Cardiovascular Disease Prevention and Control: Reducing Out-of-Pocket Costs for Cardiovascular Disease Preventive Services for Patients with High Blood Pressure and High Cholesterol

Summary Evidence Table

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
Authors and date: Alderman & Melcher 1981 **Organization(s)/Implementer/ Initiator:** Mutual Life Insurance Company - Massachusetts (MA) funded intervention and made time to participate available to their employees.; intervention implemented by Mutual Life Insurance Company – MA and Department of Public Health at Cornell University Medical College; **Funding:** Mutual Life Insurance Company - MA; **Location:** Springfield, MA; **Setting and Scale:** Patients saw their own or other community physicians; **Design:** Single group before-after; **Applicability:** White, mostly female, middle-age employees in a large company in a northeastern state;	**Target Population:** Hypertensive employees; **Inclusion:** Employees of Mutual Life Insurance Company selected if average BP from 2 screenings was: ≥ 160/95 mm Hg for age ≥30 ≥ 150/90 mm Hg for age <30 Or Automatically enrolled if already taking antihypertensive meds; **Exclusion:** Employees with borderline BP defined as: BP of ≥150/90 for age ≥30 OR BP of ≥140/80 for age <30 Employees were counseled and advised to return in four months; **Reported Baseline Demographics (n=277)** Age (mean): 43% were >55 yrs. Sex: Male: 42.0%; Female 58.0% Race/Ethnicity: White: 81.0%; NR: 19.0%; Socioeconomic Status: NR Education Level: 49.6% grade-HS education;	**ROPC Intervention Components:** All high blood pressure treatment was free to patients. This included physician charges, medications, labs, hospitalization, etc.; **Type of ROPC Service:** Medication; **Level of ROPC Reduction:** 100%; **Type of Health Plan:** Private insurance; **Additional Intervention Components:** All hypertension treatment is free but specific components are not reported **Comparison:** Not applicable (NA);	**Change in SBP (mmHg): Mean (SD)** **24 months [ITT]:** Pre (n=254): 149.5 (NR) Post (n=234): 140.1 (NR) **Mean Difference= -9.4** **Change in DBP (mmHg): Mean (SD)** **24 months [ITT]:** Pre (n=254): 92.5 (NR) Post (n=234): 88.5 (NR) **Mean Difference= -4.0** **Proportion Controlled (BP<140/90 mmHg)** **24 months[ITT]:** Pre (n=254): 36.0% Post (n=234): 69.0% **Absolute pct. pts. change= 33.0** **Additional Outcomes:** Absenteeism (mean) increased from 4.7 days to 7.4 for nonparticipants vs. 4.6 days to 5.1 for participants; hypertensives experienced fewer hospitalization days post intervention (43 days vs. 41 days).

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Quality of Execution: Fair (2 limitations); **Limitations:** Data Analysis (1) - No details of data analysis; Interpretation of Results (1) - Confounding - awareness of BP control and treatment was raised companywide;	38.0% 1-4+ years of college; Employment status: 100% employed; # of drugs currently taken: 60.6% on at least one medication; **Reported Co-morbidities:** NR;		**Summary:** All hypertensive experienced a significant reduction in blood pressure. Those with the highest baseline DBP ≥95 mmHg experienced the greatest reduction in both DBP and SBP. Those who fully participated in the program had the highest initial blood pressure, the greatest decline in blood pressure, and only this group experienced a significant mean reduction on blood pressure.
Authors: Applegate et al. 2000 **Organization(s)/Implementer/ Initiator:** Internal Medicine Clinic at Earl Long Medical Center; **Funding:** State of Louisiana; **Location:** Baton Rouge, Louisiana; **Setting and Scale:** Internal medicine clinic at an academic teaching hospital which provides primary medical care to approximately 1,300 patients per month; **Design:** Single group before-after; **Applicability:** For this study,	**Target Population:** Patients seeking care from physicians at the hospital + referrals from the emergency department; **Inclusion:** Patients referred to the clinic with a diagnosis of hypertension; **Exclusion:** Patients diagnosed with secondary hypertension; **Reported Baseline Demographics (n=51):** Age (mean): 46.7 yrs. Sex: Male: 30.0%; Female 70.0% Race/Ethnicity: White: 23.3%; Black/AA: 76.7% Socioeconomic Status: Low-income: 100% Education Level (mean):10.9	**ROPC Intervention Components:** Free medication dispensed by registered pharmacist for all patients enrolled in the program; **Type of ROPC Service:** Medication; **Level of ROPC Reduction:** 100%; **Type of Health Plan:** Indigent care/uninsured; **Additional Intervention Components:** Patients received medication counseling and education by the pharmacist on med use +	**Change in SBP (mmHg): Mean (SD)** **6 months:** Pre (n=51): 156.8 (23.8) Post (n=51): 132 (22.0) **Mean Difference= -24.8** **Change in DBP (mmHg): Mean (SD)** **6 months [ITT]:** Pre (n=51): 96.1 (12.2) Post (n=51): 83.0 (14.0) **Mean Difference= -13.1** **Proportion Controlled (BP<140/90 mmHg) [ITT]:** Pre (n=51): 12.0% Post (n=51): 63.0% **Absolute pct. pts. change= 51.0**

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mainly to middle-age, low-income, hypertensive African American women living in Louisiana; **Quality of Execution:** Fair (2 limitations); **Limitations:** Interpretation of Results (2) - Contamination due to sub-sample group being exposed to educational sessions; - Baseline group not comparable for gender and race;	**Reported Co-morbidities:** NR;	biweekly visits to the clinic during the first 4 months + changes to pharmacological regimen made by physician as necessary; reminders about appointment, **Comparison:** NA;	**Additional Outcomes:** The number of patients with stage 1 and 2 hypertension declined significantly; proportion of stage 3 patients decreased from 22% to 0%. Additionally, the group receiving free meds plus education had a lower SBP than the free meds only group. **Summary:** For the six-month intervention targeting low-income patients with hypertension, the provision of free medications + education about medication use and side effects significantly improved blood pressure levels and resulted in a higher proportion of patients achieving control.
Authors and date: Atella et al. 2006 **Organization(s)/Implementer/Initiator:** Italian Govt.; **Funding:** Pfizer; **Location:** Southern province of Treviso, Italy; **Setting and Scale:** The data	**Target Population**: All individuals born between 1910 and 1960 with prescription of ACE-inhibitor class at any time during the period 1993-2002; **Inclusion:** Individuals born between 1910 and 1960 and prescribed at least 1 drug in the ACE-inhibitor class at any time during the period 1997-2000. # in analysis=38,393 patients; **Exclusion:** Patients with compliance score greater than 2 (n=505);	**ROPC Intervention:** On January 1, 2001 a change in policy resulted in elimination of drug prescription co-payment. **Type of ROPC Service:** Medication; **Level of ROPC:** Copayment rates for medications were reduced from a flat charge of about 1.5 Euros to zero; 100%	Provided results by compliant group (high compliant vs. low compliant). Compliance measured by ratio between the average daily purchase and Italian average daily dosages according to the Italian drug prescription practice (ADD) High compliant cut off was ≥ 0.55 score.

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come from three registries (drug prescription database, hospitalization registry; death and transfer registry); **Design:** Single group before-after; **Applicability:** Low-compliant hypertensive Italian patients treated with ACE-inhibitors; **Quality of Execution:** Fair (3 limitations); **Limitations:** Sample (1) - Little description of study sample; Interpretation of results (1) - Describe subgroups but do not provide demographics about the overall sample; Other (1) - Reporting of coefficient only made the interpretation of the results difficult;	Hospitalized patients for renal disease but not for CVDs (n=1207); **Reported Baseline Demographics (n=NR):** 48% male; **Reported Co-morbidities:** NR;	**Type of Health Plan:** NR; **Additional Intervention Components:** NR; **Comparison:** NA;	**Hospitalization rate** Low compliant group. Baseline: 7.9% Post-intervention: 7.0% **Absolute pct. pts. change:** -0.9% High compliant group. Baseline: 6.9% Post-intervention: 6.8% **Absolute pct. pts. change**: -0.1% **Mortality rate** Low compliant group. Baseline: 3.4% Post-intervention: 3.2% **Absolute pct. pts. change**: -0.2% High compliant group. Baseline: 2.7% Post-intervention: 2.7% **Absolute pct. pts. change**: -0% **Adherence to medications** Low compliant group. Baseline: 35.6% Post-intervention: 57% **Absolute pct. pts. change**: 21.4% High compliant group. Baseline: 92.3% Post-intervention: 90.1% **Absolute pct. pts. change**: -2.2% **Summary:** Changes in the copayment structure appear to have a strong effect on increased compliance

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			paralleled with decreased hospitalization and mortality among low compliant group at baseline, while no such differences were found in high compliant group at baseline.
Authors and date: Bunting et al. 2008 **Organization(s)/Implementer/ Initiator:** Employers: City of Ashville + Missions Hospitals; **Funding:** Novartis + APhA Foundation; **Location:** Ashville, NC; **Setting and Scale:** 12 community and hospital pharmacy clinics + 18 pharmacists; **Design:** Single group before-after; **Applicability:** For this study, mainly to middle-aged workers employed by the City of Ashville or Missions Hospital enrolled in an employer-based health insurance plan; **Quality of Execution:** Fair (3 limitations) **Limitations:** Sampling (1) - Selection bias;	**Target Population:** City of Asheville or Missions Hospitals employees or covered spouses or dependents; **Inclusion:** Diagnosis of hypertension and /or dyslipidemia + participants who agreed to take part in a CV risk reduction program sponsored by their health plan; **Exclusion:** NR; **Reported Baseline Demographics (n=565):** Age (mean): 50.4 yrs. Sex: Female: 53.6%; Male 46.4% Race/Ethnicity: Black/AA: 13.3%; White: 83.7%; Asian: 0.9%; Hispanic: 0.9%; Other: 1.2% Education: <H.S.: 7.6%; H.S. grad: 22.5%; >H.S.: 69.9% Smoking: 13.9% Controlled BP (%): 40.2% Controlled Lipids (%): 49.9% **Reported Co-morbidities:** Diabetes: 25.3% MI: 4.8% Heart failure: 3.0% Kidney disease: 2.1%	**ROPC Intervention Components:** Employers waived or significantly reduced disease-related medication copayments for patients + provided free medication counseling and education to patients. **Type of ROPC Service:** Medication, education, and medication counseling; **Level of ROPC:** Waived or significant reduction in medication copayment; free medication counseling and education; **Type of Health Plan:** Private employer-based insurance; **Additional Intervention Components:** Patients received a six year intervention in which a pharmacist provided CVD risk factor reduction via education on HTN and dyslipidemia +one-on-one medication counseling sessions + medication compliance	**Change in SBP (mmHg): Mean (SD) 72 months [ITT]:** Pre (n=301): 137.3 (16.85) Post (n=278): 126 (14.2) **Mean Difference= -11.0** **Change in DBP (mmHg): Mean (SD) 72 months [ITT]:** Pre (n=307): 82.6 (11.62) Post (n=278): 77.8 (9.67) **Mean Difference=- 4.80** **Proportion Controlled (BP<140/90 mmHg) [ITT]:** Pre (n=565): 40.2% Post (n=423): 67.4% **Absolute pct. pts. change= 27.2** **Triglycerides (mg/dL) Mean (SD) 72 months [ITT]:** Pre (n=340): 192.8 (171.4) Post (n=323):154.4 (88.4) **Mean Difference=-38.4** **Total Cholesterol (mg/dL) Mean (SD) 72 months [ITT]:**

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Interpretation of results (2) - Loss to follow-up; - Confounding due to the pharmacist intervention;	Stroke: 0.7%.	assessment + use of national guidelines + follow-up visits every 3 months; **Comparison:** NA;	Pre (n=341): 211.4 (45.7) Post (n=326): 184.3 (38.6) **Mean Difference= -27.1** **LDL Cholesterol (mg/dL) Mean (SD) 72 months [ITT]:** Pre (n=369): 127.2 (36.6) Post (n=353):108.3 (32.1) **Mean Difference= -18.9** **HDL Cholesterol (mg/dL) Mean (SD) 72 months [ITT]:** Pre (n=374): 48.0 (13.4) Post (n=362): 46.6 (12.2) **Mean Difference= -1.4** **LDL Cholesterol Controlled (<100mg/dL) [ITT]:** Pre (n=565): 49.9 Post (n=424): 74.6 **Absolute pct. pts. change= 24.7** **Additional Outcomes:** ED and hospitalization utilization significantly decreased by 54%. **<u>Summary:</u>** The six-year pharmacist intervention targeted towards patients enrolled in an employer-based health plan was able to drastically reduce the number of CV events, while also increasing

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			the use of CV medications and reducing medical cost.
Authors and date: Chernew et al. 2008 **Organization(s) / Implementer / Initiator:** VBID implemented by Active Health Management (AHM) and Integrated Care Management company; **Funding:** GlaxoSmithKlines and Pfizer Inc.; **Location:** USA; **Setting and Scale:** The intervention site included a large employer with a comparable employer in the comparison group; scale not reported; **Design:** Pre-post with a comparison group; **Applicability:** Population of employed individuals and their dependents, employed by a large company; **Quality of Execution:** Fair (3 limitations); **Limitations:** Description (1) - Little description of study sample; Interpretation of results (2)	**Target Population**: All individuals (employee + dependents) who were already taking any of the five classes of medications for hypertension and diabetes; **Inclusion:** Inclusion criteria included employees and dependents (18–64 years) who were continuously enrolled for the relevant quarter and the entire previous quarter. They had to be also taking any of the intervention medications without a contraindication; **Exclusion:** Individuals aged ≥ 65 years; **Reported Baseline Demographics:** NR # of members: -Intervention firm: pre-intervention = 74345 and post-intervention = 70,259 -Control firm: pre-intervention = 35807 and post-intervention = 37867 **Reported Co-morbidities:** NR;	**ROPC Intervention:** VBID Components: Reduced copayment for 5 classes of medication: ACE inhibitors/ARBs, beta-blockers, diabetes medications, statins, and inhaled corticosteroids. Individuals received a letter explaining importance of taking the recommended drugs; The program was added to an already existing accredited DM program used by both the treatment and control firms; **Type of ROPC Service:** Medication; **Level of ROPC:** Copayment rates for generic medications were reduced from $5 to 0. Copays for brand-name drugs were lowered 50 % (from $25 to $12.50 for preferred drugs & from $45 to $22.50 for non-preferred drugs); **Type of Health Plan:** NR **Additional Intervention Components:** NR; **Comparison:** Individuals in the control firm who were part of DM program and/or already taking any of the intervention	**Medication Adherence:** Effects size for adherence as measured by medication possession ratio (MPR): 2.59 for ACE inhibitor/ARBs 3.02 for beta-blockers. 3.39 for Statins 4.02 for diabetic drugs (p for all <0.0001) Increased adherence was 3.79% for ACE inhibitor and 4.43% for beta blockers. The corresponding increase adherence for Statins was 6.28%. **Summary:** Value-based insurance design programs can effectively increase adherence to hypertension and diabetes medications and also complement existing disease management programs.

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- Neither study sample size nor follow-up response reported - No comparison between the control and intervention measures provided;		medications without a contraindication;	
Authors and date: Elhayany & Vinker 2011 **Organization(s)/Implementer/ Initiator:** authors affiliated with Clalit Health Services, Central district, Rishon Le Zion, Israel and Meir Medical Center, Kfar Saba Israel; **Funding:** Grant from Israel Lotus Foundation; **Location:** Israel; **Setting and Scale:** Calit Health Services - largest HMO in Israel; insuring 54% of the population (3.9 million members); **Design:** Single group before-after; **Applicability:** insured, low-SES patients with diabetes, hypertension, or hyperlipidemia eligible for elimination of copays for meds in Israel; **Quality of Execution:** Fair (2 limitations) **Limitations:** Sampling (1)	**Target Population:** low SES adult patients with hypertension, hypercholesterolemia, or diabetes; **Inclusion:** Patients 18 and older w/low SES (as defined by Israel National Insurance Institute) who did not regularly purchase prescribed medicines, identified from Clalit Health Services records; had diabetes, hypertension, or hyperlipidemia; **Exclusion:** Patients who were known abusers of alcohol or drugs; **Reported Baseline Demographics (n=355):** Mean age: 64.6 Sex: Female = 54.9%; Socioeconomic Status: 100% low income (as defined by Israel National Insurance Institute); **Reported Co-morbidities:** Diabetes: 59.2%;	**ROPC Intervention Components**: Eliminated copays for medications **Type of Health Plan:** HMO funded by the government; **Type of ROPC Service:** medication; **Level of ROPC:** 100% free; **Additional Intervention Components**: NR; **Comparison:** NA;	**Change in SBP (mmHg): Mean (SD) 24 months:** Pre (n=250): 136.2 (16.7) Post (n=248): 128.2 (13.3) **Mean difference: -8.0** **Change in DBP (mmHg): Mean (SD) 24 months:** Pre (250):78.0 (8.7) Post (248): 74.8 (8.1) **Mean difference: -3.2** **Change in LDL-C (mg/dL): Mean (SD)** Pre (304): 116.2 (38.0) Post (270): 105.3 (38.0) **Mean difference: -10.9** **A1C LEVEL: Mean (SD), %** Pre (187): 7.5 (1.5) Post (162): 7.8 (1.7) **Mean difference: 0.3** **Additional Outcomes:** NR **Summary:** This study demonstrates a significant improvement in health measures associated with decreased medication costs among low-income population in Israel.

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- patients selectively chosen by health staff; Interpretation of results (1) - did not control for secular trends;			
Authors and date: Farley et al. 2012 **Organization(s)/Implementer/ Initiator:** Blue Cross Blue Shield of North Carolina (BCBSNC) funded the ROPC; **Location:** North Carolina, US; **Funding:** Robert Wood Johnson Foundation Health Care Financing and Organization Initiative and BCBSNC; **Setting and Scale:** Employers offering health benefits through BCBSNC in 2008(# of employees not reported); **Design:** Pre/Post with comparison group; **Applicability:** older patients at increased risk of CVD who are enrolled in value-based insurance design (VBID) plan similar to BCBSNC and who were already using medications for chronic health conditions; **Quality of Execution:** Good (1 limitation);	**Target Population:** Patients enrolled in VBID for medications to treat hypertension, hyperlipidemia, diabetes, and congestive heart failure; **Inclusion:** Intervention group: continuously enrolled from January '07 and '09 in a BCBSNC plan, did not have a change in their VBID enrollment status from '08 to '09, 18 years and older in '07, taking at least 1 of 8 classes of drugs previously indicated in '07; Control: enrolled in BCBSNC Administrative Services Only benefits plan; **Exclusion:** NR; **Reported Baseline Demographics (n= 12164) median of means for all mediation classes:** Mean age: 52.3 (Median of means); Sex: Male = 61.9% (medians of the means); Socioeconomic Status: NR; # of drugs currently taken: 4.27 (mean # of unique meds); **Reported Co-morbidities:** NR;	**ROPC Intervention Components**: VBID waived copays for generic drugs for diabetes, hypertension, hyperlipidemia, and congestive heart; reduced copayment for brand-name drugs; **Type of Health Plan:** HMO; **Type of Service Provider:** NR; **Type of ROPC Service:** medication; **Level of ROPC:** 100% free for generics; copays for brand-name drugs were lowered 11% to 86% [from $15.57 to $2.42 for ACEI's, $15.05 to $2.07 for beta-blockers, $24.89 to $19.46 for statins, $16.91 to $9.14 for thiazides, $36.31 to $32.28 for ARB's, $37.09 to $32.90 for CAI's]; **Additional Intervention Components**: Some participants enrolled in disease management; **Comparison:** BCBSNC	**Medication adherence:** In adjusted analyses*, percentage point adherence improved from 2.3% for statins, 4.3% for beta-blockers, 4.8% for ACEIs, 4.5% for thiazide diuretics for intervention vs. comparison group ($p<0.001$). No significant differences in adherence trends for CAIs or ARBs; *Matched for age, sex, 90-day fills, avg. copay, # of meds used, comorbidity burden, percentage of generic prescriptions, disease management participation, case management participation, and baseline '07 healthcare expenditures; Subgroup analysis - 4.1% to 11.5% of intervention participants with poorer baseline adherence had greatest percentage point increase in adherence; participants who were not adherent at baseline became fully adherent by '09, representing a 30

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Limitations: Interpretation of results (1) - Confounding - both participants and non-participants received some ROPC; copayment for generic medication was only waived for the intervention group	Smoking: 30.0%	members in Administrative Services plan; no reduction in copays for generics ;copays for brand-name drugs were lowered 5%-20% [from $16.23 to $12.91 for ACEI's, $15.63 to $12.74 for beta-blockers, $27.15 to $25.66 for statins, $17.63 to $16.00 for thiazides, $38.42 to $32.65 for ARB's, $40.41 to $33.90 for CAI's];	percentage point improvement; **Summary:** This study demonstrates a significant improvement in average adherence for VBID participants compared to nonparticipants for eight hypertension and cholesterol drug categories. Changes were statistically significant for all categories except CAI's;
Authors and date: Gibson et al. 2010 **Organization(s)/Implementer/Initiator:** Employer initiated; **Funding:** Novartis Pharmaceutical Corporation; **Location:** US, multiple states; **Setting and Scale:** One large global pharmaceutical company with its US headquarters in New Jersey, with 25, 784 employees and their dependents; **Design:** Pre-post study with a comparison group (post-only data abstracted for this review); **Applicability:** 18-64 years self-insured employed patients with diabetes and CVD	**Target Population:** Self-insured employed individuals with prescriptions for diabetes or CVD; **Inclusion:** Employees and dependents ages 18-64 with prescription for diabetes or CVD or asthma, enrolled in the plan for ≥1 year prior to the program, had to be enrolled for at least two quarters during the post-implementation period; **Exclusion:** NR; **Reported Baseline Demographics (n=NR):** NR; **Reported Co-morbidities:** NR;	**ROPC Intervention Components:** VBID for employees and dependents offered by the company on January 1, 2005; information about the new programs was communicated to all employees in benefits newsletters and on the company intranet; **Type of ROPC Service:** Medication; **Level of ROPC:** 10% coinsurance for retail prescriptions; 7.5% coinsurance for mail-order prescriptions used to treat CVD, diabetes; **Type of Health Plan:** Private insurance; **Additional Intervention**	**Medication adherence:** **Proportion of patients who were 80% adherent to HTN medications 36months post intervention:** Intervention (n=NR):61.5 % Comparison (n=NR): 56.4% **Absolute pct. pts. change:** 5.1 **Additional outcomes:** The difference in spending was not significant in the first year after program implementation. However, the average spending was $2,122 lower in the enrolled group in the second year after program implementation and $3,722 lower in the third year. **Summary:** In a three-year

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taking medications for hypertension; **Quality of Execution:** Fair (2 limitations); **Limitations:** Description (1) - no sample description; Interpretation of results (1) - Not everyone received disease management program (potential confounder);N/A		**Components:** General disease management programs for asthma, cardiac conditions, and diabetes were also implemented for enrollees in the company's indemnity and point-of-service plans in '05 and across all self-insured plans in '07 (excludes ~30% of enrollees); **Comparison:** Matched each value-based insurance plan enrollee one-to-one with a nonelderly adult enrollee within one of four peer firms**.** Comparison group enrollees n= 154, 444;	evaluation, the authors found that people enrolled in the program significantly improved their adherence to medication regimens and that costs for the company were revenue neutral.
Authors and date: Haskell et al. 2006 **Organization(s)/Implementer/ Initiator:** Funders provided pharmaceutical support, supplies for point-of-care lipid and glucose testing; authors affiliated with Stanford University; **Location:** Santa Clara County, CA; **Funding:** Health Trust Santa Clara, CA; Cholestech, Inc., Hayward, CA; Merck & Co., Inc., Whitehouse Station, NJ; Pfizer, NY, NY., Bristol Myers Squibb Co., Princeton, NJ, Kos	**Target Population:** Patients with limited/no health insurance + low family income + at increased CVD event risk; **Inclusion:** 35 to 80 yrs.+ ≥ 1 major modifiable CVD risk factor+ currently receiving medical care at not-for-profit or free clinics or hospitals; **Exclusion:** Recent history of serious medical condition + alcoholism; **Reported Baseline Demographics (n=99):** Age (mean): 60.5 yrs. Sex: Female: 55.6%; Male: 44.4%	**ROPC Intervention Components**: Clinics provided free medical care or accepted payment on basis of ability to pay + free medications for dyslipidemia, hypertension, and diabetes management provided via existing programs at participating clinics and indigent drug programs or donations from pharmaceutical companies; **Type of Health Plan:** Medicare; indigent/uninsured; **Type of Service Provider:** physician + nurse or nurse	**Change in SBP (mm Hg): Mean (SD)** **Baseline:** Intervention (n=96):142 (2.0) Comparison (n=45): 141(3.0) **12m [ITT]:** Intervention (n=96): 128 (1.4) Comparison (n=45): 137 (2.8) **Mean difference = -10.0** **Change in DBP (mm Hg): Mean (SD)** **Baseline:** Intervention (n=96): 82 (1.1)

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Pharmaceuticals, Inc., Cranbury, NJ, Abbott Laboratories, Abbott Park, IL., SmithKline Beecham, Research Triangle Park, NC.; **Setting and Scale:** 3 primary care clinics +1 women's shelter providing free medical care + Medicare or Medi-Cal (California's Medicaid Program) **Design:** Randomized Controlled Trial; **Applicability:** low-income, predominantly Hispanics, women, and those in their early 60s who either have no health insurance or have public health insurance (Medicare) and receive care from free clinics; **Quality of Execution:** Good (1 limitation) **Limitations:** Interpretation of results (1) - confounding patients in the comparison group may have qualified for free meds as well;	Race/Ethnicity: Female: 55.6%; African American: 7.0%; White: 11.0%; Hispanic: 59.0% ; Asian: 11.0%; Other: 12.0% Education: < High school: 55.0%; High school graduate: 20.0%; Post high school: 24.0% Income: Low income: 100% Insurance status: Medicare/Medicaid: 20.0%; Uninsured: 65.0% BMI (mean): 30.4 (obese) Smoking: 10.3% **Reported Co-morbidities:** Personal hx of CHD: 24.5%	practitioner + dietitian; **Type of ROPC Service:** medication; **Level of ROPC:** 100% free; **Additional Intervention Components**: Patients randomized to intervention group received an individualized disease management program delivered by a team consisting of a specially trained nurse or nurse practitioner and a dietitian which included: treatment algorithms based on national guidelines + assessed medication compliance + lifestyle counseling + follow-up visits every 6 to 8 weeks + medication management + family involvement; **Comparison:** Patients assigned to usual care received free medical care or made payments based on ability to pay;	Comparison (n=45): 82 (1.6) **12m [ITT]:** Intervention (n=96): 76 (0.8) Comparison (n=45): 81 (1.5) **Mean difference = -5.0** **Total Cholesterol (mg/dL) Mean (SD)** **Baseline:** Intervention (n=96): 206(4.3) Comparison (n=45): 204 (5.7) **12m [ITT]:** Intervention (n=96):184 (3.4) Comparison (n=45): 197 (4.8) **Mean difference = -15.0** **LDL-C (mg/dL) Mean (SD)** **Baseline:** Intervention (n=96): 121(3.9) Comparison (n=45): 118 (5.73) **12m [ITT]:** Intervention (n=96):104 (2.9) Comparison (n=45): 115 (4.4) **Mean difference = -14.0** **HDL-C (mg/dL) Mean (SD)** **Baseline:** Intervention (n=96): 45

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			(1.3) Comparison (n=45): 47 (2.0) **12m [ITT]:** Intervention (n=96): 46 (1.2) Comparison (n=45): 44 (1.6) **Mean difference = +4.0** **Triglycerides (mg/dL)** **Mean (SD)** **Baseline:** Intervention (n=96):197 (10.4) Comparison (n=45): 192 (12.8) **12m [ITT]:** Intervention (n=96):176 (7.6) Comparison (n=45): 200 (12.2) **Mean difference = -13.0** **Additional Outcomes:** Fasting Blood Sugar **Summary:** This ROPC + multicomponent intervention achieved significant decreases in blood pressure, blood lipid profile, and fasting blood sugar in mainly Hispanic women who were at increased risk of CVD event and received care from free clinics.

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Authors and date: Hill et al. 2003 **Organization(s)/Implementer/ Initiator:** Johns Hopkins Research Center; **Funding:** National Institute of Nursing Research + Merck & Company; **Location:** Baltimore, MD; **Setting and Scale:** 1 outpatient general clinic research center + home visits; **Design:** Randomized Control Trial (RCT); **Applicability:** For this study, mainly to, inner-city, low-income, hypertensive African American males with a high rate of illicit drug use or obesity; **Quality of Execution:** Fair (2 limitations); **Limitations:** Description (1) - Study dates not reported; Interpretation of Results (1) - Baseline groups not comparable;	**Target Population** Hypertensive African American males residing in inner city Baltimore, MD; **Inclusion:** 21-54 years old +SBP >140 mm Hg and DBP >90 mm Hg on 2 separate occasions + on or off antihypertensive medication; **Exclusion:** Renal dialysis + acute or terminal illness + serious mental illness + participant in another hypertension trial; **Reported Baseline Demographics (n=157):** Age (mean): 41.0 yrs. Sex: Male: 100% Race/Ethnicity: Black/AA: 100% Socioeconomic Status: Low-income: 68.0% (<$10,000) Employment Status: Unemployed 67.0% Smoking: 84.0% **Reported Co-morbidities:** Diabetes: 7% Obesity: 26% Substance abuse: 40%	**ROPC Intervention Components:** Received free mediation and were referred to community-based sources of hypertension care and support; **Type of Health Plan:** Medicare; indigent/uninsured; **Type of Service Provider:** physician + community healthcare worker; **Type of ROPC Service:** medication; **Level of ROPC:** 100% free; **Additional Intervention Components:** Tech-enabled database software used to record information and enable tailoring of messages to patients + telephone; **Comparison:** Participants received usual care plus received healthy lifestyle classes. Clinical practice guidelines for managing hypertension were sent with each letter to the provider;	**Proportion Controlled (BP<140/90 mm Hg OR 130/80 mm Hg for persons with diabetes)** **Combined Intervention Arms (1 and 2)** **Baseline:** Usual care (n=159): 72.0% Intervention (n=319): 71.0% **24m [ITT]:** Usual care (n=159): NR Intervention (n=318) NR **Absolute pct. pts. change=7.65** **Additional Outcomes:** Adherence to intervention + utilization of medical resources + medication adherence + exercise **Summary:** A brief behavioral intervention delivered via telephone by nurses demonstrated a significant improvement in BP control in a mainly older, obese population attending primary care clinics at an academic medical center in both intervention arms. Systolic and diastolic BP improved at 12 months but these results were not sustained at 24

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
			months for the patient behavioral intervention while results remained significant for the combined (patient behavioral + home BP monitors] intervention. Self-reported medication adherence and exercise improved slightly in the intervention arms but was not significant.
Authors and date: Keeler et al. 1985 **Organization(s)/Implementer/ Initiator:** Rand Corporation **Funding:** U.S. Department of Health and Human Services; **Location:** U.S.A.; **Setting:** NR; **Design:** Randomized Controlled Trial (RCT); **Applicability:** For this study, mainly to hypertensive adults with cost-sharing free health insurance plans living in the United States; **Quality of Execution:** Fair (2 limitations); **Limitations:** Description (1) - Baseline demographic	**Target Population:** Patients from the Rand Health Insurance Experiment defined to be hypertensive; **Inclusion:** Patients defined to be hypertensive: (1) reported taking anti-hypertensive drugs, (2) had a repeated systolic blood pressure greater ≥160 mmHg or diastolic blood pressure ≥ 95 mmHg at the examination, (3) had a repeated systolic blood pressure ≥140 mmHg or diastolic blood ≥ 90 mmHg and reported a previous diagnosis of hypertension, or (4) reported that a physician had told them more than once they had hypertension and either were assigned to miss the examination or had systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg; **Exclusion:** NR; **Reported Baseline Demographics (n=294):** Age (mean): 44.0 yrs. Sex: NR Race/Ethnicity: NR	**ROPC Intervention Components:** Families enrolled in the free plan received all health care services without charge; **Type of ROPC Service:** Medication + comprehensive medical care; **Level of ROPC:** 100%; **Type of Health Plan:** Private insurance; **Additional Intervention Components:** NR; **Comparison:** Three types of cost-sharing plans: catastrophic coverage - family paid 85% of all its health bills; Individual-deductible plan – family paid 95% of the cost of each outpatient service up to a maximum out-of-pocket expenditure of $150 for each person per year; intermediate	**Change in SBP (mmHg): Mean (SD)** **Baseline:** Usual care (n=294): NR Intervention (n=294):NR **86mo:** Usual Care (n=294):138.9 Intervention (n=294): 137.1 **mean difference =-1.80** **Change in DBP (mmHg): Mean (SD)** **Baseline:** Usual care (n=562): NR Intervention (n=294): NR **86mo:** Usual Care (n=562): 88.7 Intervention (n=294): 90.6 **mean difference =-1.90** **Proportion Controlled (BP<140/90 mm Hg):** A significantly higher percentage of persons on the free than on the cost-sharing plans had controlled blood pressure at exit (43% vs. 37%, respectively);

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
information not provided for gender; Interpretation of Results (1) - Confounding by quality-of-care;	Socioeconomic Status: NR Education: NR Employment Status: NR **Reported Co-morbidities:** NR;	coinsurance – families paid 25% or 50% of all its health bill each year;	**Summary:** For this 86 month RCT comparing free health insurance plans to cost-sharing plans in hypertensive patients, significant improvements were observed for DBP and blood pressure control for patients in the free plan compared to the cost-sharing plan. Additionally, reductions in sodium in-take were also observed for the free plan group.
Authors and date: Sauvageot, 2008 **Organization(s)/Implementer/ Initiator:** Non-Profit Pharmacy (Shenandoah Valley Compassionate Pharmacy); **Funding:** Pharmaceutical Manufacturer's Assistance Programs (PMAPs); **Location:** Virginia; **Setting and Scale:** Community setting One non-profit community Pharmacy; **Design:** Single group before-after; **Applicability:** Low-income seniors, particularly women,	**Target Population:** Low-income older patients with hypertension, hyperlipidemia, or diabetes who needed help paying for their medications; **Inclusion:** Elderly, low-income patients referred to the community pharmacy by their providers. Patient advocate reviewed and matched patients' eligibility with specific PMAPs requirements; **Exclusion:** NR; **Reported Baseline Demographics (n=84):** Age (mean): 72.7 +/- 10.6 Sex: 73.8% females; 26.2% Race/Ethnicity: NR Socioeconomic Status: Education: NR Employment Status: NR Health Insurance: Most had health	**ROPC Intervention Components:** Patient advocate matched elderly, low-income patients with a PMAP; received free medication for hypertension, hyperlipidemia, or diabetes and medication counseling from a pharmacist ; **Type of ROPC Service:** Assistance in matching patients with a PMAP; medication through PMAPs; medication management counseling; **Level of ROPC:** 100%; **Type of Health Plan:** NR (most had health insurance but were not covered for prescription);	**Change in SBP (mmHg): Mean (SD)** **43 months:** Pre (n=36): 138 (15) Post (n=36): 136 (18) **Mean Difference = -2** **Change in DBP (mmHg): Mean (SD)** **43 months:** Pre (n=35): 81 (7) Post (n=35): 75 (8) **Mean Difference = -6** **Total cholesterol (mg/dL) Mean (SD)** **43m:** Pre (n=136): 195 (43.0) Post (n=25): 170 (31) **Mean difference = -25.0** **LDL-C (mg/dL) Mean (SD)** **43m:** Pre (n=21): 112 (39.0)

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
diagnosed with hypertension, dyslipidemia, and/or diabetes without prescription drug benefits living in Northern Virginia; **Quality of Execution:** Good (1 limitation); **Limitations:** Interpretation of results (1) - Confounding: Could not tell if there was any lost to follow-up over the course of this program (42 months);	insurance with inadequate prescription coverage Socioeconomic Status: Low Income Income(mean)$14,412.56+/-$6,451.50 Income Range: $1,314.20 - $31,625.10 **Reported Co-morbidities:** NR;	**Additional Intervention Components:** Patient advocate matched elderly, low-income patients with a PMAP; and a pharmacist provided medication counseling; NR; **Comparison:** NA;	Post (n=21): 98 (34) **Mean difference = -14.0** **HDL-C (mg/dL) Mean (SD)** **43m:** Pre (n=36): 47 (16.0) Post (n=36): 44 (12) **Mean difference = -3.0** **Triglycerides (mg/dL) Mean (SD)** **43m:** Pre (n=23): 198 (100) Post (n=23): 167 (84.0) **Mean difference = -25.0** **A1C level Mean (SD)** **43m:** Pre (n=13): 7.3 (0.9) Post (n=13): 7.6 (0.8) **Mean difference = -0.3** **Additional Outcomes:** NR **Summary:** In a 43 month evaluation, the authors found statistically significant improvements in patients' TC, LDL-C and diastolic blood pressure. Slight but not statistically significant decrease occurred in their DBP, TG, and A1C level.
Authors and date: Trompeter & Havrda 2009 **Organization(s)/Implementer/**	**Target Population:** Patients with no or limited prescription drug coverage; **Inclusion:**	**ROPC Intervention Components**: meds at little or no cost through a pharmaceutical company	**Change in SBP (mm Hg): Mean (SD)** **12m:** Intervention (n=191):135.5

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
Initiator: Pharmaceutical company implemented the intervention; authors affiliated with Department of Pharmacy Practice, Shenandoah University, Winchester, VA; **Location:** Virginia, US; **Funding:** NR; **Setting and Scale:** intervention included patients from a private family practice site; **Design:** Post-only w/comparison group; **Applicability:** Low-income individuals without prescription coverage provided with medication through PCAP and working with a clinical pharmacist; **Quality of Execution:** Fair (2 limitations); **Limitations:** Interpretation of results (1) - groups not comparable at baseline; Other (1) - update in guidelines may have altered physician prescribing behavior;	18 years or older + had a diagnosis of hypertension, diabetes, or dyslipidemia; and were prescribed at least one medication for one of the diseases; + For intervention group: patients with noted financial concern; For control group: patients with prescription insurance; **Exclusion:** NR; **Reported Baseline Demographics (n=208):** Age (mean): 67.3 yrs. Sex: Female: 71.2%; Race/Ethnicity: NR; Education: NR; Income: Low income: 100% ; Insurance status: NR; BMI (mean): NR; **Reported Co-morbidities:** NR;	assistance program (PCAP); **Type of Service Provider:** physician + pharmacist; **Type of ROPC Service:** medication; **Level of ROPC:** free or no cost; **Type of Health Plan:** NR; **Additional Intervention Components**: Patients required to keep regular follow-up and laboratory appointments with healthcare providers; pharmacist provided disease state information to PCAP patients, recommended cost-effective therapies, ensured routine follow-up, provided medication reminders; **Comparison:** Individuals with prescription insurance received usual care (did not interact with the pharmacist);	(17.1) Comparison (n=188): 128.8 (18.5) **Mean difference = +5.7** **Change in DBP (mm Hg): Mean (SD)** **12m:** Intervention (n=191): 75 (10.0) Comparison (n=188): 77.5 (8.5) **Mean difference = -2.5** **Proportion Controlled (BP<140/90 mm/HG)** **12m:** Intervention (n=191): 46.6% Comparison (n=188): 54.8% **Absolute pct. pts. change= -8.2** **LDL-C (mg/dL) Mean (SD)** **12m:** Intervention (n=150):95.8 (28.0) Comparison (n=136): 111.8 (37.5) **Mean difference = -16.0** **Proportion at goal LDL** **12m:** Intervention (n=150): 64.2% Comparison (n=136): 54.1% **Absolute pct. pts. change= +10.1** **HDL-C (mg/dL) Mean**

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
			(SD) **12m:** Intervention (n=150): 43.8 (12.9) Comparison (n=136): 39.1 (11.5) **Mean difference = +4.1** **Proportion at goal HDL** **12m:** Intervention (n=150): 31.5% Comparison (n=136): 32.8% **Absolute pct. pts. change= -1.3** **Additional Outcomes:** A1C level, % at A1C goal, Fasting Blood Sugar **<u>Summary:</u>** This ROPC intervention consisted of PCAP in which participants received medication for little to no cost. The study found that low-income individuals without prescription coverage provided with medication through PCAP and working with a clinical pharmacist were more likely to have lower LDL-C and higher HDL-C values compared with persons with prescription coverage. In addition, those in the PCAP group were more likely to meet goals for glycemic control than those

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
			with prescription insurance.
Authors and date: Wertz et al. 2012 **Organization(s)/Implementer/ Initiator:** VBID implemented by Anthem Blue Cross & Blue Shield. **Funding:** Novartis Pharmaceuticals Corp **Location** Ohio, USA **Setting and Scale:** The intervention site included two large employers (City of Cincinnati (COC) and Kroger); scale not reported. **Design:** Pre-post with a comparison group **Quality of Execution:** fair **Applicability:** Population of employed individuals with diabetes or hypertension, employed by large companies. **Limitations:** Difference in baseline measures between the two groups. Not everyone received the same	**Target Population**: All individuals diagnosed with hypertension. **Inclusion:** Employees + retirees of COC and Kroger, age 18 or above with ≥1 inpatient admissions or ER visits or ≥ 2 professional office visits with ICD-9 codes for hypertension. All patients were required to have a minimum of 12 months of continuous health plan enrollment before and after index date **Exclusion:** NR **Reported Baseline** N=289 Age (mean±SD): 57±12 yrs. Sex: Male: 42.2%; Female 57.8% Race/Ethnicity: White: 50.2%; Black/AA: 36.8% **Reported Co-morbidities:** Diabetes: 4.2% Dyslipidemia: 56.7% Any CVD disease: 15.3%	**ROPC Intervention:** VBID Components: copayment waivers or copayment reductions for all medications related to diabetes, hypertension, and dyslipidemia. The service provider included community-based pharmacists. **Other Simultaneous Intervention Components: --**Tailored pharmaceutical care services to help members better understand and manage their conditions via regular meetings. Depending on the incentives provided by the employer groups, some members received $100 contributions to their health saving accounts. It happened only in the City of Cincinnati **Type of ROPC Service:** Medication **Level of ROPC:** reduced or free. No details provided. **Comparison:** Employees who were offered the program but declined to participate selected using propensity	**Clinical outcomes reported-** only for the intervention group. Change in SBP(mmHg): Mean at 14.6 mo Pre (n=283): 136.1 Post (n=283): 129.5 **Mean Difference= -6.6** Change in DBP(mmHg): Mean at 14.6 months Pre (n=283): 83.5 Post (n=283): 79.3 **Mean Difference=-4.20** Change in T-chol (mg/dL): Mean at 14.2 mo Pre (n=98): 183 Post (n=98): 172 **Mean Difference= -11** Change in TG(mg/dL): Mean at 14 mo Pre (n=99): 133.8 Post (n=99): 124.0 **Mean Difference= -9.8** Change in HDL (mg/dL): Mean at 14.1 mo Pre (n=98): 49.9 Post (n=98): 49.4 **Mean Difference= -0.8** Change in LDL (mg/dL): Mean at 14.2 mo Pre (n=97): 104.1

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
intervention		score matching- comparison results are only reported for medication adherence. No comparisons for BP or cholesterol outcomes are provided.	Post (n=97): 97.2 **Mean Difference= -6.9** **Proportion Controlled (BP<140/90 mmHg):** 14.6 mo Pre (n=283): 52.0% Post (n=283): 70.0% **Absolute pct. pt change= 18.0** **Proportion Controlled (LDL-C<160, <130 or <100 mg/dL) based on CHD risk factors:** 14.2 mo Pre (n=97): 71.0% Post (n=97): 84.0% **Absolute pct. pts. change= 13.0** **Additional Outcomes:** Change in medication adherence as measured by proportion of days covered (PDC) (%): 12mo **Hypertensive drugs**: mean±SD Intervention: Pre (n=210): 82.0±26.0 % Post (n=210): 91.0±17.0% Absolute difference = 8.4% Control: Pre (n=193): 86.0±24.0% Post (n=193):86.0±21.0% Absolute difference = 0% **Difference of difference: 9%**

Study Details	Population Characteristics	Intervention + Comparison Description	Major Results and Summary
			Statin: mean±SD Intervention: Pre (n=210): 76.0±27.0 % Post (n=210): 87.0±22.0% Absolute difference = 11.0% Control: Pre (n=193): 73.0±29.0% Post (n=193):83.0±20.0% Absolute difference = 10.0% **Difference of difference: 1%** **Summary:** Value-based insurance design programs can effectively increase adherence to medications and improve clinical outcomes.