

Center for Health Care Strategies, Inc.

**Technical Assistance Tool** 

The ROI Evidence Base: Identifying Quality Improvement Strategies with Cost-Saving Potential

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## I. Introduction: Identifying Quality Improvement Strategies with Cost-Saving Potential

"ROI"—or return on investment—is one of the latest buzzwords across the health care system, with policymakers, payers, and consumers demanding greater value for dollars spent on health care. In Medicaid, state officials, legislators, health plans and other stakeholders are increasingly being challenged to identify programs with the potential to both improve quality of care and control health care costs.

The Center for Health Care Strategies (CHCS) developed a set of tools to help Medicaid stakeholders identify where opportunities may exist to realize both quality improvement and cost containment goals. One tool, the ROI Forecasting Calculator for Quality Initiatives (the "Calculator"), was designed to assess the potential of proposed quality improvement initiatives to generate a positive ROI. The Calculator is currently being piloted by a select group of states and will be released publicly in early 2008. A second tool, the ROI Evidence Base, was developed to help policymakers assess changes in utilization patterns or health care costs that may be expected as a result of specific intervention strategies. Both tools were made possible through support from the Robert Wood Johnson Foundation.

#### The ROI Evidence Base

To help identify intervention strategies with the potential to both improve quality and reduce health care costs, CHCS engaged Mathematica Policy Research (MPR) to conduct a systematic literature review of published quality improvement studies that reported cost or utilization outcomes. As a result of this work, the ROI Evidence Base includes a selection of studies for clinical conditions of high priority to Medicaid stakeholders, including asthma, congestive heart failure (CHF), depression, diabetes, and high-risk pregnancy. The ROI Evidence Base includes published studies of the highest available quality and of the greatest possible relevance to Medicaid. Studies are categorized: (1) by clinical condition and (2) by whether reported outcomes indicate decreases or increases in cost and utilization. Based on the available literature, for each clinical condition the ROI Evidence Base includes studies reporting decreases, increases, or both decreases and increases in cost and utilization.

#### **Using the ROI Evidence Base**

Users may browse the *ROI Evidence Base* to assess the relevance of included studies based on intervention strategies, target population characteristics, intervention settings, and overall study quality.

#### Study Quality

Study quality is rated based on the strength of the study design (Exhibit 1), and should be considered when interpreting the validity and replicability of a given study. In general, studies incorporating higher quality evaluation designs have greater potential to produce replicable results.

Exhibit 1. Study Quality Ranking	
Randomized controlled studies	Α
Quasi-experimental studies without obvious selection bias	В
Pre-post studies with no comparison group, or comparison groups with likely selection bias	С
Study design of lower quality than above	D

A more detailed methodological description is available upon request. Please contact Allison Hamblin at ahamblin@chcs.org for more information.

#### Generalizability

It is important to consider the generalizability of published study results to other settings and populations. When using reported outcomes of studies in the *ROI Evidence Base* to estimate the potential effectiveness of proposed initiatives, users should consider similarities and differences in the following characteristics:

- Target population,
- Sample size,
- Health care delivery environment,
- Intervention implementation, timeframe and intensity,
- Financing arrangement, and
- Evaluation design.

#### Weighing the Evidence

In some cases, the literature review identified studies of similar interventions that in one setting demonstrated decreases in cost or utilization while in another setting demonstrated the opposite trends. For example, among the asthma studies, a similar intervention strategy may appear twice, with one study reporting decreases in cost and another reporting increase. Therefore, users are encouraged to review the entire *ROI Evidence Base* for a clinical condition of interest prior to drawing specific conclusions about the cost-effectiveness of any particular strategy.

#### Early Lessons from the ROI Evidence Base

Based on a review of the studies included in the *ROI Evidence Base* and on extensive experience working with states and health plans on quality improvement, CHCS has identified a number of common themes that contribute to the ability to demonstrate both quality improvement and cost-reduction. Some cross-cutting themes that emerge include:

#### Stratify target populations to focus on the groups at highest risk.

Interventions that target resources to high-risk populations may have the greatest potential to improve outcomes while also reducing costs. This is particularly apparent in the asthma literature. By focusing on patients with the greatest needs, interventions can maximize the value of resources invested in quality improvement activities.

#### Incorporate a high and continuous degree of intensity.

By stratifying populations, limited program resources can be allocated to more intensively intervene with targeted groups. As is particularly evident in the diabetes literature, interventions that provide a continuous, reasonably intense level of contact for patients and their care coordinator and/or provider demonstrate the strongest potential to affect both quality and cost outcomes.

#### Intervene on multiple fronts.

Programs employing multifaceted intervention strategies generally demonstrate the greatest potential to achieve targeted quality and cost outcomes. By addressing gaps in care at the patient-, provider- and system-levels, these programs have potential to impact utilization patterns to a degree sufficient to cover the costs of implementing the interventions.

#### Take advantage of teachable moments.

The ability to successfully engage patients in improved self-management behaviors is closely connected to their current motivation to change. As illustrated in the CHF literature, interventions that enroll patients immediately following an acute event may have increased likelihood of engaging patients and thus greater ability to achieve desired quality and cost outcomes.

#### Beware of challenges to demonstrating incremental program effects.

When adding a new layer of intervention to an existing care management program, analyses of quality improvement and ROI will be incremental to the outcomes already being produced by current systems of care. To successfully demonstrate these marginal effects, new interventions should include either a high level of intensity or a very large sample size.

II. Asthma Studies

## **Asthma Studies Reporting Decreases in Cost/Utilization - Summary Table**

Clinical Focus	Author/Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
Asthma	Castro, 2003	Adults	Use of asthma nurse specialist in hospital to provide guideline-based recommendations to physicians, and self-management education, psychosocial support, and follow-up care to patients.	12 months	67% decrease in asthma-related hospital costs	A
Asthma	Harish, 2001	Children and families	Use of specialty clinic to provide intensive medical and environmental control, education, close monitoring and 24-hour availability	24 months	69% reduction in Year 1 ER visits; 60% reduction in Year 2 ER visits	А
Asthma	Kattan, 2006	Children and families	Use of patient feedback letters to providers combined with guideline-based recommendations for changes in therapy	12 months	24% reduction in ER visits	Α
Asthma	Krieger, 2005	Children and families	Use of community health workers to provide home visits, generate action plans, deliver resources to reduce exposures, and advocate for improved housing conditions. Free skin-prick allergy testing at multiple clinic sites and special asthma fairs.	12 months	15% reduction in combined asthmarelated urgent health services use (ED, hospital, or unscheduled clinic visit)	А
Asthma	Krishna, 2003	Children and families	Use of internet-enabled interactive multimedia asthma education program by participants in exam room and waiting rooms during clinic visits.	12 months	68% reduction in ER visits	Α
Asthma	Teach, 2006	Children and families	Use of specialized, ER-based clinic following an ER visit for asthma. Clinic provided assessment and education in asthma self-management and environmental triggers, and linkages and referrals to ongoing care.	6 months	46% reduction in ER visits for asthma	А
Asthma	Walders, 2006	Children and families	Use of interdisciplinary care team including pediatric pulmonologist, asthma nurse and social worker to provide medical care, asthma education and problemsolving therapy.	12 months	32% reduction in combined outcome of ER visits and/or hospital admissions	А

Detail for	Selected	Study –	Castro,	2003
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Castro 2003
Clinical Focus	Asthma
Target Population	Adults aged 18-65 years admitted to Barnes-Jewish Hospital with a primary diagnosis of asthma
Intervention Strategies	(1) suggestions by nurses to the primary physician regarding potential simplification or consolidation of current regimen in accordance with the National Asthma Education and Prevention Program II; (2) completion of a daily "Asthma Care" flow sheet while in the hospital; (3) provision of asthma education appropriate to the patient's education, motivation, and cultural beliefs; (4) provision of psychosocial support and screening patients for professional counseling; (5) establishment of an individualized asthma self-management plan; (6) consultation with social service professionals to facilitate discharge planning; and (7) the provision of outpatient follow-up through telephone contact, home visits, and follow-up appointments with the primary physician, as necessary.
Additional Targeting Criteria	Physician diagnosed asthma for at least 12 months, FEV1/FVC<80% and one or more hospitalizations in previous 12 months
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not stated
Geographic Location	St. Louis, MO, Barnes-Jewish Hospital
Type of Community	Urban
Health Care Setting	Academic medical center, primary care physician offices
Health Insurance	50% Medicaid, 13% Medicare, 24% private, 14% uninsured/self-pay
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	50 in intervention group, 46 in control group
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	67% reduction in asthma-related hospital costs (T=1,458, C=4,413, p=0.01) 56% reduction in number of readmissions at one year (T=31, C=71, p=0.04) 66% reduction in hospital days at one year (T=82, C=244, p=0.04) Non significant difference in ER visits
Full Citation	Castro, Mario. Zimmermann, Nina A. Crocker, Sue. Bradley, Joseph. Leven, Charles. Schechtman, Kenneth B. "Asthma intervention program prevents readmissions in high healthcare users." <i>American Journal of Respiratory &amp; Critical Care Medicine</i> . 168(9):1095-9, 2003 Nov 1.

<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Harish 2001
Clinical Focus	Asthma
Target Population	Children ages 2-17 y.o. being treated for asthma in the inner-city pediatric emergency department of Bronx Lebanon Hospital
Intervention Strategies	Use of specialty clinic, staffed by pediatric allergist, 3 certified pediatric nurse practitioners and a social worker, to provide intensive medical and environmental control, education, close monitoring and 24-hour availability. Most patients also had home visit by nurse to review medication usage and inspect for environmental allergens.
Additional Targeting Criteria	None
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	100% (300/300 agreed to be randomized; 129 sustained participation through Year 1, 119 through Year 2)
Geographic Location	Bronx, NY
Type of Community	Urban
Health Care Setting	Specialty clinic
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	Year 1: 60 in treatment group, 69 in control group; Year 2: 53 in treatment group, 66 in control group
Evaluation Timeframe	24 months
Cost/Utilization Outcomes	69% reduction in Year 1 ER visits (monthly mean visits: T=0.101, C=0.326, p=0.01) 60% reduction in Year 2 ER visits (annual mean visits: T=0.396, C=1, p<0.03) No significant difference in hospitalizations
Full Citation	Harish, Z. Bregante, A C. Morgan, C. Fann, C S. Callaghan, C M. Witt, M A. Levinson, K A. Caspe, W B. "A comprehensive inner-city asthma program reduces hospital and emergency room utilization." <i>Annals of Allergy, Asthma, &amp; Immunology.</i> 86(2):185-9, 2001 Feb.

Detail for	Selected	Study -	Kattan,	2006
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Kattan 2006
Clinical Focus	Asthma
Target Population	Children ages 5-11 y.o. receiving care in hospital- and community-based clinics and private practices in 7 inner-city urban areas
Intervention Strategies	Care taker of each child received bimonthly phone call to collect clinical information; For 12 months, providers received bimonthly computer-generated letters summarizing child's asthma symptoms, health service use, and medication use with a corresponding recommendation to step up or step down medications.
Additional Targeting Criteria	Residents of census tracts in which ≥20% of households had income <fpl (except="" 11="" 2="" 6="" all="" allergens.<="" allergy="" and="" asthma="" eligible);="" for="" hospitalization="" in="" included="" indoor="" medicaid="" months="" of="" or="" positive="" prior="" seattle="" skin="" td="" test="" to="" unscheduled="" visits="" which="" ≥1=""></fpl>
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	66% (937/1409 eligible were randomly assigned)
Geographic Location	Boston, MA; Bronx, NY; Chicago, IL; Dallas, TX; New York, NY; Seattle/Tacoma, WA; Tucson, AZ.
Type of Community	Urban
Health Care Setting	Hospital- and community-based clinics and private practices
Health Insurance	43% Medicaid, 33% Private, 21% Uninsured, 3% N/A
Quality of Evidence	Asthma
Study Design	Randomized controlled trial
Sample Size	466 in intervention group, 463 in control group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	24% reduction in ER visits (T=0.87, C=1.14, p=.013)  No significant change in unscheduled clinic visits or hospitalizations
Full Citation	Kattan, Meyer. Crain, Ellen F. Steinbach, Suzanne. Visness, Cynthia M. Walter, Michelle. Stout, James W. Evans, Richard 3rd. Smartt, Ernestine. Gruchalla, Rebecca S. Morgan, Wayne J. O'Connor, George T. Mitchell, Herman E. "A randomized clinical trial of clinician feedback to improve quality of care for inner-city children with asthma." <i>Pediatrics</i> . 117(6):e1095-103, 2006 Jun.

Detail for Selected Study –	Krieger, 2005
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Krieger 2005
Clinical Focus	Asthma
	Low-income household with a child aged 4-12 years with asthma
Target Population Intervention Strategies	Community health workers provided structured home environmental assessments and generated action plans; 4-8 additional revisits to encourage completion of action plan, provide education and social support, deliver resources to reduce exposures (e.g., allergy control pillow and mattress encasements, low-emission vacuums, commercial-quality door mats, referral to smoking cessation counseling, roach bait, rodent traps), offer assistance with roach and rodent eradication, and advocate for improved housing conditions. Free skin-prick allergy testing at multiple clinic sites and special asthma fairs. Participants were assined to either a high-intensity group receiving 7 visits and a full set of resources or a low-intensity group receiving a single visit and limited resources.
Additional Targeting Criteria	Child with a clinical diagnosis of asthma, asthma is persistent, household income < 200% 1996 FPL or child enrolled in Medicaid, caregiver fluent in English, Spanish, or Vietnamese, child spends $\geq$ 50% of nights in house
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	61% (274/447) of those eligible agreed to be randomized
Geographic Location	Seattle (King County), WA
Type of Community	Urban
Health Care Setting	Home
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	110 in intervention group, 104 in control (low-intensity) group
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	At one year, 49% reduction in combined asthma-related urgent health services use in preceding 2 months (ED, hospital, or unscheduled clinic visit; proportion with urgent health service use T=8.4%, C=16.4%, p=0.026)
Full Citation	Krieger, James W. Takaro, Tim K. Song, Lin. Weaver, Marcia. "The Seattle-King County Healthy Homes Project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers." <i>American Journal of Public Health</i> . 95(4):652-9, 2005 Apr.

Detail for Selected Study – Krishna, 2003		
<u>Characteristic</u>	<u>Description</u>	
Author and Year of Publication	Krishna 2003	
Clinical Focus	Asthma	
Target Population	Children younger than 18 y.o. with asthma attending the Pediatric Pulmonary and Allergy Clinic of Univ of Missouri- Columbia Health Sciences Center	
Intervention Strategies	Provision of the Interactive Multimedia Program for Asthma Control and Tracking (IMPACT) self-management education system during routine office visits. The computer was available in each exam room and in the waiting room. The software tracked participants' completion and mastery of 44 lessons.	
Additional Targeting Criteria	None	
Opt-in/opt-out, if available	Opt-in	
Enrollment rate, if available	not stated	
Geographic Location	Columbia, MO	
Type of Community	Unclear. Children referred from a 22 county area	
Health Care Setting	Academic medical center	
Health Insurance	not stated	
Quality of Evidence	A	
Study Design	Randomized controlled trial	
Sample Size	107 in intervention group, 121 in control group	
Evaluation Timeframe	12 months	
Cost/Utilization Outcomes	68% reduction in mean number of emergency room visits at one year (T=0.62/yr versus C=1.93/yr, p<0.01)	
Full Citation	Krishna, Santosh. Francisco, Benjamin D. Balas, E Andrew. Konig, Peter. Graff, Gavin R. Madsen, Richard W. "Internet-enabled interactive multimedia asthma education program: a randomized trial." Pediatrics, vol. 111, no. 3, March 2003,	

pp. 503-510

Detail for Selected Study – Teach, 2006		
<u>Characteristic</u>	<u>Description</u>	
Author and Year of Publication	Teach 2006	
Clinical Focus	Asthma	
Target Population	Children ages 12 months-17 years old	
Intervention Strategies	Single follow-up visit to specialized asthma clinic located in the ER, 2-15 days after discharge from ER. Education on asthma self-monitoring and self-management, evaluation of potential home environmental triggers and recommendations for control. Report of clinic visit, digital photo of child, and copy of medical action plan mailed to PCP, insurance asthma case manager, and school nurse. Scheduling of a follow-up appt. with PCP in 4 weeks or, for children with severe, persistent asthma, referral to an asthma specialist.	
Additional Targeting Criteria	ER visit with a primary diagnosis of asthma, prior physician-diagnosed asthma, one or more acute visits (ER or other) for asthma in previous 6 months or one or more hospitalizations for asthma in past 12 months	
Opt-in/opt-out, if available	Opt-in	
Enrollment rate, if available	94% (490/521) of eligibles agreed to be randomized	
Geographic Location	Washington, DC	
Type of Community	Urban	
Health Care Setting	Children's National Medical Center	
Health Insurance	68% public insurance, 28% private, 4% uninsured	
Quality of Evidence	A	
Study Design	Randomized controlled trial	
Sample Size	219 in intervention group, 218 in control group	
Evaluation Timeframe	6 months	
Cost/Utilization Outcomes	46% reduction in ER visits for asthma (T=0.64 mean visits/6 mos., C=1.19, p<0.05) 40% reduction in total acute visits for asthma other than to ER(T=0.68 mean visits/6 mos., C=1.13, p<0.05) Non-significant effects on acute visits to non-ER sites, hospital admissions, and scheduled visits with PCP	
Full Citation	Teach, Stephen J. Crain, Ellen F. Quint, Deborah M. Hylan, Michelle L. Joseph, Jill G. "Improved asthma outcomes in a high-morbidity pediatric population: results of an emergency department-based randomized clinical trial." <i>Archives of Pediatrics &amp; Adolescent Medicine</i> . 160(5):535-41, 2006 May.	

### Detail for Selected Study – Walders, 2006

<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Walders 2006
Clinical Focus	Asthma
Target Population	Children ages 4-12 y.o. receiving care at University Hospitals of Cleveland
Intervention Strategies	All participants received written asthma management plans, peak flow meters, and spacer devices. The intervention group also received asthma education, an asthma risk profile assessment, brief problem-solving therapy, and access to a 24-hour nurse advice line. Intervention provided by an interdisciplinary team including an pediatric pulmonologist, asthma nurse and social worker.
Additional Targeting Criteria	Physician-diagnosis of asthma for at least 3 months, two or more ER visits for asthma in past year and/or one or more asthma hospitalizations in past year, and lack of an asthma treatment plan
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not stated
Geographic Location	Cleveland, OH
Type of Community	Urban
Health Care Setting	Academic medical center
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	89 in intervention group, 86 in control group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	32% reduction in combined outcome of ER visits and/or hospital admissions (Proportion with one or more ER visits and/or hospitalizations for asthma at 12 months $T=28\%$ , $C=41\%$ , $p=0.05$ )
Full Citation	Walders, Natalie. Kercsmar, Carolyn. Schluchter, Mark. Redline, Susan. Kirchner, H Lester. Drotar, Dennis. "An interdisciplinary intervention for undertreated pediatric asthma." <i>Chest.</i> 129(2):292-9, 2006 Feb.

## Asthma Studies Reporting No Changes or Increases in Cost/Utilization - Summary Table

Clinical Focus	Author/Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
Asthma	Butz, 2006	Children and families	Use of home-based asthma education and supervision delivered by community health nurses with pediatric asthma training and pediatric nurse asthma specialists.	12 months	No significant differences in ED visits or hospitalizations between groups	А
Asthma	Finkelstein, 2006	Children and families	Use of physician peer leader interventions or peer leaders in combination with the introduction of asthma education nurses to facilitate care improvement.	24 months	No statistically significant difference in ED visits or hospitalizations	А
Asthma	Gorelick, 2006	Children and families	Use of emergency department (ED)-based intensive primary care linkage and initiation of asthma case management.	16 months	No statistically significant differences among 3 treatment groups in number of ED visits	А
Asthma	Smith, 2004	Children and families	Use of telephone-coaching and monetary incentives targeting caregivers to enforce importance of seeking follow-up care from PCP post-ED visit.	6 months	No statistically significant difference in number of ED visits or hospitalizations	А
Asthma	Tierney, 2005	Adults	Provision of evidence-based care suggestions concerning drugs and monitoring to physicians (general internists and internal medicine residents) and outpatient pharmacists when writing orders or filling prescriptions on computer workstations.	36 months	No statistically significant difference in number of ED visits or hospitalizations	А

### Detail for Selected Study - Butz, 2006

<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Butz 2006
Clinical Focus	Asthma
Target Population	Children ages 2-9 y.o. receiving primary care, pulmonary/allergy, and ED services from the University of Maryland Medical System and The Johns Hopkins Hospital, Baltimore.
Intervention Strategies	Parents or caregiver of children received 6 home education visits of 1-hour sessions delivered by one of three community health nurses with pediatric asthma training who were supervised monthly by a pediatric nurse asthma specialist (A.M.B.).
Additional Targeting Criteria	Daytime asthma symptom frequency ≥2 times a week within past 30 days; Nighttime asthma symptom frequency ≥2 times a month for the past 30 days; Use of nebulizer within past 30 days; resident of Baltimore; ≥1 ED visits or hospitalization for asthma within past 12 months.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	87.0% (221/254 eligible were randomly assigned)
Geographic Location	Baltimore, MD
Type of Community	Urban
Health Care Setting	Pediatric practices within the University of Maryland Medical System and The Johns Hopkins Hospital, Baltimore.
Health Insurance	79.6% Medicaid
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	95 in intervention group, 86 in control group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	No statistically significant difference in the number of hospitalizations ( $T = 4$ ; $C = 11$ ; $RR = 3.03$ , 95% CI [1.00 - 9.18]); No statistically significant difference in the number of ED visits in the past 6 months ( $T = 27$ ; $C = 40$ ; $RR = 1.60$ , CI [1.08 - 2.37]); No significant differences in home nebulizer practice, asthma morbidity, ED visits, or hospitalizations between groups ( $P = 1.00 - 1.00$
Full Citation	Butz , A M. M G. Tsoukleris, M. Donithan, V D. Hsu, I. Zuckerman, K E. Mudd, R E. Thompson, C. Rand, and M E. Bollinger. "Effectiveness of nebulizer use-targeted asthma education on underserved children with asthma." <i>Archives of Pediatrics &amp; Adolescent Medicine</i> , vol. 160, no. 6, 2006, pp. 622-8.

Detail for Selected Study -	Finkelstein, 2006
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Finkelstein 2006
Clinical Focus	Asthma
Target Population	Children 5-17 y.o. with asthma in 40 primary care practices, affiliated with managed health care plans enrolled in the Pediatric Asthma Care Patient Outcomes Research Team (PORT) randomized trial.
Intervention Strategies	Use of physician peer leader interventions (PLE) or peer leaders in combination with the introduction of asthma education nurses (PCI) to facilitate care improvement and to assess the practice levels of physicians within practice groups affiliated with three health care systems.
Additional Targeting Criteria	Continuous health plan enrollment and assignment to a study practice for the 12 month period; claims-based evidence of at least one ER, hospital, or ambulatory encounter for asthma.
Opt-in/opt-out, if available	Opt-out
Enrollment rate, if available	72% (5169/7283 eligible were randomly assigned)
Geographic Location	Washington State, Chicago, IL, and eastern Massachusetts
Type of Community	Urban
Health Care Setting	Washington State - clinics of single-insurer-group model; Chicago - staff model managed care organizations or network divisions of a mixed model health plan; eastern Massachusetts - independent group practices affiliated with health plans.
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	Randomization at practice level
Evaluation Timeframe	24 months
Cost/Utilization Outcomes	No statistically significant differences between intervention and control groups in the proportion of patients dispensed a single controller or dispensed these medicines chronically (PLE = 0.09[CI, 0.01, 0.17]; PCI = 0.04[CI, -0.02, 0.10]; C = 0.04[CI, -0.04, 0.12]); Statistically significant increase in ambulatory care (8-10% increase beyond control group) in first year; No statistically significant differences in ambulatory care in second year (PLE = 0.06[-0.02,0.14]; PCI = 0.08[-0.01,0.18]); No statistically significant difference in ED visits or hospitalizations (PLE = 0[-0.06,0.06]; PCI = 0.03[-0.003, 0.06]).
Full Citation	Finkelstein, J A. P. Lozano, A L. Fuhlbrigge, V J. Carey, T S. Inui, S B. Soumerai, S D. Sullivan, E H. Wagner, S T. Weiss, K B. Weiss, and Pediatric Asthma Care Patient Outcomes Research Team. "Practice-level effects of interventions to improve asthma care in primary care settings: the Pediatric Asthma Care Patient Outcomes Research Team." <i>Health Serv Res</i> , vol. 40, no. 6 Pt 1, 2005, pp. 1737-57.

Detail <sup>•</sup>	for Se	lected	Study -	Goreli	ck, 2006
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Gorelick 2006
Clinical Focus	Asthma
Target Population	Children ages 2-17 y.o. treated in a pediatric ED for acute asthma.
Intervention Strategies	Intervention groups received asthma education, discharge planning, primary care linkage, a copy of the ED chart, and either a letter with recommendations for an asthma care plan (Group 1) or enrollment in a case management program (6 home visits and several telephone calls from case manager) (Group 2).
Additional Targeting Criteria	Wheezing or respiratory distress that was treated with $\geq 1$ inhaled bronchodilator treatment; physician diagnosis of asthma; prior history of wheezing treated with $\beta_z$ agonists; residence in Milwaukee County, Wisconsin; primary caregiver is English-speaking.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	57% agreed to participate
Geographic Location	Milwaukee, WI
Type of Community	Urban
Health Care Setting	Children's Hospital of Wisconsin
Health Insurance	60.4% Medicaid (166/275 completed follow-up on Medicaid)
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	95 in intervention group 1, 81 in intervention group 2, 99 in control group
Evaluation Timeframe	16 months
Cost/Utilization Outcomes	No statistically significant differences among 3 treatment groups in number of ED visits (Group 1: 17.9; Group 2: 35.8; C: 19.2; P = 0.94).
Full Citation	Gorelick, M H. J R. Meurer, C M. Walsh-Kelly, D C. Brousseau, L. Grabowski, J. Cohn, E M. Kuhn, and K J. Kelly. "Emergency department allies: a controlled trial of two emergency department-based follow-up interventions to improve asthma outcomes in children." <i>Pediatrics</i> , vol. 117, no. 4 Pt 2, 2006, pp. S127-34.

Detail for S	Selected	Study -	Smith,	2004
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Smith 2004
Clinical Focus	Asthma
Target Population	Children 2-12 y.o. who were treated for asthma in the ED and had Medicaid or no insurance.
Intervention Strategies	A coach who has a Masters in social work provided telephone coaching to child's caregiver on day two and day five after the index visit. Coaching regarded importance of seeking follow-up care with child's PCP and strategies for overcoming barriers to follow-up care. Caregiver was also notified of a monetary incentive prior to group randomization; incentive was distributed based on parental report of a follow-up visit. All children were also instructed to follow-up with PCP within the following 72 hours after the index visit.
Additional Targeting Criteria	Child was considered to have asthma if the parent stated a physician had made the diagnosis.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	97% (527/543 eligible were enrolled)
Geographic Location	St. Louis, MO
Type of Community	Urban
Health Care Setting	St. Louis Children's Hospital
Health Insurance	93.4% Medicaid (492/527 enrolled were on Medicaid)
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	148 in intervention group completed 6 month call, 154 in control group completed 6 month call
Evaluation Timeframe	6 months
Cost/Utilization Outcomes	35.7% of intervention group attended asthma-planning visit with PCP as opposed to 18.9% of control group within 15-days of index ED visit ( $P$ <.0001); No statistically significant difference in the number of asthma-emergent visits ( $T$ = 4.1%; $C$ = 5.3%); No statistically significant difference in the number of ED visits within 15 days of index ED visits ( $T$ = 3.0%; $C$ = 2.7%); No statistically significant difference in the number of hospital admissions within 15 days of index ED visits ( $T$ = 0.8%; $C$ = 0.4%).
Full Citation	Smith, S.R. D.M. Jaffe, E.B. Fisher Jr, K.M. Trinkaus, G. Highstein, and R.C. Strunk "Improving follow-up for children with asthma after an acute Emergency Department visit." <i>J Pediatr</i> , vol. 145, no. 6, 2004, pp. 772-7.

Detail for Selected Study -	Tierney, 2005
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Tierney 2005
Clinical Focus	Asthma
Target Population	Primary care patients 18+ y.o. with asthma or chronic obstructive pulmonary disease.
Intervention Strategies	Evidence-based care suggestions concerning drugs and monitoring were delivered to physicians (general internists and internal medicine residents) and outpatient pharmacists when writing orders or filling prescriptions using computer workstations. 2 x 2 factorial randomization resulted in 4 groups of patients: physician intervention (P), pharmacist intervention (PH), both interventions (B), and controls (C).
Additional Targeting Criteria	Patient visited the study practices in the past year, and had either 1) the diagnosis of asthma or COPD recorded during any inpatient, emergency, or outpatient visit; 2) emphysema recorded as a reading on any prior chest radiography or CT scan; or 3) two or more prescriptions for inhaled $\beta$ -agonists, corticosteroids, ipratropium, or cromolyn, or oral $\beta$ -agonists or theophylline.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	82% (706/865) of eligibles agreed to be randomized
Geographic Location	Indianapolis, IN
Type of Community	Inner-City
Health Care Setting	Indiana University Medical Group-Primary Care
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	194 in P group. 161 in PH group. 182 in B group. 162 in C group were included in utiliazation analyses.
Evaluation Timeframe	36 months
Cost/Utilization Outcomes	No statistically significant differences in number of all-cause emergency department visits (P = 1.4 $\pm$ 1.7; PH = 1.5 $\pm$ 2.3; B = 1.4 $\pm$ 2.1; C = 1.4 $\pm$ 1.9);
	No statistically significant difference in number of reactive airways disease emergency department visits (P = 0.3 $\pm$ 0.7; PH = 0.4 $\pm$ 0.8; B = 0.4 $\pm$ 0.8; C = 0.3 $\pm$ 0.8);
	No statistically significant difference in number of all-cause hospitalizations (P = 0.5 $\pm$ 1.6; PH = 0.5 $\pm$ 1.1; B = 0.4 $\pm$ 1.1; C = 0.4 $\pm$ 0.8);
	No statistical significance in number of reactive airways disease hospitalizations (P = 0.1 $\pm$ 0.5; PH = 0.1 $\pm$ 0.5; B = 0.1 $\pm$ 0.5; C = 0.1 $\pm$ 0.3);
	No statistically significant difference in total health care charges (P = $\$8,006 \pm 18,720$ ; PH = $\$5,333 \pm 9,400$ ; B = $\$5,652 \pm 10,579$ ; C = $\$5,800 \pm 8,536$ ).
Full Citation	Tierney, W M. J M. Overhage, M D. Murray, L E. Harris, X H. Zhou, G J. Eckert, F E. Smith, N. Nienaber, C J. McDonald, and F D. Wolinsky. "Can computer-generated evidence-based care suggestions enhance evidence-based management of asthma and chronic obstructive pulmonary disease? A randomized, controlled trial." <i>Health Serv Res</i> , vol. 40, no. 2, 2005, pp. 477-97.

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III. Congestive Heart Failure Studies

### Congestive Heart Failure (CHF) Studies Reporting Decreases in Cost/Utilization - Summary Table

Clinical Focus	Author/ Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
CHF	Naylor, 2004	Adults (elderly)	Advanced practice nurses provided education, care management, and individualized plans of care to patients and caregivers and collaborated with patients' physicians on patient care and management	52 weeks	36% reduction in total number of re- hospitalizations	А
CHF	Krumholz, 2002	Adults	Cardiac care nurse provided education on early signs and symptoms, information on when and how to seek physician care, and telemonitoring through regular phone contact with patients.	12 months	39% decrease in total number hospital readmissions	А
CHF	Sisk, 2006	Adults	Nurses managed patients by phone and sent patients' clinicians notes on contacts with recommendations on medication changes or subsequent examinations	18 months	21% decrease in total hospitalizations over 12 months; 24% decrease in total hospitalizations in months 12 to 18	А
CHF	Koelling, 2005	Adults	A one time one-on-one 60 min educational session prior to hospital discharge	6 months	35% reduction in hospital costs	А
CHF	Dunagan 2005	Adults	Regularly scheduled telephone contacts by special study nurses for education and support, home visits if necessary. Adjustment of diuretic dosage if previously authorized by primary physician.	12 months	31% decrease in total number of re- hospitalizations at 6 months	А
CHF	Hilleman 2004	Adults	Hospital pharmacists sent letters or called patients' primary care physicians following patients' hospital discharge with recommendations for lipid management.	2 years	35% reduction in proportion hospitalized for myocardial ischemia	В
CHF	Riegel, 2002	Adults (elderly)	Nurses provided telephonic case management, ensured physician follow-up, sent reports to physicians on patient progress and guidelines for treatment	6 months	45.5% decrease in inpatient costs at 6 months	В
CHF	Fonarow 2004	Adults	Implementation of a detailed treatment algorithm for lipid management for all patients hospitalized with coronary artery disease.	1 year	60% reduction in proportion with acute myocardial infarction 45% reduction in proportion with rehospitalization	С
Heart Disease	Wheeler 2003	Adult women	Weekly group meetings for 4 weeks with participants developing their own solutions to specific health problems following an approach taught by the program. Program provided reimbursement for transportation costs and a toll-free number for participants to call program staff with questions.	2 years	49% reduction in inpatient charges	А

Wherever possible, impacts on service utilization (such as hospital admissions or ER visits) are expressed as percentage reductions in the number of services per person per unit time. If the article does not present numbers of services per person per unit time but does provide the total number of services, service use/person/time is estimated by dividing the number of services by the sample size, without accounting for variable lengths of follow up or for mortality. In cases where only numbers or proportions of people with any (one or more) service use are reported, service use impacts are expressed as percentage reductions in the proportion with any service use.

Detail for Selected	d Study - Naylor 2004
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Naylor 2004
Clinical Focus	CHF
Target Population	Adults 65 and older who were hospitalized with heart failure
Intervention Strategies	Use of advanced practice nurses to provide transitional care intervention, education, care management strategies and individualized plans of care to patients and caregivers and to collaborate with patients' physicians regarding patient care and management. Nurses visited with patients in the hospital and eight additional times at patients' homes to identify changes in health status and provide support.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	37.3% (239 out of 641 screened)
Geographic Location	Philadelphia, Pennsylvania
Type of Community	Urban
Health Care Setting	Six academic and community hospitals
Health Insurance	HMO (42% of intervention group); Medicare (13%); Medicare + Medicaid (9%); Medicare + supplemental (54%)
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	239 total; intervention group = 118, control group = 121
Evaluation Timeframe	52 weeks
Cost/Utilization Outcomes	34% reduction in re-hospitalizations per patient per year (T = 1.18, C = 1.79, p< .001); 52% reduction in cost of re-hospitalization from months 0 to 3 (T = $$236,144$ , C = $$489,420$ , p = .01); 55% reduction in cost of re-hospitalization from months 0 to 6 (T = $$381,725$ , C= $$841,164$ , p<.03); Reduction in cost of re-hospitalization months 0-12 was not statistically significant
Full Citation	Naylor, Mary. Brooten, Dorothy. Campbell, Roberta. Maislin, Greg. McCauley, Kathleen. Schwartz, Sanford. "Transitional Care of Older Adults Hospitalized with Heart Failure: A Randomized, Controlled Trial." <i>Journal of American Geriatrics Society</i> . 52(5): 675-684, 2004 May.

<b>Detail for Selecte</b>	d Study - Krumholz 2002
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Krumholz 2002
Clinical Focus	CHF
Target Population	Adults 50 or older who met clinical criteria for presence of HF on admission to hospital
Intervention Strategies	Use of cardiac care nurse to provide education on early signs and symptoms, information on when and how to seek physician care, and telemonitoring through regular phone contact with patients. The first contact was an in-person meeting either at the hospital or at the patient's home (if patient couldn't travel to the hospital). Contact continued with weekly phone calls that gradually were scaled back to bi-weekly and then monthly calls.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	23% (88 out of 390 screened)
Geographic Location	New Haven, Connecticut
Type of Community	Urban
Health Care Setting	Hospital and patient home
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	88 (T= 44, C=44)
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	39% decrease in number of all-cause hospital readmissions (T = 49, C= 80 [roughly T=1.1 per person per year, C=1.8 per person per year] <sup>a</sup> p=0.06); 48% reduction in number of readmissions for heart failure (T = 22, C= 42, [roughly T=0.5 per person per year, C=0.95 per person per year] <sup>a</sup> p=0.07); 47% reduction in number of readmissions for heart failure or CVD (T = 35, C=66, [roughly T=0.8 per person per year, C=1.5 per person per year] <sup>a</sup> p=0.03);
Full Citation	Krumholz, Harlan. Amatruda, Joan. Smith, Grace. Mattera, Jennifer. Roumanis, Sarah. Radford, Martha. Crombie, Paula. Vaccarino, Viola. "Randomized Trial of an Education and Support Intervention to Prevent Readmission of Patients with Heart Failure." <i>Journal of the American College of Cardiology</i> . 39(1): 83-89, 2002 January.
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<sup>\*</sup>calculated from information provided in the paper as the total number of events in each group divided by the sample size of that group, without taking into account variations in lengths of follow-up for patients or patients who died.

### Detail for Selected Study - Sisk, 2006

<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Sisk, 2006
Clinical Focus	CHF
Target Population	Adults, African American and other non-white populations; documented systolic dysfunction in cardiac tests
Intervention Strategies	Use of nurses to counsel and manage patients by phone (on diet, adherence, etc.) and coordinate with patients' clinicians by sending them notes on contact with patients and recommendations on medication changes or subsequent examinations. Nurse work was supervised by an internist at the hospital.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	26% (406 out of 1555 initially screened)
Geographic Location	Harlem, New York
Type of Community	Urban
Health Care Setting	1 large private academic medical center, 2 municipal hospitals, 1 small private community hospital
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	406 (T= 203, C=203) up to 12 months; 254 (T=174, C=174) between 12 and 18 months
Evaluation Timeframe	18 months
Cost/Utilization Outcomes	20% decrease in number of all-cause hospitalizations per person over 12 months (T=.74, C=.93, p=.05) 24% decrease in number of all-cause hospitalizations per person in the period between months 12 and 18 (T=.63, C=.83, p=.05)
Full Citation	Sisk, Jane. Hebert, Paul. Horowitz, Carol. McLaughlin, Mary Ann. Wang, Jason. Chassin, Mark. "Effects of Nurse Management on the Quality of Heart Failure Care in Minority Communities." <i>Annals of Internal Medicine</i> . 145(4): 273-284, 2006 August.

Detail for Selecte	d Study - Koelling, 2005
Characteristic	<u>Description</u>
Author and Year of Publication	Koelling, 2005
Clinical Focus	CHF
Target Population	Adult hospital inpatients admitted with a diagnosis of heart failure and with documented left ventricular systolic dysfunction
Intervention Strategies	60 minute long, one-on-one teaching session with a nurse educator before discharge. Topics covered included causes of heart failure, rationale for drug therapies, mechanisms of diuretic medications, importance of and specific instruction on dietary restriction of sodium and free water intake, importance of and instruction in daily weight monitoring, smoking cessation, avoidance of heavy alcohol intake and non-steroidal drugs, and action plans for worsening of symptoms. Printed materials in laymen's terms.
Additional Targeting Criteria	Exclusion for non-cardiac illness likely to increase 6 month mortality or hospitalization risk, and if undergoing evaluation for cardiac transplantation
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	38% (223 out of 590 initially screened)
Geographic Location	Ann Arbor, MI
Type of Community	Urban/suburban
Health Care Setting	Academic medical centerUniversity of Michigan Hospital
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	223 (T= 107, C=116)
Evaluation Timeframe	6 months
Cost/Utilization Outcomes	35% reduction in hospital costs (T=\$5369, C=\$8,292, p=0.034).  Adjusted relative risk of combined endpoint of all-cause re-hospitalization or death=0.65 (p=0.018). Since there was a non-significant difference in mortality rate (T=6.5%, C=8.6%), this is approximately equivalent to a 35% reduction in the proportion with any all cause hospitalization.  Adjusted relative risk of heart failure hospitalization was 0.56 (p=0.065), or a 44% reduction in the proportion with any heart failure hospitalization.  Estimated cost of the intervention was \$100 per participant based on \$50/hour nursing time.
Full Citation	Koelling, Todd M., Monica L. Johnson, Robert J. Cody, and Keith D. Aronson. "Discharge Education Improves Clinical Outcomes in Patients with Chronic Heart Failure." <i>Circulation</i> , vol. 111, January 18, 2005, pp. 179-185.

<b>Detail for</b>	· Selected	Study -	Dunagan,	2005
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Dotail 101 Delette	ed Study – Dunagan, 2005
Characteristic	<u>Description</u>
Author and Year of Publication	Dunagan 2005
Clinical Focus	CHF
Target Population	Adult hospital inpatients admitted with a diagnosis of heart failure
Intervention Strategies	Education by specially trained study nurses during index hospitalization and/or by telephone after discharge; regularly scheduled telephone contact, with frequency individualized by nurses (weekly to start). Home visits and bathroom scales if deemed appropriate (20 and 18 patients respectively). Telephone calls emphasized self-management skills, appropriate diet, and medication adherence. Screening for signs or symptoms of decompensation at each contact. If worsening, advice to take extra diuretics if physician had previously granted permission for program to adjust, or to call primary physician if not.
Additional Targeting Criteria	Documented left ventricular systolic dysfunction, and meeting clinical criteria for moderate HF severity. English fluency, absence of severe cognitive or psychological impairments, and not homeless
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	55% (151 of 276 meeting all inclusion/exclusion criteria)
Geographic Location	St. Louis, MO
Type of Community	Urban
Health Care Setting	Academic medical center (Barnes-Jewish Hospital)
Health Insurance	Group Health Advanta (Medicare HMO), Medicaid, FFS Medicare, no insurance
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	151 (T=76; C=75)
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	At six months, 31% decrease in number of hospitalizations per person per 6 months (T=0.9, C=1.3, p=0.01). At six months, 17% reduction in hospital costs (T=\$695,777, C=\$841,893, p=0.012). Differences in hospitalizations and costs at 12 months were not statistically significant, however.
Full Citation	Dunagan, William Claiborne, Benjamin Littenberg, Gregory A. Ewald, Catherine A. Jones, Valerie Beckham Emery, Brian M. Waterman, Daniel C. Silverman, and Joseph G. Rogers. "Randomized Trial of a Nurse-Administered, Telephone-Based Disease Management Program for Patients with Heart Failure." <i>Journal of Cardiac Failure</i> , vol. 11, no. 5, June 2005, pp. 358-365

Detailed for Selec	cted Study – Hilleman, 2004
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Hilleman 2004
Clinical Focus	Coronary Artery Disease
Target Population	Adults hospitalized with coronary disease
Intervention Strategies	Hospital pharmacists sent letters or called patients' primary care physicians at 2, 8, 12, 24, and 52 weeks after hospital discharge with recommendations for lipid testing and medication therapy based on the National Cholesterol Education Program guidelines.
Additional Targeting Criteria	Patients admitted to the Coronary Care Unit with coronary disease documented or confirmed during the hospitalization
Opt-in/opt-out, if available	Not applicable
Enrollment rate, if available	Not applicable
Geographic Location	Omaha, NE
Type of Community	Rural
Health Care Setting	Rural primary care practices and Creighton University Medical Center
Health Insurance	Not stated (84% with prescription coverage)
Quality of Evidence	В
Study Design	Quasi-randomized study: treatment patients were hospitalized from Jan. 1 1999 – Mar. 31, 1999; control patients were hospitalized Oct. 1, 1998 – Dec. 31, 1998.
Sample Size	612 (T=303, C=309)
Evaluation Timeframe	2 years
Cost/Utilization Outcomes	35% reduction in proportion hospitalized for myocardial ischemia (T=15%, C=23%, p<0.05); 45% reduction in proportion with acute myocardial infarction (T=6%, C=11%, p<0.05); 43% reduction in proportion with any coronary revascularization (T=12%, C=21%, p<0.05); 36% reduction in proportion with percutaneous coronary intervention (T=9%, C=14%, p<0.05)
Full Citation	Hilleman, Daniel E., Michele A. Faulkner, and Michael S. Monaghan. "Cost of a Pharmacist-Directed Intervention to Increase Treatment of Hypercholesterolemia." <i>Pharmacotherapy</i> , vol. 24, no. 8, pp. 1077-1083.

Detail for Selecte	d Study – Riegel, 2002
Characteristic	<u>Description</u>
Author and Year of Publication	Riegel 2002
Clinical Focus	CHF
Target Population	Elderly adults who were hospitalized at one of two Southern California hospitals and had a confirmed clinical diagnosis of heart failure
Intervention Strategies	Use of nurses to provide telephonic case management, educate patients, ensure contact with physicians is made, send reports to physicians on patient progress and guidelines for treatment. Nurses also arranged for supply of medications if necessary. Each patient received an average of 17 phone calls, which decreased in length over time, and about 16 hours of case management time.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	31% (358 out of 1145 screened)
Geographic Location	Southern California
Type of Community	Not stated
Health Care Setting	Patient home nurses provided telephonic case management
Health Insurance	Not stated
Quality of Evidence	B
Study Design	Cluster Randomized Controlled Trial
Sample Size	281 physicians; 358 patients (T = 130, C = 228)
Evaluation Timeframe	6 months
Cost/Utilization Outcomes	47% decrease in average number of accumulated hospital days due to heart failure at 3 months (T = .85, C= 1.6, p= .054); 48% decrease in average number of accumulated hospital days due to heart failure at 6 months (T = 1.1, C= 2.1, p= .03); 45.5% decrease in inpatient costs at 6 months (T = \$1,192, C= \$2,186, p=.04); Results on inpatient costs at 3 months were not statistically significant
Full Citation	Riegel, Barbara. Carlson, Beverly. Kopp, Zoe. LePetri, Barbara. Glaser, Dale. Unger, Alan. "Effect of a Standardized Nurse Case-Management Telephone Intervention on Resource Use in Patients with Chronic Heart Failure." <i>Archives of Internal Medicine</i> . 162: 705-712, 2002 March.

<b>Detail for Selecte</b>	d Study – Fonarow, 2004
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Fonarow 2004
Clinical Focus	Coronary Artery Disease
Target Population	Adults hospitalized with acute myocardial infarction
Intervention Strategies	Implementation of a detailed treatment algorithm for all patients hospitalized with coronary artery disease with guidelines for lipid testing and treatment (as well as for treatment with aspirin, beta-blockers, ACE inhibitors; and for patient education on smoking, diet, and exercise).
Additional Targeting Criteria	Not stated
Opt-in/opt-out, if available	Not applicable
Enrollment rate, if available	Not applicable
Geographic Location	Los Angeles
Type of Community	Urban
Health Care Setting	Academic Medical Center (UCLA Medical Center)
Health Insurance	Not stated
Quality of Evidence	C
Study Design	Pre- post design at the program level (patient cohorts from 1994 – 1995, after program implementation, compared to those from 1992 – 1993, before the program)
Sample Size	558 (T=302, C=256)
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	60% reduction in proportion with acute myocardial infarction (T=3.1%, C=7.8%, p<0.05); 45% reduction in proportion with rehospitalization (T=7.6%, C=14.8%, p<0.05)
Full Citation	Fonarow, Gregg C., Anna Gawlinski, Samira Moughrabi, and Jan H. Tillisch. "Improved Treatment for Coronary Heart Disease by Implementation of a Cardiac Hospitalization Atherosclerosis Management Program (CHAMP)." <i>American Journal of Cardiology,</i> vol. 87, April 1, 2001, pp. 819-822.

<b>Detail for Selecte</b>	d Study – Wheeler, 2003
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Wheeler 2003
Clinical Focus	"Heart Disease" (angina, myocardial infarction, arrhythmia, and valvular disease)
Target Population	Women 60 years or older
Intervention Strategies	Weekly group meetings of 6-8 women, each lasting 2.5 hours, for 4 weeks, led by a health educator and by a peer leader. Participants received "Women take PRIDE" workbooks, videotapes, and self-monitoring tools (logs, pedometers). Participants selected their own topics to work on as a group and as individuals (e.g., exercise, taking medications, diet), using the "Women take PRIDE" process (Problem Identification, Researching one's routine, Identifying a management goal, Developing a plan to reach it, Expressing one's reactions and establishing rwards for goal achievement) under the guidance of the group leaders. Program provided reimbursement for transportation costs and a toll-free number for participants to call program staff with questions.
Additional Targeting Criteria	exclusions for terminal illness or memory deficits
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	48%
Geographic Location	Ann Arbor, MI and southeastern Michigan
Type of Community	suburban/urban
Health Care Setting	not based in health care setting
Health Insurance	not stated
Quality of Evidence	A
Study Design	Randomized, controlled trial
Sample Size	443 (T=227, C=216)
Evaluation Timeframe	24 months (21 months after 3 month intervention period)
Cost/Utilization Outcomes	49% reduction in inpatient charges (p=.10) 41% reduction in cardiac hospitalizations (p=0.05)
Full Citation	Wheeler, John R.C. "Can a Disease Self-Management Program Reduce Health Care Costs? The Case of Older Women with Heart Disease." <i>Medical Care</i> , vol. 41, no. 6, pp. 706-715.

### Congestive Heart Failure (CHF) Studies Reporting No Changes or Increases in Cost/Utilization - Summary Table

Clinical Focus	Author/Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
CHF	DeBusk, 2004	Adults	Nurse care management to provide structured telephone surveillance, treatment for heart failure, and coordination of patients' care with primary care physicians	12 months	No statistically significant difference in number of rehospitalizations for heart failure	А
CHF	Galbreath, 2004	Adults	Telephonic disease management administered by a registered nurse with specialized cardiac training	18 months	No statistically significant decrease in CHF-related office or ED visits, or hospitalizations	А
CHF	Goldberg, 2003	Adults	Daily reporting of weight and symptoms by patients to physicians using home telehealth-based heart failure monitoring system	6 months	No statistically significant difference in number of cardiovascular related rehospitalizations	А
CHF	Riegel, 2006	Adults (elderly)	Telephone case management delivered by a bilingual/bicultural Mexican-American registered nurse with special training in HF	6 months	No statistically significant group differences were found in HF hospitalizations	А
CHF	Ross, 2004	Adults	Use of patient-accessible online medical record, SPPARO (System Providing Access to Records Online) to improve patient care and clinic operations	12 months	No statistical significance in number of hospitalizations	А
CHF	Tierney, 2003	Adults	Evidence-based cardiac care suggestions, approved by a panel of local cardiologists and general internists, were displayed on computers to physicians and pharmacists as they cared for enrolled patients	12 months	No statistically significant differences in the number of cardiac-specific ED visits or hospitalizations	А

Detail for Selected Study - DeBusk, 2004		
<u>Characteristic</u>	<u>Description</u>	
Author and Year of Publication	DeBusk 2004	
Clinical Focus	CHF	
Target Population	Patients who were hospitalized with a provisional diagnosis of heart failure.	
Intervention Strategies	Physician-directed, nurse-managed program. The telephone mediated intervention included the following elements: initial educational session, including videotape; baseline telephone counseling session; nurse-initiated follow-up telephone contacts; pharmacologic management; and nurse-initiated communication with physicians. Nurse-patient phone follow-ups were scheduled at weekly intervals for 6 weeks; biweekly for 8 weeks; monthly for 3 months; bimonthly for 6 months; and as needed to monitor patients' medications, symptoms, and other medical problems throughout the 12 month period of the intervention.	
Additional Targeting Criteria	New-onset or worsening heart failure on the basis of 1) shortness of breath (dyspnea at rest, including orthopnea or paroxysmal nocturnal dyspnea) and 2) at least 1 corroborating clinical sign (pulmonary congestion on examination, including rales, crackles, or wheezes) or radiologic abnormality (pulmonary congestion on chest radiograph) consistent with heart failure.	
Opt-in/opt-out, if available	Opt-in	
Enrollment rate, if available	55% (462/835 eligible were randomly assigned)	
Geographic Location	Northern California	
Type of Community	Various communities	
Health Care Setting	Kaiser Permanente medical centers in San Francisco, Vallejo, Walnut Creek, Sacramento, and Roseville, California	
Health Insurance	Not Stated	
Quality of Evidence	A	
Study Design	Randomized controlled trial	
Sample Size	199 in intervention group, 191 in control group	
Evaluation Timeframe	12 months	
Cost/Utilization Outcomes	No statistically significant difference in the number of all-cause rehospitalizations (T = 237; C = 232; p > 0.2); No statistically significant difference in the number of rehospitalizations for heart failure (T = 76; C = 86; p > 0.2); Rate of first rehospitalization for heart failure was similar in both groups (proportional hazard, 0.85 [95% CI, 0.46 to 1.57])	
Full Citation	DeBusk, R F. N H. Miller, K M. Parker, A. Bandura, H C. Kraemer, D J. Cher, J A. West, M B. Fowler, and G. Greenwald. "Care management for low-risk patients with heart failure: a randomized controlled trial." <i>Ann Intern Med</i> , vol. 141, no. 8, 2004, pp. 606-13.	

<b>Detail for</b>	Selected	Study	- Galbreath,	2004
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Galbreath 2004
Clinical Focus	CHF
Target Population	Patients ≥18 years of age with symptoms of CHF.
Intervention Strategies	Disease management (DM) program was administered telephonically by a disease manager who was a registered nurse with specialized cardiac training. DM managers provided patient education and medication management in conjunction with the PCP. Initial call frequency was weekly, with a transition to monthly for the duration of the intervention. Frequency of calls was also adjusted for acuity or need.
Additional Targeting Criteria	Systolic or echocardiographically confirmed diastolic heart failure.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	1069 enrolled in study
Geographic Location	South Texas
Type of Community	Urban, suburban, and rural settings
Health Care Setting	Medical centers
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	Total of 502 patients assessed at 18-month follow-up for ejection fraction
Evaluation Timeframe	18 months
Cost/Utilization Outcomes	No statistically significant decrease in total and CHF-related healthcare utilization, including medications, office or emergency department visits, procedures, or hospitalizations; No statistically significant differences in healthcare cost by group.
Full Citation	Galbreath, A D. R A. Krasuski, B. Smith, K C. Stajduhar, M D. Kwan, R. Ellis, and G L. Freeman. "Long-term healthcare and cost outcomes of disease management in a large, randomized, community-based population with heart failure." <i>Circulation</i> , vol. 110, no. 23, 2004, pp. 3518-26.

<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Goldberg 2003
Clinical Focus	CHF
Target Population	Patients hospitalized with New York Heart Association (NYHA) class III or IV hear failure, with a left ventricular ejection fraction, measured within 6 months of enrollment.
Intervention Strategies	Nurses administered heart failure care and patient education about heart failure, including advice on daily weights, dietary restrictions including sodium and fluid, and signs and symptoms of a heart failure decompensation. Patients were advised to report changes in weight and symptoms to their physician. Patient also received the technology-based remote monitoring system, AlereNet, to monitor weight and symptoms daily and provide direct nurse-to-patient contact. AlereNet included an electronic scale and an individualized symptom response system.
Additional Targeting Criteria	Treatment with a diuretic and vasodilator; weight <400 pounds; ability to stand for at least 20 seconds without holding the wall; speak either English or Spanish; available phone line within patient's home.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	280 enrolled in study
Geographic Location	16 medical centers throughout continental United States.
Type of Community	Unclear. Patients referred from clinical sites throughout continental United States.
Health Care Setting	Cardiac transplant centers and community-based cardiology practices.
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	138 in intervention group, 142 in control group (with 32 lost to follow-up and 37 lost to death)
Evaluation Timeframe	6 months
Cost/Utilization Outcomes	No statistically significant difference in number of all-cause rehospitalizations (Average utilization T = 0.19 $\pm$ 0.46; C = 0.20 $\pm$ 0.30; P = 0.28); No statistically significant difference in number of cardiovascular related rehospitalizations (Average utilization T = 0.08 $\pm$ 0.24; C = 0.11 $\pm$ 0.26; P = 0.28); 56% decrease in mortality (P < 0.003).
Full Citation	Goldberg, L. R. J. D. Piette, M. N. Walsh, T. A. Frank, B. E. Jaski, A. L. Smith, R. Rodriguez, D. M. Mancini, L. A. Hopton, E. J. Orav, E. Loh, and WHARF Investigators. "Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial." Am Heart J, vol. 146, no. 4, 2003, pp. 705-12

Detail for Selected Study - Riegel, 2006				
<u>Characteristic</u>	<u>Description</u>			
Author and Year of Publication	Riegel 2006			
Clinical Focus	CHF			
Target Population	Elderly patients (72 $\pm$ 11 years) who self-identified as being Hispanic and were hospitalized with a primary or secondary diagnosis of HF.			
Intervention Strategies	Telephone case management delivered by a bilingual/bicultural Mexican-American registered nurse with special training in HF. Registered nurses who were guided by a decision-support software program - At Home with Heart Failure - monitored patient symptoms and provided guidance and education on self-care skills. Printed educational material in the desired language was mailed to patients monthly and as needed when specific information was requested. Nurse case managers telephoned physicians as needed and mailed reports on patient progress at regular intervals.			
Additional Targeting Criteria	Lived in the community (i.e., not institutionalized); planned to return to the community after hospital discharge; spoke Spanish or English			
Opt-in/opt-out, if available	Opt-in			
Enrollment rate, if available	60% (135/225 of eligibles agreed to be randomized)			
Geographic Location	Southern California			
Type of Community	Unclear			
Health Care Setting	Community Hospitals			
Health Insurance	10.4% Medicaid, 59.7% Medicare, 23.9% HMO, 32.0% uninsured			
Quality of Evidence	A			
Study Design	Randomized controlled trial			
Sample Size	69 in intervention group, 65 in control group			
Evaluation Timeframe	6 months			
Cost/Utilization Outcomes	No statistically significant difference in number of all-cause hospitalizations (Average utilization T = 1.06 $\pm$ 1.3 [95% CI 0.74-1.4]; C = 1.08 $\pm$ 1.4 [CI 0.75-1.4]); No significant group differences were found in HF hospitalizations at 6 months (T = 0.55 $\pm$ 1.1 [CI 0.32-0.78]; C = 0.49 $\pm$ 0.81 [CI 0.25-0.73]); No significant group differences in proportion with HF readmissions at 6 months (T = 31.9%; C = 33.8%); No significant group differences in HF cost of care (T = \$5567 $\pm$ \$13137 [CI \$2009-9126]; C = \$6151 $\pm$ \$16650 [CI \$2485-9818]).			
Full Citation	Riegel, B. B. Carlson, D. Glaser, and T. Romero. "Randomized controlled trial of telephone case management in Hispanics of Mexican origin with heart failure." <i>J Card Fail</i> , vol. 12, no. 3, 2006, pp. 211-9.			

<b>Detail for</b>	Selected	Study -	Ross	2004
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Ross 2004
Clinical Focus	CHF
Target Population	Patients >18 y.o. with heart failure who were followed in the specialty clinic for heart failure at the University of Colorado Hospital.
Intervention Strategies	Patients given access to SPPARO (System Providing Access to Records Online) and a written user guide to the system. SPPARO provided patients with their medical record, an educational guide, and a messaging system that allowed patients to exchange messages with the nursing staff in the practice.
Additional Targeting Criteria	Spoke English; used a Web browser before.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	27% (107/394 of eligibles agreed to be randomized)
Geographic Location	Denver, Colorado
Type of Community	Urban
Health Care Setting	Specialty clinic at the University of Colorado Hospital
Health Insurance	19% on Safety-Net Insurance Program
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	38 in intervention group, 43 in control group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	No statistical significance in number of hospitalizations (T = 22; C = 21; P = 1.00); 14% increase in number of emergency room visits (T = 20; C = 8; P = 0.03); No significant group differences in HF practice visits (T = 324; C = 325; P = 0.66).
Full Citation	Ross, S E. L A. Moore, M A. Earnest, L. Wittevrongel, and C T. Lin. "Providing a web-based online medical record with electronic communication capabilities to patients with congestive heart failure: randomized trial." <i>Journal of Medical Internet Research</i> , vol. 6, no. 2, 2004, pp. e12.

Detail for Selected Study -	Tierney, 2003
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Tierney 2003
Clinical Focus	CHF
Target Population	Patients with heart failure who had evidence of left ventricular dysfunction on an echocardiogram or cardiac scintigram report.
Intervention Strategies	Evidence-based care suggestions concerning drugs and monitoring were delivered to physicians (general internists and internal medicine residents) and outpatient pharmacists when writing orders or filling prescriptions using computer workstations. 2 x 2 factorial randomization resulted in 4 groups of patients: physician intervention (P), pharmacist intervention (PH), both interventions (B), and controls (C).
Additional Targeting Criteria	Patients with ischemic heart disease eligible with 1 of the following: 1) inpatient, outpatient, or ED diagnosis of coronary artery disease, angina, or myocardial infarction; 2) definitive diagnostic test; or 3) more than 2 prescriptions for long-acting nitrates.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	81% (706/870 of eligibles were enrolled, randomization at practice and pharmacists level)
Geographic Location	Indianapolis, IN
Type of Community	Urban
Health Care Setting	Indiana University Medical Group - Primary Care (IUMG-PC)
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	142 in P group, 107 in PH group, 113 in B group, 119 in C group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	No statistically significant effect from either P or PH intervention on whether patients' cardiac care was compliant with the suggestions (P > 0.8 across the 4 intervention groups, P > 0.7 and P > 0.4 for P and PH interventions separately); No statistically significant differences between groups in the total number of cardiac-specific ED visits or hospitalizations (ED visit rates: $P = 0.2 \pm 0.4$ ; $PH = 0.2 \pm 0.6$ ; $PH = 0.2 \pm 0.4$ ; $PH = $
Full Citation	Tierney, W M. J M. Overhage, M D. Murray, L E. Harris, X H. Zhou, G J. Eckert, F E. Smith, N. Nienaber, C J. McDonald, and F D. Wolinsky. "Effects of computerized guidelines for managing heart disease in primary care." <i>J Gen Intern Med</i> , vol. 18, no. 12, 2003, pp. 967-76.

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IV. Diabetes Studies

### Diabetes Studies Reporting Decreases in Cost/Utilization - Summary Table

Clinical Focus	Author/ Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
Diabetes	Sadur 1999	Adults	Six monthly group meetings led by a diabetes nurse educator and a multidisciplinary team. Meetings included health and diet education, and medication review. Phone contacts with nurse between meetings to review diabetes management.	1 year	43% reduction in number of hospitalizations; 28% reduction in number of physician visits;	А
Diabetes	Wagner 2001	Adults	Group meetings every 3-6 months over 2 years, consisting of one- on-one visits with physician, nurse, and pharmacist; and group educational/peer support sessions. Nurses developed individualized plans for each participant and the entire group prior to each meeting.	2 years	50% reduction in number of ER visits	А
Diabetes	Wolf 2004	Adults	Registered Dietitian led individual, group, and telephone patient educational and support sessions.	1 year	14% reduction in total number of medications per day	А
Diabetes	Barnett 2006	Adults	Patients used a simple messaging device (requiring only basic phone service and an electrical outlet) to answer scripted questions about symptoms and health status. Nurse care coordinators monitored responses daily and acted according to clinical judgment	2 years	9% reduction in all-cause hospitalizations.	В
Diabetes	Villagra 2004	Adults	Telephonic disease management; web-based patient education; home remote patient monitoring devices; reminders and educational mailings for patients. Mail, fax, or telephone progress reports to primary care doctors.	1 year	24% reduction in hospitalizations; 14% reduction in ER visits; 5% reduction in office visits	В
Diabetes	Davidson 2007	Adults	Specially trained nurse, under endocrinologist supervision, treated patients following detailed diabetes care algorithms.	1 year	71% reduction in combined outcome of preventable diabetes-related ER visits and hospitalizations	С
Diabetes	Sidorov 2002	Adults	Scheduled one-on-one or group diabetes patient education sessions at primary care offices provided by traveling nurse educators. Promotion of guideline-based care to primary care doctors by nurse educators, and program sponsorship of diabetes CME for doctors.	2 years	25% reduction in number of all-cause hospitalizations	С

Wherever possible, impacts on service utilization (such as hospital admissions or ER visits) are expressed as percentage reductions in the number of services per person per unit time. If the article does not present numbers of services per person per unit time but does provide total number of services, this quantity is estimated by dividing the number of services by the sample size, without accounting for variable lengths of follow up or for mortality. In cases where only numbers or proportions of people with any (one or more) service use are reported, service use impacts are expressed as percentage reductions in the proportion with any service use.

Detail for Selecte	d Study - Sadur 1999
<b>Characteristic</b>	<u>Description</u>
Author and Year of Publication	Sadur 1999
Clinical Focus	Diabetes
Target Population	Members of Northern California Kaiser Health Plan with either Type 1 or Type 2 diabetes
Intervention Strategies	In addition to regular care from primary care doctor, a total of six monthly group meetings at the clinic (Diabetes Cooperative Care Clinics). Groups consisted of 10-18 patients, each meeting lasting 2 hours, led by a diabetes nurse educator and a multidisciplinary team of a dietitian, a behaviorist, and a pharmacist. Meetings included blood pressure measurement, education on home blood glucose monitoring; individual and group consultations with dietitian, behaviorist, and pharmacist; and referrals to podiatrist, ophthalmologist, and smoking cessation programs. Additional health education talks as voted on by group, e.g., diabetes complications, foot care, exercise, stress and emotional issues in diabetes, sexual dysfunction. Between meetings, phone contacts by nurse with patients to review diabetes management with frequency ranging from every 3d. to 2 weeks. Nurses regularly reviewed all cases with diabetologist.
Additional Targeting Criteria	Ages 16-75 y.o., hemoglobin A1c>8.5% or no hemoglobin A1c measured within past year.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	70%
Geographic Location	Pleasanton, CA
Health Care Setting	Kaiser-Permanente Pleasanton Clinic
Health Insurance	HMO (Kaiser-Permanente Northern California)
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	185 (T=97; C=88)
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	43% reduction in number of hospitalizations over 18 months after randomization, including the 6 month intervention period (T=16/1,000 persons/month, C=28/1,000 persons/month, p=0.04).  28% reduction in number physician visits in the 6 months after the six month intervention period, (T=242/1,000 persons/month, C=338/1,000 persons/month, p=0.06)  50% reduction in number of non-physician visits in the 6 months after the six month intervention period, (T=167/1,000 persons/month, C=333/1,000 persons/month, p=0.001)
Full Citation	Sadur, Craig N., Nancy Moline, Mary Costa, Dorothea Michalik, Debra Mendlowitz, Sharon Roller, Randy Watson, Bix E. Swain, Joe V. Selby, and W. Curtis Javorski. "Diabetes Management in a Health Maintenance Organization: Efficacy of Care Management Using Cluster Visits." <i>Diabetes Care</i> , vol. 22, no. 12, December 1999, pp. 2011-2017.

<b>Detail for Selecte</b>	d Study – Wagner, 2001
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Wagner 2001
Clinical Focus	Diabetes
Target Population	Members of Group Health Cooperative with diabetes
Intervention Strategies	Group meetings at the clinic every 3-6 months over 2 years. Groups consisted of 6-10 patients, each meeting consisted of one-on-one visits with the primary care physician, a nurse, and a pharmacist; and a 1 hour group educational/peer support session. Prior to each meeting, intervention nurses developed individualized plans and goals for each participant during the upcoming meeting, as well as plans and goals for the entire group.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	70%
Geographic Location	Seattle, WA
Health Care Setting	Seattle area clinics of Group Health Cooperative
Health Insurance	HMO (Group Health Cooperative)
Quality of Evidence	A
Study Design	Group randomized (practice-level) controlled trial
Sample Size	35 practices (T=14, C=21), 707 patients (T=278; C=429)
Evaluation Timeframe	2 years
Cost/Utilization Outcomes	50% reduction in number of ER visits over 2 years (T=0.1/year, C=0.2/year, p=0.04) 16% increase in number of primary care visits over 2 years (T=6.4/year, C=5.5/year, p=0.05). 24% reduction in number of specialty visits over 2 years (T=2.8/year, C=3.7/year, p=0.007) 20% reduction in proportion with hospital admission (T=16.9%, C=21.0%, $p=0.10$ ) Effects on total costs non-significant (p=0.79)
Full Citation	Wagner, Edward H., Lois C. Grothaus, Nirmala Sandhu, Mary Sue Galvin, Mary McGregor, Karen Artz, and Eric A. Coleman. "Chronic Care Clinics for Diabetes in Primary Care." <i>Diabetes Care</i> , vol. 25, no. 5, April 2001, pp. 695-700.

Detail	for	Se	lected	Study -	- Wolf,	2004

	u 3tuay – Woll, 2004
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Wolf 2004
Clinical Focus	Diabetes
Target Population	Members of commercial health insurance plan in Virginia (Southern Health Services Plan) with obesity and diabetes
Intervention Strategies	Over the course of 1 year, participants had 6 individual sessions (approximately 4 hours total) and 6 one-hour small group sessions with a Registered Dietitian (RD). RD also conducted brief monthly phone contacts with participants for support.
Additional Targeting Criteria	Use of diabetes medications, body mass index $\geq$ 27 kg/m <sup>2</sup> , age $\geq$ 20 y.o.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	11%
Geographic Location	Charlottesville, VA
Health Care Setting	Academic Medical Center
Health Insurance	Commercial
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	144 (T =73; C = 71)
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	14% reduction in total number of medications per day ( $T = 5$ medications/day; $C = 5.8$ medications/day; $p = 0.03$ ). No other cost/utilization outcomes reported.
Full Citation	Wolf, Anne M., Mark R. Conaway, Jayne Q. Crowther, Kristen Y. Hazen, Jerry L. Nadler, Beverly Oneida, and Viktor E. Bovbjerg. "Translating Lifestyle Intervention to Practice in Obese Patients with Type 2 Diabetes." <i>Diabetes Care</i> , vol. 27, no. 7, July 2004, pp. 1570-1576.

<b>Detail for Selecte</b>	d Study – Barnett, 2006
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Barnett 2006
Clinical Focus	Diabetes
Target Population	Adults (veterans) with diabetes
Intervention Strategies	Patients were provided with a home messaging device requiring only basic telephone service and an electrical outlet. Using this device, patients answered scripted questions every day on their diabetes symptoms and health status. Nurse care coordinators (RNs or nurse practitioners) monitored patients' responses daily and made clinical judgments on whether responses required actions and the types of appropriate follow-up (for example, assessing the patient over the phone, scheduling follow-up appointments, refilling medications, helping with medication management, calling to remind patients about appointments).
Additional Targeting Criteria	Two or more VA hospitalizations or VA ER visits in the 12 months before enrollment.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	not stated
Geographic Location	Florida, southern Georgia, and Puerto Rico
Health Care Setting	4 VA Medical Centers
Health Insurance	VA
Quality of Evidence	В
Study Design	Comparison group design using propensity scoring and difference-in-differences
Sample Size	782 (T=391; C=391)
Evaluation Timeframe	24 months
Cost/Utilization Outcomes	9% reduction in all-cause hospitalization. <sup>a</sup> Impact on ER visits not assessable (because of propensity score design, comparison group had a very high rate of ER visits at baseline)

#### Barnett, 2006 continued

#### **Full Citation**

Barnett, Tracey E., Neale R. Chumbler, W. Bruce Vogel, Rebecca J. Beyth, Haijing Qin, and Rita Kobb. "The Effectiveness of a Care Coordination Home Telehealth Program for Veterans with Diabetes Mellitus." *American Journal of Managed Care*, vol. 12, no. 8, August 2006, pp. 467-474.

"The authors actually estimated a 25% reduction in hospitalizations between the intervention and comparison groups, using combined "propensity score matching" and "difference-in-differences" methodologies. We derived the 9% listed here from the raw numbers of admissions at baseline and follow-up for the two groups (Barnett personal communication), assuming that the fixed baseline difference in admissions between intervention and comparison groups also applies to the post-period, and that half of the admissions in the two year follow-up period occurred in the first year of follow-up. We used the following formula for this calculation: {(treatment post)-(comparison post plus baseline T-C difference)}/(comparison post plus baseline T-C difference). For more information on the results, please refer to the article directly.

<b>Detail for Selecte</b>	d Study – Villagra, 2004
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Villagra 2004
Clinical Focus	Diabetes
Target Population Intervention Strategies	Employees of self-insured employers covered under HMO and POS plans with diabetes  Telephonic disease management; web-based patient education; remote patient monitoring devices; reminders and educational mailings for patients. Mail, fax, or telephone progress reports to primary care doctors.
Additional Targeting Criteria	None
Opt-in/opt-out, if available	Opt-out
Enrollment rate, if available	97%
Geographic Location	10 areas of the sponsoring MCO: Nashville, TN; Florida; Denver, CO; mid-Atlantic states (Baltimore, Washington, DC, Philadelphia, Delaware, and southern NJ); Dallas, TX; Houston, TX; Chicago, IL; Kansas; Ohio; and NYC metro area (including northern NJ, and CT)
Health Care Setting	Private physician offices
Health Insurance	Managed care
Quality of Evidence	B
Study Design	Presents two separate analyses: A regression adjusted parallel group comparison using the 5 early implementation sites as treatments and 5 late implementation sites as controls, and a regression adjusted pre-post comparison (at the program level with all 10 sites aggregated). In addition, 2 sub-analyses conducted for each of these 2 analyses: <i>full</i> participants (those enrolled in the first 2 months of the intervention who remained in the program until the completion of the first year) and <i>all</i> participants (any who had at least one month of exposure to the program even if they subsequently dropped out).
Sample Size	Pre/post comparison all participants: 75,759 (Pre=32,267; Post=43,492) Parallel group comparison all participants: 39,292 (T=27,188; Comparison=12,104)
Evaluation Timeframe	1 year

## Villagra, 2004 continued

Cost/Utilization Outcomes	Parallel group comparison all participants (preferred method):  22% reduction in total costs (T=\$431/person/month, C=\$551/person/month, p<0.0001);  2% reduction in inpatient costs (T=\$145/person/month, C=\$147/person/month, p<0.10);  24% reduction in hospitalizations (T=157/1,000 persons/month, C=206/1,000 persons/month, p<0.0001);  14% reduction in ER visits (263/1,000 persons/month, C=307/1,000 persons/month, p<0.0001);  5% reduction in office visits (T=6.56/1,000 persons/month, C=6.93/1,000 persons/month, p<0.0001).  Pre/post comparison all participants:  5% reduction in total costs (post=\$464/person/month, pre=\$490/person/month, p<0.001);  12% reduction in inpatient costs (post=\$137/person/month, pre=\$156/person/month, p<0.0001);  17% reduction in number of hospitalizations (post=172/1,000 persons/month, pre=206/1,000 persons/month, p<0.0001);  9% increase in ER visits (post=286/1,000 persons/month, pre=262/1,000 persons/month, p<0.0001).
Full Citation	Villagra, Victor G. and Tamim Ahmed. "Effectiveness of a Disease Management Program for Patients with Diabetes." <i>Health Affairs</i> , vol. 23, no. 4, July/August 2004, pp. 255-266.

Detail for Selecte	d Study – Sidorov, 2002
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Davidson 2007
Clinical Focus	Diabetes
Target Population	Patients with diabetes attending a county-sponsored community clinic (patients were predominantly low-income and from minority groups)
Intervention Strategies	Specially trained nurse followed detailed diabetes treatment algorithms to provide diabetes care. Cholesterol targets and recommended processes of care were based on the ADA guidelines. An endocrinologist also met with the nurse once a week, but was available by phone at all other times.
Additional Targeting Criteria	None
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not available
Geographic Location	Los Angeles
Health Care Setting	County-sponsored community clinic affiliated with Charles A. Drew University
Health Insurance	Not reported
Quality of Evidence	C
Study Design	Pre-post Pre-post
Sample Size	367
Evaluation Timeframe	1 year
Cost/Utilization Outcomes	71% reduction in combined outcome of "preventable diabetes-related urgent care visits/ER visits/hospitalizations" (Pre-: 21 events [15 urgent care/ER + 6 hospitalizations]; post-: 6 events [5 urgent care/ER + 1 hospitalization]; p<0.001).
Full Citation	Davidson, Mayer B., Adeela Ansari, and Vicki J. Karlan. "Effect of a Nurse-Directed Diabetes Disease Management Program on Urgent Care/Emergency Room Visits and Hospitalizations in a Minority Population." Diabetes Care, vol. 30, no. 2, February 2007, pp. 224-227. (Additional details of the intervention in Davidson, Mayer B., Maria Castellanos, Petra Duran, and Vicki Karlan. "Effective Diabetes Care by a Registered Nurse Following Treatment Algorithms in a Minority Population." American Journal of Managed Care, vol. 12, no. 4, April 2006, pp. 226-232.

Detail for Selecte	d Study – Sidorov, 2002
<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Sidorov 2002
Clinical Focus	Diabetes
Target Population	Enrollees with diabetes in Geisinger Health Plan's commercial HMO or Medicare-risk HMO
Intervention Strategies	Team of roughly 50 nurse educators each assigned to cover 1 to 15 primary care sites depending on geography and patient load. Educators provided scheduled one-on-one or group education sessions with enrollees at the primary care offices and recorded visits in practices' medical records for physician review and co-signature. Nurse educators also provided informal, guideline based recommendations to primary care doctors, performed case management, and facilitated specialty referrals. Program offered CME sessions to doctors. To encourage enrollment, nurses could offer glucose meters and 100 test strips at no cost to patients meeting criteria.
Additional Targeting Criteria	none
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	46%
Geographic Location	41 counties in northeastern and central Pennsylvania
Health Care Setting	Primary care physician offices
Health Insurance	Commercial and Medicare-risk HMOs by Geisinger Health Plan
Quality of Evidence	C
Study Design	Comparison of participants and non-participants with regression adjustment for measured differences
Sample Size	6,799 (T=3,118; comparison=3,681).
Evaluation Timeframe	2 years
Cost/Utilization Outcomes	25% reduction in number of all-cause hospitalizations (T=0.12/person/year, C=0.16/person/year, p=0.026) 21% reduction in paid claims excluding pharmacy (T=\$394.62/person/month, C=\$502.48/person/month, p<0.0001) 43% reduction in inpatient days (T=0.56/person/year, C=0.98/person/year, p=0.003) 8% increase in primary care office visits (T=8.36/person/year, C=7.78/person/year, p=0.001)
Full Citation	Sidorov, Jaan, Robert Shull, Janet Tomcavage, Sabrina Girolami, Nadine Lawton, and Ronald Harris. "Does Diabetes Disease Management Save Money and Improve Outcomes?" <i>Diabetes Care</i> , vol. 25, no. 4, April 2002, pp. 684-689

V. Depression Studies

# **Depression Studies Reporting No Changes or Increases in Cost/Utilization - Summary Table**

Clinical Focus	Author/Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
Depression	Capoccia, 2004	Adults	Collaborative care intervention employed in the primary care clinic where a clinical pharmacist or pharmacy resident in conjunction with the primary care physician and study psychiatrist followed-up with patient	12 months	No statistically significant differences between treatment groups in number of emergency room visits	А
Depression	Katon, 2002	Adults	Multifaceted intervention targeting patient, physician, and process of care, using collaborative management by a psychiatrist and a primary care physician	28 months	No significant differences in total ambulatory costs between treatment groups	А
Depression	Schoenbaum, 2001	Adults	Local practice teams were trained in 2-day workshop for enhanced educational and assessment resources, and patients were followed-up either by 1) nurses, or 2) trained local psychotherapists	24 months	No statistically significant difference in average total health care costs	А
Depression	Simon, 2006	Adults	Nurse case managers collaborated with patient's mental health provider to provide 2-year systematic intervention involving telephone monitoring and medication adherence	24 months	19% increase (unadjusted) in mental health treatment costs	А
Depression	Simon, 2006	Adults	Three-session telephone-based care management program conducted by trained registered nurses	6 months	No statistically significant difference in number of visits for mental health treatment	А

<b>Detail for S</b>	elected S	tudy - Car	poccia, 2004
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<u>Characteristic</u>	<u>Description</u>
Author and Year of Publication	Capoccia 2004
Clinical Focus	Depression
Target Population	Patients >18 y.o. diagnosed with a new episode of depression and started on an antidepressant medication.
Intervention Strategies	Pharmacists collaborated with primary care providers to facilitate patient education, the initiation and adjustment of antidepressant dosages, the monitoring of patient adherence to the regimen, the management of adverse reactions, and the prevention of relapse. Patients received follow-up phone calls from the clinical pharmacist or pharmacy resident, in conjunction with the PCP and study psychiatrist on a weekly basis for the first four weeks, then every two weeks for the duration of the study.
Additional Targeting Criteria	Spoke English; excluded if pregnant or nursing; had 2 or more suicide attempts; recent alcohol or substance abuse.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	70% (74/106 eligible were randomly assigned)
Geographic Location	Washington State
Type of Community	Unclear.
Health Care Setting	University of Washington Family Medical Center (UWFMC)
Health Insurance	11% Medicaid or Medicare, 78% private or managed care, 4% other, 7% uninsured
Quality of Evidence	A
Study Design	Randomized controlled trial
Sample Size	37 in intervention group, 30 in control group
Evaluation Timeframe	12 months
Cost/Utilization Outcomes	No statistically significant differences in the number of visits to all health care providers (Median: $T = 9$ ; $C = 9$ ; $p = 0.99$ ), physicians ( $T = 4$ ; $C = 5$ ; $p = 0.88$ ), psychiatrists or psychologists ( $T = 0$ ; $C = 0$ ; $p = 0.99$ ), emergency rooms ( $T = 0$ ; $C = 0$ ; $p = 0.27$ ), counselors or other mental health providers ( $T = 0$ ; $C = 1$ ; $p = 0.30$ ), and alternative medicine providers ( $T = 0$ ; $C = 0$ ; $p = 0.45$ ); No statistical difference between groups during follow-up period in mean SCL-20 score ( $p = 0.92$ ), mean SF-12 mental health score ( $p = 0.46$ ), and mean SF-12 physical health score ( $p = 0.18$ ).
Full Citation	Capoccia, K L. D M. Boudreau, D K. Blough, A J. Ellsworth, D R. Clark, N G. Stevens, W J. Katon, and S D. Sullivan. "Randomized trial of pharmacist interventions to improve depression care and outcomes in primary care." <i>Am J Health Sys Pharm</i> , vol. 61, no. 4, 2004, pp. 364-72.

<u>Characteristic</u>	<u>Description</u>		
Author and Year of Publication	Katon 2002		
Clinical Focus	Depression		
Target Population	Patients between the ages of 18 and 80 who received a new antidepressant prescription (no prescriptions within the last 120 days) from a primary care physician for the diagnosis of depression or anxiety.		
Intervention Strategies	Each patient received an educational book and a companion videotape. Patients were also scheduled 2 sessions conducted in the primary care clinic with a psychiatrist who reported patient progress and consulted with patients' primary care provider.		
Additional Targeting Criteria	Excluded if currently seeing a psychiatrist, pregnant or nursing, screened a score of 2 or more on the CAGE alcohol screening questionnaire, limited command of English, planned to disenroll from the Group Health insurance plan within the next 12 months, or had recently used lithium or antipsychotic medication.		
Opt-in/opt-out, if available	Opt-in		
Enrollment rate, if available	33% (228/694 eligible were randomly assigned)		
Geographic Location	Western Washington		
Type of Community	Unclear.		
Health Care Setting	Primary care clinics of Group Health Cooperative of Puget Sound (GHC)		
Health Insurance	Not stated		
Quality of Evidence	A		
Study Design	Randomized controlled trial		
Sample Size	171 completed the 28-month follow-up		
Evaluation Timeframe	28 months		
Cost/Utilization Outcomes	No significant differences in total ambulatory costs between the treatment and control group (P = 0.40), total health care costs (P = 0.34), depression treatment costs (P= 0.10), or non-depression-related outpatient costs (P = 0.74); Significant treatment effect for moderate-severity strata in 28-month SCL-Depression Scores (T = 0.88 $\pm$ 0.52; C = 1.23 $\pm$ 0.62; P = 0.004); No statistical significant difference within high-severity strata for 28-month SCL-Depression Scores (T = 1.16 $\pm$ 0.85; C = 1.19 $\pm$ 0.72; P = 0.88).		
Full Citation	Katon, W. J. Russo, M. Von Korff, E. Lin, G. Simon, T. Bush, E. Ludman, and E. Walker. "Long-term effects of a collaborative care intervention in persistently depressed primary care patients." <i>J Gen Intern Med</i> , vol. 17, no. 10, 2002, pp. 741-8.		

<u>Characteristic</u>	<u>Description</u>		
Author and Year of Publication	Schoenbaum 2001		
Clinical Focus	Depression		
Target Population	Patients >18 y.o. who screened positive for depression.		
Intervention Strategies	2 interventions; QI-Meds and QI-Therapy. For both intervention groups, local practice teams were trained in a 2-day workshop to provide clinician education through lectures, academic detailing, or audit and feedback, and to supervise intervention staff and conduct team oversight. Practice teams were given patient education pamphlets and videotapes, patient tracking forms, and clinician manuals and pocket reminder cards and were encouraged to distribute them. Patient follow-up was either conducted by a nurse specialist trained to support medication adherence via telephone contacts or visits on a monthly basis for 6-12 months (QI-meds) or by a practice therapist trained to provide individual and group cognitive behavioral therapy for 6 months (QI-therapy).		
Additional Targeting Criteria	Fluent in English or Spanish; insurance coverage for intervention therapists; intended to use the practice over the next 12 months.		
Opt-in/opt-out, if available	Opt-in		
Enrollment rate, if available	56% (1356/2417 eligible were enrolled, randomized at group level)		
Geographic Location	Not stated		
Type of Community	Unclear.		
Health Care Setting	Primary care clinics in community-based managed care organizations		
Health Insurance	Managed care		
Quality of Evidence	A		
Study Design	Randomized controlled trial		
Sample Size	371 in QI-Meds group, 401 in QI-Therapy group, 386 in control group completed mail surveys at 24 months		
Evaluation Timeframe	24 months		
Cost/Utilization Outcomes	No statistically significant difference in average total health care costs (Percent increase QI-Med: 11% [P = 0.35]; QI-Therapy: 13% [P = 0.28]); Estimated costs per QALY gained were between \$15,331 and \$36,367 for QI-Meds and \$9,478 and \$21,478 for QI-Therapy; Decreased days with depression burden: 25 (QI-Meds: $P = 0.19$ ) and 47 (QI-Therapy: $P = 0.01$ ); Increased employed days: 17.9 (QI-Meds: $P = 0.07$ ) and 20.9 (QI-Therapy: $P = 0.03$ ).		
Full Citation	Schoenbaum, M. J. Unutzer, C. Sherbourne, N. Duan, L V. Rubenstein, J. Miranda, L S. Meredith, M F. Carney, and K. Wells. "Cost-effectiveness of practice initiated quality improvement for depression: results of a randomized controlled trial." <i>JAMA</i> , vol. 286, no. 11, 2001, pp. 1325-30.		

Detail for Selected Study - Simon, 2006			
<u>Characteristic</u>	<u>Description</u>		
Author and Year of Publication	Simon 2006		
Clinical Focus	Depression		
Target Population	Patients >18y.o. having a diagnosis of bipolar spectrum disorder (bipolar disorder type I or type II, schizoaffective disorder, or cyclothymia) during prior 12 months.		
Intervention Strategies	Nurse case managers provided 2-year systematic intervention program, including the following: a structured group psychoeducational program, monthly telephone monitoring of mood symptoms and medication adherence, feedback to treating mental health providers, facilitation of appropriate follow-up care, and as-needed outreach and crisis intervention.		
Additional Targeting Criteria	Structured Clinical Interview for DSM-IV (SCID) used to confirm diagnosis of bipolar disorder type I or II.		
Opt-in/opt-out, if available	Opt-in		
Enrollment rate, if available	98% (441/450 of eligibles agreed to be randomized)		
Geographic Location	Washington State		
Type of Community	Unclear.		
Health Care Setting	Mental health clinics of a group-model prepaid health plan, Group Health Cooperative		
Health Insurance	Group-model prepaid health plan		
Quality of Evidence	A		
Study Design	Randomized controlled trial		
Sample Size	156 in intervention group, 175 in control group included in cost analyses		
Evaluation Timeframe	24 months		
Cost/Utilization Outcomes	19% increase (unadjusted) in incremental mental health treatment costs ( $$1251$ increase [adjusted]; 95% CI, $$55-$2446$ , including approximately $$800$ for intervention program services and $$500$ increase in costs of other mental health services); Significantly reduced mean level of mani symptoms ( $P = 0.04$ ); No significant intervention effect on mean level of depressive symptoms ( $P = 0.85$ ).		

Simon, G E. E J. Ludman, M S. Bauer, J. Unutzer, and B. Operskalski. "Long-term effectiveness and cost of a systematic care program for bipolar disorder." *Arch Gen Psychiatry*, vol. 63, no. 5, 2006, pp. 500-8.

**Full Citation** 

Detail for Selected Study - Simon, 2006			
<u>Characteristic</u>	<u>Description</u>		
Author and Year of Publication	Simon 2006		
Clinical Focus	Depression		
Target Population	Patients >18y.o. who received a new antidepressant prescription from a psychiatrist (no antidepressant use in the past 90 days).		
Intervention Strategies	Case managers who were registered nurses with a minimum of five years' experience in inpatient and outpatient mental health practice conducted a three-session telephone care management program that included assessment of depressive symptoms, medication adherence, and medication side effects with structured feedback to treating psychiatrists.		
Additional Targeting Criteria	Received visit diagnosis of a depressive disorder in the past 30 days; no recorded diagnosis of bipolar disorder or schizophrenia in the past 2 years.		
Opt-in/opt-out, if available	Opt-in		
Enrollment rate, if available	95% (207/217 of eligibles agreed to be randomized)		
Geographic Location	Washington State and northern Idaho		
Type of Community	Unclear.		
Health Care Setting	Mental health clinics of a group-model prepaid health plan, Group Health Cooperative		
Health Insurance	Group-model behavioral health clinics of Group Health Cooperative		
Quality of Evidence	A		
Study Design	Randomized controlled trial		
Sample Size	98 in intervention group, 97 in control group included in utilization analyses		
Evaluation Timeframe	6 months		
Cost/Utilization Outcomes	20% increase in the number of medication management visits to the specialty clinic (T = $2.4 \pm 1.6$ ; C = $2.0 \pm 2.0$ ; P = $0.035$ ); No statistically significant difference in number of visits to nonprescribing therapist (T = $2.0 \pm 3.3$ ; C = $2.1 \pm 3.3$ ; P = $0.91$ ); No statistically significant difference in number of visits to primary care with mental health diagnosis (T = $0.3 \pm 0.7$ ; C = $0.4 \pm 0.7$ ; P = $0.13$ ).		
Full Citation	Simon, G E. E J. Ludman, and B H. Operskalski. "Randomized trial of a telephone care management program for outpatients starting antidepressant treatment." <i>Psychiatr Serv</i> , vol. 57, no. 10, 2006, pp. 1441-5.		

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VI. High-Risk Pregnancy Studies

### High-Risk Pregnancy Studies Reporting Decreases in Cost/Utilization - Summary Table

Clinical Focus	Author/Year	Target Population	Intervention Strategies	Evaluation Timeframe	Cost/Utilization Outcomes	Quality of Evidence
High-Risk Pregnancy	Brooten 2001	Pregnant women	Advanced practice nurses to perform prenatal home visits including education and counseling, clinical assessments, and medication monitoring. Intervention included one postpartum home visit and daily phone access.	8 weeks postpartum	9% decrease in maternal prenatal acute care visits; 39% decrease in mean prenatal hospitalization charges; 79% decrease in mean length of stay for postpartum rehospitalizations	А
High-Risk Pregnancy	Koniak-Griffin 2002	Newborns (of pregnant teens)	Prenatal and postpartum home visits by case manager public health nurses. During pregnancy, education on preparation for childbirth and self-care during pregnancy. Prenatal classes for mothers on parenting and health. Postpartum home visits on health, sexuality and family planning, motherhood, life skills, and social and emotional support.	1 year postpartum	52% reduction in total hospital days in first year of life.	А
High-Risk Pregnancy	Olds 2004	Pregnant women	Intensive home visits by nurses to promote prenatal health, maternal/parental parenting skills and child health, and maternal/parental adult development.	6 years postpartum	16% reduction in number of subsequent pregnancies and births over 3 years; 9% reduction in months on Medicaid for mothers	А
High-Risk Pregnancy	York 1997	Newborns	Advanced practice nurses to perform intensive education during hospitalization. Additional home visits and phone calls either until delivery, or for those enrolled at delivery, 8 weeks postpartum.	8 weeks postpartum	64% reduction in infants' hospital charges.	А
High-Risk Pregnancy	Svikis 1997	Newborns (of pregnant women with active drug use)	One week of residential drug treatment followed by intensive outpatient day treatment services through labor and delivery.	Immediate postpartum period	62% reduction in NICU admissions	С
High Risk Pregnancy	Ruiz 2001	Newborns (twins)	Use of advanced practice nurse to provide prenatal care, which included weekly clinic visits, home visits, and 24 hour availability for phone support.	Immediate postpartum period	65% decrease in mean hospital charges	С
High Risk Pregnancy	Luke 2003	Newborns (twins)	Specialized clinic providing additional maternal education and nutritional assessment and monitoring.	3 years postpartum	31% reduction in NICU admissions	С
High Risk Pregnancy	Reece 2002	Newborns	RN and SW home visit, health education, nutritional assessments, and parenting classes. Free transportation and on-site child care, coordination of care. Well baby care, and immunizations for 1 year after birth.	Immediate postpartum period	58% reduction in NICU admissions	С
High Risk Pregnancy	Stankaitis 2005	Newborns	Identification of high-risk pregnant women through reimbursement incentives to obstetric practices; perinatal nurse care coordinators; psychosocial and medical support including home visits, transportation assistance, skilled home care, and social service referrals.	Immediate postpartum period	47% reduction in NICU admissions;	С

Wherever possible, impacts on service utilization (such as hospitalizations or acute care visits) are expressed as percentage reductions in the number of services per person per unit time. If the article does not present numbers of services per person per unit time but does provide the total number of services, service use/person/time is estimated by dividing the number of services by the sample size, without accounting for variable lengths of follow up. In cases where only numbers or proportions of people with any (one or more) service use are reported, service use impacts are expressed as percentage reductions in the proportion with any service use. For studies that reported on delivery and the immediate postpartum period, and that only reported a proportion of neonates with a NICU admission during this initial hospitalization, we have approximated the relative reduction in numbers of NICU admissions by the relative reduction in proportion with NICU admissions, under the assumption that most critically ill neonates will only have one NICU admission immediately following their birth.

<sup>&</sup>lt;sup>b</sup>See study detail on how the study's results on the program's effects on the proportion of infants requiring hospitalization were converted into a percentage relative reduction.

# Detail for Selected Study - Brooten, 2001

<u>Characteristic</u>			
Author and Year of Publication	Brooten, 2001		
Clinical Focus	High-risk pregnancy		
Target Population	Women with high-risk pregnancies (gestational or pregestational diabetes mellitus, chronic hypertension, preterm labor, or high risk of preterm labor).		
Intervention Strategies	Use of advanced practice nurses specialized in caring for high-risk pregnant women and infants to perform prenatal home visits to provide education and counseling, perform clinical assessments, monitor medication and consult patient's physician about adjusting medication. Nurses also made one postpartum home visit to assess complications and medications, confirm appointments for medical follow-up, and provide referrals to community resources. Patients had daily phone access to nurses.		
Additional Targeting Criteria	None stated		
Opt-in/opt-out, if available	Opt-in		
Enrollment rate, if available	Not stated		
Geographic Location	Philadelphia, PA		
Type of Community	Urban		
Health Care Setting	Large urban tertiary care hospital (Hospital of the University of Pennsylvania)		
Health Insurance	Mostly public insurance (95.5% of Treatment group and 91.8% of Control group)		
Quality of Evidence	A		
Study Design	Randomized Controlled Trial		
Sample Size	173 (T=85, C=88)		
Evaluation Timeframe	8 weeks postpartum		
Cost/Utilization Outcomes	12% decrease in total number of maternal prenatal acute care visits (T=230, C=261, p<0.05);  ost/Utilization Outcomes 79% decrease in mean length of stay for postpartum rehospitalizations (T=1.2, C=5.7, p<0.05); 39% decrease in mean prenatal hospitalization charges (T=\$6213, C=\$10196, p<0.05)		
Full Citation	Brooten, Dorothy. JoAnne Youngblut, Linda Brown, Steven Finkler, Donna Neff, and Elizabeth Madigan. "A Randomized Trial of Nurse Specialist Home Care for Women with High-Risk Pregnancies: Outcomes and Costs." American Journal of Managed Care, 7(8): 793-803, 2001 August.		

<b>Detail for Selected</b>	Study -	Koniak-Griffin,	2002
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<u>Characteristic</u>		
Author and Year of Publication	Koniak-Griffin 2002	
Clinical Focus	High-risk pregnancy	
Target Population	Pregnant adolescents aged 14-19 referred to a county health department for public health nursing	
Intervention Strategies	Case manager public health nurses conducted home visits1 or 2 prenatal visits in 2nd or 3rd trimester, then approximately 15 postpartum visits. Participants attended four classes in 3rd trimester on preparation for motherhood, parenting, and health. In prenatal home visits, nurses educated on preparation for childbirth and self-care during pregnancy, in postpartum visits nurses focused on health, sexuality and family planning, motherhood, life skills, and social and emotional support. Home visits lasted 1.5-2 hours.	
Additional Targeting Criteria	No prior live births, gestation $\leq$ 26 weeks, planning on keeping infant, no history of drug dependence, and no medical or obstetric complications.	
Opt-in/opt-out, if available	Opt-in	
Enrollment rate, if available	Not available	
Geographic Location	Southern California county with population 1.6 million	
Type of Community	Not stated	
Health Care Setting	County health department and home	
Health Insurance	84% of mothers on Medi-Cal	
Quality of Evidence	A	
Study Design	Randomized controlled trial	
Sample Size	102 (T=55, C=47)	
Evaluation Timeframe	1 year postpartum	
Cost/Utilization Outcomes	52% reduction in total hospital days for infants in first year of life (T=74 total days, C=154 total days, p<0.001);  42% reduction in hospitalizations (T=14, C=24, p<0.05);  12% increase in proportion of children adequately immunized (T=96%, C=86%, p<0.05)	
Full Citation	Koniak-Griffin, Deborah, Nancy L. Anderson, Mary-Lynn Brecht, Inese Verzemnieks, Janna Lesser, and Sue Kim. "Public Health Nursing Care for Adolescent Mothers: Impact on Infant Health and Selected Maternal Outcomes at 1 Year Postbirth." <i>Journal of Adolescent Health</i> , vol. 30, January 2002, pp. 44-54.	

Detail for Selected Study - Olds, 2004	
<u>Characteristic</u>	
Author and Year of Publication	Olds 2004
Clinical Focus	High-risk pregnancy
Target Population	Low-income, unmarried pregnant women
Intervention Strategies	Treatment: Free, round-trip cab transportation to all scheduled prenatal care visits, intensive nurse home-visiting services during pregnancy, 1 in-hospital postpartum visit, and home visits from hospital discharge through child's 2 <sup>nd</sup> birthday. Nurses followed detailed guidelines to promote (1) health prenatal behaviors in mother, (2) mother's/parents' parenting skills and child's health and development, and (3) parent(s) planning of future pregnancies, completion of education, and seeking of employment.  Control: Free cab transportation as above, developmental screening and referral services for child at 6, 12, and 24 months of age.
Additional Targeting Criteria	<29 weeks gestation, no previous live births, at least two of following: unmarried, <12 years of education, or unemployed.
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not stated
Geographic Location	Memphis, TN
Type of Community	Urban
Health Care Setting	Home
Health Insurance	Not stated
Quality of Evidence	A
Study Design	Randomized Controlled Trial
Sample Size	641 (T=197, C=444)
Evaluation Timeframe	6 years
Cost/Utilization Outcomes	16% reduction in subsequent pregnancies and births for mothers (T=1.16 pregnancies, 1.08 children; C=1.38, 1.28, p=0.01) 9% reduction in months on Medicaid for mothers (T=11.98, C=13.08, p=0.08)
Full Citation	Olds, David L., Harriet Kitzman, Robert Cole, JoAnn Robinson, Kimberly Sidora, Dennis W. Luckey, Charles R. Henderson, Carole Hanks, Jessica Bondy, and John Holmberg. "Effects of Nurse Home-Visiting on Maternal Life Course and Child

similar intervention in rural New York state in Olds et al. JAMA 1997; 278(8): 637-643.

Development: Age 6 Follow-up Results of a Randomized Trial." *Pediatrics*, vol. 114, no. 6, December 2004, pp. 1550-1559. Most recent of a series of papers from this group of researchers on two important, related studies. Previous papers (among others) on the Memphis project were on pregnancy outcomes and child outcomes through age 2 (Kitzman et al. *JAMA* 1997; 278(8): 644-652), and maternal outcomes for 3 years after birth (Kitzman et al. *JAMA* 2000; 283(15): 1983-1989). Report of a

Detail for Selected Study – York, 1997		
<u>Characteristic</u>		
Author and Year of Publication	York 1997	
Clinical Focus	High-risk pregnancy	
Target Population	Women with either diabetes or hypertension during pregnancy.	
Intervention Strategies	For women hospitalized before delivery: Masters-level perinatal nurse specialists to perform education and discharge planning during admission. Earlier discharge than the standard care group and at somewhat higher blood sugars if women had mastered specific knowledge and skills. After discharge, nurse specialists provided education, support, and referrals until delivery (daily home visits for three days starting on the day of discharge, at least two more home visits after that, and telephone or clinic contacts three times per week).  For women hospitalized for labor and delivery: After delivery, nurse specialist performed assessments, education, and discharge planning; women were discharged once they mastered specific knowledge and skills. After discharge, nurse specialists provided education, support, and referrals for 8 weeks (minimum of 2 home visits and 10 telephone callstwice a week for first 2 weeks, then weekly for next 6 weeks). Nurse specialists available for calls 12 hours per day M-F and 4 hours per day weekends.	
Additional Targeting Criteria	Enrollment during first hospitalizationwhether hospitalized before delivery (mainly mothers with diabetes hospitalized for glucose control) or hospitalized at the time of labor and delivery.	
Opt-in/opt-out, if available	Opt-in	
Enrollment rate, if available	Not stated	
Geographic Location	Not stated	
Type of Community	Urban	
Health Care Setting	Academic medical center	
Health Insurance	60 and 70% public, 40 and 30% private (treatment and control groups, respectively)	
Quality of Evidence	A	
Study Design	Randomized controlled trial	
Sample Size	96 (T=44, C=52)	
Evaluation Timeframe	8 weeks after discharge from hospitalization for delivery	
Cost/Utilization Outcomes	26% reduction in hospital charges for mother antepartum through delivery (T=\$7,087, C=\$8,952, p=0.02); 64% reduction in hospital charges for neonates (T=\$4,957, C=\$13,793, p=0.02).	
E II C'r r'	York, Ruth, Linda P. Brown, Philip Samuels, Steven A. Finkler, Barbara Jacobsen, Cynthia A. Persely, Anne Swank, and	

Deborah Robbins. "A Randomized Trial of Early Discharge and Nurse Specialist Transitional Follow-Up Care of High-Risk

Childbearing Women." Nursing Research, vol. 46, no. 5, September/October 1997, pp. 254-261.

**Full Citation** 

### **Detail for Selected Study - Svikis 1997**

Cost/Utilization Outcomes

**Full Citation** 

<u>Characteristic</u>	
Author and Year of Publication	Svikis 1997
Clinical Focus	High-risk pregnancy
Target Population	Women with active drug use and drug dependence
Intervention Strategies	1 week of residential drug treatment followed by intensive outpatient day treatment services through labor and delivery.
Additional Targeting Criteria	Women voluntarily admitted to a treatment program
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not stated
Geographic Location	Baltimore, MD
Type of Community	Urban
Health Care Setting	Center for Addiction and Pregnancy at Johns Hopkins Bayview Medical Center
Health Insurance	100% Medicaid
Quality of Evidence	C
Study Design	Cross-sectional comparison group design; comparison group women included women refusing treatment or failing to seek treatment
Sample Size	146 (T=100, comparison=46)
Evaluation Timeframe	Immediate postpartum period
Cost/Utilization Outcomes	62% reduction in NICU admissions (T=10% with NICU admission, C=26% with NICU admission, p=0.01);

abusing Pregnant Women." Drug and Alcohol Dependence, vol. 45, 1997, pp. 105-113.

92% reduction in NICU days across all newborns (T=0.8 days/neonate, C=10.2 days/neonate, p=0.01)

Svikis, Dace S., Archie S. Golden, George R. Huggins, Roy W. Pickens, Mary E. McCalu, Martha L. Velez, C. Todd Rosendale, Robert K. Brooner, Preston M. Gazaway, Maxine L. Stitzer, and Carol E. Ball. "Cost-effectiveness of Treatment for Drug-

<sup>&</sup>lt;sup>a</sup>As stated in the Summary Table, we have approximated the relative reduction in the number of NICU admissions by the relative reduction in the proportion of neonates requiring NICU admission, under the assumption that most critically ill neonates will only have one NICU admission.

<b>Detail for</b>	Selected	Study -	Ruiz, 2001
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Detail for Selected Study -	Tale, 2001
<u>Characteristic</u>	
Author and Year of Publication	Ruiz, 2001
Clinical Focus	High-risk pregnancy
Target Population	Mothers and infants (twins)
Intervention Strategies	Use of advanced practice nurse to provide prenatal care, which included weekly clinic visits, home visits, and 24 hour availability for phone support. Nurse assessed premature labor risk, psychosocial environment (support of partner, home situation, etc), and nutrition. The nurse worked in consultation with a perinatologist.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in for intervention group
Enrollment rate, if available	Not stated
Geographic Location	Travis County, Texas
Type of Community	Urban and rural
Health Care Setting	Specialized twin clinic
Health Insurance	Majority on public insurance
Quality of Evidence	C
Study Design	Retrospective historical cohort. Data for the comparison group was extracted from a review medical records of mothers that received standard care the year before.
Sample Size	71 (T=30, C= 41)
Evaluation Timeframe	Immediate postpartum period
Cost/Utilization Outcomes	42% decrease in mean length of stay for newborns in days (T=10.5, C=18, p<0.02); 54% decrease in mean neonatal intensive-care unit days (T=7.8, C=17, p<0.007); 65% decrease in mean hospital charges for newborns (T=\$16,116, C=\$46,796, p<0.004)
Full Citation	Ruiz, Jeanne. Brown, Charles. Peters, Mark. Johnston, Amy. "Specialized Care for Twin Gestations: Improving Newborn Outcomes and Reducing Costs." <i>Journal of Obstetric, Gynecologic, and Neonatal Nursing, 30(1): 52-60, 2001 January/February.</i>

#### **Detail for Selected Study – Luke, 2003**

<u>Characteristic</u>	
Author and Year of Publication	Luke 2003
Clinical Focus	High-risk pregnancy
Target Population	Pregnant women with twin gestations
Intervention Strategies	In addition to routine prenatal care with woman's own OB, twice-monthly prenatal visits to registered dietitian and nurse practitioner, additional maternal education, modification of maternal activity, individualized dietary prescription, multimineral supplementation, and serial monitoring of nutritional status
Additional Targeting Criteria	Excludedemergency transfers, shared placenta, fetal death of one twin, major fetal congenital anomalies
Opt-in/opt-out, if available	Opt-in for intervention group
Enrollment rate, if available	Not stated
Geographic Location	Ann Arbor, Michigan
Type of Community	Suburban/urban
Health Care Setting	Specialized "multiples" clinic at academic medical center (Univ. of Michigan Health Systems)
Health Insurance	Approximately 17% Medicaid (8% of treatment group and 20% of comparison group), 83% private
Quality of Evidence	C
Study Design	Comparison group with regression adjustment
Sample Size	529 (T=190, C= 339)
Evaluation Timeframe	3 years
Cost/Utilization Outcomes	31% reduction in proportion of infants with NICU admission (T=43%, C=62%, p<0.0001) <sup>a</sup> 47% reduction in cost of twin births (T=\$16,115, C=\$30,398, p=0.002) Adjusted odds ratio for re-hospitalizations of infants in 3 years after birth of 0.31 (p=0.05) <sup>b</sup>
Full Citation	Luke, Barbara, Morton B. Borwn, Ruta Misiuna, Elaine Anderson, Clark Nugent, Cosmas van de Ven, Barbara Burpee, and Shirley Gogliotti. "Specialized Prenatal Care and Maternal and Infant Outcomes in Twin Pregnancy." <i>American Journal of Obstetrics and Gynecology</i> , vol. 189, no. 4, October 2003, pp. 934-938.

<sup>a</sup>As stated in the Summary Table, we have approximated the relative reduction in the number of NICU admissions by the relative reduction in the proportion of neonates requiring NICU admission, under the assumption that most critically ill neonates will only have one NICU admission.

<sup>&</sup>lt;sup>b</sup>Using the formulas that define odds ratios (OR) and the percentage reduction in proportion with an event, an OR of 0.31 corresponds to a relative reduction in proportions of about 68%, depending on the underlying control group proportion and the relative risk ratio.

Detail for Selected Study – Reece, 2002	
<u>Characteristic</u>	
Author and Year of Publication	Reece 2002
Clinical Focus	High-risk pregnancy
Target Population	Low-income, unmarried, pregnant women
Intervention Strategies	RN and SW made initial home visit to explain program, conduct physical examination, and assess family needs. Prenatal visits with certified nurse-midwives for prenatal care and health education (with supervision and consultation by attending and resident obstetricians), nutritional assessments, parenting classes. Program provided transportation and on-site child care, made referrals, coordinated and followed-up on care, and followed-up on missed appointments. Well baby care, developmental assessments, and immunizations (including for siblings) by pediatric nurse practitioner for 1 year after birth
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-in
Enrollment rate, if available	Not stated
Geographic Location	Philadelphia, PA
Type of Community	Low-income urban
Health Care Setting	Home and special clinic at academic medical center (Temple University Hospital)
Health Insurance	Not stated
Quality of Evidence	C
Study Design	Comparison group study
Sample Size	818 (T=381, C=437)
Evaluation Timeframe	Immediate postpartum period
Cost/Utilization Outcomes	58% reduction in proportion with NICU admissions <sup>a</sup> (T=2.8%, C=6.6%; p<0.05)
Full Citation	Reece, E.A., G. Lequiamon, J. Silva, V. Whiteman, and D. Smith. "Intensive Interventional Maternity Care Reduces Infant Morbidity and Hospital Costs." <i>Journal of Maternal-Fetal and Neonatal Medicine</i> , vol. 11, no. 3, 2002, pp. 204-210.

<sup>a</sup>As stated in the Summary Table, we have approximated the relative reduction in the number of NICU admissions by the relative reduction in the proportion of neonates requiring NICU admission, under the assumption that most critically ill neonates will only have one NICU admission during their initial hospitalization following birth.

Detail for Selected Study –	· Stankaitis, 2005
<u>Characteristic</u>	
Author and Year of Publication	Stankaitis 2005
Clinical Focus	High-risk pregnancy
Target Population	At-risk pregnant women
Intervention Strategies	Health plan instituted reimbursements to obstetric practices to submit health risk assessments on each pregnant health plan member in a timely fashion; perinatal nurse care coordinator to coordinate care between clinicians, community outreach programs, health plan's social work program, and skilled nursing and home care services. Psychosocial support for those needing it including home visits, transportation assistance, referral to social work services; behavioral health support for those with mental health and substance abuse problems.
Additional Targeting Criteria	None stated
Opt-in/opt-out, if available	Opt-out
Enrollment rate, if available	Not stated
Geographic Location	Rochester, NY
Type of Community	Not stated
Health Care Setting	outpatient
Health Insurance	Medicaid managed care plan
Quality of Evidence	C
Study Design	Pre-post at program level (successive years of birth outcomes before and after the program); comparison with experience of all Upstate NY Medicaid enrollees over the same time period.
Sample Size	Not stated
Evaluation Timeframe	Immediate postpartum period
Cost/Utilization Outcomes	47% reduction in number per 1,000 live births with NICU admissions <sup>a</sup> (pre=108, post =57; p<0.01)
Full Citation	Stankaitis, Joseph A., Howard R. Brill, and Darlene M. Walker. "Reduction in Neonatal Intensive Care Unit Admission Rates in a Medicaid Managed Care Program." <i>American Journal of Managed Care</i> , vol. 11, March 2005, pp. 166-172.

<sup>a</sup>As stated in the Summary Table, we have approximated the relative reduction in the number of NICU admissions by the relative reduction in the proportion of neonates requiring NICU admission, under the assumption that most critically ill neonates will only have one NICU admission during their initial hospitalization following birth.