Reducing Tobacco Use and Secondhand Smoke Exposure: Reducing Out-of-Pocket Costs for Evidence-Based Cessation Treatments

Summary Evidence Table

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	**Location Intervention Comparison**	**Study population Sample size**	**Effect measure**	**Reported Baseline**	**Reported effect**	**Value used in summary**	**Follow-up time**
Boyle 2002 (1998-1999) Greatest (Quasi-randomized control trial) Fair (2 limitations) Tobacco use cessation Quit Attempts NRT use	Minnesota <u>Intervention:</u> Health insurance benefits for pharmacological aids <u>Comparison:</u> No benefits	Recruitment via postcard to a sample of adult insurance members. Stratified into random samples. N=2,898 deemed eligible N=2,327 completing f/u at 12 months 767 no P benefit 1560 P benefit 80% loss to f/u (not reported by benefit status)	Self-reported continuous abstinence for more than 6 months	No Pharmacologic benefit (self-insured) 4.1%	New Pharmacological benefit in insurance 4.1%	0.0 pct pts p=0.97	12 months
			Self-reported point prevalence abstinence	Comparison 13.5%	Intervention 14.3%	+0.8 pct pts p=0.81	12 months
			Self-report quit attempts for more than 1 day	Comparison 37.8%	Intervention 40.3%	+2.5 pct pts p=0.30	12 months
			Any NRT use	Comparison 28.3%	Intervention 26.4%	-1.9 pct pts p=0.46	12 months
			Any Zyban use	Comparison 18.9%	Intervention 23.5%	+4.6 pct pts p=0.17	12 months

NOTE: At 12 months follow-up only 30% of smokers with the benefit reported knowing that it was covered, but 6% of smokers without the benefit thought they had it.

Use of Zyban 49.3% among people who know they had coverage compared to 15.5% who had no knowledge of the benefit (< 0.0001). No statistically significant difference for any NRT use among both groups.

Covered treatment was not tied to participation in a behavioral program

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	2001	2002	Value used in summary	Follow-up time
Burns 2005 (Mar – Jun, 2001 and Mar-Jun 2002) Least: (post-only time series) Fair (4 limitations) Benefit use Benefit awareness Smoking prevalence	Wisconsin <u>Intervention:</u> New benefit covered counseling and prescription meds for smoking cessation (P+C) Counseling not required to receive meds. No lifetime limit. <u>Comparison:</u> Availability and scope of coverage for SCTs varied widely. Significant up front patient cost sharing often required with reimbursement contingent upon completion of counseling, or maintaining abstinence or both.	Telephone survey of state employees, retirees and adult dependents N=5609 in 2001 N=6518 in 2002 Response rate = 64% in both years	Self-reported use of benefit (weighted)	7.1% (4.7-9.5)	13.6% (10.2-16.9)	Not comparable	NA
			Estimate of smoking cessation: 100%- Self-reported smoking% (weighted) (smoked every day or some days)	84.4% (100%-15.6%)	86.8% (100%-13.2%)	+2.4 pct pts p-value = .01	NA
			Aware of benefit	20.6% (17.0-24.2)	27.4% (23.1-31.7)	+6.8 pct pts p-value = .02	NA

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Cox 2006 (Nov 6, 1984 – Jan 7, 1986) Greatest: (Individual Non-Randomized Trial) Fair (4 limitations) Continuous smoking cessation NRT use	California, Travis AFB <u>Intervention:</u> Nicotine gum free for smoking cessation group participants (pharmacotherapy + counseling: P+C) <u>Comparison:</u> Group counseling but had to pay for nicotine gum (CO)	Recruited smoking patients who enrolled in one of 25 free Travis Smoking Cessation Programs N=454 eligible N=344 received free or purchased nicotine gum (76% of eligible) <u>Free</u> <u>Bought</u> <u>No gum</u> 137 207 31	Self-reported continuous smoking cessation for 12 m **	Buy gum 27%	Free Gum 38%	+11 pct pts p=0.033	12 months
			Self-reported Gum use	Buy gum 84%	Free Gum 91%	+7 pct pts p=0.044	12 months

NOTE: 12 month cessation reported by age and gender

** smoking cessation rates corrected for 3% of participants who claimed to have quit but validation test indicted they were still smoking (random 13 sample had validation tests)

Higher quit success rates among older smokers but not statistically significant difference among men and women

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Curry, 1998 (1993 – 1994) Greatest: (Prospective Cohort) Fair (3 limitations) Tobacco cessation at 6 months Use of smoke cessation services	Washington State <u>Intervention(s)</u> Flipped NRT - free ($5) counseling - 50% Reduced NRT - 50% counseling - free Full NRT - free ($5) counseling - free <u>Comparison</u> Standard NRT - free ($5) counseling - 50% copay	Recruitment via postcard to adult smokers in PPO (94% motivated to quit) N=803 determined eligible N=393 randomized (intention to treat) 4 insurance plans compared Plans N Response Rate Standard 217 74% Reduced 215 74% Flipped 204 70% Full 227 66%	Self-reported 7 day smoke cessation at 6 mos	Standard 38%	Interventions (Full) 28%	-10 pct pts	6 months
			Self-reported 7 day smoke cessation at 6 mos	Standard 38%	Intervention (Flipped) 33%	-5 pct pts	6 months
			Self-reported 7 day smoke cessation at 6 mos	Standard 38%	Intervention (Reduced) 31%	-7 pct pts	6 months
			Use Of Counseling only	Standard 1.1%	Intervention (Full) 1.7%	+0.6 pct pts	6 months
			Use Of Counseling only	Standard 1.1%	Intervention (Flipped) 0.5%	-0.6 pct pts	6 months
			Use Of Counseling only	Standard 1.1%	Intervention (Reduced) 1.3%	+0.2 pct pts	6 months
			Use Counseling + NRT	Standard 4.2%	Intervention (Full) 5.2%	+1.0 pct pts	6 months
			Use Counseling + NRT	Standard 4.2%	Intervention (Flipped) 3.2%	-1.0 pct pts	6 months
			Use Counseling + NRT	Standard 4.2%	Intervention (Reduced) 2.9%	-1.3 pct pts	6 months

NOTE: Enrollment in behavioral therapy was required in order to obtain NRT

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Dey, 1999 (May – Dec, 2001) Greatest: (Individual Randomized Controlled Trial) Fair (4 limitations) Tobacco use cessation at 14 weeks Filled prescription	East Lancashire <u>Intervention:</u> (free group) Prescriptions for Nicorette patches were dispensed free of charge at nominated pharmacies <u>Comparison:</u> (purchase group) Private prescriptions for Nicorette patches were dispensed at nominated pharmacies at slightly less than the retail charge	Recruitment in doctor's office N=129 determined eligible N=122 agreed (94%) <u>Random Analysis loss to f/u</u> Free patches 64 58 9% Reduced cost 58 39 33%	Self-reported abstinence 6-14 weeks	Comparison (Reduced cost) 12.1%	Intervention (Free Patches) 21.9%	+9.8 pct pts	14 weeks
			Abstinence validated *	Comparison (Reduced cost) 8.6%	Intervention (Free Patches) 9.4%	+0.8 pct pts (-16.5-10.9%)	14 weeks
			Filled at least one weekly prescription	Comparison (Reduced cost) 48.3%	Intervention (Free Patches) 96.9%	+48.6 pct pts	14 eeks

* 16 of 21 (76.2%) self-reported abstainers were tested to confirm that they were abstaining.

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Halpin 2006 (May – Dec, 2001) Greatest: (Individual Randomized Controlled Trial) Fair (2 limitations) Tobacco use cessation Quit Attempts Use of benefit	California <u>Intervention:</u> Pharmacotherapy and telephone counseling (P+C) Pharmacotherapy conditional on telephone counseling (PCC) <u>Comparison:</u> Pharmacotherapy only (PO)	Recruitment via postcard to adult smokers in PPO (94% motivated to quit) N=803 determined eligible N=393 randomized (intention to treat) <u>Random</u> <u>Analysis</u> <u>loss to f/u</u> PO 126 104 17% P+C 140 115 18% PCC 127 104 18%	Self-reported prevalent abstinence (>=7days at 8 mos fu)	Comparison PO 19%	Intervention P+C 13%	-6 pct pts OR: 0.7 (0.3, 1.4)	8 months
			Self-reported prevalent abstinence (>=7days at 8 mos fu)	Comparison PO 19%	Intervention PCC 18%	-1 pct pts OR: 1.0 (0.5, 1.9)	8 months
			Self-reported quitting during study (>=7days)	Comparison PO 37%	Intervention P+C 26%	-11 pct pts OR: 0.6 (0.3, 1.0)	8 months
			Self-reported quitting during study (>=7days)	Comparison PO 37%	Intervention PCC 31%	-6 pct pts OR: 0.7 (0.4, 1.2)	8 months
			Self-reported quit attempts	Comparison PO 55%	Intervention P+C 43%	-12 pct pts OR: 0.5 (0.3, 0.9)*	8 months
			Self-reported quit attempts	Comparison PO 55%	Intervention PCC 47%	-8 pct pts OR: 0.7 (0.4, 1.1)	8 months
			Filled RX for Pharmacotherapy	Comparison PO 21%	Intervention P+C 21%	0 pct pts	8 months
			Filled RX for Pharmacotherapy	Comparison PO 21%	Intervention PCC 18%	-3 pct pts	8 months
			Enrolled in Counseling	Comparison PO NA	P+C 8%	+16 pct pts	8 months
			Enrolled in Counseling	Comparison PO NA	PCC 24%		8 months

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	Reported Baseline	Reported effect	Value used in summary	Follow-up time
Hughes, 1991 (Time not reported) Greatest: (Individual Randomized Trial) Fair (3 limitations) Tobacco use cessation Quit Attempts NRT use	Vermont <u>Intervention(s)</u> Provider counseling + f/u appt + NRT (free NRT) Provider counseling + f/u appt + NRT ($6/box) <u>Comparison:</u> Provider counseling + f/u appt + NRT ($20/box)	Recruited in clinics N=106 enrolled (198 (54%) declined) N=106 randomized (intention to treat) Sample sizes Free NRT 32 $6 box 36 $20 box 38	Self-reported point prevalence abstinence	Comparison (NRT=$20/box) 8%	Intervention (NRT=$6/box) 6%	-2 pct pts	6 months
			Self-reported point prevalence abstinence	Comparison (NRT=$20/box) 8%	Intervention (NRT=free) 19%	+11 pct pts	6 months
			Self-reported quit attempts	Comparison (NRT=$20/box) 66%	Intervention (NRT=$6/box) 78%	+12 pct pts	6 months
			Self-reported quit attempts	Comparison (NRT=$20/box) 66%	Intervention (NRT=free) 85%	+19 pct pts	6 months
			NRT Use (obtained gum)	Comparison (NRT=$20/box) 47%	Intervention (NRT=$6/box) 58%	+11pct pts	6 months
			NRT Use (obtained gum)	Comparison (NRT=$20/box) 47%	Intervention (NRT=free) 75%	+28 pct pts	6 months

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	1987	1988*	Follow-up time
Johnson 1991 (1987-1989) Moderate (Retrospective Cohort) Fair (4 limitations) Gum use	USA: Portland, Oregon and Vancouver, Washington metro areas <u>Intervention</u> Prepaid prescription drug benefit <u>Comparison</u> Member without prepaid prescription drug benefits	*Study Population* HMO members filling nicotine gum prescription 1970 members filled nicotine gum prescriptions 4505 prescriptions for nicotine gum 1644 with benefit coverage level available Note: Coverage status was not available for the first 6 months of the study. Only Jan 1988- 1989 data had information on level of drug benefit Results are based on 1644/1970 (83%) users >= 15 years of age with coverage data. The researchers looked at only users of gum, and described users by drug benefit copayment. The only denominator is all users – no denominator for each copayment group - so can't calculate rates of use by copayment	Percentage of members prescribed gum	0.37%	0.42%	NA
			Percentage of users by benefit level status	27.9% 50% copay and no benefit	72.1% < 50% copay	1.5 yrs

*This study conducted in an HMO setting reported significant differences in the use of nicotine gum (measured in pieces of gum per user) by the level of drug co-payment, but the results could not be meaningfully expressed as a percentage-point difference.

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	Reported Baseline	Reported effect	Value used in summary*	Follow-up time
Joyce 2008 (2002 - 2004) Greatest: (Randomized Comparison Trial) Fair (3 limitations) Tobacco use cessation Quit Attempts Smoking abstinence	5 U.S. States <u>Intervention(s)</u> Reimbursement for provider counseling (C) Reimbursement for provider counseling with pharmacotherapy (C+P) Telephone counseling Quitline with nicotine patch (Q+NRT) <u>Comparison</u> "Usual care" = information only	Recruitment of Medicare beneficiaries that were smokers via messages of new services N= 13,577 assessed for eligibility N= 8,904 deemed eligible N= 7,354 enrolled Response rate 6 months= 67.5% Response rate 12 months= 60.6% Usual care = 2,230 C=829 C+P=2,605 Q=1,690	Counseling	Info only 21.6%	Intervention C 33.2%	+11.6 pct pts	12 months
			Counseling	Info only 21.6%	Intervention C+P 36.2%	+14.6 pct pts	12 months
			Counseling	Info only 21.6%	Intervention Q+NRT 44.7%	+23.1 pct pts	12 months
			Nicotine Patch Use	Info only 25.8% (24.0-27.6)	Intervention C+P 39.8% (37.9-41.7)	+14 pct pts	12 months
			Nicotine Patch Use	Info only 25.8% (24.0-27.6)	Intervention Q+NRT 47.2% (44.8-49.5)	+21.4 pct pts	12 months
			Bupropion Use	Info only 17.6%	Intervention C+P 33.3%	+15.7 pct pts	12 months
			Self-reported point prevalence 7 day smoking abstinence	Info only 10.2% (9.0 – 11.5)	Intervention C 14.1%* (11.7- 16.5)	+3.9 pct pts	12 months
			Self-reported point prevalence 7 day smoking abstinence	Info only 10.2% (9.0 – 11.5)	Intervention C+P 15.8%* (14.4 – 17.2)	+5.6 pct pts	12 months
			Self-reported point prevalence 7 day smoking abstinence	Info only 10.2% (9.0 – 11.5)	Intervention Q+NRT 19.3%* (17.4 – 21.2)	+9.1 pct pts	12 months
			Self-report of quit attempts	Info only 64.2% (62.2 – 66.2)	Intervention C 63.4% (60.2 - 66.7)	-0.8 pct pts	12 months
			Self-report of quit attempts	Info only 64.2% (62.2 – 66.2)	Intervention C+P 69.1%* (67.4 – 70.9)	+4.9 pct pts	12 months
			Self-report of quit attempts	Info only 64.2% (62.2 – 66.2)	Intervention Q+NRT 69.2%* (67.0 – 71.4)	+5 pct pts	12 months

* Statistically different from Usual Care

NOTE: Medicare population
Pharmacotherapy not covered in usual care and provider counseling groups, however, 20% of participants in those arms reported using bupropion and 25% used the nicotine patch

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	No Benefit	Benefit	Value used in summary	Follow-up time
Kaper 2006 (2000) Related study: Kaper 2005 (24 mos data) Greatest (Individual Randomized Trial) Fair (3 limitations) Self-reported quit attempts. Self-reported abstinence rates. Biochemically validated 7-day point prevalence.	Netherlands – Northern Province (Friesland) <u>Intervention</u> Full reimbursement for smoking cessation therapy, behavioral counseling or a combination of both. <u>Comparison</u> No reimbursement.	*Study Population* Recruited smokers via telephone Eligible participants had to be 18 years of age, a Dutch inhabitant insured by De Friesland Zorgverzekeraart; only one smoker per household - did not have to be motivated to quit Random sample: 42,000 Contacted: 8,716 (22%) Refusal: 2,568 (29%) Interviewed: 2,018 (23%) N=2018 assessed as eligible N=1320 randomized (intention to treat (ITT) and per protocol (PP) Random assignment: Intervention (n=632), control group (n=634) Ineligible: Intervention (n=26), control (n=28)	Self-reported prolonged abstinence (at least past 7 days)	No P reimbursement 2.8%	P + C reimbursement. 5.5%	+2.7 pct pts OR: 1.5 (1.0-2.3)	6 mos
			Biochemically validated prolonged abstinence:	No P reimbursement 0.9%	P + C reimbursement 3.8%	+2.9 pct pts OR: 2.3 (1.2-4.1)	6 mos
			Quit attempts	No P reimbursement 20.8%	P + C reimbursement 23.4%	+2.6 pct pts OR: 1.2. (0.9-2.4)	6 mos
			Use of NRT	No P reimbursement 0.9%	P reimbursement 3.6%	+2.7 pct pts OR: 2.9 (1.8-4.7)	6 mos
			Use of Bupropion	No P reimbursement 0.9%	P Reimbursement 4.3%	+3.4 pct pts	6 mos
			Use of Counseling	No C reimbursement 1.1%	C reimbursement 5.1%	+4.0 pct pts	6 mos

*self reported quits 49 interv grp + 35 in cntrl grp = 84. 17 not tested +7 refused. 54/84 tested = 64.3%

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Keller 2011 (2006-2007) Least: (Before-After) Fair (3 limitations) Estimated changes in % of adult smokers with a pharmacy claim.	USA: Wisconsin <u>Intervention</u> HMO Medicaid targeted for advertising print materials for clinicians and consumers distributed to 13 health maintenance organizations (HMOs) serving WI Medicaid HMO enrollees <u>Comparison</u> Fee-for-service (FFS) used to monitor secular trends in pharmacy claims for smoking cessation medications (not likely to have exposure to campaigns)	Study Population: Enrollees in the Wisconsin Family Medicaid program. Sample for pharmacy claims for adult Medicaid enrollees Sample for WI Quit Line of adult callers reportedly enrolled in Medicaid Inclusion: adults in HMO Medicaid Excluded: 1) Bupropion SR 2) FFS Medicaid enrollees in county with > 1 HMO 3) 10/2006-12/2006 Average enrollment=169,870	Smoke cessation pharmacy claims (Rate of change between intervention (HMO) and comparison groups (FFS) pre-campaign)	NR	NR	t=2.29 p=0.03	NA
			Smoke cessation pharmacy claims (Rate of change between intervention (HMO) and comparison groups (FFS) post-campaign)	NR	NR	t= -222 p=0.04	NA
			Smoke cessation pharmacy claims (increases among 13 HMOs from pre-campaign to post-campaign)	NR	NR	10/13 (77%) p<0.05	NA
			Smoke cessation pharmacy claims (HMO+FFS) (Increase from beginning to end of campaign)	1.5%	4.4%	+2.9 pct pts	NA

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Land 2010a (1999-2008) Moderate: Interrupted Time Series Fair (2 limitations) Quit Attempts Smoking cessation Smoking prevalence Trend in smoking prevalence	Massachusetts <u>Intervention</u> Medicaid coverage of behavioral counseling and smoking cessation medications. <u>Comparison</u> "Usual care" Pre-benefit	Study Population: MassHealth 16% of BRFSS respondents used MassHealth Subscribers 18-64 years 70,140 MassHealth subscribers used benefit between 7/1/2006 and 12/31/2008 Pre-benefit N=2,016 Weighted Sample Size=892,919 Post-benefit N=1,969 Weighted Sample Size=454,851	Self-reported Quit Attempts (stopped smoking for 1 day or more during last 12 months)	Pre-Benefit 62.6% (55.9-69.4)	Post-Benefit 67.6% (60.5-74.7)	+5.0 pct pts	6 months
			Self-reported smoking cessation (stopped smoking during last 12 months)	Pre-Benefit 6.6% (3.8-9.3)	Post-Benefit 19.1%* (13.0-25.2)	+12.5 pct pts	6 months

NOTE: A smoking prevalence trend (joinpoint analysis) was calculated. The long term trend in smoking prevalence over the entire time period (1999 through 2008) was non-significant (p =0.60). However, the trend in the post-benefit period showed a significant decrease (p,001) with an estimated annual decrease of 15.0% per year.

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	Location Intervention Comparison	Study population Sample size	Effect measure	Annualized Change In Admission (Postutilization)	p-value Annualized Change in Admissions	95% Annualized Change in Admissions	Follow-up time
Land 2010b (2003-2008) Least: (Time series) Fair (2 limitations) Inpatient hospitalizations	Massachusetts <u>Intervention:</u> Medicaid (MassHealth) coverage of behavioral counseling and smoking cessation medications – patient utilization of pharmacotherapy after July 1, 2006 <u>Comparison:</u> Same MassHealth patient's hospital rates prior to benefit	Study Population: MassHealth Subscribers ≥18 years with a prescription filled between July 1, 2006 and November 17, 2007. N=74,454 MassHealth patients that filled prescriptions N=21,656 for analysis after exclusions N= 8,194 with at least 1 inpatient visit	Claims for inpatient hospitalization				5 years
			Cardiovascular group codes				
			AMI	-46%	0.049	0.31-0.98	
			Coronary atherosclerosis and other heart disease	-49%	0.042	0.28-0.94	
			Nonspecific chest pain	-32%	0.07	0.45-1.03	
			Congestive heart failure	14%	0.74	0.54-2.37	
			Respiratory group codes				
			Pneumonia	14%	0.40	0.82-1.62	
			COPD and bronchiectasis	21%	0.39	0.79-1.84	
			Asthma	-1%	0.95	0.67-1.46	
			Respiratory failure insufficiency arrest	-6%	0.84	0.55-1.64	
			Other conditions				
			Diabetes mellitus with complications	-3%	0.93	0.51-1.92	
			Biliary tract disease	-13%	0.67	0.45-1.68	
			Pancreatic disorders not diabetes	42%	0.30	0.73-2.79	
			Skin and subcutaneous skin infections	-26%	0.24	0.45-1.22	
			Abdominal pain	-18%	0.46	0.48-1.39	
			Mood disorders	37%	0.18	0.77-2.43	
			Schizophrenia and other psychotic disorders	42%	0.31	0.67-3.44	
			All hospitalizations	-2%	0.74	0.90-1.08	

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Petersen 2005 (1998-2000) Least: (Cross Sectional) Fair (3 limitations) Self-reported quit rates Self-reported cessation maintenance	15 States participating in PRAMS <u>Intervention(s)</u> Extensive coverage: both counseling and pharmacotherapies Some coverage: either counseling or pharmacotherapies <u>Comparison</u> No benefits	Study Population: Women whose prenatal care was paid by Medicaid N=7513 <u>None Some Extensive</u> States 53% 33% 13% Subjects 50% 46% 4% Estimated samples None 3756 Some 3456 Extensive 301	Quitting (Stopped smoking during pregnancy)	Comparison group (No benefit) 39%	Intervention group (Some): 43% OR: 1.18 (1.03 to 1.34)	+4.0 pct pts	Mean time to f/u = 4.1 months
			Quitting (Stopped smoking during pregnancy)	Comparison group (No benefit) 39%	Intervention group (Extensive): 51%, OR: 1.58 (1.00 to 2.49)	+12.0 pct pts	Mean time to f/u = 4.1 months
			Maintaining cessation (no smoking after pregnancy <4.1 months)	Comparison group (No benefit) 37%	Intervention group (Some): 37% OR: 1.02 (0.89 to 1.18)	0.0 pct pts	Mean time to f/u = 4.1 months
			Maintaining cessation (no smoking after pregnancy <4.1 months)	Comparison group (No benefit) 37%	Intervention group (Extensive): 48% OR: 1.63 (1.04 to 2.56)	+11.0 pct pts	Mean time to f/u = 4.1 months

Smoker defined as a woman who reported smoking before pregnancy

Quit smoking – smoker who quit during pregnancy

Prolonged quit – smoker who quit during pregnancy and didn't smoke after pregnancy

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Schauffler 2000 (1998) Greatest: (Individual Randomized Trial) Fair (2 limitations) Self-reported Abstinence (last 7 days) at 12 month f/u Quit attempts NRT use	California <u>Intervention(s)</u> Free NRT mailed to home + ALA smoking cessation program + Patient education <u>Comparison</u> Patient education -Self-help cessation video -Pamphlet based on AHCPR guidelines	Study Population: employees of 16 large employers covered by two IPA model HMOs Recruited smokers: n=1204 ineligible at f/u: n=224 Eligible at f/u: n=980 12m f/u : n=881 (89.9%) 32% refusal rate Comparison 26% loss to f/u Intervention 27% loss to f/u Intervention n=601 control group n=603	Self-reported abstinence (no smoking in the past 7 days)	Info kit 13%	Free patch or gum mailed to home 18%	+5 pct pts p=0.04 OR: 1.6 (1.1-2.4)	12 mos
			Self-reported quit attempts (No smoking at least 1 day)	Info kit 48%	Intervention 55%	+7 pct pts p=0.03 OR: 1.4 (1.1-1.8)	12 mos
			Nicotine gum or patch used	Info kit 14%	Intervention 25%	+11 pct pts p=0.001 OR: 2.3 (1.6-3.2)	12 mos
			Participated in Counseling	Info kit 1.1%	Intervention 1.2%	+0.1 pct pts p=0.8	12 mos

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Solomon 2000 (not reported) Greatest: (Individual Randomized Trial) Fair (2 limitations) Self-reported Abstinence (last 7 days) Biochemically verified abstinence (@10 days, 3 and 6 mos.)	Chittenden County, Vermont <u>Intervention</u> Free nicotine patches were sent via mail plus proactive telephone support provided by one of five ex-smokers who received 7 hours of training. <u>Comparison</u> Free nicotine patches were sent via mail.	Study Population: 214 Medicaid-eligible women smokers of childbearing age, with high intent to quit in next 2 weeks and home phone. N: 219 eligible 214 randomized to Intervention n: 106 Comparison n: 108 Response Rates <u>n 3 mos 6 mos</u> I: 106 101(95) 78 (approx. 73%) C: 108 92(85) 80 (approx. 73%)	Self-reported abstinence (no smoking in the past 7 days)	Free patches 19% (20/108)	Free patches + phone counseling 23% (24/106)	+4 pct pts	6 mos
			Biochemically validated abstinence*	Free patches 11.5% (12.8/108)	Free patches + phone counseling 15.5% (16.4/106)	+4.0 pct pts	6 mos
			Self-reported abstinence at 3 and 6 months	Free patches 15% (16/108)	Free patches + phone counseling 20% (21/106)	+5 pct pts	6 mos
			Predictors of abstinence at 3 months			OR: 2.0 (1.09-3.68)	3 mos
			Use of patch	Patch sent via mail 80.6%	Patch sent via mail + Phone Counseling 91.5%	+10.9 pct pts	3 mos

- 6 mos 59% of experimental and 67% of control groups
- had CO readings`. .59*24= 14.16 tested .82*14.6=16.4 confirmed abstinent 16.4/106= 15.5%
- .67*20=13.4 tested; .93*13.4=12.5 confirmed abstinent 12.5/108=11.6

Author & year (study period) Design suitability (design) Quality of execution (# of Limitations) Outcome Measurement	**Location** **Intervention** **Comparison**	**Study population** **Sample size**	**Effect measure**	**Reported Baseline**	**Reported effect**	**Value used in summary**	**Follow-up time**
Twardella 2007 (2002 - 2003) Greatest: (Group Randomized Controlled Trial) Fair (2 limitations) Tobacco use cessation	Germany <u>Intervention(s)</u> GP Training + Financial incentives (TI) GP Training + Cost free prescriptions (TM) GP Training + Financial incentives +Cost free prescriptions (TI+TM) <u>Comparison</u> "Usual care"	94 general practitioners from 82 practices recruited adult smokers irrespective of intention to quit N=587 randomized by practice N=577 at 12-months f/u (487/577 (84%) self-reported at f/u) <u>Random</u> <u>Analysis</u> <u>loss to f/u</u> Comp 76 61 19% TI 146 123 15% TM 144 121 14% TI+TM 221 183 17%	Self-reported point prev. smoking abstinence	Usual care 4%	Intervention Provider traininger + frre P (TM) 15%	+11 pct pts	12 months
			Self-reported point prev. smoking abstinence	Usual care 4%	Intervention (TI +TM) 17%	+13 pct pts	12 months
			Self-reported continuous smoking abstinence for <u>></u> 6 months	Usual care 1%	TM 9%	+8 pct pts OR: 6.13(1.65-22.68)	12 months
			Self-reported continuous smoking abstinence for <u>></u> 6 months	Usual care 1%	TI + TM 8%	+7 pct pts OR not reported	12 months
			Biochemically verified point prev. smoking abstinence validated=65/72 (90.3%)	Usual care 2.6%	TM 11.8%	+9.2 pct pts OR: 4.77 (2.03–11.22)	12 months
			Biochemically verified point prev. smoking abstinence validated=65/72 (90.3%)	Usual care 2.6%	TI + TM 14.5%	+11.9 pct pts p=0.02	12 months
			Provider reported NRT or bupropion	Usual care 11%	TM 50%	+39 pct pts	12 months
			Provider reported NRT or bupropion	Usual care 11%	TI + TM 31%	+20 pct pts	12 months
			Provider reported individual counseling	Usual care 59%	TM 67%	+8 pct pts	12 months
			Provider reported individual counseling	Usual care 59%	TI+TM 65%	+6 pct pts	12 months

Author & year **(study period)** **Design suitability (design)** **Quality of execution (# of Limitations)** **Outcome Measurement**	**Location** **Intervention** **Comparison**	**Study population** **Sample size**	**Effect measure**	**Reported Baseline**	**Reported effect**	**Value used in summary**	**Follow-up time**
Zeng 2011 (2007-2008) Moderate (Retrospective cohort) Fair (3 limitations) Use of varenicline	Minnesota <u>Intervention</u> No real intervention implemented. Researchers compared patients whose varenicline claim had been reversed and looked at use by copay category <u>Comparison</u> Patients that did not fill prescription	Study population patients new to varenicline who had a full drug benefit within MedImpact's database and a reverse varenicline claim N=20,451 met inclusion criteria 3,423 did not fill meds 17,028 filled meds	Any smoke cessation medication filled within 183 days of reversal	Comparison > $60 copay 70.5%	Intervention $0-$5 copay 88.6%	+18.1 pct pts p=0.46	183 days
			Initiating smoke cessation med use	Comparison $0-$5 copay OR: 1.0 (ref)	Intervention >$60 pay OR: 0.35		183 days

NOTE: Zeng concluded that "the findings suggest that some patients might have been deterred by a high copayment (>= $31) and, ultimately did not fill any smoking cessation treatments within 183 days of reversed varenicline claims.