Too Much, Too Little or Just Right: Tobacco Cessation Treatment from an Economic Perspective

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August 1, 2024

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Significance

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Health Burden and Economic Costs of Tobacco Use

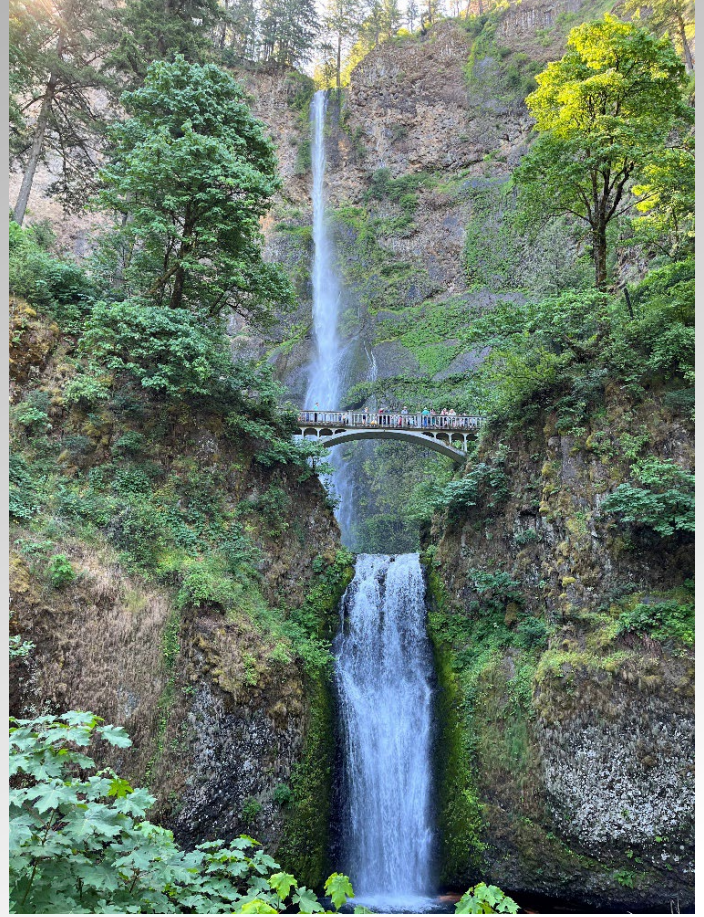
- Tobacco use is the single most preventable cause of morbidity and mortality[1]
- Close to 16 million Americans suffer from smoking-induced illness[1]
- Smoking is associated with every one out of five deaths in the USA each year[2]
- Annual smoking-related costs average $225 billion in direct health care costs[3]

[1]Smoking Cessation: A Report of the Surgeon General (2020); [2]Baker CB, Ding Y, Ferrufino CP, et al (2018); [3]Xu X, Bishop EE, Kennedy SM, et al. (2015)

Tobacco Cessation Treatment

- Smoking cessation medications combined with counseling are effective in helping smokers quit[4]
- The US Preventive Task Force (USPSTF) gives tobacco cessation interventions (counseling and medications) for adults an “A” grade, the highest rating for preventive services[5]

[4]Fiore MC, Jaen CR, Baker TB, et al (2008); [5]USPSTF (2021)



Primer on Health Economics Analysis

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Treatment Cost-Effectiveness

- Policy decision makers, community stakeholders, medical care providers and health advocates need cost-benefit data to reach evidence-informed decisions about providing highest quality of care at lowest cost in tobacco cessation treatment

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Cost-Effectiveness?

"It took 279 nicotine patches, but I no longer have the urge to smoke."

©The Quit Smoking Company

www.quitsmoking.com

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Cost-Effectiveness Analysis of Tobacco Cessation Treatment

- **Cost-Effectiveness Analysis (CEA)** is a form of health economic analysis that compares the relative costs and outcomes (effects) of different courses of treatments

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Cost-Effectiveness Decision Model

Define the Baseline:

- What is the current standard-of-care?

Incorporate the Intervention:

- How will the intervention change resource use?

Model Long-Term Costs and Outcomes:

- What will be the long-term result on costs and outcomes?

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Cost-Effectiveness Measures

Cost Measures:

- Incentive Costs
- Service/Administration Costs
- Medication Costs

Effectiveness Measures:

- Smoking Cessation Status
- Patient Health Outcomes/Quality of Life
- Health Care Utilization

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Cost-Effectiveness Analysis Plan

- Compute proportion of smokers receiving cessation treatment for both the incentive and control groups
- Calculate cumulative costs and the cumulative probability of smoking abstinence by study group determined by the weighted sum of the individual pathways for each study arm
- Determine confidence intervals through Monte Carlo simulation

The Incremental Cost-Effectiveness Ratio (ICER)

- The **incremental cost-effectiveness ratio (ICER)** of tobacco cessation treatment determines the cost per smoker who quit:

$$ICER = \frac{\sum(Intervention\ Group\ Costs) - \sum(Control\ Group\ Costs)}{\sum(Intervention\ Group\ Quit\ Rate) - \sum(Control\ Group\ Quit\ Rate)}$$

Too Much: Cost-Effectiveness of the Quitting Through Intensive Treatment (QUITS) Study

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Quitting Through Intensive Treatment (QUITS) Study

- This NHLBI-funded (R01 HL109031) research project sought to increase smoking cessation among patients who smoke

- Conducted by the University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) from 2017-2020

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Background

- Varenicline pharmacotherapy lowers nicotine reinforcement and nicotine withdrawal during smoking cessation[6]

- Varenicline treatment has been demonstrated to be effective for aiding smoking cessation in a variety of populations of those who smoke[7]

[6]Fagerström K & Hughes J (2008)

[7]Patnode CD, et al. (2021)

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Background

- There have been mixed results in studies on the effectiveness of varenicline combination therapy with nicotine replacement therapy (NRT) patch vs varenicline alone[8]

[8]Chang PH, et al. (2015)

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Background

- Limited research exists on the benefits of extending varenicline treatment beyond the standard 12-week protocol

- Two smoking relapse prevention studies and a Cochrane meta-analysis suggest that prolonged duration of varenicline treatment may increase long-term cessation rates among individuals who have quit smoking from prior treatment[9]

[9]Livingstone-Banks J, et al. (2019)

Research Gap

- There is a gap in our understanding on whether combining varenicline with NRT patch or prolonging varenicline treatment duration increases smoking cessation rates and/or whether the enhanced varenicline treatments are cost-effective

QUITS Research Question

- What is the cost-effectiveness of combining varenicline with the nicotine patch and/or extending the standard varenicline treatment duration from 12 weeks to 24 weeks?

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The QUITS Study Design

- QUITS was a 2x2 factorial double-blind randomized trial of standard varenicline treatment (12 weeks) vs enhanced varenicline treatment (24-week treatment with/without nicotine patch

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QUITS Intervention

Treatment assignment was to 1 of 4 groups:

1) Varenicline for 12 weeks (n=315)
2) Varenicline + nicotine patch for 12 weeks (n=314)
3) Varenicline for 24 weeks (n=311)
4) Varenicline + nicotine patch for 24 weeks (n=311)

All enrolled participants were scheduled to receive six 15-minute counseling sessions at -2, -1, 0, 2, 4 and 8 weeks post-Target Quit Date

Cost Evaluation Measures

- Medicare reimbursement rates were applied to tobacco cessation counseling sessions (99406/99407) and to tobacco cessation medications
  - $19 per cessation counseling session
  - $392 per 4-week prescription for varenicline
  - $84 per 4-week prescription for NRT
- Costs were calculated based on the actual treatments used by the participants

QUITS Effectiveness Outcome

- The primary outcome endpoint was 52-week biochemically confirmed tobacco abstinence

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Cost-Effectiveness Analysis

- The incremental cost-effectiveness ratio (ICER) of is the cost per smoker who quits

$$ICER = \frac{\sum(Costs_B) - \sum(Costs_A)}{\sum(Effectiveness_B) - \sum(Effectivness_A)}$$

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Results: QUITS Efficacy

Efficacy by randomization group at 52 weeks:

Group	% abstinent
Varenicline for 12 weeks	25.079%
Varenicline + patch for 12 weeks	23.567%
Varenicline for 24 weeks	24.437%
Varenicline + patch for 24 weeks	25.080%

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Results: QUITS Average Costs

Average Cost by Randomization Group	Cost (sd)
Group 1: Varenicline for 12 weeks	$1,074 ($338)
Group 2: Varenicline + nicotine patch for 12 weeks	$1,271 ($389)
Group 3: Varenicline for 24 weeks	$1,917 ($795)
Group 4: Varenicline + patch for 24 weeks	$2,018 ($933)

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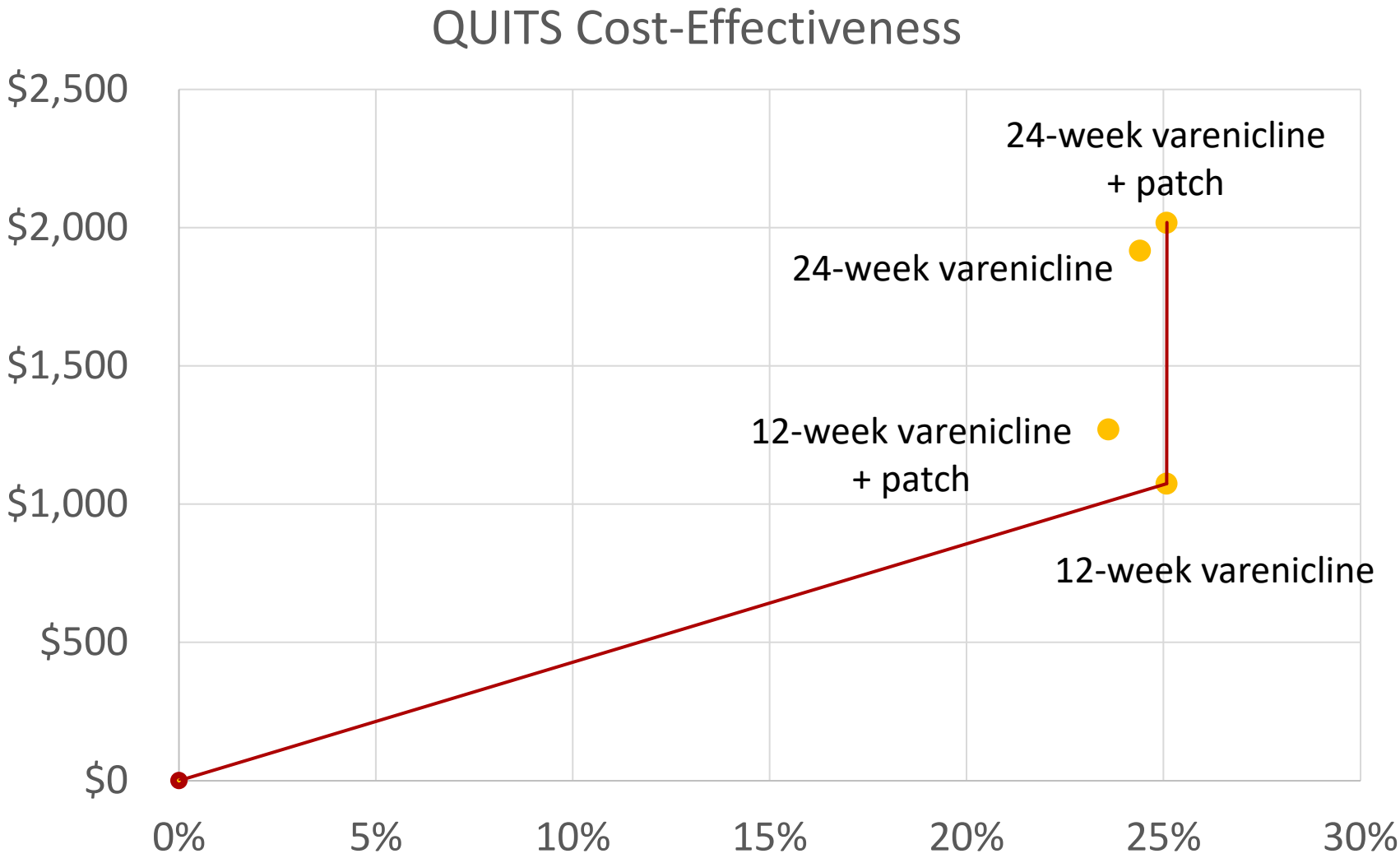
Results: QUITS Cost-Effectiveness



Results: Incremental Cost-Effectiveness Ratios in QUITS study

In comparison to 12-week varenicline monotherapy:

- ICER for 12-week varenicline+NRT patch group = ∞ (more costly and less efficacious) per additional quitter
- ICER for 24-week varenicline monotherapy group = ∞ (more costly and less efficacious) per additional quitter
- ICER for 24-week varenicline+NRT patch group = $94,400,000 (95% CI: $16,113,∞) for one additional quitter
- ICER for 24-week varenicline+NRT patch group = $92,000,000 (95% CI: $15,703,∞) for one additional QALY gained

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QUITS Results

- ICER of $92,000,000/QALY greatly exceed the cost-effectiveness threshold of $50,000-$100,000/QALY = Not Cost-Effective
- Longer-duration varenicline and varenicline enhanced with NRT patch are equivalent efficacy-wise, but not equivalent from a cost-effectiveness perspective

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Too Much: QUITS Takeaway

Too much: *Extending varenicline treatment beyond 12 weeks or adding NRT patch to varenicline treatment may not be the optimal use of limited tobacco cessation resources*

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Too Little: Cost-Effectiveness of Striving to Quit Quitline Incentive Study (STQ)

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CEA for the Striving to Quit Quitline Incentive Study

- "Striving to Quit" leveraged financial incentives for treatment engagement with the Wisconsin Tobacco Quit Line (WTQL) for Wisconsin Medicaid enrollees who smoked[10,11]

[10]Fraser DL, Fiore MC, Kobinsky K, et al (2017); [11]Mundt MP, Baker TB, Fraser DL, et al (2019)

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Study Sample in STQ RCT

- Medicaid recipients were recruited via primary care clinic referral (n=444), community-based referral (n=476), and callers to the WTQL (n=980)

- Community-based referral sources included public health agencies contracted by the Wisconsin Department of Health Services to support smoking cessation

- Eligible smokers were randomized to either an Incentive (n=948) or a Control condition (n=952)

Methods in STQ RCT

- All participants offered 5 WTQL smoking cessation counseling calls (once a month for 5 months) and payment for completing a baseline assessment ($40) and a 6-month assessment ($40)

- Incentive group participants received $30 per call for each of the 5 WTQL counseling calls and $40 for biochemically-verified abstinence at the 6-month visit

Fraser DL, Fiore MC, Kobinsky K, et al. A Randomized Trial of Incentives for Smoking Treatment in Medicaid Members. *Am J Prev Med.* Dec 2017;53(6):754-763.

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Cost and Effectiveness Measures

Cost Measures:

- **Incentive Costs**: Actual cost of incentives received by study participants (enrollment, 6-month follow-up, quit line call incentives)
- **Service Costs**: Costs of staff time to enroll, schedule, and follow-up participants, counselor time, staff time and materials for biochemical verification of smoking status
- **Medication Costs**: Pharmacy record search for smoking cessation medications purchased by Medicaid during the 6-month study period with Medicaid weighted average reimbursement rates applied

Effectiveness Measures: 7-day point-prevalence abstinence at 6-month follow-up visit verified by biochemical confirmation

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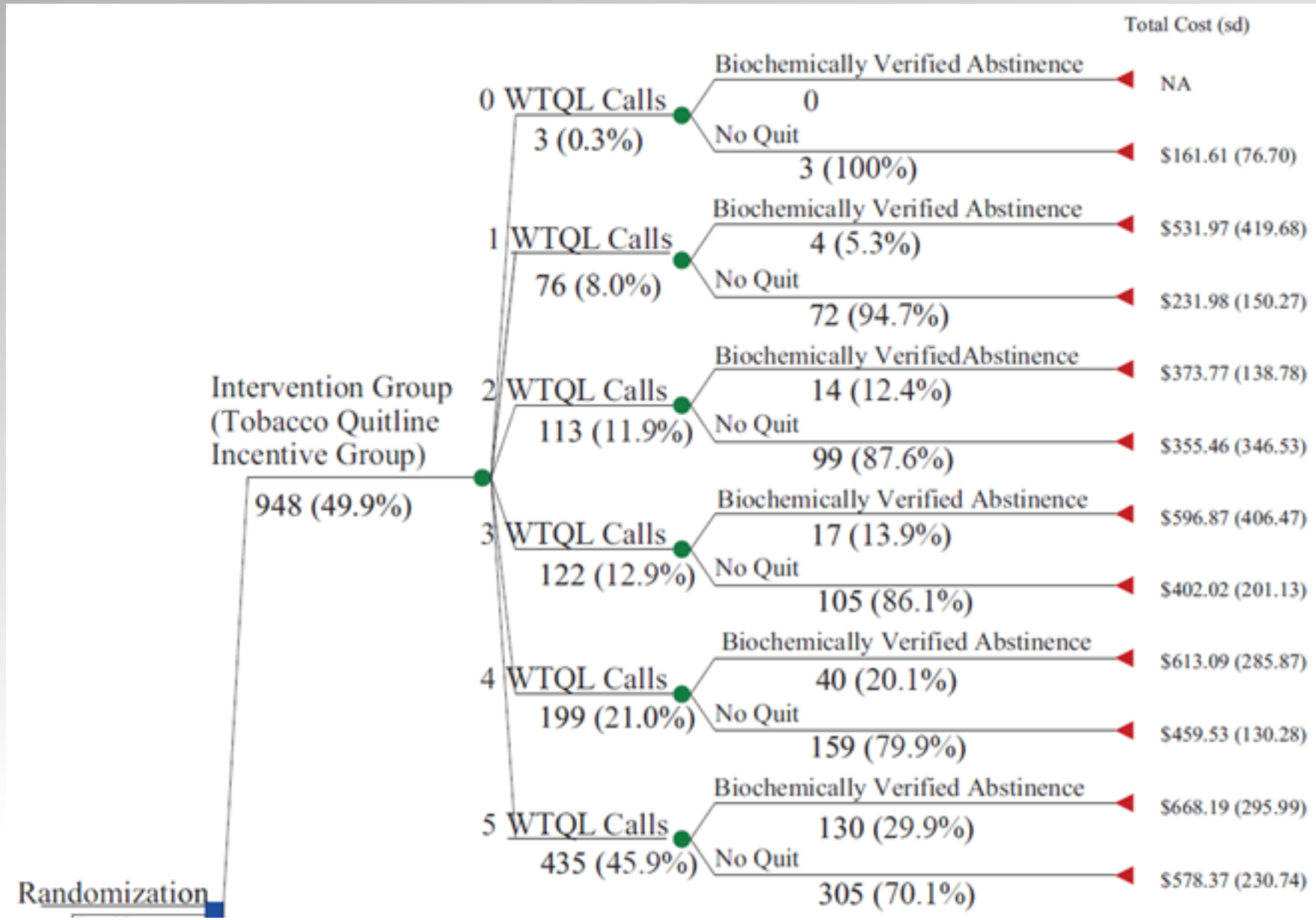
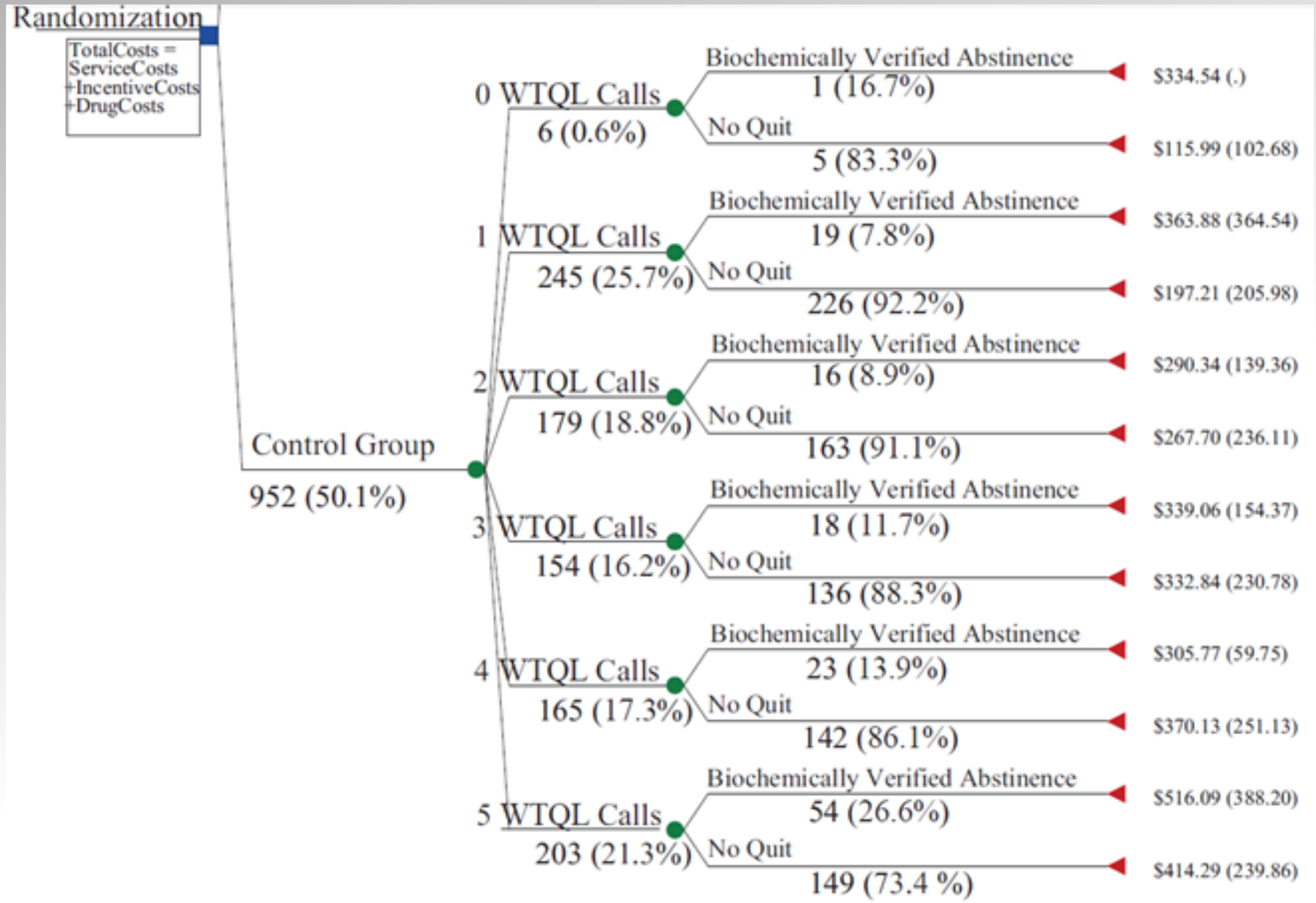
Engagement in Wisconsin Tobacco Quit Line (WTQL) Calls for Incentive Group



Engagement in Wisconsin Tobacco Quit Line (WTQL) Calls for Control Group



Quit Rate Effectiveness

- Overall, 21.6% (205/948) of Incentive group participants and 13.8% (131/952) of Control group participants had biochemically verified abstinence at 6-month follow-up

- Differential effectiveness of the financial incentive intervention = 7.9%

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CEA for Striving to Quit

- Investing $183 per participant in financial incentives, medications and staff time, the smoking cessation rate increased by 7.9 percentage points among Medicaid enrollees at 6-month follow-up[12]
- The cost-effectiveness of offering financial incentives for smoking cessation treatment engagement was $2,316 for getting one additional smoker to quit (~$3000/QALY)[12]

[12]Mundt MP, Baker TB, Fraser DL, et al (2019)

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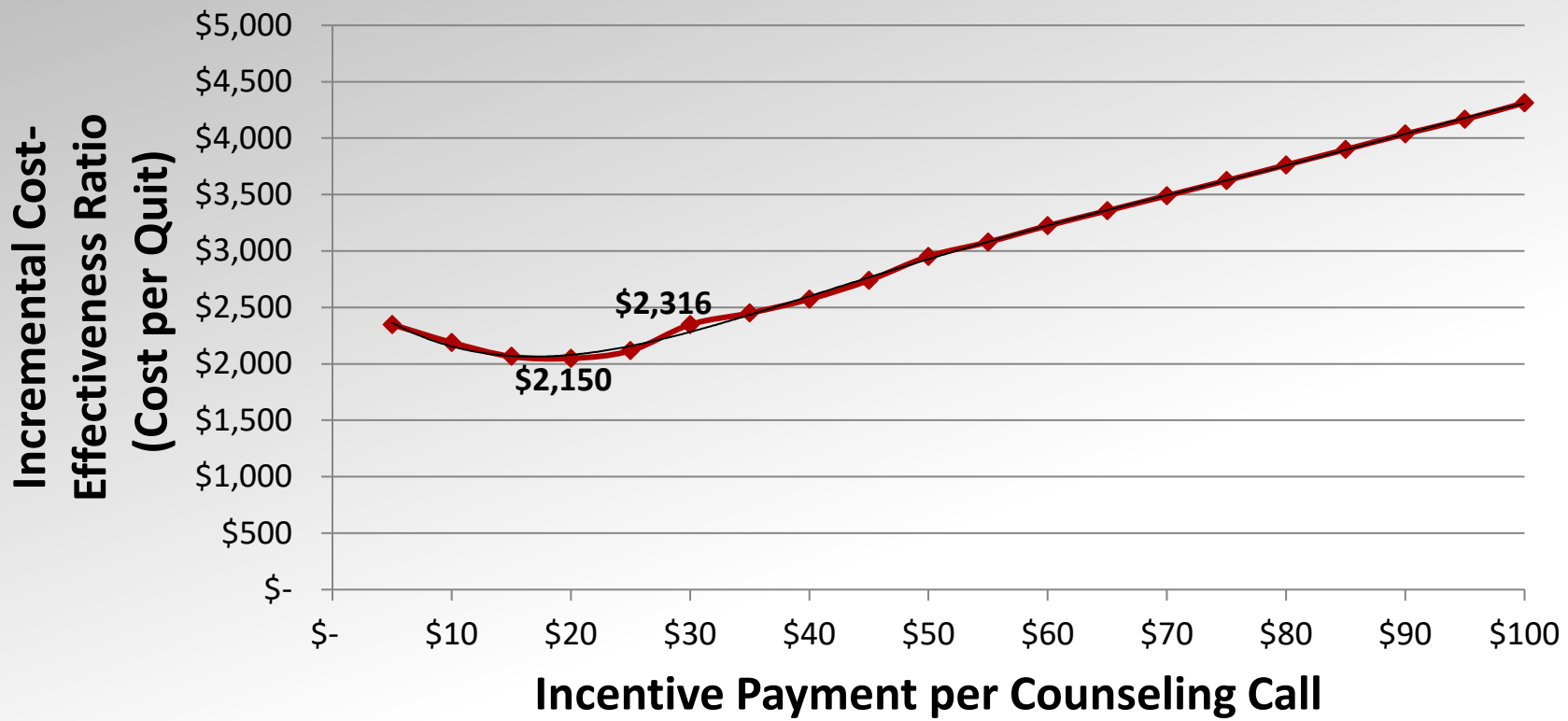
Maximizing Benefits: ICER Based on Uniform Incentive per Counseling Call



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Too Little: STQ Takeaway

Too little: *Incentives may be underutilized in helping patients quit smoking*

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Just Right: The Comprehensive Tobacco Intervention Program (CTIP)

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The Comprehensive Tobacco Intervention Program (CTIP)

- This NCI-funded (R35 CA197573) research project sought to increase smoking cessation outreach and support to patients who smoke

- Conducted by the University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) from 2017-2021

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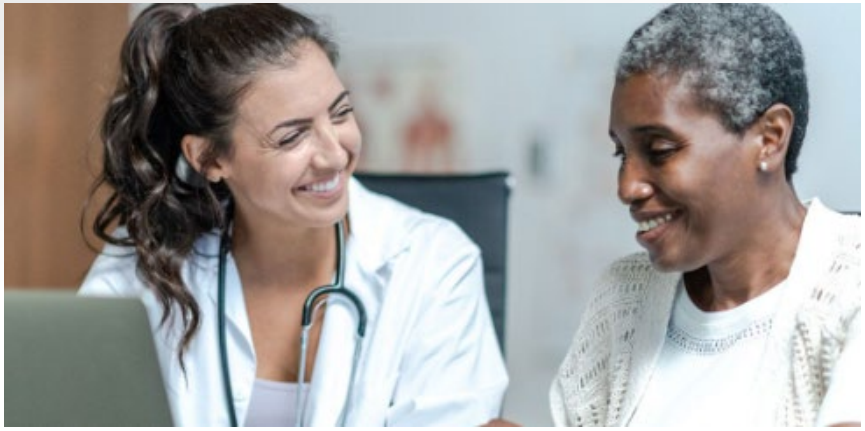
Background

- Primary care offers a unique opportunity to deliver chronic illness care management to patients who smoke (Papadakis et al, 2010)
- Family practitioners can provide the repeated, evidence-based interventions that are most effective in addressing the physical dependence and deeply rooted patterns of behavior associated with smoking (Fiore et al, 2008)



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The Comprehensive Tobacco Intervention Program (CTIP)

- Add Electronic Health Record (EHR) prompts and tools for clinicians to offer tobacco treatment at routine clinic encounters
- Integrate certified tobacco treatment specialists (CTTS) into the primary care clinics to provide phone outreach and cessation support
- Conduct quarterly mailings and outreach, including mailing sample Nicotine Replacement Therapy (NRT) patches to all patients on the smoking registry

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CTIP Research Question

- What is the cost-effectiveness of CTIP?

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Multiple Baseline Design

Cohort	Period 1 (Jan 2017-Dec 2017)	Period 2 (Jan 2018-Jun 2018)	Period 3 (Jul 2018-Oct 2018)	Period 4 (Nov 2018-Feb 2020)
1 (Clinics 1-2)	Baseline	Active	Active	Active
2 (Clinics 3-4)	Baseline	Baseline	Active	Active
3 (Clinics 5-6)	Baseline	Baseline	Baseline	Active

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Cost Measures

- Salary and benefits for certified tobacco treatment specialists (CTTSs)
- Quarterly outreach/NRT resources and postage
- Incremental costs of clinic physician counseling for tobacco
- Incremental costs of tobacco cessation medications prescribed

Effectiveness Measures

- Reach
  - Phone contact by the CTTS
  - Received counseling and/or medication to stop smoking
- Effectiveness
  - Conversion to former smoking status in EHR

Cost Offset Analysis: Acute Healthcare Utilization

Pre- vs post-implementation comparison of urgent care, emergency department, and inpatient hospitalization costs for patients on the smoking registry

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Results: Effectiveness

Outcome	Pre	Post	Incremental Effectiveness
Phone Contact by CTTS	0% (0)	51.8% (3099)	51.8% (3099)
Received Counseling and/or Medication	9.8% (598)	24.0% (2564)	14.2% (1517)
Quit Smoking	1.0% (107)	9.0% (962)	8.0% (855)

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Incremental Cost-Effectiveness Ratios in CTIP study

ICER = $628 (95% CI: $568, $695) per patient who quit smoking

ICER= $905 (95% CI: $822, $1001) per one additional QALY gained

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Incremental Cost per QALY

- Traditional cost-effectiveness thresholds for meaningful care are $50,000-$100,000 per one additional QALY gained
- $905/QALY is far below the cost-effectiveness threshold = Highly Cost-Effective

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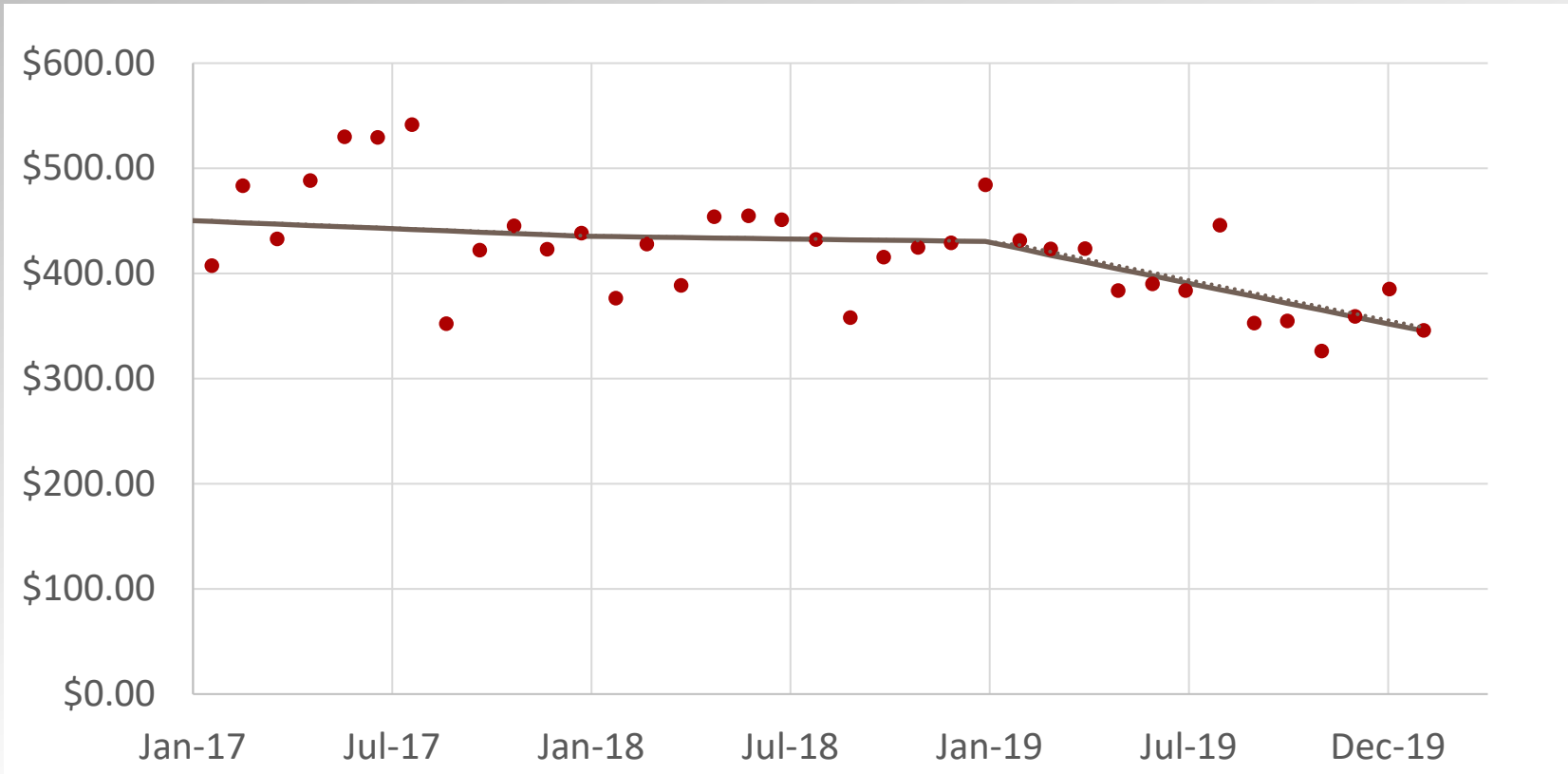
Pre and Post STIP Implementation: Acute Healthcare Utilization

Monthly Acute Care Costs for Persons on the Primary Care Clinic Smoking Registry



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Pre and Post STIP Implementation: Acute Healthcare Utilization

- Pre-implementation acute care (urgent care, emergency department, hospital) costs = $432 (95% CI: $329, $535) per patient per month
- Post-implementation acute care costs = $390 (95% CI: $308, $471) per patient per month
- Cost differential = -$42 (95% CI: -$145, $59) per patient per month for patients on the smoking registry

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Just Right: CTIP Takeaway

- ***Just Right:*** *CTIP is a cost-effective tobacco cessation treatment approach in real-world primary care clinics*

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Questions