report cards on quality of care measures.^{11,29} The trials did not report process changes at the hospital level implemented as a result of the performance feedback; hence, there may be substantial heterogeneity across hospitals in their local quality improvement activities. The trials that focused primarily on patient education were small in size (n = 38 to 282 participants) and may have been underpowered to demonstrate a potential effect on measured outcomes.^{17,21,22,27,28}

Notably, there were no RCTs evaluating in-hospital HF quality improvement interventions from low- and middle-income countries. The overall baseline quality of care in the United States, Sweden, Japan, and Italy at the time of these trials may have been too high to demonstrate a significant effect of these interventions because of background improvements in the quality and safety of in-hospital HF care. Countries with lower quality of HF care including lower

baseline use of guideline-recommended therapy may have a greater opportunity to benefit from in-hospital HF quality improvement interventions. For example, in contrast to baseline rates of ACE-I or ARB at discharge in ADHERE (72.5%), OPTIMIZE-HF (84% in first quarter), and GWTG-HF (93.9% in control), the Trivandrum Heart Failure Registry in India revealed lower rates of participants with left ventricular systolic dysfunction prescribed ACE-I at discharge (41.0%).^{7,10,11,13} The Acute Coronary Syndrome Quality Improvement in Kerala (ACS QUIK) cluster randomized, stepped wedge trial evaluated the effect of an in-hospital quality improvement toolkit for participants with acute myocardial infarction in India and demonstrated modestly higher rates of discharge medical therapy (aspirin, statin, BB, ACE-I or ARB) among the intervention group. This suggests potential gains in process of care measures with hospital-based HF quality improvement interventions may be possible in this setting.³⁰ Whether such gains would translate into improvements in clinical outcomes, which were not observed in ACS QUIK, remains uncertain.

This systematic review has several strengths. First, this review includes only RCTs to examine the potential effect of quality improvement interventions. Second, the pre-specified published protocol prior to initiation of the systematic review guided the search strategy and evidence synthesis to minimize the risk of bias in the review process.¹⁵ Third, title screening, data extraction, and quality assessments were performed in duplicate to minimize error or bias in the review process.

This review also has important limitations. First, HF type was not consistently reported across studies and hence, we have limited ability to comment on the effect of the interventions in patients with HF with preserved ejection fraction versus HF with reduced ejection fraction. Second, there is substantial heterogeneity in the types of in-hospital quality improvement interventions included in this review. Third, pooling of summary estimates was not performed due to substantial and unexplained heterogeneity across the studies. We did not include non-randomized studies during which time there have been temporal improvements in process of care measures and clinical outcomes; however, randomized studies are needed to assess the causal relationships between complex interventions and outcomes.

5. CONCLUSIONS

This systematic review demonstrates that randomized trials of in-hospital quality improvement interventions do not have a consistent effect on process of care measures and clinical outcomes in hospitalized participants with HF. The overall quality of evidence for the pre-specified primary and key secondary outcomes is very low to moderate, suggesting that future research will likely influence these estimates. This review demonstrates the gaps in the evidence base for in-hospital quality improvement interventions for acute HF and suggests future areas of inquiry including the need for trials in LMIC settings where baseline quality of care may be lower.

FIGURES AND TABLES

Figure 1. PRISMA flow chart of included studies.

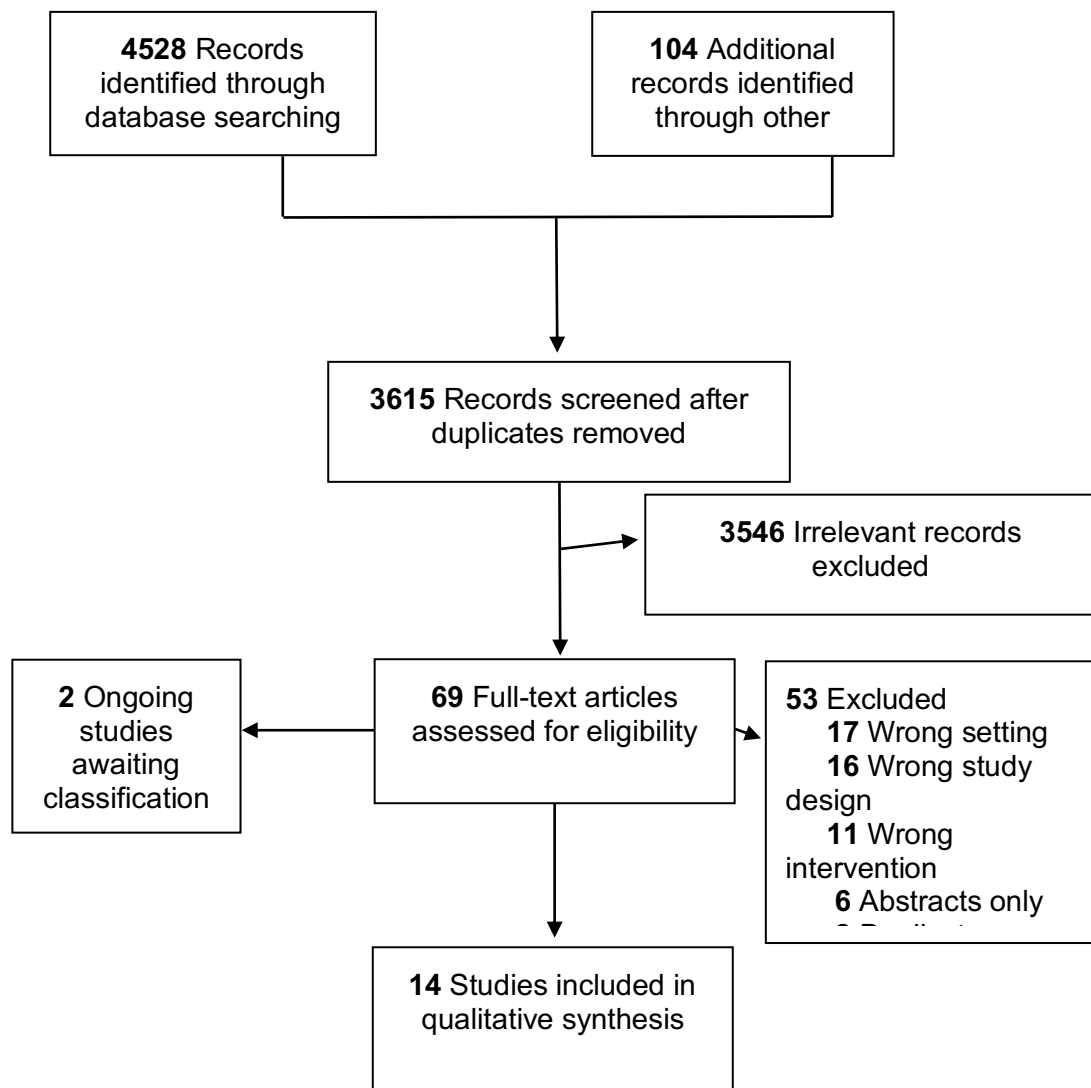


Table 1. Characteristics of included studies.

Study	Setting	N	Population	Intervention and comparator	Key outcomes
Cline 1998	RCT in single academic medical center in Malmo, Sweden	I: 80 patients C: 110 patients N: 190 patients	Hospitalized patients, mean (SD) age 75.6 (5.2) years, 46.8% female	Intervention: Inpatient HF education to patients and families including guidelines for self-management of diuretics, follow-up at an easy-access nurse directed outpatient clinic Comparator: Usual care	<ul style="list-style-type: none"> • One-year mortality • Time to readmission from discharge • Hospital length of stay • Healthcare costs • Treatment with evidence-based medications at one year
DeVore 2015	Cluster RCT in hospitals participating in GWTG-HF program in the US	I: 83 hospitals C: 82 hospitals N: 71,829 patients analyzed	Hospitalized patients, median (IQR) age 74 (62-84) years, 48.6% female	Intervention: Personalized QI reports pushed directly to each site, tailored teleconferences, webinars and specialized toolkits Comparator: Usual GWTG-HF quality improvement tools including on-demand reports and webinars	<ul style="list-style-type: none"> • Opportunity-based composite score for adherence to 5 achievement measures and 9 quality measures • Defect-free composite score • In-hospital mortality • Hospital length of stay
Hayes 2002	Cluster RCT in hospitals in Georgia, Connecticut, Oklahoma, and Colorado in the US	I: 16 hospitals C: 16 hospitals N: 3276 patients eligible	Hospitalized patients, age and % female not reported	Intervention: High-intensity intervention: hospital physician liaison, HF guideline education session, ACE-I dosing chart reminder, echocardiography reporting protocol, and hospital specific feedback delivered face-to-face Comparator: Low-intensity intervention: mailed package of materials including hospital specific feedback, HF guidelines	<ul style="list-style-type: none"> • Measurement of left ventricular function • Use of ACE-I • Target doses of ACE-I • Use of warfarin in patients with HF and atrial fibrillation
Heidenreich 2005**	RCT in single Veterans Affairs hospital in California, US	I: 292 patients C: 308 patients N: 600 patients	Inpatients and outpatients with LVEF < 40% undergoing echocardiography, mean (SD) age 67.5 (11.5) years, 1% female	Intervention: Reminder for use of ace-inhibitor in patients with LVEF ≤ 40% attached to echocardiography report Comparator: Usual care (no reminder)	<ul style="list-style-type: none"> • Prescription for moderate or greater daily dose of ACE-I (lisinopril, fosinopril, captopril) or appropriate alternative (losartan, irbesartan, hydralazine + isosorbide dinitrate)

Heidenreich 2007**	RCT in single Veterans Affairs hospital in California, US	I: 755 patients C: 791 patients N: 1546 patients	Inpatients and outpatients with LVEF < 45% undergoing echocardiography, mean (SD) age 69 (11.5) years, 2% female	Intervention: Reminder for use of beta-blocker in patients with LVEF < 45% and cardiology follow-up attached to echocardiography report Comparator: Usual care (no reminder)	<ul style="list-style-type: none"> • Prescription for any beta-blocker during 9 months after echocardiography • Prescription for specifically carvedilol or metoprolol succinate during 9 months after echocardiography
Kato 2016	RCT in single academic medical center in Tokyo, Japan	I: 20 patients C: 18 patients N: 38 patients	Hospitalized patients, mean (SD) age 63 (14), 31% female	Intervention: Multidisciplinary HF education program with face-to-face counseling from a dietician, pharmacist and nurses on HF self-care, diet, and medication management. Comparator: Usual care	<ul style="list-style-type: none"> • HF self-care behavior • HF knowledge • Rate of HF hospitalization and/or cardiac death over 2 years
Koelling 2005	RCT in single academic medical center in Michigan, US	I: 107 patients C: 116 patients N: 223 patients	Hospitalized patients, mean (SD) age 64.8 (14.2), 42% female	Intervention: 1-hour individual teaching session with nurse educator at discharge Comparator: Usual care	<ul style="list-style-type: none"> • Number of days hospitalized and/or dead within 180 days • Medications at 30, 90, 180 days • Quality of life scores • Self-care behaviors • Costs of care
Laramee 2003	RCT in single academic medical center in Vermont, US	I: 141 patients C: 146 patients N: 287 patients	Hospitalized patients, mean (SD) age 70.7 (11.8), 46% female	Intervention: Coordination of in-hospital and discharge care by case manager, individualized patient/family HF education, 12 weeks post-discharge telephone surveillance, promotion of optimal HF medications and doses Comparator: Usual care	<ul style="list-style-type: none"> • All-cause readmission in 90 days • Adherence to treatment plan • Patient satisfaction • ACE-I, ARB and beta-blocker doses • Cost of medical care
Newhouse 2013	Phased cluster RCT in hospitals in Delaware, Maryland, Pennsylvania, Virginia, West Virginia, North Carolina in US	I: 15 hospitals C: 14 hospitals N: Not reported	Hospitalized patients, age and % female not reported	Intervention: Rural hospital quality collaborative including HF toolkit (fact sheet, education modules, discharge checklist), 2-day in person meeting, monthly group teleconference call Comparator: Usual care	<ul style="list-style-type: none"> • HF core measures (LVEF assessment, ACE-I/ARB use, discharge instructions, smoking cessation counseling) • Context measures (nursing skill mix, nursing care hours, nurse turnover) • Practice environment survey (administered to RNs)

Panella 2009	Cluster RCT in four regions in Italy	I: 7 hospitals C: 7 hospitals N: 429 patients	Hospitalized patients, mean (SD) age 80.7 (8.5), 51% female	Intervention: Clinical pathway (appropriate therapeutic guidelines use, new organization and procedures, patient education) Comparator: Usual care	<ul style="list-style-type: none"> In-hospital mortality Hospital length/appropriateness of stay Rate of unscheduled readmissions Patient satisfaction Treatment costs Discharge quality indicators
Philbin 2000	Cluster RCT in community hospitals in New York, US	I: 5 hospitals C: 5 hospitals N: 2906 patients analyzed	Hospitalized patients, mean (SD) age 76 (11), 56% female	Intervention: Inpatient critical pathway for heart failure management, standardized admission orders, staff and patient education on HF, hospital-specific performance reports Comparator: Usual care	<ul style="list-style-type: none"> Hospital length of stay In-hospital and 6-month mortality Hospital readmission Quality of life 1-month after discharge Hospitalization cost
Rich 1995	RCT in single academic medical center in Missouri, US	I: 142 patients C: 140 patients N: 282 patients	Hospitalized geriatric patients, mean (SD) age 79.3 (6.0), 63% female	Intervention: Patient education, diet and social service consultations, medication review, intensive post-discharge follow-up Comparator: Usual care	<ul style="list-style-type: none"> Readmissions Cost of care Quality of life Medication compliance
Sales 2013	RCT in single community hospital in New York, US	I: 70 patients C: 67 patients N: 137 patients	Hospitalized patients, mean (SD) age 73 (14), 58% female	Intervention: HF disease, medication review and dietary counseling by trained volunteers, weekly follow-up phone calls for one-month post-discharge Comparator: Usual care	<ul style="list-style-type: none"> 30-day readmission rates for HF NYHA functional classification All-cause mortality
Tu 2009	Cluster RCT in acute care hospital corporations in Ontario, Canada	I: 44 hospitals C: 42 hospitals N: 17,544 patients with HF analyzed	Hospitalized patients, median (IQR) age 77 (69-85), 51% female	Intervention: Early feedback public report card on baseline performance on HF quality indicators with media coverage Comparator: Delayed feedback public report card on baseline performance on HF quality indicators	<ul style="list-style-type: none"> Composite HF quality indicator Individual HF process-of-care indicators Hospital report card impact survey All-cause HF mortality

*Total number of participants: 99,287

I: intervention, C: comparator, TP: Total number of participants, RCT: randomized controlled trial, HF: heart failure, QI: quality improvement, GWTG-HF: Get With The Guidelines-Heart Failure, US: United States, ACE-I: angiotensin converting enzyme inhibitor, RN: registered nurse

**Disaggregated data for hospitalized patients with HF not available.

Figure 2. Risk of bias assessment of included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Cline 1998	+	?	-	+	+	?	?
DeVore 2015	+	?	-	?	?	+	?
Hayes 2002	?	?	-	+	?	?	?
Heidenreich 2005	+	+	-	?	-	?	?
Heidenreich 2007	+	+	+	+	-	-	?
Kato 2016	+	?	-	?	-	?	-
Koelling 2005	+	+	-	?	+	?	?
Laramée 2003	+	?	-	-	-	?	?
Newhouse 2013	+	?	-	?	-	?	?
Panella 2009	+	?	-	?	?	+	?
Philbin 2000	+	?	-	?	+	?	?
Rich 1995	+	+	-	?	+	?	?
Sales 2013	+	?	-	+	+	?	?
Tu 2009	+	?	-	?	+	-	?

Table 2. Summary of outcomes from included studies.

Outcome	Trials	Intervention	Comparator	Significance
In-hospital mortality	DeVore 2015 n = 165 hospitals randomized, 71829 participants analyzed	Baseline mean (SE): 2.9% (0.26) Post-intervention absolute change mean (SE): 0.49% (0.44)	Baseline mean (SE): 2.9% (0.28) Post-intervention absolute change mean (SE): 0.48% (0.34)	Estimated treatment effect (95% CI): -0.03 (-1.12, 1.05); P = 0.96
	Panella 2009 n = 14 hospitals, 429 participants analyzed	No: 12/214 5.6% (95% CI: 2.5%, 8.7%)	No: 33/215 15.4% (95% CI: 10.5%, 20.2%)	P = 0.001
	Philbin 2000 n = 10 hospitals, 2906 participants analyzed	Baseline mean: 5.9% Post-intervention mean: 5.2%	Baseline mean: 5.4% Post-intervention mean: 3.7%	Intervention effect (95% CI): 1.0% (-3.0%, 5.0%); P = 0.57
In-hospital medical therapy	Panella 2009 n = 14 hospitals, 429 participants analyzed	ACE-I %: 57.9% BB %: 46.7% Diuretics %: 95.3%	ACE-I %: 40.0% BB %: 10.2% Diuretics %: 95.8%	P <0.001 P <0.001 P = 0.8
Discharge medical therapy	DeVore 2015 n = 165 hospitals randomized, 71829 participants analyzed	Baseline mean (SE): ACE-I/ARB* %: 92.8% (1.02) BB* %: 95.3% (0.76) AA* %: 16.2% (2.85) Post-intervention absolute change mean (SE): ACE-I/ARB* %: 2.11% (1.30) BB* %: 1.54% (0.87) AA* %: -0.18% (1.75)	Baseline mean (SE): ACE-I/ARB* %: 93.9% (1.11) BB* %: 95.0% (0.57) AA* %: 19.6% (2.70) Post-intervention absolute change mean (SE): ACE-I/ARB* %: 1.36% (1.16) BB* %: 0.49% (0.73) AA* %: 3.93% (2.37)	Estimated treatment effect (95% CI): ACE-I/ARB*: 0.75 (-2.66, 4.16) P = 0.67 BB*: 1.05 (-1.17, 3.27) P = 0.36 AA*: -4.10 (-9.95, 1.74) P = 0.17
	Hayes 2002 n = 32 hospitals, 3276 participants eligible	Difference between baseline and post-intervention %: ACE-I*: 3%	Difference between baseline and post-intervention %: ACE-I*: 3%	No significance value reported
	Laramie 2003 n = 287 participants	No (%) ACE-I/ARB: 121/141 (86%) No (%) BB: 91/141 (65%)	No (%) ACE-I/ARB: 115/145 (79%) No (%) BB: 89/145 (61%)	P = 0.16 P = 0.63 P = 0.23
	Panella 2009 n = 14 hospitals, 429 participants analyzed	No (%) ACE-I*: 48/80 (60%)	No (%) ACE-I*: 5/12 (41.7%)	Intervention effect (95% CI): -7% (-20%, 5%) P = 0.20
	Philbin 2000 n = 10 hospitals, 2906 participants analyzed	Baseline mean ACE-I*: 79% Post-intervention mean ACE-I*: 78%	Baseline mean ACE-I*: 79% Post-intervention mean ACE-I*: 83%	Absolute difference % (95% CI): 5.9% (1.0%, 10.7%); P = 0.02 3.5% (-6.1%, 13.1%); P = 0.47

	Tu 2009 n = 86 hospitals, 17544 participants analyzed	Absolute change % (95% CI): ACE-I/ARB*: 4.2% (0.7%, 7.8%) BB*: 31.7% (22.6%, 40.9%)	Absolute change % (95% CI): ACE-I/ARB*: -0.4% (- 7.4%, 6.5%) BB*: 29.4% (18.9%, 39.8%)	
Hospital readmission (up to 90 days after discharge)	Laramie 2003 n = 287 participants	No (%): 49/131 (37%)	No (%): 46/125 (37%)	P > 0.99
	Rich 1995 n = 282 participants	No (%): 53/142 (37%)	No (%): 94/140 (67%)	P = 0.02
	Sales 2013 n = 137 participants	No (%): 5/70 (7%)	No (%): 13/67 (19%)	Absolute risk reduction %: 12% P = 0.04
30-day all- cause mortality	Sales 2013 n = 137 participants	No (%): 5/70 (7%)	No (%): 5/67 (7%)	Absolute risk reduction %: 0.4% P = 1.00
	Tu 2009 n = 86 hospitals, 17544 participants analyzed	Absolute change % (95% CI): -1.7% (-3.4%, 0%)	Absolute change % (95% CI): 0.2% (-1.6%, 1.9%)	Absolute difference % (95% CI): -1.1% (-3.2%, 0.9%); P = 0.26
Hospital length of stay	Panella 2009 n = 14 hospitals, 429 participants analyzed	Mean (95% CI) days: 10.4 (9.6, 11.0)	Mean (95% CI) days: 11.4 (10.5, 12.3)	P = 0.028
	Philbin 2000 n = 10 hospitals, 2906 participants analyzed	Baseline mean days: 8.0 Post-intervention mean days: 6.2	Baseline mean days: 7.7 Post-intervention mean days: 7.0	Intervention effect (95% CI): -1.1 (-2.9, 0.7) days P = 0.18
Patient-level health- related quality of life	Koelling 2005 n = 223 participants	MLHF score baseline mean (SD): 56 (23)	MLHF score baseline mean (SD): 59 (22)	No significance value reported
		MLHF score 30-day mean (SD): 38 (22)	MLHF score 30-day mean (SD): 45 (25)	P = 0.049
		MLHF score 180-day mean (SD): 41 (22)	MLHF score 180-day mean (SD): 42 (25)	No significance value reported
	Philbin 2000 n = 10 hospitals, 2906 participants analyzed	LOL score baseline mean: 6.6 LOL score post- intervention mean: 6.5	LOL score baseline mean: 6.3 LOL score post- intervention mean: 6.5	Intervention effect (95% CI): -0.3 (-1.6, 1.0) P = 0.58 0 (-0.4, 0.3) P = 0.88
Rich 1995 n = 282 participants**	NYHA class baseline mean: 2.2 NYHA class post- intervention mean: 2.1	NYHA class baseline mean: 2.4 NYHA class post- intervention mean: 2.4	P = 0.001	
		CHFQ mean (SD) change: 22.1 (20.8)	CHFQ mean (SD) change: 11.3 (16.4)	

*In patients with reduced left ventricular ejection fraction (ranging from \leq or $<40.0\%$)

**CHFQ assessed in subset of 126 participants

CI: confidence interval, ACE-I: angiotensin converting enzyme inhibitor, ARB: angiotensin receptor blocker, BB: beta-blocker, AA: aldosterone antagonist, MLHF: Minnesota Living with Heart Failure Questionnaire (lower scores reflect better quality of life), LOL: Ladder of Life (higher scores reflect better quality of life), NYHA: New York Heart Association, CHFQ: Chronic Heart Failure Questionnaire (higher scores reflect better quality of life)

Table 3. Summary of findings.

In-hospital heart failure quality improvement interventions compared to usual care				
Patient or population: hospitalized patients with heart failure				
Intervention: in-hospital heart failure quality improvement interventions				
Comparison: usual care				
Outcome	Effect on outcome	Number of hospitals and/or participants (studies)	Quality of the evidence (GRADE)	Comments
In-hospital mortality	Two of three trials (n = 74,735) showed no effect of the intervention on in-hospital mortality (estimated treatment effect -0.03, 95% CI -1.12, 1.05; intervention effect 1.0%, 95% CI -3.0%, 5.0%). One trial (n = 429) had lower in-hospital mortality in the intervention (5.6%, 95% CI: 2.5%, 8.7%) compared to usual care (15.4%, 95% CI: 10.5%, 20.2%).	Hospitals = 189 Participants = 75,164 (3 cluster RCTs)	⊕⊕○○ LOW ^{1,2}	The point estimates vary, and the direction of effect is not consistent. ¹ There are small number of included studies (n = 3) but with high overall sample size. ²
In-hospital medical therapy	One trial demonstrated a positive effect of the intervention towards increased in-hospital medical therapy for ACE-I (57.9% vs 40.0%) and BB (46.7% vs 10.2%) but no change in in-hospital diuretics (95.3% vs 95.8%).	Hospitals = 14 Participants = 429 (1 cluster RCTs)	⊕⊕○○ LOW ^{1,2}	Although the magnitude of sample size is high, only one study reported this outcome. ^{1,2}
Discharge medical therapy	Five out of six trials (n = 78,727) showed no effect of the intervention on discharge medical therapy for ACE-I/ARB (estimated treatment effect 0.75, 95% CI -2.66, 4.16; 3% vs 3%; 86% vs 79%; 60% vs 41.7%; intervention effect -7%, 95% CI -20%, 5%). Three out of three trials (n = 89,660) showed no effect of the intervention on discharge medical therapy for BB (estimated treatment effect 1.05, 95% CI -1.17, 3.27; 65% vs 61%; absolute difference 3.5%, 95% CI -6.1%, 13.1%).	Hospitals = 307 Participants = 96,271 (5 cluster RCTs, 1 RCT)	⊕⊕⊕○ MODERATE ¹	The direction of effect is inconsistent, and the point estimates vary across studies. ¹ Magnitude of included studies is moderate (n = 6) with high overall sample size.
Hospital readmission (up to 90 days after discharge)	Two out of three trials (n = 419) showed a trend towards decreased hospital readmissions in the intervention compared to usual care (37% vs 67%; 7% vs 19%).	Participants = 706 (3 RCTs)	⊕⊕○○ LOW ^{1,2}	The point estimates vary and the direction of effect is not consistent. ¹ There are small number of included studies (n = 3) with moderate overall sample size. ²
30-day all-cause mortality	Two out of two trials showed no effect of the intervention on 30-day all-cause mortality (7% vs 7%; absolute difference -1.1%, 95% CI -3.2%, 0.9%).	Hospitals = 86 Participants = 17,681 (1 cluster RCT, 1 RCT)	⊕⊕○○ LOW ^{1,2}	Although the direction of effect is consistent, the point estimates vary in the setting of small number of included studies (n = 2) with high overall sample size. ^{1,2}

Hospital length of stay	The mean days in the intervention ranged from 6.2 to 10.4 days and in usual care from 7.0 to 11.4 days.	Hospitals = 24 Participants = 3,335 (2 cluster RCTs)	⊕⊕○○ LOW ^{1,2}	The point estimates vary and the direction of effect is not consistent. ¹ There are small number of included studies (n = 2) with moderate overall sample size. ²
Patient-level health-related quality of life	One out of three trials (n = 282) showed a trend towards better quality of life in the intervention compared to usual care (mean change [SD] 22.1 [20.8] vs. 11.3 [16.4]).	Hospitals = 10 Participants = 3,411 (1 cluster RCT, 2 RCT)	⊕○○○ VERY LOW ^{1,2,3}	The direction of effect is not consistent ¹ in the setting of small number of included studies (n = 3). All studies likely have high risk of detection bias in use of questionnaires to assess self-reported outcomes. ³

CI: Confidence interval, ACE-I: angiotensin converting enzyme inhibitor, ARB: angiotensin receptor blocker, BB: beta-blocker

1. Downgraded due to inconsistency.
2. Downgraded due to imprecision.
3. Downgraded due to study limitations.

GRADE Working Group grades of evidence (Guyatt G, et al. BMJ 2008; 336(7650):924-926.)

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

SUPPLEMENTARY APPENDICES

Appendix 1: Inclusion criteria using PICOTSS (Patients, Interventions, Comparators, Outcomes, Timing, Setting, and Study Design) format.

Appendix 2: Search documentation details.

Appendix 3: List of excluded studies and reasons for exclusion.

Appendix 4: Characteristics of ongoing studies.

Appendix 5: Characteristics of included studies and risk of bias assessment.

Appendix 1. Inclusion criteria using PICOTSS (Patients, Interventions, Comparators, Outcomes, Timing, Setting, and Study Design) format.

Patients

- Adults \geq 18 years of age
- People with heart failure

Interventions

- In-hospital heart failure quality improvement interventions that test the effect of a variety of individual or combined interventions including but not limited to: audit and feedback reporting systems, admission and discharge checklists, chart case management, patient educational or behavioral change materials, health care quality training that are directed at the hospital system, doctors, nurses, or allied health professionals, or information management systems with the goal of being inclusive in the type and target of intervention.

Comparators

- Usual care

Outcomes:

Primary

- Rates of in-hospital mortality
- Rates of in-hospital and discharge medical therapy (combined and separate)
- Rates of hospital readmissions up to 90 days after discharge

Secondary

- Rates of 30- and 90-day all-cause mortality
- Hospital length of stay
- Uptake of quality improvement intervention components
- Rates of cardiac rehabilitation referral
- Rates of ICD placement to prevent sudden death
- Patient-level health-related quality of life using a validated instrument
- Patient-related direct costs

Timing:

- Studies of any duration

Setting:

- In-hospital

Study Design:

- Randomized and quasi-randomized (i.e. interrupted time series) clinical trials

Appendix 2. Search documentation details.

Database searched	Date searched	Results
Ovid MEDLINE(R) 1946 to January Week 4 2017	2/6/2017	803
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations November 02, 2016; Ovid MEDLINE(R) Epub Ahead of Print November 02, 2016	2/6/2017	243
Embase 1974 to present; Embase Classic 1947 to 1973 (embase.com)	2/6/2017	1,516
CINAHL with Full Text (EBSCOhost)	2/6/2017	508
Conference Proceedings Citation Index- Science (CPCI-S) --1990-present (Web of Science)	2/6/2017	28
Cochrane Database of Systematic Reviews: Issue 11 of 12, November 2016 (Cochrane Library—Wiley)	2/6/2017	31
Cochrane Central Register of Controlled Trials: Issue 10 of 12, October 2016 (Cochrane Library—Wiley)	2/6/2017	1,365
Database of Abstracts of Reviews of Effect: Issue 2 of 4, April 2015 (Cochrane Library—Wiley)	2/6/2017	32
Health Technology Assessment Database: Issue 4 of 4, October 2016 (Cochrane Library—Wiley)	2/6/2017	2
Total		4,528
After de-duplication		3,511

For the MEDLINE search, we used the McMaster multi-term filter with the best balance of sensitivity and specificity for retrieving randomized controlled trials (Haynes 2005). For EMBASE, we translated from Ovid to embase.com syntax the multi-term EMBASE filter with the best balance of sensitivity and specificity (Wong 2006). We translated from Ovid to EBSCOhost syntax the McMaster highly sensitive filter for retrieving randomized controlled trials and systematic reviews for CINAHL (Wong 2006b). For Conference Proceedings Citation Index-Science we used a modified version of the combination of terms for identifying trials from EMBASE described in the Cochrane Handbook section 6.3.2.2 (Lefebvre 2011). In addition to the filters above, we also employed search terms to capture crossover studies and interrupted time series per the review protocol. No search filters were used in the Cochrane Library databases.

Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Haynes, R. B., McKibbin, K. A., Wilczynski, N. L., Walter, S. D., & Werre, S. R. (2005). Optimal search strategies for retrieving scientifically strong studies of treatment from Medline: analytical survey. *BMJ*, 330(7501), 1179. doi: [bmj.38446.498542.8F](https://doi.org/10.1136/bmj.38446.498542.8F).

Wong, S. S., Wilczynski, N. L., & Haynes, R. B. (2006). Developing optimal search strategies for detecting clinically sound treatment studies in EMBASE. *J Med Libr Assoc*, 94(1), 41-47.

Wong, S. S., Wilczynski, N. L., & Haynes, R. B. (2006). Optimal CINAHL search strategies for identifying therapy studies and review articles. *J Nurs Scholarsh*, 38(2), 194-199.

Database search strategies

Database: Ovid MEDLINE(R) <1946 to January Week 4 2017>

Search Strategy: 2017 HFQI Medline 1

- 1 exp Heart Failure/ (101583)
- 2 ((heart or cardia* or myocardial) adj3 (failure or insufficienc* or decompensat*)).tw. (136258)
- 3 1 or 2 (165308)
- 4 "Outcome and Process Assessment (Health Care)"/ (23601)
- 5 "Outcome Assessment (Health Care)"/ (58639)
- 6 (outcome* adj3 assessment*).tw. (10333)
- 7 "Process Assessment (Health Care)"/ (3697)
- 8 (process* adj3 assessment*).tw. (4811)
- 9 "Quality of Health Care"/ (63837)
- 10 Quality Assurance, Health Care/ (52835)
- 11 quality assurance.tw. (19379)
- 12 Quality Improvement/ (12859)
- 13 quality improvement.tw. (19028)
- 14 (improvement adj intervention*).tw. (842)
- 15 (improvement adj program*).tw. (3889)
- 16 (improvement adj initiative*).tw. (1923)
- 17 (process* adj improvement).tw. (1130)
- 18 Quality Indicators, Health Care/ (12658)
- 19 quality indicator*.tw. (4874)
- 20 Management Quality Circles/ (1222)
- 21 quality circle*.tw. (330)
- 22 Reminder Systems/ (2869)
- 23 reminder*.tw. (8007)
- 24 Total Quality Management/ (12175)
- 25 (total quality management or tqm or six sigma*).tw. (1504)
- 26 Program Evaluation/ (53646)
- 27 (program* adj3 effectiveness).tw. (4284)
- 28 (program* adj3 evaluation*).tw. (9138)
- 29 Checklist/ (4085)
- 30 (checklist* or check list*).tw. (25043)
- 31 exp Patient Education as Topic/ (77408)
- 32 patient education.tw. (12457)
- 33 Health Education/ (56384)
- 34 exp Consumer Health Information/ (5796)
- 35 Critical Pathways/ (5542)
- 36 critical pathway*.tw. (1210)
- 37 clinical pathway*.tw. (2195)
- 38 care pathway*.tw. (2075)
- 39 Education, Medical, Continuing/ (23116)
- 40 (continuing adj2 education).tw. (16408)
- 41 exp Inservice Training/ (26940)
- 42 (inservice or in service).tw. (6205)
- 43 (staff adj3 train*).tw. (7403)
- 44 Guideline Adherence/ (25924)
- 45 Clinical Competence/ (76943)

- 46 Peer Review, Health Care/ (1362)
- 47 Medical Audit/ (15933)
- 48 (audit adj3 feedback).tw. (722)
- 49 or/4-48 (611127)
- 50 randomized controlled trial.pt. or randomized.mp. or placebo.mp. (698369)
- 51 Interrupted Time Series Analysis/ (236)
- 52 interrupted time series.tw. (1395)
- 53 cross-over studies/ (40687)
- 54 (crossover or cross-over).tw. (62759)
- 55 or/50-54 (721030)
- 56 3 and 49 (5557)
- 57 55 and 56 (803)

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 03, 2017>, Ovid MEDLINE(R) Epub Ahead of Print <February 03, 2017>
 Search Strategy: 2017 HFQI Medline 1

-
- 1 exp Heart Failure/ (0)
 - 2 ((heart or cardia* or myocardial) adj3 (failure or insufficienc* or decompensat*)).tw. (14796)
 - 3 1 or 2 (14796)
 - 4 "Outcome and Process Assessment (Health Care)"/ (0)
 - 5 "Outcome Assessment (Health Care)"/ (0)
 - 6 (outcome* adj3 assessment*).tw. (1537)
 - 7 "Process Assessment (Health Care)"/ (0)
 - 8 (process* adj3 assessment*).tw. (773)
 - 9 "Quality of Health Care"/ (0)
 - 10 Quality Assurance, Health Care/ (0)
 - 11 quality assurance.tw. (2259)
 - 12 Quality Improvement/ (0)
 - 13 quality improvement.tw. (4140)
 - 14 (improvement adj intervention*).tw. (178)
 - 15 (improvement adj program*).tw. (1016)
 - 16 (improvement adj initiative*).tw. (464)
 - 17 (process* adj improvement).tw. (192)
 - 18 Quality Indicators, Health Care/ (0)
 - 19 quality indicator*.tw. (947)
 - 20 Management Quality Circles/ (0)
 - 21 quality circle*.tw. (17)
 - 22 Reminder Systems/ (0)
 - 23 reminder*.tw. (1489)
 - 24 Total Quality Management/ (0)
 - 25 (total quality management or tqm or six sigma*).tw. (127)
 - 26 Program Evaluation/ (0)
 - 27 (program* adj3 effectiveness).tw. (659)
 - 28 (program* adj3 evaluation*).tw. (1225)
 - 29 Checklist/ (0)
 - 30 (checklist* or check list*).tw. (4898)
 - 31 exp Patient Education as Topic/ (0)
 - 32 patient education.tw. (1694)

- 33 Health Education/ (0)
- 34 exp Consumer Health Information/ (0)
- 35 Critical Pathways/ (0)
- 36 critical pathway*.tw. (171)
- 37 clinical pathway*.tw. (392)
- 38 care pathway*.tw. (585)
- 39 Education, Medical, Continuing/ (0)
- 40 (continuing adj2 education).tw. (1488)
- 41 exp Inservice Training/ (0)
- 42 (inservice or in service).tw. (918)
- 43 (staff adj3 train*).tw. (1245)
- 44 Guideline Adherence/ (0)
- 45 Clinical Competence/ (0)
- 46 Peer Review, Health Care/ (0)
- 47 Medical Audit/ (0)
- 48 (audit adj3 feedback).tw. (170)
- 49 or/4-48 (23766)
- 50 3 and 49 (243)

Trials Registers

ClinicalTrials.gov

<https://clinicaltrials.gov/ct2/home>

Search Date: 2/13/2017

Due to character limits in ClinicalTrials.gov, we had to break up the ClinicalTrials.gov search into 3 segments and then merge the results into a single Excel spreadsheet. A total of 139 records were retrieved from the 3 searches. **After de-duplication and removal of records with non-interventional study types, 102 records remained.** Here are the 3 searches:

("heart failure") AND ("quality improvement" OR "quality assessment" OR "outcome assessment" OR

"process assessment" OR "quality assurance" OR "improvement intervention" OR "improvement program" OR "improvement initiative" OR "quality indicator")

<https://goo.gl/xZ8hAx>

Search Date: 2/13/2017

26 Results

("heart failure") AND ("quality circle" OR "reminder system" OR "total quality management" OR

"program evaluation" OR "program effectiveness" OR checklist OR "patient education" OR "health education" OR "consumer health")

<https://goo.gl/XOTGSP>

Search Date: 2/13/2017

79 Results

("heart failure") AND ("critical pathway" OR "clinical pathway" OR "care pathway" OR inservice OR "guideline adherence" OR audit)

<https://goo.gl/CT7X8H>

Search Date: 2/13/2017

34 Results

Appendix 3. List of excluded studies and reasons for exclusion.

Study	Reason for exclusion
Abstracts of the Society of General Internal Medicine 33rd Annual Meeting. Minneapolis, Minnesota, USA. April 28-May 1, 2010. <i>Journal of General Internal Medicine</i> . 2010;25 Suppl 3:S205-567.	Abstract only
The T.O.S.C.A. project: Research, education and care. 2011. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/446/CN-01196446/frame.html .	Abstract only
Abstracts of EuroHeartCare 2013. March 22-23, 2013. Glasgow, Scotland, United Kingdom. <i>European Journal of Cardiovascular Nursing</i> . 2013;12 Suppl 1:S1-84.	Abstract only
Agarwal KS, Kazim R, Xu J, Borson S, Taffet GE. Unrecognized cognitive impairment and its effect on heart failure readmissions of elderly adults. <i>Journal of the American Geriatrics Society</i> . 2016;64(11):2296-2301.	Wrong study design
Albanese M, Bulfoni A, Rossi P, et al. The SCOOP II trial in heart failure. 2001;2(4):390-395. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/305/CN-00699305/frame.html .	Wrong setting
Albert NM, Buchsbaum R, Li J. Randomized study of the effect of video education on heart failure healthcare utilization, symptoms, and self-care behaviors. <i>Patient Education and Counseling</i> . 2007;69(1-3):129-139.	Wrong study design
Albert NM, Fonarow GC, Abraham WT, et al. Predictors of delivery of hospital-based heart failure patient education: a report from OPTIMIZE-HF. <i>Journal of Cardiac Failure</i> . 2007;13(3):189-198.	Wrong study design
Amarasingham R, Patel PC, Toto K, et al. Allocating scarce resources in real-time to reduce heart failure readmissions: a prospective, controlled study. <i>BMJ Quality & Safety</i> . 2013;22(12):998-1005.	Wrong intervention
Ansari M, Shlipak MG, Heidenreich PA, et al. Improving guideline adherence: a randomized trial evaluating strategies to increase β -blocker use in heart failure. <i>Circulation</i> . 2003;107(22):2799-2804.	Wrong setting
Assyag P, Renaud T, Cohen-Solal A, et al. RESICARD: East Paris network for the management of heart failure: absence of effect on mortality and rehospitalization in patients with severe heart failure admitted following severe decompensation. <i>Archives of Cardiovascular Diseases</i> . 2009;102(1):29-41.	Wrong study design
Baker DW, Dewalt DA, Schillinger D, et al. The effect of progressive, reinforcing telephone education and counseling versus brief educational intervention on knowledge, self-care behaviors and heart failure symptoms. <i>Journal of Cardiac Failure</i> . 2011;17(10):789-796.	Wrong study design
Banerjee D, Thompson C, Kell C, et al. An informatics-based approach to reducing heart failure all-cause readmissions: the Stanford heart failure dashboard. <i>Journal of the American Medical Informatics Association</i> . 2016;23:23.	Wrong study design
Basoor A, Cotant J, Patel K, Choksi N, Halabi A, DeGregorio M. Decreased readmissions and improved quality of care with use of	Wrong study design

inexpensive checklist in heart failure. <i>Journal of the American College of Cardiology</i> . 2012;59(13):E1026.	
Basoor A, Doshi NC, Cotant JF, et al. Decreased readmissions and improved quality of care with the use of an inexpensive checklist in heart failure. <i>Congestive Heart Failure</i> . 2013;19(4):200-206.	Duplicate Wrong study design
Basoor A, Saleh T, Cotant JF, et al. Effect of quality improvement discharge tool in heart failure. <i>Circulation: Cardiovascular Quality and Outcomes</i> . 2011;4(6).	Duplicate Wrong study design
Bekelman D, Plomondon M, Carey E, et al. Primary Results of the Patient-Centered Disease Management (PCDM) for Heart Failure Study: A Randomized Clinical Trial. 2015;175(5):725-732. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/212/CN-01075212/frame.html .	Wrong setting
Bell SP, Schnipper JL, Goggins K, et al. Effect of pharmacist counseling intervention on health care utilization following hospital discharge: A randomized control trial. <i>Journal of General Internal Medicine</i> . 2016;31(5):470-477.	Wrong intervention
Blue L, Lang E, McMurray JJV, et al. Randomized controlled trial of specialist nurse intervention in heart failure. <i>BMJ: British Medical Journal (International Edition)</i> . 2001;323(7315):715-718.	Wrong setting
Bouvy ML, Heerdink ER, Urquhart J, Grobbee DE, Hoes AW, Leufkens HG. Effect of a pharmacist-led intervention on diuretic compliance in heart failure patients: a randomized controlled study.[Erratum appears in J Card Fail. 2003 Dec;9(6):481 Note: Hoe Arno W [corrected to Hoes Arno W]]. <i>Journal of Cardiac Failure</i> . 2003;9(5):404-411.	Wrong setting
Boyde M, Turner C, Thompson DR, Stewart S. Educational interventions for patients with heart failure: a systematic review of randomized controlled trials. <i>Journal of Cardiovascular Nursing</i> . 2011;26(4):E27-35.	Wrong study design
Brodie DA, Inoue A, Shaw DG. Motivational interviewing to change quality of life for people with chronic heart failure: a randomised controlled trial. <i>International Journal of Nursing Studies</i> . 2008;45(4):489-500.	Wrong setting
Brown MM, Mack KM, Guzetta CE, Tefera E. The feasibility of using teach-back to reinforce discharge instructions and its influence on the number of 30-day readmissions of heart failure patients. <i>Heart and Lung</i> . 2014;43(4):379.	Abstract only
Bull MJ, Hansen HE, Gross CR. A professional-patient partnership model of discharge planning with elders hospitalized with heart failure. <i>Applied Nursing Research</i> . 2000;13(1):19-28.	Wrong study design
Carlisle AJ, Vader JM, Sudarshan S, Novak E, Ewald GA. A simple provider education tool improves heart failure knowledge and discharge process measures. <i>Journal of Cardiac Failure</i> . 2014;20(8):S115.	Abstract only
Cavusoglu Y, Zoghi M, Eren M, et al. Does cardiologist lead enhanced heart failure education and follow-up program affect cardiovascular mortality rate?: Hit-point. <i>Circulation</i> . 2013;128(22).	Wrong setting
Costantini O, Huck K, Carlson M, et al. Impact of a guideline-based disease management team on outcomes of hospitalized patients with congestive heart failure. 2001;161(2):177-182.	Wrong study design

http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/579/CN-00497579/frame.html .	
Coutance G, Belin A, Biannic C, et al. Educative telemedicine reduces the severity of rehospitalizations for acute heart failure in an elderly population: Post-hoc analysis of SEDIC study. <i>European Journal of Heart Failure</i> . 2013;12:S144.	Wrong study design
Cruz F, Issa VS, Ayub-Ferreira SM, et al. Effect of a sequential education and monitoring programme on quality-of-life components in heart failure. <i>European Journal of Heart Failure</i> . 2010;12(9):1009-1015.	Wrong setting
Davis KK, Mintzer M, Dennison Himmelfarb CR, Hayat MJ, Rotman S, Allen J. Targeted intervention improves knowledge but not self-care or readmissions in heart failure patients with mild cognitive impairment. <i>European Journal of Heart Failure</i> . 2012;14(9):1041-1049.	Wrong intervention
DeBusk RF, Miller NH, Parker KM, et al. Improving patient care. Care management for low-risk patients with heart failure: a randomized, controlled trial. <i>Annals of Internal Medicine</i> . 2004;141(8):606-658.	Wrong setting
Drozda JP, Jr., Smith DA, Freiman PC, Pursley J, VanSlette JA, Smith TR. Heart failure readmission reduction: Outcomes of a quality improvement initiative implemented by St. John's Physician Group practice demonstration. <i>American Journal of Medical Quality</i> . 2016;30:30.	Wrong setting
Filardo G, Nicewander D, Herrin J, et al. A hospital-randomized controlled trial of a formal quality improvement educational program in rural and small community Texas hospitals: one year results. <i>International Journal for Quality in Health Care</i> . 2009;21(4):225-232.	Wrong intervention
Gattis WA, Hasselblad V, Whellan DJ, O'Connor CM. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team: results of the Pharmacist in Heart Failure Assessment Recommendation and Monitoring (PHARM) Study. <i>Archives of Internal Medicine</i> . 1999;159(16):1939-1945.	Wrong setting
Granger B, Ekman I, Hernandez A, et al. Results of the chronic heart failure intervention to improve medication adherence study: A randomized intervention in high-risk patients. 2015;169(4):539-548. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/570/CN-01070570/frame.html .	Wrong intervention
Harrison MB, Browne GB, Roberts J, Tugwell P, Gafni A, Graham ID. Quality of life of individuals with heart failure: a randomized trial of the effectiveness of two models of hospital-to-home transition. <i>Medical Care</i> . 2002;40(4):271-282.	Wrong intervention
Israel EN, Farley TM, Farris KB, Carter BL. Underutilization of cardiovascular medications: Effect of a continuity-of-care program. <i>American Journal of Health-System Pharmacy</i> . 2013;70(18):1592-1600.	Wrong study design
Jackevicius CA, Alter D, Cox J, et al. Acute treatment of myocardial infarction in Canada 1999-2002. <i>The Canadian journal of cardiology</i> . 2005;21(2):145-152.	Wrong patient population
Kakutani N, Fukushima A, Nakamura R, et al. Critical pathway for elderly patients with heart failure based on physical activity reduces length of hospital stay. <i>Circulation</i> . 2014;130:A11606.	Abstract only

Kimmelstiel C, Levine D, Perry K, et al. Randomized, controlled evaluation of short- and long-term benefits of heart failure disease management within a diverse provider network: the SPAN-CHF trial. <i>Circulation</i> . 2004;110(11):1450-1455.	Wrong setting
Koberich S, Lohrmann C, Mittag O, Dassen T. Effects of a hospital-based education programme on self-care behaviour, care dependency and quality of life in patients with heart failure--a randomised controlled trial. <i>Journal of Clinical Nursing</i> . 2015;24(11-12):1643-1655.	Wrong setting
LaPointe NM, DeLong ER, Chen A, et al. Multifaceted intervention to promote beta-blocker use in heart failure. <i>American Heart Journal</i> . 2006;151(5):992-998.	Wrong study design
Lee DS, Austin PC, Rouleau JL, Liu PP, Naimark D, Tu JV. Predicting mortality among patients hospitalized for heart failure: derivation and validation of a clinical model. <i>JAMA</i> . 2003;290(19):2581-2587.	Wrong study design
Li X, Chen C, You GY, Zhang Q. Post-discharge text messaging intervention improved clinical outcomes in patients with heart failure. <i>European Heart Journal</i> . 2016;37:727-728.	Wrong setting
Matthews J, Johnson M, Koelling T. The impact of patient-specific quality-of-care report cards on guideline adherence in heart failure. 2007;154(6):1174-1183. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/231/CN-00621231/frame.html .	Wrong setting
McCarren M, Furmaga E, Jackevicius C, et al. Improvement of guideline B-blocker prescribing in heart failure: a cluster-randomized pragmatic trial of a pharmacy intervention. 2013;19(8):525-532. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/218/CN-01122218/frame.html .	Wrong setting
Nucifora G, Albanese MC, De Biaggio P, et al. Lack of improvement of clinical outcomes by a low-cost, hospital-based heart failure management programme. <i>Journal of Cardiovascular Medicine (Hagerstown)</i> . 2006;7(8):614-622.	Wrong intervention
Reilly K, West E, Jung S, Friedberg JP, Natarajan S. A multicomponent transitional care intervention to improve clinical outcomes among patients being discharged after a heart failure admission: A pilot randomized clinical trial. <i>Journal of General Internal Medicine</i> . 2016;31(2):S99.	Wrong intervention
Sahay A, Heidenreich PA. Facilitation of the va hospital-to-home initiative to reduce readmissions for heart failure patients: CHF QUERI. <i>Circulation: Cardiovascular Quality and Outcomes</i> . 2011;4(6).	Wrong intervention
Trofimov E, Poskrebysheva A, Gurskaya A, Novikova A. Therapeutic education for patients with heart failure: Effect on medication adherence and clinical outcomes. 2015;17:294. http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/723/CN-01088723/frame.html .	Wrong intervention
Tsuyuki RT, Fradette M, Johnson JA, et al. A multicenter disease management program for hospitalized patients with heart failure. <i>Journal of Cardiac Failure</i> . 2004;10(6):473-480.	Wrong study design
Vinluan CM, Wittman D, Morisky D. Effect of pharmacist discharge counselling on medication adherence in elderly heart failure patients: A	Wrong intervention

pilot study. <i>Journal of Pharmaceutical Health Services Research</i> . 2015;6(2):103-110.	
Wang SP, Lin LC, Lee CM, Wu SC. Effectiveness of a self-care program in improving symptom distress and quality of life in congestive heart failure patients: a preliminary study. <i>Journal of Nursing Research</i> . 2011;19(4):257-266.	Wrong setting
Yu M. The effectiveness of a heart failure disease management programme on clinical outcomes, <i>Health-related Quality of Life, and Psychological Status of Patients with Heart Failure in China</i> , Chinese University of Hong Kong (Hong Kong); 2011.	Wrong study design

Appendix 4. Characteristics of ongoing studies.

DeVore A. Care optimization through patient and hospital engagement clinical trial for heart failure (CONNECT-HF). *Clinicaltrials.gov* NCT03035474.
<https://clinicaltrials.gov/show/NCT03035474>

DeVore (estimated n = 8,000 participants): Study characteristics.

	Description
Population description	Patients hospitalized with acute HF and reduced ejection fraction
Inclusion criteria	<ul style="list-style-type: none"> • Age ≥ 18 years • Acute HF as the primary cause of hospitalization and a previous clinical diagnosis of HF • LVEF ≤ 40% based on last local measurement using echocardiography, multi-gated acquisition scan, computed tomography scanning, magnetic resonance imaging, or ventricular angiography • Planned discharge to home or other supported care facility where patients are individually responsible for medication management
Exclusion criteria	<ul style="list-style-type: none"> • Prior heart transplant or current/planned left ventricular assistance device • Chronic kidney disease requiring dialysis • Terminal illness other than HF, such as malignancy, or with a life expectancy of less than 1 year as determined by the enrolling clinician-investigator • Unable to use mobile applications or participate in longitudinal follow-up, such as plans to move outside the US in the following year
Description of intervention	<p>Two QI initiatives evaluated in this randomized factorial assignment trial are:</p> <ul style="list-style-type: none"> • A health-system engagement strategy (direct) that will involve site visits and ongoing mentoring from teams of healthcare professionals with specialized training and field experience to help health systems and individual hospitals to design local quality improvement plans • A participant engagement strategy (digital) or mobile applications utilizing behavioral tools to reinforce health behaviors, including self-monitoring/self-management and medication adherence
Description of comparison	Usual care
Primary outcomes	Time-to-first HF re-hospitalization or death during the 12-months after discharge Improvement in an opportunity-based composite score of adherence to quality metrics for HF
Secondary outcomes	Improvement in an opportunity-based composite score for adherence to site-level HF discharge quality measures Participant-level healthcare expenditures at 6 months and 1-year post-discharge
Estimated study completion	July 2020

Pascual CR, Galan EP, Guerrero JL, et al. Rationale and methods of the multicenter randomised trial of a heart failure management programme among geriatric patients (HF-Geriatrics). *BMC Public Health*. 2011;11:627.
Clinicaltrials.gov NCT01076465

Pascual (estimated n = 700 participants): Study characteristics.

	Description
Population description	Patients with heart failure, aged over 75 years, admitted to the acute-care units of the Geriatrics Departments in 8 hospitals in Spain
Inclusion criteria	<ul style="list-style-type: none"> • Age ≥ 75 years • Co-morbidity or dependency. At least one of the following criteria: Charlson index >3, dependency in 2 or more basic activities of daily living, treatment with 5 or more drugs, urgent hospitalization in the last 3 months, three or more diseases with active treatment, limitation in daily living because of vision or hearing impairment, cognition deficit, Parkinson disease, diabetes mellitus, chronic obstructive lung disease, severe anemia, constitutional syndrome • Hospital admission with a main diagnosis of heart failure (according to the criteria of the European Society of Cardiology or Framingham criteria) in NYHA functional class II-IV
Exclusion criteria	<ul style="list-style-type: none"> • Participation refusal • Terminal illness • Cognitive decline or severe cognitive deficit, which does not permit a minimum knowledge of the disease, or lack of carers which give consent to study participation • Clinical instability as assessed with the Kosecof index • Being in waiting list for organ transplant or cardiac surgery • Inability to be followed-up because of other reasons (i.e. change of place of residence) • Institutionalization
Description of intervention	Disease Management Programme with three main components: <ul style="list-style-type: none"> • Patient education to improve disease knowledge and self-care • Monitoring of clinical status • Therapeutic adherence
Description of comparison	Usual care
Primary outcomes	Mortality or readmission over one year
Secondary outcomes	Health related quality of life over one year
Estimated study completion	November 2013, methods manuscript published in <i>BMC Public Health</i> in 2011. Principal investigator contacted regarding trial results with no response.

Appendix 5. Characteristics of included studies and risk of bias assessment.

Cline 1998 (n = 190 participants): Study characteristics.

	Description
Population description	Patients aged 65-84 years hospitalized for heart failure between December 1991 and October 1993 at Malmö University Hospital in Sweden
Inclusion criteria	Patients aged 65-84 years hospitalized for heart failure between December 1991 and October 1993 at Malmö University Hospital in Sweden
Exclusion criteria	<p>Exclusion criteria:</p> <ul style="list-style-type: none"> • The presence of other serious disease that either prevented participation or was expected to significantly influence quality of life, morbidity, or mortality in the following year • Foreseeable follow up problems such as residence outside the hospital catchment area, serious alcohol or drug abuse, or psychiatric disease • Inability to understand or answer the study questionnaires • Participation in another clinical trial • Discretion of the treating physician
Description of intervention	<p>Education program for patients and families on heart failure (two 30-minute visits by nurse during hospitalization, one-hour information visits for patients and families two weeks after discharge)</p> <p>Seven-day medication organizer</p> <p>Patients received guidelines for self-management of diuretics and patient diary to record symptoms</p> <p>Follow-up at a nurse directed, outpatient clinic</p>
Description of comparison	Usual care
Age (years), mean (SD)	Control: 76.0 (5.3) years Intervention: 75.1 (5.1) years
Sex, % women	Control: 48.2% Intervention: 45.0%
LVEF (%), mean (SD)	Control: 35.7 (12.3) % Intervention: 31.6 (8.4) %

Cline 1998 (n = 190 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Eligible patients were randomized by computer generated allocation".
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	The authors do not state details of the allocation sequence.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Both participants and personnel were aware of the participant being in the intervention arm.
Blinding of outcome assessment <i>(detection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Blinding of outcome assessors is not explicitly stated; however, the outcomes are objective and obtained from the electronic health record. "Clinical assessment and registration of sociodemographic data were pre-specified and followed a set protocol. Data on hospitalization and outpatient visits after randomization were collected prospectively using questionnaires and hospital records. Data on hospitalization before randomization were collected retrospectively from hospital records."
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Outcomes at one year presented for all survivors. "Patients were followed up for one year. All patients were accounted for and deaths were verified by hospital records or death certificates."
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper or registration on clinicaltrials.gov
Other bias	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Recruitment bias from 16 patients who were initially randomized but did not give consent to participate in the study. "A total of 206 eligible patients were randomized. Randomized consent was withheld by 16 patients (8%) randomized to the intervention group and by none randomized to the control group."

DeVore 2015 (n = 165 hospitals randomized; 71,829 participants analyzed): Study characteristics.

	Description
Population description	Hospitals participating in the Get With The Guidelines Heart Failure (GWTG-HF) program treating hospitalized patients with heart failure
Inclusion criteria	All sites participating in GWTG-HF that had at least 30 patient records for the preceding 12 months and at least 1 admission per quarter.
Exclusion criteria	Sites in GWTG-HF which opt out of participation
Description of intervention	Personalized quality improvement reports pushed directly to the site by email each quarter, tailored teleconferences, webinars and specialized tool kits (patient instructions, order set templates). The personalized quality improvement reports described the site's heart failure population compared with other GWTG-HF hospitals, highlighted performance on GWTG-HF achievement measures/quality metrics, and suggested process improvement targets based on site trends. Quality improvement webinars were conducted by a study coordinator and clinician designed to provide education on the personalized quality improvement reports, and provide a forum for quality improvement leaders to share successful improvement strategies. The lowest performing hospitals were targeted with additional phone calls and webinars.
Description of comparison	The control hospitals continued to receive access to the usual on-demand reports, GWTG-HF quality improvement tools, and publicly available GWTG-HF webinars. These reports continued to be available on request but were not actively pushed to the sites on a routine basis. These reports also focused on composite and specific metrics based on recommendations from the 2006 American College of Cardiology/American Heart Association Clinical Performance Measures (evaluation of left ventricular systolic function, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker use, anticoagulants use for patients with atrial fibrillation, discharge instructions, and smoking cessation).
Age (years), median (IQR)	Control: 74 (62-83) years Intervention: 75 (63-84) years
Sex, % women	Control 48.8% Intervention: 48.3%
LVEF (%), median (IQR)	Control: 40 (25-55) % Intervention: 40 (25-55) %

DeVore 2015 (n = 165 hospitals randomized; 71,829 participants analyzed): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Hospitals were randomized on a 1:1 basis to the control or intervention arm."
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Details regarding allocation sequence concealment not provided.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	The hospitals in the intervention arm received personalized quality improvement reports and were aware of being in the intervention arm.
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Objective outcomes abstracted from the chart. Unclear if the outcome assessor/abstractor was blinded but likelihood of bias low due to objective outcomes.
Incomplete outcome data <i>(attrition bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>There was missing outcome data but amount and distribution of incomplete outcome data across intervention groups is unclear. Authors imputed missing data to account for missingness though missingness not likely completely at random.</p> <p>"Some sites did not have patients eligible for each measure in every quarter. For these sites, we imputed missing data using multiple imputation involving treatment group and all measures in all 6 study period quarters. We imputed all measures, including the composite, at once. Twenty imputations were performed with a maximum number of iterations set at 25 000. We assumed that the missing data pattern was missing completely at random, and Markov chain Monte Carlo methods with ridge priors were used."</p>
Selective outcome reporting? <i>(reporting bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Outcomes match pre-specified outcomes in clinicaltrials.gov and entry completed prior to enrolment of first participant.

Hayes 2002 (n = 32 hospitals; 3,276 participants eligible): Study characteristics.

	Description
Population description	Hospitals in the states of Colorado, Connecticut, Georgia and Oklahoma that had discharged at least 50 Medicare patients with a primary diagnosis of CHF during the period of January 1, 1996 through June 30, 1996, as indicated by Medicare claims data, were eligible to participate in the study.
Inclusion criteria	See above.
Exclusion criteria	Patients were excluded if they had left the hospital against medical advice, had been transferred to another facility, or died in the hospital. Additionally, patients were excluded if they had a diagnosis of valvular heart disease, acute myocardial infarction, cor pulmonale, chronic obstructive pulmonary disease requiring home oxygen, chronic renal failure, or heart failure attributed to thiamine deficiency, amyloidosis, or thyrotoxicosis.
Description of intervention	<p>High intensity intervention: written materials below were disseminated under conditions believed to promote more effective feedback (i.e. face-to-face presentations by a credible role model)</p> <ul style="list-style-type: none"> • A copy of the AHCPR Heart Failure Guidelines • Hospital-specific feedback • An executive summary with information regarding statewide and multistate HF practice patterns • A copy of the data collection tool and instructions • A sample quality improvement plan • References for articles supporting the guidelines <p>Additional quality improvement tools provided to the hospital sites:</p> <ul style="list-style-type: none"> • Educational slide show on HF guidelines • Chart reminder system to reinforce target dosing of ACE-I • Monthly newspaper discussing management of HF • A protocol designed to improve echocardiography reporting so that patients' left ventricular systolic function is more clearly identified
Description of comparison	<p>Low intensity intervention group received a mailed package of written materials including:</p> <ul style="list-style-type: none"> • A copy of the AHCPR Heart Failure Guidelines • Hospital-specific feedback • An executive summary with information regarding statewide and multistate HF practice patterns • A copy of the data collection tool and instructions • A sample quality improvement plan • References for articles supporting the guidelines
Age (years), median (IQR)	Not reported
Sex, % women	Not reported
LVEF (%), median (IQR)	Not reported

Hayes 2002 (n = 32 hospitals; 3,276 participants eligible): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Insufficient description of random sequence generation to assess risk of bias. "Hospitals were stratified by bed size and location (urban or rural) and then randomly assigned to either low intensity intervention or high-intensity intervention."
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Not reported
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Personnel were aware of being in the high-intensity intervention as the site received additional quality improvement activities.
Blinding of outcome assessment <i>(detection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Assessed outcomes are objective and abstracted from electronic medical records. Abstractors were trained by following a standardized abstractor training protocol who then collected data from the study subjects' medical records. A formal assessment of interrater reliability was conducted with Kappa values 0.81 to 0.92.
Incomplete outcome data <i>(attrition bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	At the hospital level, outcome data available for 32 hospitals randomized suggesting low risk of bias. At the patient level, there were 3,276 eligible patients in the participating hospitals over the study period and ultimately 2,365 patients were included in the analysis after exclusions suggesting higher risk of bias. "We excluded 71 (2%) patients with incomplete charts, 4 (0.1%) patients who were transferred to another acute care facility, 2 (0.1%) patients who died during hospitalization, and 114 (3%) patients aged less than 65 years. We also excluded 720 patients with 1 or more of the following medical conditions: cor pulmonale or chronic obstructive pulmonary disease requiring home oxygen (n = 359), aortic stenosis (n = 227), chronic renal failure on dialysis (n = 57), AMI (n = 41), mitral stenosis (n = 40), and heart failure attributed to thyrotoxicosis (n = 8) and amyloidosis (n = 2)."
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov

Heidenreich 2005* (n = 600 participants): Study characteristics.

	Description
Population description	Patients undergoing echocardiography at 1 of 3 echocardiography laboratories in the Veterans Affairs Palo Alto Health Care System in California, United States. The study population included both inpatients and outpatients.
Inclusion criteria	"Patients undergoing echocardiography at 1 of 3 echocardiography laboratories in the Veterans Administration Palo Alto Health Care System were eligible if they had an ejection fraction 40%, as determined by the attending echocardiographer."
Exclusion criteria	"Patients were not eligible if they had a mean aortic valve gradient of 20 mm Hg or greater, mitral stenosis with a mean gradient of 5 mm Hg or greater, or any left ventricular outflow tract obstruction."
Description of intervention	"Echocardiography reports randomized to the reminder included the following statement: 'Note: Patients with ejection fraction 40% have a survival benefit with ACE inhibitors (goal dose lisinopril or fosinopril 30-40 mg/day).' The drug examples were chosen because these are the long-acting ACE inhibitors available on the Veterans Administration Palo Alto Health Care System formulary. The high goal dose was chosen for the reminder to match goal doses used when randomized trials of ACE inhibitors have demonstrated improved survival benefit."
Description of comparison	Usual care (no reminder)
Age (years), mean (SD)	Control: 67 (12) years Intervention: 68 (11) years
Sex, % women	Control 1% Intervention: 1%
LVEF (%), mean (SD)	Control: 29 (7) % Intervention: 28 (7) %

*Disaggregated data for hospitalized patients with HF not available.

Heidenreich 2005 (n = 600 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement (include direct quotes where available with explanatory comments)
Random sequence generation (<i>selection bias</i>)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Patient selection and randomization were computerized and performed in conjunction with the generation of the echocardiography report using an electronic database. Patients who met study criteria were randomized using a computerized random number generator either to have a reminder attached to their report or not to have a reminder."
Allocation concealment (<i>selection bias</i>)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Allocation was concealed from all echocardiographers until the reminder appeared in the report."
Blinding of participants and personnel (<i>performance bias</i>)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Primary author contacted who stated the study design was similar to Heidenreich 2007 in which the "implementation process (identification of patients, determination of eligibility, randomization, and addition of reminder) was entirely computerized, occurring within 3 seconds of report approval and invisible to the attending echocardiographer."
Blinding of outcome assessment (<i>detection bias</i>)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Medication data was abstracted from the electronic medical record; however, it is unclear whether the outcome assessors were blinded. "Medication use was determined from review of inpatient or outpatient encounters closest to 6 months (and between 2 and 9 months) following randomization."
Incomplete outcome data (<i>attrition bias</i>)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	"Patients were excluded from analysis if they were already on a moderate or greater dose of an ACE inhibitor or an appropriate alternative at the time of randomization (n = 201), died within 2 months of the echocardiogram (n = 46), left the Veterans Administration health care system (n = 71), or had an allergy or adverse reaction to ACE inhibitors (n = 5)."
Selective outcome reporting? (<i>reporting bias</i>)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov.

Heidenreich 2007* (n = 1,546 participants): Study characteristics.

	Description
Population description	Patients undergoing echocardiography between May 2001 and November 2005 at 1 of 3 echocardiography laboratories in the Veterans Affairs Palo Alto Health Care System in California, United States. The study population included both inpatients and outpatients.
Inclusion criteria	"Patients undergoing echocardiography between May 2001 and November 2005 at 1 of 3 echocardiography laboratories in the Veterans Affairs (VA) Palo Alto Health Care System were eligible if they had an LVEF 45% as determined by the attending echocardiographer."
Exclusion criteria	Patients were excluded if they had aortic stenosis with a mean aortic valve gradient of 20 mmHg or mitral stenosis with a mean gradient of 5 mmHg.
Description of intervention	"Echocardiography reports randomized to the reminder included the following statement: 'Note: Patients with reduced left ventricular ejection fraction have a survival benefit with beta-blockers (initial dose: carvedilol 3.125 mg BID or metoprolol succinate 12.5 mg BID).' The drug examples were chosen because they are the blockers known to improve survival and are available on the VA Palo Alto Health Care System formulary. The reminder also recommended cardiology follow-up if the patient had New York Heart Association class III or IV symptoms."
Description of comparison	Usual care (no reminder)
Age (years), mean (SD)	Control: 69 (12) years Intervention: 69 (11) years
Sex, % women	Control 2.5% Intervention: 1.0%
LVEF (%), mean (SD)	Control: 32.4 (6.9) % Intervention: 32.8 (7.5) %

*Disaggregated data for hospitalized patients with HF not available.

Heidenreich 2007 (n = 1,546 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Randomization was carried out in conjunction with the formation of the echocardiography report with an electronic database (Microsoft Access, Microsoft Corp, Redmond, Wash). In the process of printing the completed report, the computer algorithm checked the electronic report for eligibility and exclusion criteria. Patients meeting study criteria were randomized with a computerized random-number generator either to have a reminder attached to their report or to have no reminder. Randomization was performed separately at each site."
Allocation concealment <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Allocation was concealed from all echocardiographers until the reminder appeared in the report."
Blinding of participants and personnel <i>(performance bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"The implementation process (identification of patients, determination of eligibility, randomization, and addition of reminder) was entirely computerized, occurring within 3 seconds of report approval and invisible to the attending echocardiographer."
Blinding of outcome assessment <i>(detection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Outcomes abstracted from the VA pharmacy database. Outcomes (prescription of beta-blocker) objective and hence, overall risk of bias from outcome assessment likely low.
Incomplete outcome data <i>(attrition bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Approximately 18% of initially randomized participants were excluded from the analysis. "Patients were excluded from analysis if they died within 1 month of the echocardiogram (n = 89), left the healthcare system (n = 180; defined as no prescriptions after the echocardiogram), or had echocardiography at 1 site and were randomized to different groups (n = 6)."
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Reported outcomes match pre-specified outcomes listed on clinicaltrials.gov; however, study protocol registered on clinicaltrials.gov after study was completed.

Kato 2016 (n = 38 participants): Study characteristics.

	Description
Population description	This was a single-center, exploratory, randomized controlled pilot study conducted among Japanese patients with HF in an academic medical center in Tokyo, Japan.
Inclusion criteria	"Eligible patients were older than 20 years, hospitalized with a primary diagnosis of systolic or diastolic HF."
Exclusion criteria	"Exclusion criteria were as follows: 1) stage D HF, owing to the low likelihood of benefit from behavioral treatment; 2) New York Heart Association (NYHA) functional class I because the new HF program targeted patients with HF symptoms; 3) uncertain 12-month prognosis; 4) severe medical or psychiatric comorbid condition; 5) logistical barriers (eg, non-speaking, non-reading Japanese); 6) physician refusal; and 7) patient refusal."
Description of intervention	Multidisciplinary HF management program including face-to-face education and counseling from a dietician, pharmacist and nurses over 68±32 minutes. Educational topics included an overview of HF, examination and treatment of HF, self-monitoring of daily weights, medication education, and salt-restriction.
Description of comparison	All patients assigned to usual care received standard care and were not provided structured patient education.
Age (years), mean (SD)	Control: 65 (17) years Intervention: 64 (15) years
Sex, % women	Control 41% Intervention: 20%
LVEF <50%, n (%)	Control: 12 (71%) LVEF <50% Intervention: 9 (60%) LVEF <50%

Kato 2016 (n = 38 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement (include direct quotes where available with explanatory comments)
Random sequence generation (selection bias)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>“Patients were randomized in a 1:1 ratio into a usual care or intervention group and followed up for 2 years.”</p> <p>“Patients were recruited by four research nurses through inpatient screening. After the baseline examination, one of the research nurses contacted the randomization service office and was sent the treatment assignment. Stratified blocked randomization with regard to age and NYHA class was performed.”</p>
Allocation concealment (selection bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>Unclear whether or how the research staff was blinded to the allocation.</p> <p>“The patients were blinded to the allocation.”</p>
Blinding of participants and personnel (performance bias)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<p>Both participants and study staff were aware of which participants were in the intervention arm given the nature of the intervention.</p>
Blinding of outcome assessment (detection bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>Details of the scoring of the questionnaire surveys is not reported.</p>
Incomplete outcome data (attrition bias)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<p>38 participants initially randomized and 32 participants actually received allocated intervention or control. The 1-month survey analysis included 22 participants, 6-month survey analysis included 19 participants, and the 2-year follow-up had 29 participants. Participants excluded at various stages of analysis due to non-response and/or missing data.</p> <p>“The number of missing data for items was estimated with the average score for valid items in the questionnaire. When the missing data accounted for more than 30% of the questionnaire, we excluded it from the analysis.”</p>
Selective outcome reporting? (reporting bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>No entry on clinicaltrials.gov and no published methods paper.</p>
Other bias	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<p>Response bias arising from self-report of HF self-care behaviour and HF knowledge from surveys completed by participants who were aware of being in the intervention or control arm.</p>

Koelling 2005 (n = 223 participants): Study characteristics.

	Description
Population description	This study was performed at the University of Michigan Hospital and study subjects were recruited from the inpatient services of the hospital from April 2001 through October 2002.
Inclusion criteria	Admitted to the hospital with a diagnosis of heart failure and documented left ventricular systolic dysfunction (ejection fraction ≤ 0.40).
Exclusion criteria	"Of those screened, 367 were excluded from enrollment. The most common reasons for non-enrollment included evaluation for cardiac surgery (63), non-cardiac illness likely to increase 6-month mortality or hospitalization risk (59), and inpatient cardiac transplantation evaluation (57)."
Description of intervention	"The patient education program included a 60-minute-long, one-on-one teaching session with a nurse educator before discharge. The nurse educator discussed heart failure specific information that covered the basic principles of the causes of heart failure and rationale for pharmaceutical therapies. The education session contained material covering the causes of intravascular volume overload in heart failure and the mechanism of action of diuretic medications. The role of dietary restriction of sodium and limitation of dietary free water intake was also covered. Additionally, the patient education session contained the rationale for self-care behaviors: daily weight monitoring, smoking cessation, avoidance of heavy alcohol intake and nonsteroidal anti-inflammatory drugs, and what to do if symptoms worsened. Patients in the education arm of the study were also given a copy of the treatment guidelines for heart failure treatment written in layman's terms."
Description of comparison	Usual care (standard written discharge information)
Age (years), mean (SD)	Control: 64.7 (13.9) years Intervention: 65 (14.6) years
Sex, % women	Control: 42% Intervention: 42%
LVEF (%), mean (SD)	Control: 27 (9) % Intervention: 26 (9) %

Koelling 2005 (n = 223 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"a random number was generated by a computer program and was used to assign patients to receive usual care (standard discharge information, controls) or usual care plus patient-targeted heart failure education (education group)."
Allocation concealment <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Treatment assignment was concealed from the patients and study personnel until after the randomization step."
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	"The care providers for the patient in the hospital and in the outpatient arena were not informed of the treatment assignment." Although the care providers were blinded to whether the patient received the nurse-led education program or usual care, the patients were aware of being in the intervention arm.
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	"Costs for hospital readmissions were estimated using Medicare diagnosis-related group (DRG) reimbursement rate estimation software (IRP, Inc). For each hospitalization, the ICD-9 primary diagnosis, secondary diagnoses, and major ICD-9 procedure codes were entered to derive the appropriate DRG reimbursement. Adjudication of hospitalization events and DRG assignment was performed in a manner blinded to treatment assignment." Assessment of primary outcome (number of days hospitalized and/or dead in the 180-day follow-up period) was blinded to treatment assignment. However, patients completing secondary outcome questionnaires (i.e. Minnesota Living with HF questionnaire, self-care behaviors) were aware of their assignment.
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Both the intervention and control arms had zero participants lost to follow-up and all 223 participants initially randomized were included in the analysis.
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov.

Laramée 2003 (n = 287 participants): Study characteristics.

	Description
Population description	"This study is characterized by a heterogeneous HF population, one that includes patients of all ages, of all insurance types, with either normal left ventricular function or dysfunction, in all New York Heart Association (NYHA) classes, having any comorbidity, and with either primary or secondary heart failure. All were hospitalized at Fletcher Allen Health Care, Burlington, Vermont, a 550-bed academic medical center, which serves the largely rural geographic areas of Vermont and Upstate New York."
Inclusion criteria	<p>Clinical signs and symptoms for HF and either moderate-to-severe left ventricular dysfunction or radiographic evidence of pulmonary congestion and symptomatic improvement following diuresis were required for study participation.</p> <p>Patients with confirmed HF also had to be at risk for early readmission as defined by the presence of 1 or more of the following criteria: history of HF, documented knowledge deficits of treatment plan or disease process, potential or ongoing lack of adherence to treatment plan, previous HF hospital admission, living alone, and 4 or more hospitalizations in the past 5 years.</p>
Exclusion criteria	Discharge to a long-term care facility, planned cardiac surgery, cognitive impairment, anticipated survival of fewer than 3 months, and long-term hemodialysis.
Description of intervention	<p>Four major components of the intervention included:</p> <ul style="list-style-type: none"> • Coordination of in-hospital and discharge care by case manager with early discharge planning • Individualized daily patient and family education (HF booklet, weight logs, computerized medication lists, home scales, pillboxes) • 12 weeks of enhanced telephone follow-up and surveillance (reviewed symptoms, medication adherence, follow-up appointments) • Promotion of optimal HF medications and medication doses (ACE-I or ARB and beta-blocker) based on guidelines
Description of comparison	Usual standard of care in tertiary care hospital
Age (years), mean (SD)	Control: 70.8 (12.2) years Intervention: 70.6 (11.4) years
Sex, % women	Control: 50% Intervention: 42%
Severe LV dysfunction, n (%)	Control: 58 (43) Intervention: 73 (54)

Laramée 2003 (n = 287 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"After simple randomization of the first 42 patients resulted in large amounts of patients being assigned to one group or the other, patients were randomized in blocks of 8 to ensure an even group allocation across time."
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Details of the allocation sequence not reported.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	"One limitation to this study was the inability to blind patients and researchers to group assignment; there was no practicable alternative"
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	The outcome assessors were not blinded as follow-up post-discharge outcome data was collected by the case manager in the intervention group and CRC in the usual care group. Adherence to treatment plan and patient satisfaction were collected by self-report through questionnaires to patients who were aware of being in the intervention or control arm.
Incomplete outcome data <i>(attrition bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	There was >18% differential study attrition (13% in intervention, 24% in control). "Early attrition accounted for 53 patients because of death, withdrawal of consent, failure to continue to meet study criteria, or loss to follow-up. A total of 122 patients in the intervention group and 112 patients in the usual care group completed the 90-day study period."
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov.

Newhouse 2013 (n = 29 hospitals randomized, number of participants not reported): Study characteristics.

	Description
Population description	Rural hospitals from the eastern United States
Inclusion criteria	<p>Hospital inclusion criteria were:</p> <ul style="list-style-type: none"> • designated as rural by federal or state reimbursement or program definitions • located in the eastern US (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and North Carolina) • reports HF measures, discharging at least 25 HF patients per year (considered adequate for public reporting)
Exclusion criteria	None reported
Description of intervention	<p>“The quality collaborative intervention included a 2-day in-person meeting, an evidence-based HF tool kit, and monthly group teleconference calls with the site coordinators and study team. The agenda for each call was driven by the sites (e.g., study progress, interim results, issues experience or new HF guidelines or research reports). Site coordinators attended an in-person meeting at the beginning of the intervention phase (by group for training) and at the end of the study (both groups to present their results). The HF toolkit included resources that could be tailored for implementation in each organization (e.g., fact sheet, education modules, discharge checklist, patient education).”</p>
Description of comparison	Usual care for 6 months until group 2 received the delayed intervention
Age (years), mean (SD)	Not reported
Sex, % women	Not reported
LVEF (%), mean (SD)	Not reported

Newhouse 2013 (n = 29 hospitals randomized, number of participants not reported): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement (include direct quotes where available with explanatory comments)
Random sequence generation (selection bias)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"The 29 rural hospitals were randomly assigned to one of the 2 groups using computer-generated randomization."
Allocation concealment (selection bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Details regarding allocation sequence concealment not provided.
Blinding of participants and personnel (performance bias)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Given the nature of the quality collaborative intervention, blinding of participants and personnel was not possible leading to high risk of performance bias.
Blinding of outcome assessment (detection bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>The details regarding blinding of outcome assessment is not provided. The primary outcomes were abstracted from hospital data systems other than the Practice Environmental Scale survey, which was administered to nurses.</p> <p>"Secondary and survey data were collected using written Teleform survey. Secondary data for HF core measures, and contextual factors (nursing skill mix, nurse-turnover, HPPD) for 7 quarters (quarter ending September 2007 through March 2009) were abstracted from hospital data systems."</p>
Incomplete outcome data (attrition bias)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<p>29 hospitals were randomized (15 in group 1/intervention and 14 in group 2/control/delayed intervention) and a total of 6 hospitals (4 in group 1/intervention and 2 in group 2/control/delayed intervention) did not attend the collaborative. Hence, 11 hospitals in group 1 and 12 hospitals in group 2 were included in the analysis. There were varying levels of missingness in the outcomes.</p> <p>"Multiple imputation method was applied to impute the missing data (ranging between 1.3% for ACEi/ARB and 8.9% for nurse turnover) and outliers (z-scores >3 or <3) were treated as missing."</p> <p>"The PES (Practice Environmental Scale) was administered to medical surgical RNs and licensed practical nurses that care for HF patients pre-intervention at baseline with a 37% response rate (N = 683/1852). Only the RN responses (N=591) were used for this analysis as the PES has only been tested in the RN population."</p>
Selective outcome reporting? (reporting bias)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov.

Panella 2009 (n = 14 hospitals, 429 participants analyzed): Study characteristics.

	Description
Population description	Hospitals in four Italian regions with hospitalized HF patients
Inclusion criteria	At the hospital level: "the administrations of the hospitals had to be allow the institution to be allocated to either of the two strategies (clinical pathway or current practice) for a 1-year period and to agree not to implement a clinical pathway for the treatment of heart failure if assigned to the usual care group." At the participant level: principal diagnosis of HF.
Exclusion criteria	At the participant level: current acute myocardial infarction, current unstable angina.
Description of intervention	"One physician or nurse with at least 2 years of experience of CP was assigned to each hospital in the experimental group, in order to facilitate project implementation (including staff education in the use of CP). The teams included internal medicine physicians, cardiologists, epidemiologists, pathologists, psychologists, nurses, hospital pharmacists, social workers and support staff. The teams were formed on a voluntary basis, received three days of training in the development of CP and constructed the CP over a 6-month period. All groups analyzed their care processes, reviewed best evidence provided by senior investigators, defined the appropriate goals of the pathways, detailing the results into protocols and documentation, including the sequence of events and expected progress of the patients over time. Essentially, the CP used in the study were not completely identical because of organizational adaptations in some sites. However, they coincided substantially with the existing European guidelines on the hospital treatment for HF."
Description of comparison	Usual care
Age (years), mean (SD)	Control: 79.7 (8.5) years Intervention: 81.7 (8.5) years
Sex, % women	Control: 48.8% Intervention: 52.3%
LVEF (%), mean (SD)	Not reported

Panella 2009 (n = 14 hospitals, 429 participants analyzed): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement (include direct quotes where available with explanatory comments)
Random sequence generation (<i>selection bias</i>)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The study protocol registered on clinicaltrials.gov states that the randomization was done by parallel assignment. No additional details regarding the randomization sequence generation is provided in the methods paper or primary manuscript. "we randomly assigned hospitals, rather than individual patients, to either introduce the pathway or continue usual care."
Allocation concealment (<i>selection bias</i>)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Details regarding allocation sequence concealment not provided.
Blinding of participants and personnel (<i>performance bias</i>)	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Hospitals, participants and personnel were aware of being in the intervention or control arm given the nature of the quality improvement clinical pathway study.
Blinding of outcome assessment (<i>detection bias</i>)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	It is unclear whether outcome assessors were blinded. "Data were prospectively collected by local staff both in intervention and in control groups (physician and nurses who were trained in two pre-study educational events). We did not use incentives for the local staff."
Incomplete outcome data (<i>attrition bias</i>)	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	All 14 hospitals initially randomized participated in the study. There were 429 participants included in the final sample analysed; however, the number of participants eligible is not reported.
Selective outcome reporting? (<i>reporting bias</i>)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Reported outcomes match pre-specified outcomes in methods paper and clinicaltrials.gov protocol.

Philbin 2000 (n = 10 hospitals, 2906 participants): Study characteristics.

	Description
Population description	10 acute care community hospitals in upstate New York participated in this trial
Inclusion criteria	Admitted patients assigned a diagnostic code of heart failure
Exclusion criteria	None explicitly stated
Description of intervention	<p>“The quality improvement intervention attempted to maximize the implementation of an inpatient critical pathway for heart failure management, which was designed by the study leadership. Its format was a Gantt chart or time-task matrix. The pathway recommended diagnostic tests and treatments that were considered to be highly indicated based on published clinical trial results, expert guidelines, or wide acceptance as current standards, but omitted those considered experimental or controversial. Standardized admission orders, which supplemented the pathway, were also made available.</p> <p>In addition, we provided several other components aimed at improving provider and patient knowledge, expediting diagnosis and treatment, and reducing readmission. These included a critical pathway for use in the emergency department, which emphasized rapid diagnosis of heart failure and initiation of intravenous diuretic therapy, and a home care pathway for use by home health personnel after hospital discharge. An experienced consulting firm (The Center for Case Management, Natick Massachusetts) assisted in implementation of the pathways and other components of the intervention. Three medical grand rounds were given at each hospital by regional or national experts in heart failure, and five lectures about clinical issues in heart failure were provided for nurses and other health professionals at each hospital. Videotapes of all eight lectures were available to assist in dissemination of the didactic message. Teaching aids were given to patients and their families. Finally, comprehensive hospital-specific performance and benchmarking reports about process and outcomes of care from the baseline period were presented to the intervention hospitals orally and as a written 45-page report as catalysts for changes in clinical practice.”</p>
Description of comparison	Usual care
Age (years), mean (SD)	Control: 75 years (SD not reported) Intervention: 76 years (SD not reported)
Sex, % women	Control: 60% Intervention: 53%
LVEF (%), mean (SD)	Control: 28% (SD not reported) Intervention: 39% (SD not reported)

Philbin 2000 (n = 10 hospitals, 2906 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Details of the random sequence generation unclear, but likely low risk of bias as the authors describe a method of stratified randomization. "Subsequently, 5 of the 10 hospitals were randomly assigned to the intervention group and were the active sites for implementation of the quality improvement intervention. The remaining 5 hospitals were randomly assigned to the usual care control group. Hospitals were randomly assigned based on heart failure case load and average length of stay for heart failure during the baseline period."
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No details provided regarding allocation concealment.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Hospitals and study personnel were aware of being in the intervention or control arm given the nature of the quality improvement study. "Control hospitals were not restricted from initiating their own local quality management programs, but were barred access to study-related data, documents, and resources."
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Study nurses (who were employees of the hospital) at each site abstracted chart data and were blinded to the treatment assignment only pre-intervention. Most outcomes (hospital length of stay, in-hospital and 6-month mortality, hospital readmission, hospitalization cost) were objective. Patients were contacted by the study nurses by telephone for post-discharge assessment of quality of life (by the Ladder of Life scale), which is a subjective outcome susceptible to detection bias. "Each nurse and institution was also provided with a comprehensive manual of operations that contained explicit instructions about chart abstraction. During the baseline period, study nurses were unaware of treatment assignment; this blinding was not maintained during the post-intervention phase. "Rigorous assessment of interrater reliability was not performed to validate the chart abstraction process. Therefore, there is some unmeasured uncertainty about the accuracy of the diagnosis and etiology of heart failure and the causes of readmission and death."
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Data were reported for all 10 hospitals randomized (unit of randomization was the hospital) and 2906 participants analysed. No data were provided for the number of participants eligible for the analysis at each participating hospital.
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No entry on clinicaltrials.gov nor explicitly stated pre-specified outcomes in methods paper.

Rich 1995 (n = 282 participants): Study characteristics.

	Description
Population description	Patients 70 years of age or older who were admitted to the medical wards of Jewish Hospital at Washington University Medical Center in Missouri, United States with HF
Inclusion criteria	The criteria for inclusion in the study were age 70 years or older admitted to Jewish Hospital at Washington University Medical Center with HF (diagnosis required radiographic evidence of pulmonary congestion or typical symptoms and signs of heart failure with response to diuresis). Furthermore, eligible patients needed to have one of the following risk factors for early readmission: prior history of HF, four or more hospitalizations for any reason in the preceding five years, HF precipitated by acute myocardial infarction or uncontrolled hypertension.
Exclusion criteria	The criteria for exclusion from the study included residence outside the catchment area of the hospital, planned discharge to a long-term-care facility, severe dementia or other serious psychiatric illness, anticipated survival of less than three months, refusal to participate by either the patient or the physician, and logistic or discretionary reasons not specified.
Description of intervention	"The study treatment consisted of intensive education about congestive heart failure and its treatment by an experienced cardiovascular research nurse, using a teaching booklet developed by the study investigators for geriatric patients with heart failure; individualized dietary assessment and instruction given by a registered dietitian with reinforcement by the study nurse; consultation with social-service personnel to facilitate discharge planning and care after discharge; an analysis of medications by a geriatric cardiologist who made specific recommendations to eliminate unnecessary medications and simplify the overall regimen; and intensive follow-up after discharge through the hospital's home care services , supplemented by individualized home visits and telephone contact with the members of the study team . The principal goals of follow-up were to reinforce the patient's education, ensure compliance with medications and diet, and identify recurrent symptoms amenable to treatment on an outpatient basis." (emphasis added for clarity)
Description of comparison	Usual care
Age (years), mean (SD)	Control: 78.4 (6.1) years Intervention: 80.1 (5.9) years
Sex, % women	Control: 59% Intervention: 68%
LVEF (%), mean (SD)	Control: 41 (13) % Intervention: 44 (14) %

Rich 1995 (n = 282 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"The patients underwent blinded randomization with the use of a computer-generated list of random numbers immediately after consenting to participate in the study."
Allocation concealment <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Neither the patient nor the members of the study team were aware of the treatment assignment until after randomization."
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Both participants and personnel were aware of being in the intervention or control arm given the nature of the quality improvement intervention.
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	The outcomes of readmissions and death are objective and were collected during subsequent hospitalizations. Quality of life was assessed in a sub-group of participants using the Chronic Heart Failure Questionnaire and these participants would be aware of being in the intervention or control arm. Cost of care was assessed in a sub-group of participants using cost logs filled out by both participants and study personnel who were not blinded to the treatment assignment.
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Primary outcome data provided for all participants randomized and secondary outcomes provided for pre-specified sub-groups.
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor clinicaltrials.gov entry.

Sales 2013 (n = 137 participants): Study characteristics.

	Description
Population description	Patients admitted with heart failure at New York Methodist Hospital in the US.
Inclusion criteria	Criteria for inclusion in the study were age ≥ 18 years, admitted to New York Methodist hospital with a primary diagnosis of HF (confirmed by a cardiologist based on symptoms and pro-BNP level $> 1,000$ pg/mL).
Exclusion criteria	Criteria for exclusion from the study included dementia or other severe psychiatric illness, and patients transferred to another hospital before discharge.
Description of intervention	The intervention consisted of volunteers providing education to patients regarding HF disease and management plan. The education addressed diagnosis information, review of discharge medications, review of follow-up plan including primary care physician's name and telephone number, low-salt diet and fluid restriction counseling, and instructions to monitor daily weights. The patients received a one-page discharge sheet with the above information written down. The volunteers were selected from a group of students pursuing the premedical track at New York City universities. These selected volunteers received training on HF from a cardiologist, nutrition from a nutritionist and general HF management from a nurse.
Description of comparison	Patients in the control arm received standard hospital care (standardized discharge instruction sheet, nurse-led review of medications and patient education) in accordance with the current clinical guidelines for patients with HF. Unit clerks arranged appointments with primary care physicians for patients prior to discharge.
Age (years), mean (SD)	Control: 72.6 (13.4) years Intervention: 72.5 (14.8) years
Sex, % women	Control: 52% Intervention: 63%
LVEF (%), mean (SD)	Control: 35.8 (15.6) % Intervention: 34.9 (18.2) %

Sales 2013 (n = 137 participants): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"The included patients were randomized to either the intervention group (arm A), who received education, instructions, and follow-up telephone calls via trained volunteer staff regarding their post-discharge care, or the control group (arm B), who received standard care." Additional details of random sequence generation not provided but risk of selection bias likely low.
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	Details regarding allocation concealment not provided.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Blinding of participants and personnel is not possible given the nature of the quality improvement intervention.
Blinding of outcome assessment <i>(detection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"Primary and secondary outcomes were obtained by independent staff blinded to the care the patient received during the duration of the study."
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Four patients in control arm were lost to follow-up, which was less than 5% overall.
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No methods paper nor registration on clinicaltrials.gov.

**Tu 2009 (n = 86 hospital corporations, 17,544 participants with HF analyzed):
Study characteristics.**

	Description
Population description	Participating hospitals were acute care hospital corporations in Ontario, Canada.
Inclusion criteria	Hospital level: <ul style="list-style-type: none"> • Treatment of >30 HF patients per year in Ontario Patient level: <ul style="list-style-type: none"> • Diagnosis of HF (ICD-9 code 428)
Exclusion criteria	Patient level for HF: <ul style="list-style-type: none"> • Not admitted to an acute care hospital • Age <20 years or >105 years • Invalid health card number • Admitted to surgical service • Transferred from another acute care facility • Coded as an in-hospital complication • Admission within the past 3 years
Description of intervention	Early feedback publicly released report card on baseline performance for a set of national process of care quality indicators which were developed and endorsed by the Canadian Cardiovascular Outcomes Research Team and the Canadian Cardiovascular Society. "The early feedback hospitals received their baseline performance data in October 2003 to permit internal validation checks; following this, the results were publicly released at a press conference and on the Web (http://www.ccort.ca/effect.asp) in January 2004. The baseline EFFECT study data received extensive media coverage through multiple television (n = 28), radio (n = 34), and newspaper (n = 41) stories in Canada, with an estimated audience of more than 12 million Canadians being exposed to the study results. Based on the baseline performance data, hospitals were encouraged to develop standardized admitting orders and discharge plans for cardiac patients, although the exact nature of quality improvement activities was left to the discretion of the hospitals."
Description of comparison	Delayed feedback publicly released report card which was released September 2005 to all participating hospitals and published on the web. There was no associated press release or media coverage.
Age (years), median (IQR)	Control: 78 (69-85) years Intervention: 77 (70-84) years
Sex, % women	Control: 51% Intervention: 51%
LVEF (%), mean (SD)	Not reported

Tu 2009 (n = 86 hospital corporations, 17,544 participants with HF analyzed): Risk of bias assessment.

Domain	Risk of bias Low High Unclear	Support for judgement <i>(include direct quotes where available with explanatory comments)</i>
Random sequence generation <i>(selection bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	"The randomization of participating hospitals was stratified by type of hospital and was performed by a study statistician."
Allocation concealment <i>(selection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	No details provided regarding allocation concealment.
Blinding of participants and personnel <i>(performance bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	"Data were collected from the hospitals in the early feedback group of the study first; however, it was not possible to blind the hospitals to their status."
Blinding of outcome assessment <i>(detection bias)</i>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<p>Outcomes of process of care indicators abstracted from the chart by study nurses (not explicitly stated but study nurses were likely aware of the treatment assignments). Mortality was determined by linking the study data to the Ontario Registered Persons vital statistics database. The hospital report card impact survey was mailed to the clinical contact or hospital CEO who was aware of the hospital corporation treatment assignment. Overall, unclear risk of detection bias as low risk of detection bias in mortality outcome and higher risk of detection bias in process of care indicators and hospital report card impact survey results.</p> <p>"The nurse abstractors involved in the study were employed by the central study team and traveled to the participating hospitals. All study data were transmitted electronically to a secure database at the Institute for Clinical Evaluative Sciences in Toronto, Ontario."</p>
Incomplete outcome data <i>(attrition bias)</i>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	There were 44 hospital corporations randomized to the intervention (early feedback report card) and 42 hospital corporations to the control (delayed feedback report card). One hospital corporation withdrew from the study in the control arm prior to receiving allocated intervention. Two hospital corporations were lost-to follow-up (unable to participate in follow-up) in both the intervention and control groups. Hence, 42 hospital corporations were included in the intervention and 39 hospital corporations in the control analysis. Characteristics of all eligible HF patients presented.
Selective outcome reporting? <i>(reporting bias)</i>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Clinicaltrials.gov entry lists HF composite quality indicator as primary outcome and HF individual quality indicators as secondary outcome measures. Thirty-day, 1-year and hospital report card impact survey were not reported as pre-specified outcomes in the published protocol. First protocol published on clinicaltrials.gov on September 15 th , 2005 after trial had commenced (and after release of public report cards).

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