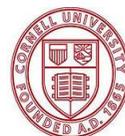


# Evaluation of cigarette package inserts for enhanced communication with smokers

August 23, 2024



UNIVERSITY OF  
**SOUTH CAROLINA**



Cornell University

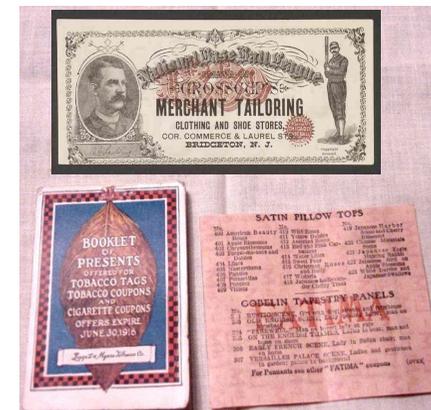


# DISCLOSURES

- **Funding**: Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health (R01CA215466). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
- I have served as an expert witness on behalf of governments in international litigation brought by the tobacco industry; I have received funding from tobacco control advocacy organizations for research on tobacco in video games (Truth Initiative) and research to inform tobacco control policy (Bloomberg)
- I have not received funding from pharmaceutical companies or tobacco companies.

# BACKGROUND

- The tobacco industry has used cigarette package inserts to communicate with smokers for over a century
- Canada is the only country that has used inserts for communicating cessation messages to smokers.
- FDA has regulatory power to adopt inserts for communicating with smokers, but more research is needed to determine their effectiveness.



# Inserts with “efficacy” messages:

- Quitting Benefits → response efficacy
- Cessation Tips → self-efficacy



**Quitting...  
What's in it for me?**

**WHY SHOULD I QUIT SMOKING?**

I want to regain control over myself by getting rid of my tobacco addiction...

I want to be at my best with my activities...

I want to be healthier and have more energy...

I will reward myself with the money saved...

Health Canada

Thrasher et al.  
*Nicotine & Tobacco Research* (2015)

**How can the quitline help me?**

**WHEN YOU CALL THE TOLL-FREE QUITLINE 1-866-366-3667**

You'll speak one-on-one with a quit specialist who will help you:

- Create a quit plan that works for you.
- Access information and tools to become smoke-free.
- Cope with cravings and withdrawal symptoms.
- Find services and resources in your community.

**There are many reasons to quit. What's yours?**

Tobacco is the single most preventable cause of premature death and disease.  
Health Canada

**They only last an average of a few minutes...**

**For most, when cravings occur they usually last only a few minutes.**

When you quit smoking, you may get strong cravings. This is part of the quitting process.

The brain gets used to not having nicotine. The more you resist, the fewer cravings you'll have.

**You've got what it takes to go smoke-free!**

Nicotine is the drug in tobacco that causes addiction.  
Health Canada

**"I had enough of feeling guilty..."**

"Quitting is hard and it takes a lot of will power."  
"I had enough of feeling guilty. I was ashamed of being a smoker."  
"When I was ready to quit, I called a quitline and, with their support, I made it through the first few days of cravings."  
"As the days went by, I was more and more proud of myself and my will to keep going got stronger."  
- Susan

1-866-366-3667  
Tobacco products are highly addictive.  
Health Canada

**Never quit trying to quit.**

**Most smokers try to quit several times before they succeed.**

Think of every attempt as a learning experience, not a failure. Never quit trying to quit.

Pick a quit date, write it down or tell someone about it.

Nicotine is the drug in tobacco that causes addiction.  
Health Canada

**It's never too late...**

**Quitting smoking increases life expectancy and improves quality of life.**

People who quit smoking increase their chances of living longer. They improve their general health, leading to a better quality of life.

It's never too late to quit. No matter how old you are, you'll start to feel major and immediate health benefits and have more energy to help you live life to the fullest.

**Talk to a health care provider.**  
Health Canada

**Morning cough?**

**Coughing is your lungs warning you it's time to quit.**

When you quit smoking:

- **Within the first few months**, you'll cough and wheeze less and you'll be short of breath less often.
- **In the first 5 years**, respiratory problems like bronchitis and pneumonia will decrease significantly.

**You can quit and breathe easier!**  
Health Canada

**Thinking of having a baby?**

**Quitting smoking before pregnancy will increase your chances of having a healthy baby.**

You'll lower your risk of:

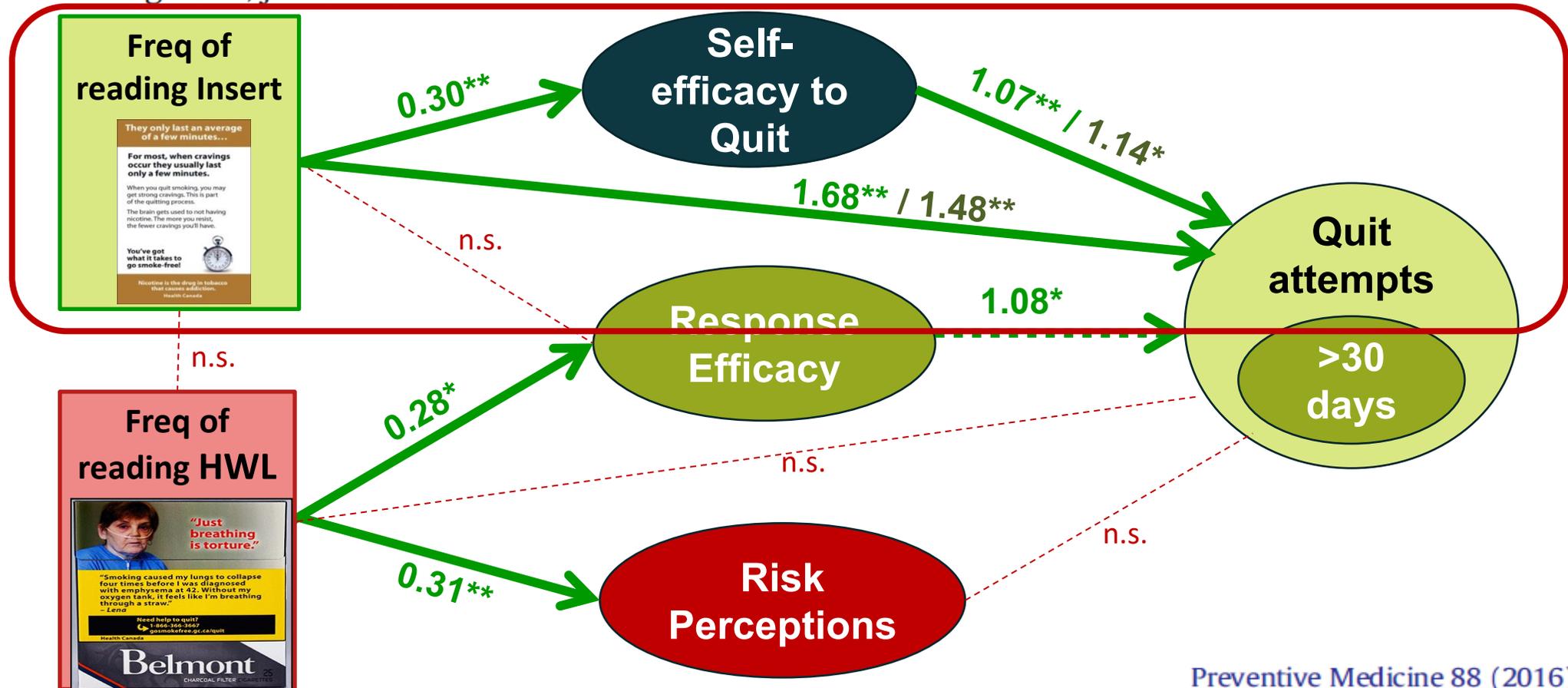
- Miscarriage
- Stillbirth
- Having a baby with serious health problems.

Although quitting is most beneficial before conception, there are some benefits to quitting at any time during your pregnancy.

**Talk to a health care provider.**  
Health Canada

# Cigarette package inserts can promote efficacy beliefs and sustained smoking cessation attempts: A longitudinal assessment of an innovative policy in Canada

James F. Thrasher<sup>a,b,\*</sup>, Kamala Swayampakala<sup>a</sup>, K. Michael Cummings<sup>c</sup>, David Hammond<sup>d</sup>, Dien Anshari<sup>a,e</sup>, Dean M. Krugman<sup>f</sup>, James W. Hardin<sup>g</sup>



FOOD AND DRUG  
LAW JOURNAL

**FDA-Required Tobacco Product Inserts &  
Onserts—and the First Amendment**

*Eric N. Lindblom, Micah L. Berman, and James F. Thrasher*

VOLUME 72 NUMBER 1 2017

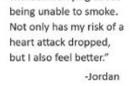
## **Why inserts for the US context?**

- Inside packs – can target smokers, not all consumers
  - Framed for smokers who want to quit (i.e., most smokers)
- Could contain “factual,” “uncontroversial” information about harmful constituents, harms, and cessation

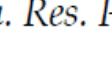
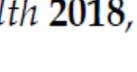
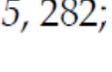
# Pilot studies: Insert content for US smokers



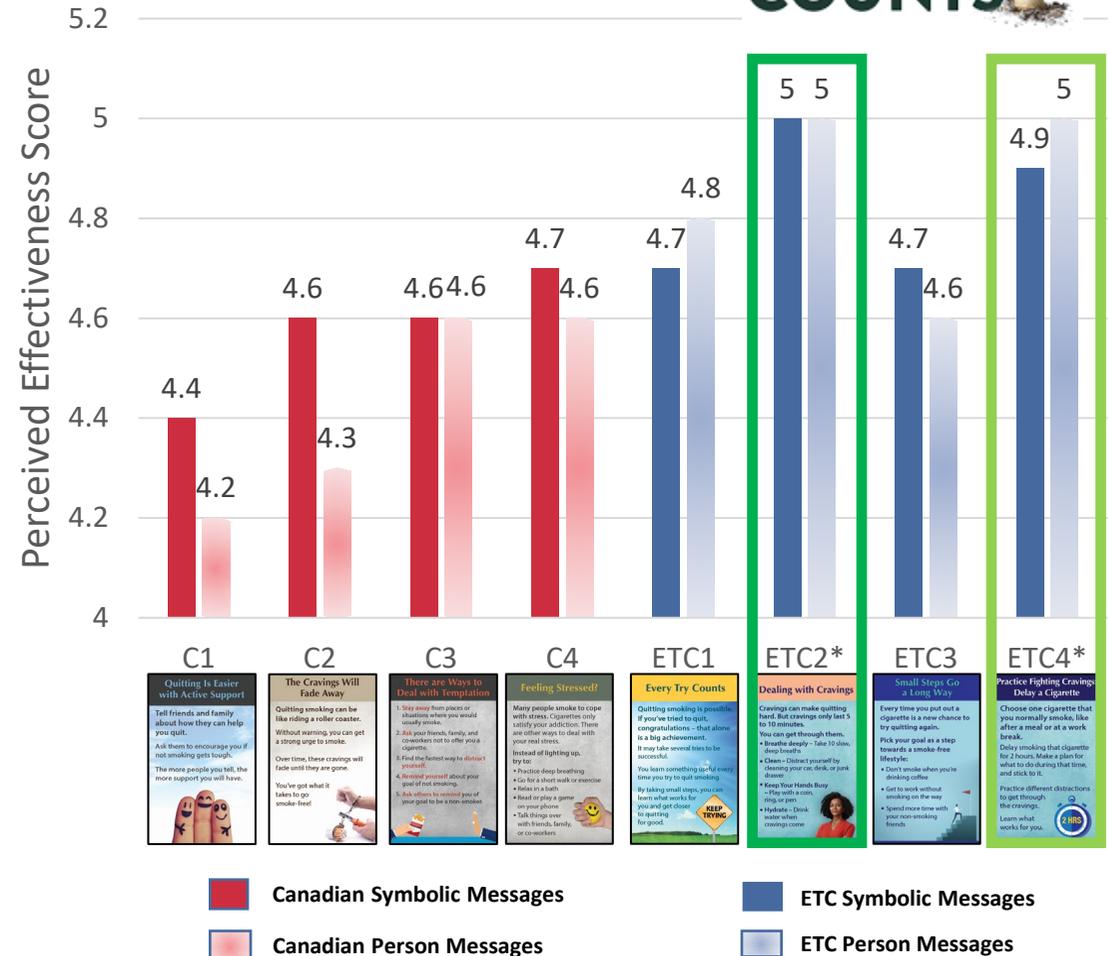
Which insert would be **MOST helpful** and which one would be **LEAST helpful** for you, **if you decided to quit smoking?**

	<p><b>After quitting, the cravings will fade away.</b></p> <p>"Quitting felt like a roller coaster ride at first. Out of nowhere, I'd get a strong urge to smoke. Over time, though, the cravings faded until they were gone." - Jeff</p>  <p>If you want help to quit, call 1-800-784-8669 or visit <a href="http://smokefree.gov">http://smokefree.gov</a></p>	<p><b>Quit now to be healthier and happier!</b></p> <p>"Since I quit smoking, my senses of taste and smell have come back to life. I can go anywhere without worrying about being unable to smoke. Not only has my risk of a heart attack dropped, but I also feel better." -Jordan</p>  <p>If you want help to quit, call 1-800-784-8669 or visit <a href="http://smokefree.gov">http://smokefree.gov</a></p>	<p><b>Get support to quit now!</b></p> <p>"I told friends and family how to help me quit. I asked them to encourage me when not smoking was tough. The more people I told, the more support I got." -Hannah</p>  <p>Quit now! Call 1-800-QUIT-NOW for help, or visit <a href="http://smokefree.gov">http://smokefree.gov</a></p>	<p><b>Quitting saves money.</b></p> <p>If you smoke a pack a day, quitting will save you at least \$1,500 each year.</p> <p>In some states, you would save more than \$25,000 over ten years.</p> <p>Quitting leaves more money for paying bills and doing the things you enjoy.</p> <p>If you want help to quit, call 1-800-784-8669 or visit <a href="http://smokefree.gov">http://smokefree.gov</a></p>
Most helpful	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Least helpful	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*Tob Regul Sci.*™ 2018;4(2):73-87

	Lung Health	Diabetes	New Diseases	Well-Being	Financial
<b>Young Man</b>	<p><b>Feeling winded? Breathe better.</b></p> <p>When you quit smoking, your heart and lung health start to improve right away. Within months, your lung function and blood circulation improve.</p> <p>Physical activity gets easier. You're more likely to walk or run comfortably and keep up with your children or grandchildren without being breathless.</p> <p>Enjoy the benefits of being smoke-free.</p> 	<p><b>Lower Your Risk of Diabetes</b></p> <p>Quitting smoking lowers your risk of developing diabetes (type 2). If you have diabetes, quitting smoking will help you manage your blood sugar level and lower your risk of serious health problems, such as foot amputations or blindness.</p> <p>There have never been more ways to quit. Talk to your health care provider for support.</p> 	<p><b>The Benefits of Quitting Keep Growing</b></p> <p>People who quit have healthier hearts and lungs. They lower their risk of developing many different types of cancer. But, did you know that quitting can also lower your risk for:</p> <ul style="list-style-type: none"> <li>Rheumatoid arthritis</li> <li>Osteoporosis</li> <li>Weakened immune system</li> </ul> <p>Enjoy the benefits of a smoke-free life.</p> 	<p><b>Don't Quit Quitting</b></p> <p>Most people try several times before they quit for good, but the fight is worth it. By quitting you'll:</p> <ul style="list-style-type: none"> <li>Breathe easier</li> <li>Have a stronger heart and lungs</li> <li>Exercise without wheezing</li> <li>Save money</li> <li>Be a healthy role model for children or grandchildren</li> </ul> <p>You've got what it takes.</p> 	<p><b>Invest In Your Health</b></p> <p>The average Canadian who smokes every day will save about \$221 a month or \$2652 a year by quitting smoking. Think of what you could do with the extra money...</p> <ul style="list-style-type: none"> <li>Go stress with a vacation</li> <li>Worry less about money</li> <li>Save for your future</li> </ul> <p>How will you reward yourself?</p> 
<b>Young Woman</b>					
<b>Older Man</b>					
<b>Older Woman</b>					
<b>Symbolic</b>					

*Int. J. Environ. Res. Public Health* 2018, 15, 282;



*Tob Regul Sci.*™ 2021;7(3):203-209

# RCT - Cigarette Labeling Policy Alternatives

- 2 X 2 Between Subject RCT
- Adult smokers (10+CPD; 46% <=High School)
- Provide a 14-day supply of preferred cigarettes with packs modified to reflect experimental condition
- Ecological Momentary Assessment
  - Approx. 4-5 per day (cigarette surveys)
  - Evening reports

### Tips – Self-efficacy

#### Dealing with Cravings

Cravings can make quitting hard, but cravings only last 5 to 10 minutes.

Some ways to deal with cravings:

- Breathe Deeply – Take 10 slow, deep breaths
- Clean – Distract yourself by cleaning your car, desk, or junk drawer
- Keep Your Hands Busy – Play with a coin, ring, or pen
- Hydrate – Drink water when cravings come



#### Delaying a Cigarette is Practice for Quitting

Choose one cigarette you normally smoke, like after a meal or at a work break.

Delay smoking that cigarette for 2 hours. Make a plan for what to do during that time, and stick to it.

Practice different types of distractions to get through the cravings.

Learn what works for you.



### Cessation Benefits

#### Good Things Happen When You Quit

When you quit, in...

- 20 Minutes - Your heart rate and blood pressure will drop.
- 2 Weeks - 3 Months - Your blood circulation and lung function improve.
- 1 Year - Your risk of heart disease is half of someone who still smokes. Your risk of a heart attack drops dramatically.
- 5 - 10 Years - Your risk of lung cancer is cut in half.



#### Quitting Saves Money

For the pack-a-day smokers, quitting saves thousands of \$ each year.

Quitting leaves more money for paying bills, buying necessities, and doing fun things.





## Study Conditions

Condition	Warnings	Inserts
Control		None
Insert only		
Pictorial HWL only		None
Insert + Pictorial HWL		

# Intercept recruitment in low-income neighborhoods to enhance participation among disadvantaged groups

- Participant demographics similar to neighborhood area-level demographics
- Data quality similar to, but a little lower than, traditional voluntary recruitment



## Recruitment Methods, Inclusion, and Successful Participation in a Longitudinal Clinical Trial Using Ecological Momentary Assessment

Norman Porticella, PhD<sup>1</sup>, Julie S. Cannon, PhD<sup>2</sup>, Chung Li Wu, PhD<sup>3</sup>, Stuart G. Ferguson, PhD<sup>4</sup>, James F. Thrasher, PhD<sup>3</sup>, Emily E. Hackworth, MPH<sup>3</sup>, and Jeff Niederdeppe, PhD<sup>1,5</sup>

# Study Sample: Socio- demographics

Participant Characteristics		Control n=101	Insert only n=87	Pictorial HWL only n=90	Insert + Pictorial HWL n=89	Total n=367
Age	<i>18-35</i>	27(27%)	27(31%)	26(30%)	21(24%)	101(28%)
	<i>36-55</i>	54(53%)	41(48%)	44(50%)	49(55%)	188(52%)
	<i>56+</i>	20(20%)	18(21%)	18(20%)	19(21%)	75(20%)
Sex	<i>Male</i>	41(41%)	35(41%)	37(42%)	28(31%)	141(39%)
	<i>Female</i>	60(59%)	50(59%)	51(58%)	61(69%)	222(61%)
Race	<i>White</i>	77(76%)	74(85%)	73(81%)	72(81%)	296(81%)
	<i>Black</i>	17(17%)	8(9%)	8(9%)	14(16%)	47(13%)
	<i>American Indian</i>	2(2%)	1(1%)	0(0%)	1(1%)	4(1%)
	<i>Asian</i>	1(1%)	0(0%)	1(1%)	0(0%)	2(1%)
	<i>Native Hawaiian /Pacific Islander</i>	0(0%)	0(0%)	1(1%)	0(0%)	1(0%)
	<i>Not reported</i>	4(4%)	2(2%)	4(4%)	2(2%)	12(3%)
	<i>More than one</i>	2(2%)	2(2%)	3(3%)	1(1%)	8(2%)
Education	<i>&lt;=High School</i>	48(48%)	36(42%)	30(34%)	39(44%)	153(42%)
	<i>&gt; High School</i>	53(53%)	49(58%)	57(66%)	50(56%)	209(58%)
Income	<i>&lt;\$10,000</i>	17(17%)	11(13%)	14(16%)	14(16%)	56(15%)
	<i>\$10,000-29,999</i>	43(34%)	18(21%)	24(27%)	24(27%)	100(28%)
	<i>\$30,000-44,999</i>	19(19%)	12(14%)	16(18%)	22(25%)	69(19%)
	<i>\$45,000-59,999</i>	14(14%)	19(22%)	8(9%)	13(15%)	54(15%)
	<i>\$60,000-74,999</i>	6(6%)	11(13%)	9(10%)	6(7%)	32(9%)
	<i>&gt;\$75,000</i>	9(8%)	11(13%)	13(15%)	9(9%)	42(11%)
	<i>No answer</i>	2(2%)	3(4%)	4(5%)	1(1%)	10(3%)

# Study Sample

Compared to other RCTs on HWLs, **heavier smokers** and **less interested in quitting**

Participant Characteristics		Control n=101	Insert only n=87	Pictorial HWL only n=90	Insert + Pictorial HWL n=89	Total n=367
Health literacy	<i>Limited</i>	9(9%)	7(8%)	5(6%)	7(8%)	28(8%)
	<i>Possibly limited</i>	26(26%)	19(22%)	19(21%)	19(21%)	83(22%)
	<i>Adequate</i>	66(65%)	61(70%)	66(73%)	63(71%)	256(70%)
Cigarettes per Day	<i>10-15</i>	30(30%)	22(26%)	27(31%)	26(29%)	105(29%)
	<i>16-20</i>	44(43%)	38(44%)	30(34%)	38(43%)	150(41%)
	<i>&gt;20</i>	27(27%)	26(30%)	31(35%)	25(28%)	109(30%)
Intend to quit ( <u>next</u> 6 months)	<i>Yes</i>	32(32%)	29(34%)	31(35%)	27(30%)	119(33%)
	<i>No</i>	69(68%)	57(66%)	57(65%)	62(70%)	245(67%)
Quit attempt (last 12 months)	<i>Yes</i>	30(30%)	26(30%)	29(33%)	22(25%)	107(29%)
	<i>No</i>	71(70%)	60(70%)	58(66%)	65(73%)	254(70%)
	<i>Don't know</i>	0(0%)	0(0%)	1(1%)	2(2%)	3(1%)
Self-efficacy to quit - Mean (SD)		2.32(1.06)	2.30(0.92)	2.39(1.05)	2.21(0.81)	2.31(0.97)
Perceived risk – Mean (SD)		3.52(1.14)	3.72(1.16)	3.57(1.25)	3.79(1.10)	3.64(1.16)
Cigarette surveys submitted		18,290	16,063	17,126	16,351	67,830
Evening surveys submitted		1,164	979	1,031	1,022	4,196

The ns shown are at the level of the individual participant; HWL=health warning label

# EMA MEASURES:

## Cigarette Surveys

- Proximal to pack labeling exposures
- Approx 4-5 Xs/day



Log all cigarettes



- baseline CPD → survey freq

- **Feeling about smoking**
  - Right now, you feel like smoking is...(1 “VERY BAD!!” – 7 “VERY GOOD!!”)
- **Worry about harms from smoking**
  - How WORRIED are you about getting a serious disease from smoking? (1 “not at all” – 7 “extremely”)
- **Self-efficacy to cut down on smoking**
  - How EASY would it be to cut down on the number of cigarettes you smoke? (1 “not at all” – 7 “extremely”)
- **Self-efficacy to quit**
  - How CONFIDENT are you that you could quit smoking altogether right now? (1 “not at all” – 7 “extremely”)
- **Hopefulness about quitting**
  - When you think about quitting smoking, how HOPEFUL do you feel? (1 “not at all” – 7 “extremely”)
- **Motivation to quit**
  - How MOTIVATED are you to quit smoking? (1 “Not at all” – 7 “extremely”)

# EMA MEASURES:

## Evening Survey

Text-prompted  
survey at the end  
of each of 14 days



- **Cognitive elaboration of smoking harms**
  - In the last 24 hours, How often have you thought about the harms from smoking? (1 “not at all” – 7 “all the time”)
- **Cognitive elaboration of cessation benefits**
  - In the last 24 hours, How often have you thought about the potential benefits from quitting smoking? (1 “not at all” – 7 “all the time”)
- **Perceived susceptibility**
  - How likely are you to get a serious disease if you continue smoking the same amount? (1 “no chance” – 7 “certain to happen”)
- **Talked about smoking harms & cessation benefits**
  - In the last 24 hours, have you talked with someone else about [harms from smoking; benefits of smoking cessation]? (Yes, No)
- **Stubbing out cigarettes**
  - In the last 24 hours, have you stubbed out a cigarette before finishing it? (Yes/No)
- **Forgoing cigarettes**
  - In the last 24 hours, have you not had a cigarette at a time when you would normally? (Yes, No)

# Analysis

Clinicaltrials.gov:  
NCT04075682

- Mixed-effects ordered and logistic models, adjusting for repeated measures (day- & individual-level)

$$y_{ij} = g^{-1} [\beta_0 + (InsN_i \times PicN_i)\beta_1 + (InsN_i \times PicY_i)\beta_2 + (InsY_i \times PicN_i)\beta_3 + (InsY_i \times PicY_i)\beta_4 + Z_{ij}\tau + \gamma_i + \epsilon_{ij}]$$

Hyp	Test	Marginal Means
H1 – Inserts	$H_0^1: \beta_1 + \beta_2 = \beta_3 + \beta_4$	$\mu_{InsY} - \mu_{InsN} = 0$
H2 - PHWLs	$H_0^2: \beta_1 + \beta_3 = \beta_2 + \beta_4$	$\mu_{PicY} - \mu_{PicN} = 0$

H1 alt:  $\mu_{PicNInsY} - \mu_{PicNInsN} = 0$

H2 alt:  $\mu_{PicYInsN} - \mu_{PicNInsN} = 0$

## Pictorial HWLs



Marginal means

No

Yes

Inserts

No



$\mu_{InsN}$

Yes



$\mu_{InsY}$

Marginal means

$\mu_{PicN}$

$\mu_{PicY}$

# Combining Inserts With Warning Labels on Cigarette Packs to Promote Smoking Cessation: A 2-Week Randomized Trial

**H1:** Exposure to packs with inserts will result in stronger efficacy beliefs than packs without inserts, which, in turn, will lead to stronger cessation-related outcomes (e.g., motivation to quit, interpersonal discussions about quitting, foregoing cigarettes).



Hypotheses	Self-efficacy to quit <sup>1</sup> b (95% CI)	Self-efficacy to cut down cigs <sup>1</sup> b (95% CI)	Feel hopeful about quitting <sup>1</sup> b (95% CI)	Frq thinking about Quitting Benefits <sup>2</sup> b (95% CI)	Motivated to quit <sup>1</sup> b (95% CI)	Talked about cessation/harm <sup>2</sup> OR (95% CI)	Forwent/stubbed out a cigarette <sup>2</sup> OR (95% CI)
H1 - Insert Main Effects (insert only & insert + PHWL vs. PHWL only & control)	0.26 (-0.73,1.25)	0.28 (-0.68,1.24)	0.55 (-0.75,1.85)	<b>0.69*</b> <b>(0.02,1.37)</b>	0.44 (-0.69,1.57)	1.26 (0.82,1.96)	<b>2.47**</b> <b>(1.42,4.31)</b>
Effect size	0.18	0.19	0.29	0.38	0.25	0.14	0.54
ICC	0.89	0.88	0.93	0.76	0.91	0.48	0.70
H1 Alt - Insert Main Effects (Insert only vs. control)	0.78 (-0.61,2.18)	1.13 (-0.15,2.40)	1.49 (-0.08,3.06)	<b>1.14*</b> <b>(0.23,2.06)</b>	1.36 (-0.14,2.86)	1.26 (0.70,2.25)	<b>3.45**</b> <b>(1.57,7.62)</b>
Effect size	0.53	0.75	0.80	0.63	0.80	0.13	0.77
ICC	0.89	0.87	0.91	0.74	0.90	0.46	0.70

\*p<0.05; \*\*p<0.0071 (Bonferroni corrected alpha for 7 tests); 1=cigarette survey; 2=evening survey; PHWL=Pictorial Health Warning Label

Effect sizes: small=0.2; medium=0.5; large=0.8

# Combining Inserts With Warning Labels on Cigarette Packs to Promote Smoking Cessation: A 2-Week Randomized Trial

**H2:** Exposure to packs with large pictorial HWLs will produce stronger negative affective responses toward smoking than text-only HWLs, which, in turn, will lead to stronger cessation-related outcomes.



Hypotheses	Feeling about smoking <sup>1</sup> b (95% CI)	Worry about smoking harms <sup>1</sup> b (95% CI)	Frq thinking about Smoking Harms <sup>2</sup> b (95% CI)	Perceived Susceptibility <sup>2</sup> b (95% CI)	Motivated to quit <sup>1</sup> b (95% CI)	Talked about cessation/harm <sup>2</sup> OR (95% CI)	Forwent/stubbed out a cigarette <sup>2</sup> OR (95% CI)
H2 - PHWL Effects (PHWL only & insert + PHWL vs. insert only & control)	-0.40 (-1.33,0.53)	-0.33 (-1.48,0.82)	-0.31 (-0.98,0.36)	-0.26 (-1.15,0.64)	-0.48 (-1.61,0.66)	1.19 (0.77,1.85)	<b>1.89*</b> <b>(1.09,3.30)</b>
Effect size	0.24	0.18	0.16	0.13	0.27	0.09	0.38
ICC	0.87	0.91	0.76	0.78	0.91	0.49	0.70
H2 Alt - PHWL Effects (PHWL only vs. control)	-1.04 (-2.36,0.28)	0.61 (-1.13,2.34)	0.10 (-0.87,1.07)	0.57 (-0.85,1.98)	0.53 (-1.13,2.19)	1.19 (0.60,2.38)	<b>2.62*</b> <b>(1.20,5.70)</b>
Effect size	0.61	0.31	0.05	0.31	0.31	0.10	0.60
ICC	0.88	0.92	0.65	0.94	0.92	0.58	0.69

\*p<0.05; \*\*p<0.0071 (Bonferroni corrected alpha for 7 tests); 1=cigarette survey; 2=evening survey.

Effect sizes: small=0.2; medium=0.5; large=0.8

# Main effects of labeling conditions: Conclusions

- Mostly null results
  - Results consistent across different sensitivity analyses (i.e.,  $\geq 30\%$ , 50%, 70% of expected cigarette surveys;  $\geq 6, 9, 12$  evening reports; MI for missing data).
  - ICCs higher than anticipated (i.e., statistical power lower)
  - Compared to other RCTs, heavier smokers ( $\geq 10$  CPD) less interested in quitting
- Insert effects limited to stubbing out/forgoing (after adjustment)
  - Predictor of cessation attempts and sensitive to labeling
  - Larger effect than other studies
  - Unclear why psychosocial variables would not mediate the association
    - Reactivity to EMA (vs evening report) given timing around smoking sessions?
    - Need more statistical power?
- No evidence that insert + PHWLs was better than either alone
  - Combination weakens effects across outcomes?

# Differential Responses to Cigarette Package Labeling Alternatives Among Adults Who Smoke: Results From a Randomized Trial

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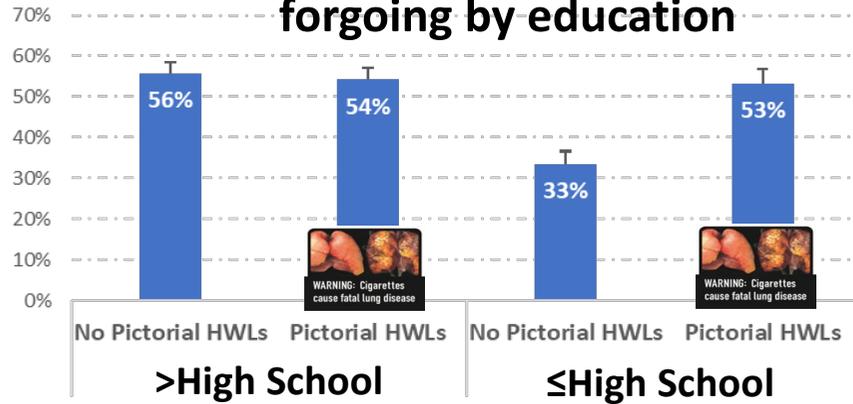
## Moderation of label effects on stubbing/forgoing by sociodemographic & psychological risk

Moderating variables	Labeling group contrasts											
	Pictorial HWL vs. not <sup>2</sup>			Insert only vs. insert + Pictorial HWL			Insert vs. not <sup>3</sup>			Pictorial only vs. insert + Pictorial HWL		
	OR	(95% CI)	<i>p</i> -val	OR	(95% CI)	<i>p</i> -val	OR	(95% CI)	<i>p</i> -val	OR	(95% CI)	<i>p</i> -val
Education	0.20	(0.06,0.60)	.004	5.45	(1.18,26.53)	.036	2.18	(0.72,6.61)	.167	0.49	(0.10,2.42)	.380
Literacy	1.13	(0.33,3.83)	.849	0.59	(0.10,3.47)	.563	0.46	(0.14,1.57)	.216	1.45	(0.24,8.71)	.682
Quit intention	0.66	(0.21,2.08)	.479	0.78	(0.15,4.11)	.770	1.89	(0.60,5.92)	.276	0.27	(0.05,1.42)	.123
Self-efficacy	1.19	(0.39,3.58)	.758	0.79	(0.16,3.89)	.771	1.19	(0.39,3.58)	.759	0.79	(0.16,3.80)	.768
Time discounting	0.92	(0.33,2.94)	.969	0.58	(0.11,2.68)	.459	3.66	(1.15,10.37)	.027	0.15	(0.03,0.75)	.021

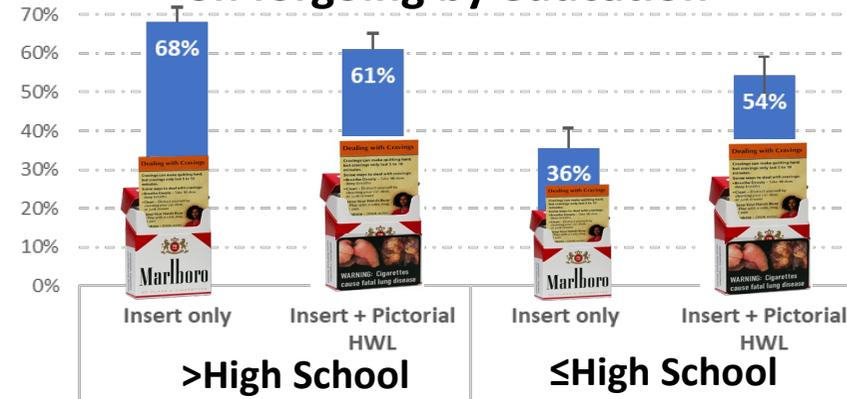
Baseline health literacy (NVS), quit intention, and self-efficacy to quit did **not** moderate labeling effects

# Labeling effects on stubbing/forgoing by education & delay discounting

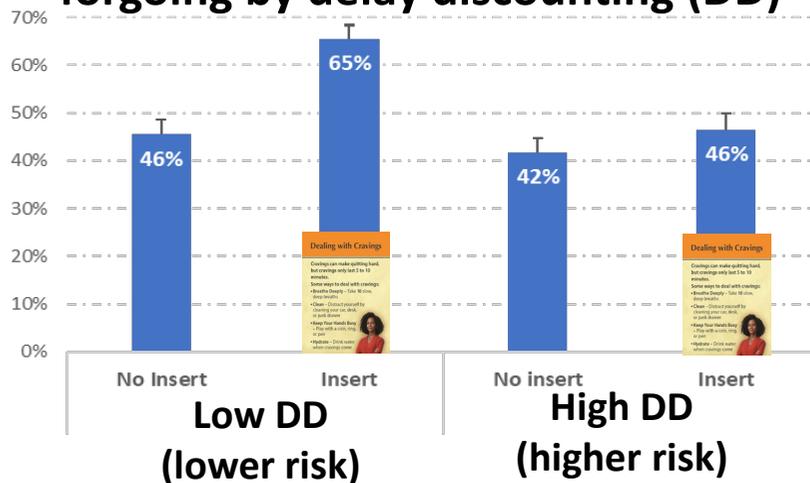
**Pictorial HWL effects (vs none) on forgoing by education**



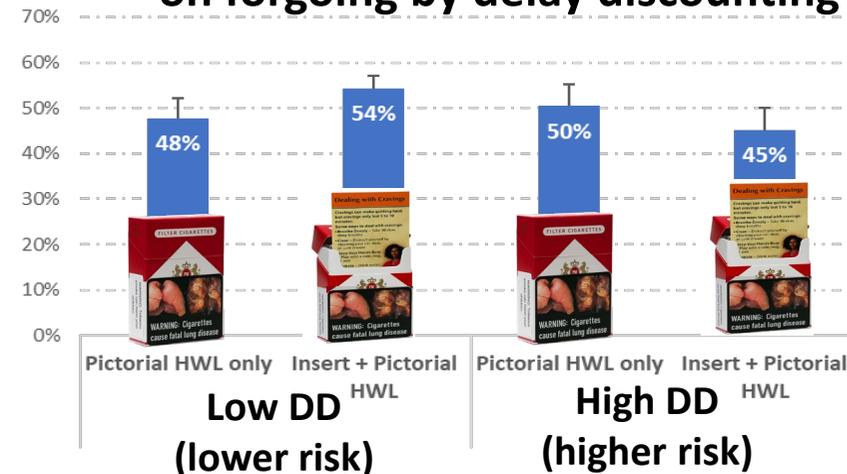
**Insert only vs. Insert + Pictorial HWL on forgoing by education**



**Insert (vs no insert) effects on forgoing by delay discounting (DD)**



**Pictorial HWL only vs. PHWL + Insert on forgoing by delay discounting**



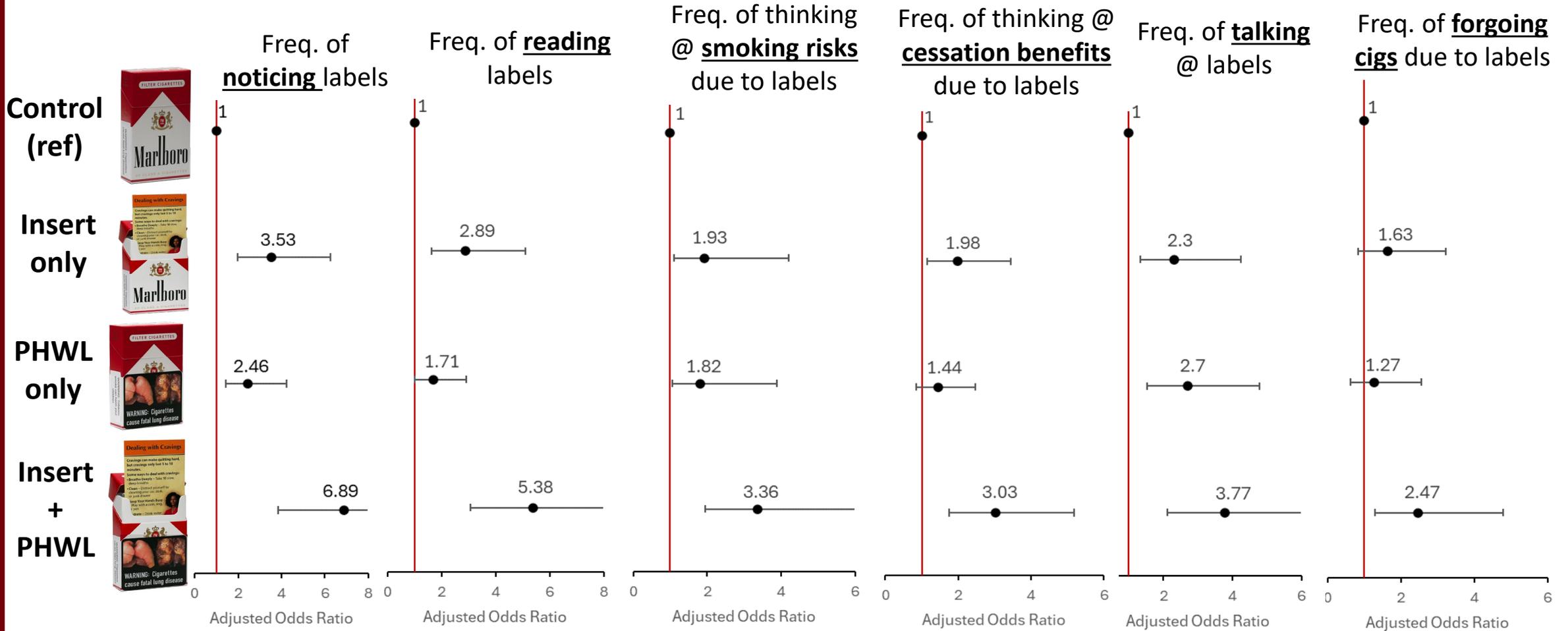
Thrasher et al. *Nicotine & Tobacco Research* (In press)

# Moderation Effects: Conclusions

- Mostly null effects for moderation hypotheses
  - Neither pictorial HWL nor insert effects modified by health literacy, quit intention, or self-efficacy
  - Same concerns about ICCs, power, and sample
- Pictorial HWLs appear particularly effective for people with lower educational attainment (health equity effects)
  - Consistent with prior experimental and observational studies
- Insert effects appear limited to smokers with low delay discounting (preference for larger rewards later over smaller rewards now)
  - Contingency Management and Cognitive Behavioral Therapy interventions (n=9) more effective if low vs. high DD

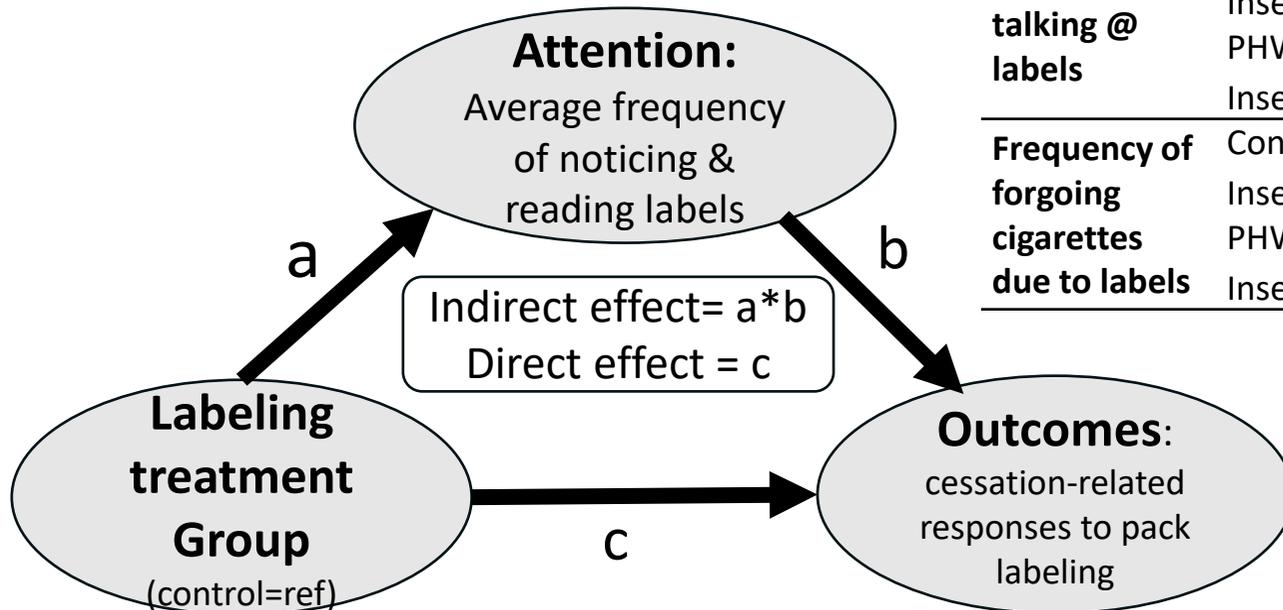
# Self-reported attention and responses to cigarette package labels at the end of a two-week randomized trial of cigarette package labeling configurations

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Results from ordered logistic regression; statistical significance, valence and strength consistent in linear regression models

# Attention to labels mediates treatment effects (except for PWHs only)



Outcome	Treatment groups	Mediation by Attention <sup>1</sup>	
		Indirect effect B (95% CI)	Direct effect B (95% CI)
Freq. of thinking @ smoking risks	Control	Ref.	Ref.
	Insert-only	<b>0.91 (0.15-1.67)*</b>	-0.10 (-0.70-0.49)
	PHWLs-only	0.64 (-0.12-1.39)	0.16 (-0.41-0.72)
	Inserts+PHWLs	<b>1.47 (0.68-2.26)***</b>	0.12 (-0.47-0.72)
Freq. of thinking @ cessation benefits	Control	Ref.	Ref.
	Insert-only	<b>0.69 (0.09-1.29)*</b>	0.16 (-0.41-0.74)
	PHWLs-only	0.48 (-0.10-1.07)	-0.01 (-0.56-0.55)
	Inserts+PHWLs	<b>1.15 (0.52-1.77)***</b>	0.22 (-0.36-0.80)
Frequency of talking @ labels	Control	Ref.	Ref.
	Insert-only	<b>0.71 (0.13-1.28)*</b>	0.27 (-0.35-0.89)
	PHWLs-only	0.47 (-0.09-1.03)	0.69 (0.09-1.30)*
	Inserts+PHWLs	<b>1.14 (0.53-1.74)***</b>	0.48 (-0.14-1.10)
Frequency of forgoing cigarettes due to labels	Control	Ref.	Ref.
	Insert-only	<b>0.92 (0.18-1.66)*</b>	-0.35 (-1.14-0.45)
	PHWLs-only	0.60 (-0.12-1.32)	-0.25 (-1.03-0.52)
	Inserts+PHWLs	<b>1.49 (0.69-2.29)***</b>	-0.29 (-1.05-0.48)

\*: p-value <0.05; \*\*: p-value <0.01; \*\*\*: p-value <0.001.

All models adjusted for age, sex, race, education, health literacy, number of cigarettes per day, intent to quit, quit attempt, and self-efficacy (all at baseline).

1. Attention calculated as the average of two attention variables: how often participants reported noticing warning labels over the prior two weeks and how often participants reported reading or looking at warning labels over the prior two weeks (Response options for both items: 1. Never – 5. All the time).

# End-of-trial survey: Conclusions

- Inserts + PHWLs appear more effective than either alone
  - Consistent with theory and evidence
- Attention mediates effects of labeling (vs control) for insert-only and insert + PHWL conditions
  - Lack of mediation for PHWLs due to less effortful processing of PHWLs than for insert messages (cessation benefits & tips)?
  - Power issues?
- Inconsistent with results from EMA data analyses
  - Retrospective report with attribution (i.e., to labels)
    - Does recall better reflect meaningful integration of message content?
    - “Experienced utility” (momentary reports) vs “Decision utility” (retrospective reports)
  - Systematically varying data collection approaches (e.g., Solomon 4 group design) may be necessary to assess the effects of different measurement approaches

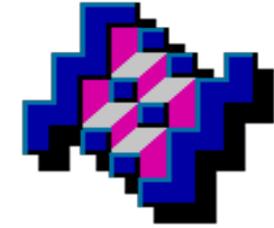




# Thanks!

## Any questions?

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