NYU Langone Health

Department of Population Health

Changing the Default: Comparing the Effectiveness of an Opt-out Approach to an Opt-in Approach for Smoking Cessation Treatment

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Background

- Prevalence of smoking in the VA has decreased from 33% to 11%
- Smoking is still the leading preventable cause of death in the US
- Rates of asking and advising in the VA are high
- Rates of offering medications, counseling and referral also high
  - >93% annually since 2012
- New approaches needed to help people quit

Impetus for these studies

Addiction

SSA SOCIETY FOR THE STUDY OF ADDICTION

FOR DEBATE

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It's time to change the default for tobacco treatment

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ABSTRACT

The World Health Organization estimates that 1 billion people will die from tobacco-related illnesses this century. Most health-care providers, however, fail to treat tobacco dependence. This may be due in part to the treatment 'default'. Guidelines in many countries recommend that health-care providers: (i) ask patients if they are 'ready' to quit using

Use of an opt-out approach

- For most diseases/conditions, we use an opt-out approach
  - High blood pressure, diabetes
- For smoking cessation, we use an opt-in approach
- Behavioral economics suggests framing matters a lot (*default bias*)

Offering vs Providing = It's Optional and Not That Important

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"Are you willing to try to quit now?"

- It's optional and not important for your recovery

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After a nice meal - "Can I help you with those dishes?"

- (= please say no!)
- More effective – just get up and start helping

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"Are you willing to try to quit now?"

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After a nice meal - "Can I help you with those dishes?"

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A physician discovers high blood pressure –

- Are you willing to try to lower your blood pressure now?
- Clinical guidelines – list treatment options and ask Pt to choose

Does an opt-out approach work?

- Richter *et al* – inpatient study in Kansas
  - Increased cessation medications
  - Increased chance of receiving at least one counseling call
  - No effect on abstinence at 6 months
- Selby *et al* – cluster RCT of a cessation decision aid for PCPs in Switzerland and France
  - Increased cessation medications
  - No effect on abstinence at 6 months

Study 1 – Mental health setting

- R34 from NIDA (Rogers/Sherman) – started 9/2018
- Could not get providers to refer smokers in TeleQuit MH
- Could get people to quit smoking in Proactive MH study, but it bypassed MH providers

Specific Aims

1. Estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on the proportion of mental health patients who are screened and treated for tobacco use by their psychiatrist.
2. Assess intervention fidelity, provider perceptions of the Opt-Out System, and barriers and facilitators to implementation of the Opt-Out System.
3. Estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on use of cessation treatment and abstinence among mental health patients who smoke.

Implementation science frameworks

1. Consolidated Framework for Implementation Research
2. Proctor Framework
   - Selection of evidence-based process
   - Development of implementation interventions
   - Measurement of outcomes

Methods

- Setting: VA NY Harbor Healthcare System
- Participants:
  - 21/24 psychiatrists (88% enrollment)
- Turned smoking clinical reminder on for psychiatrists
- All psychiatrists received 1-hour training in tobacco use
  - Adapted from training developed by J. Prochaska

Treatment arms

- Cluster randomized design
- Psychiatrists randomized to

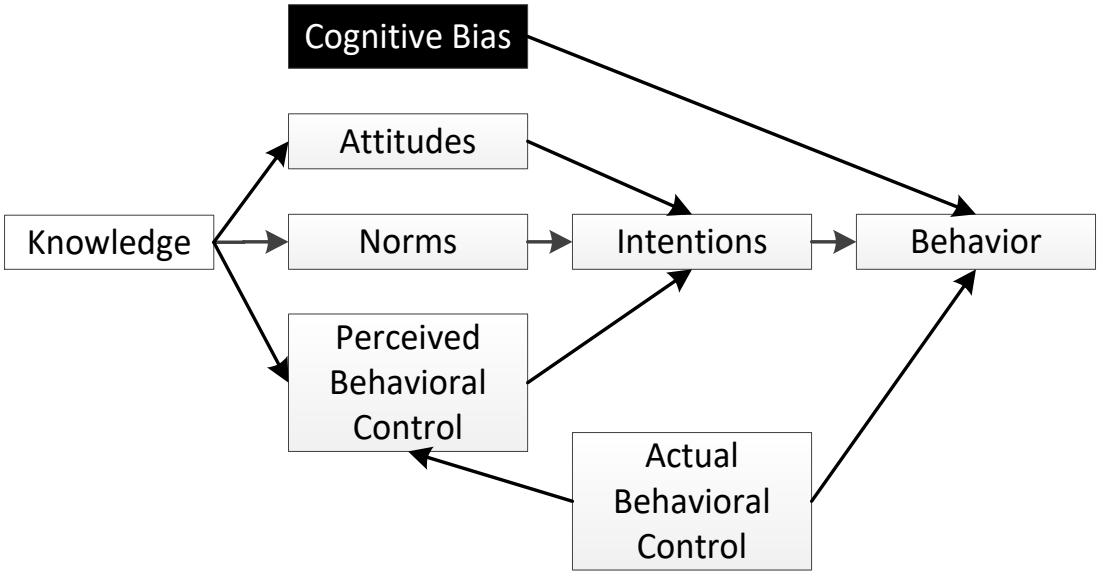
Opt-in arm (UC)

- Encourages referral to smoking counseling and medication order

Opt-out arm

- Generates referral to smoking counseling and NRT order
- Psychiatrist can cancel (opt-out) of the order

Figure 3. Theoretical Framework for the Implementation Strategies



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Implementation Strategy Component	Targeted Barriers to Treating Tobacco
Both Arms: Psychiatrist Training and Academic Detailing	• Lack of provider knowledge about tobacco treatment • Low provider perceived behavioral control in treating patients for smoking and dealing with resistant patients • Negative attitudes and subjective norms toward the treatment of tobacco
Arm 1: Opt-In Clinical Reminder	• Low provider perceived behavioral control in tobacco treatment • Low organizational prioritization (norms) of tobacco treatment
Arm 2: Opt-Out Clinical Reminder	• Cognitive bias to accept the default treatment • Low provider perceived behavioral control in tobacco treatment • Low prioritization (norms) of tobacco treatment • Limited time to screen and treat (actual behavioral control)

Primary outcomes

Assessed via EHR data

1. % of smokers referred to counseling
2. % of smokers prescribed NRT

Secondary Outcomes

(not powered for these, to inform future trial)

1. % of patients making quit attempts by 6 months
2. % of patients reporting 7-day abstinence at 6 months

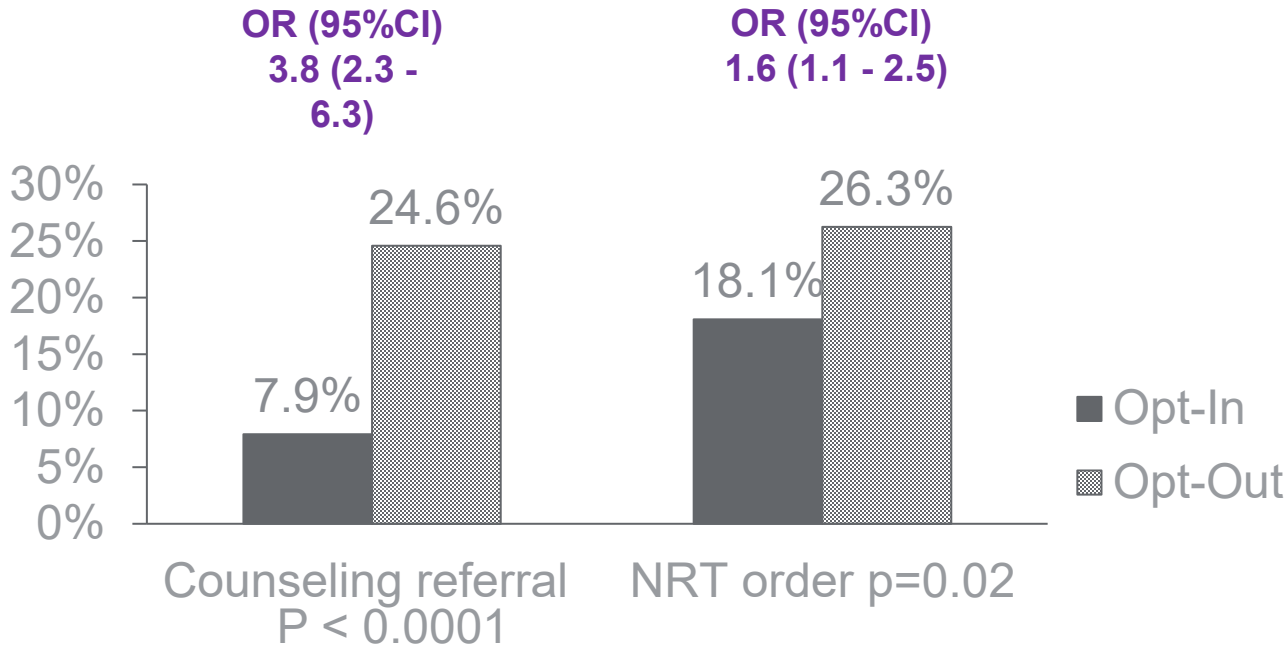
Assessed with post-visit survey

- Enrolled 125 patients within 48 hours of psych. visit
- Telephone F/U survey 6 mo. later (70% response)

Results – Psychiatrist characteristics

- 2 former smokers (9.5%), no current smokers
- Race: 8 White, 1 Black, 5 Asian, 1 other
- Ethnicity: 14 non-Hispanic, 2 Hispanic
- Years in practice: 11.2 (SD 12.4)

Primary outcomes – counseling and medications



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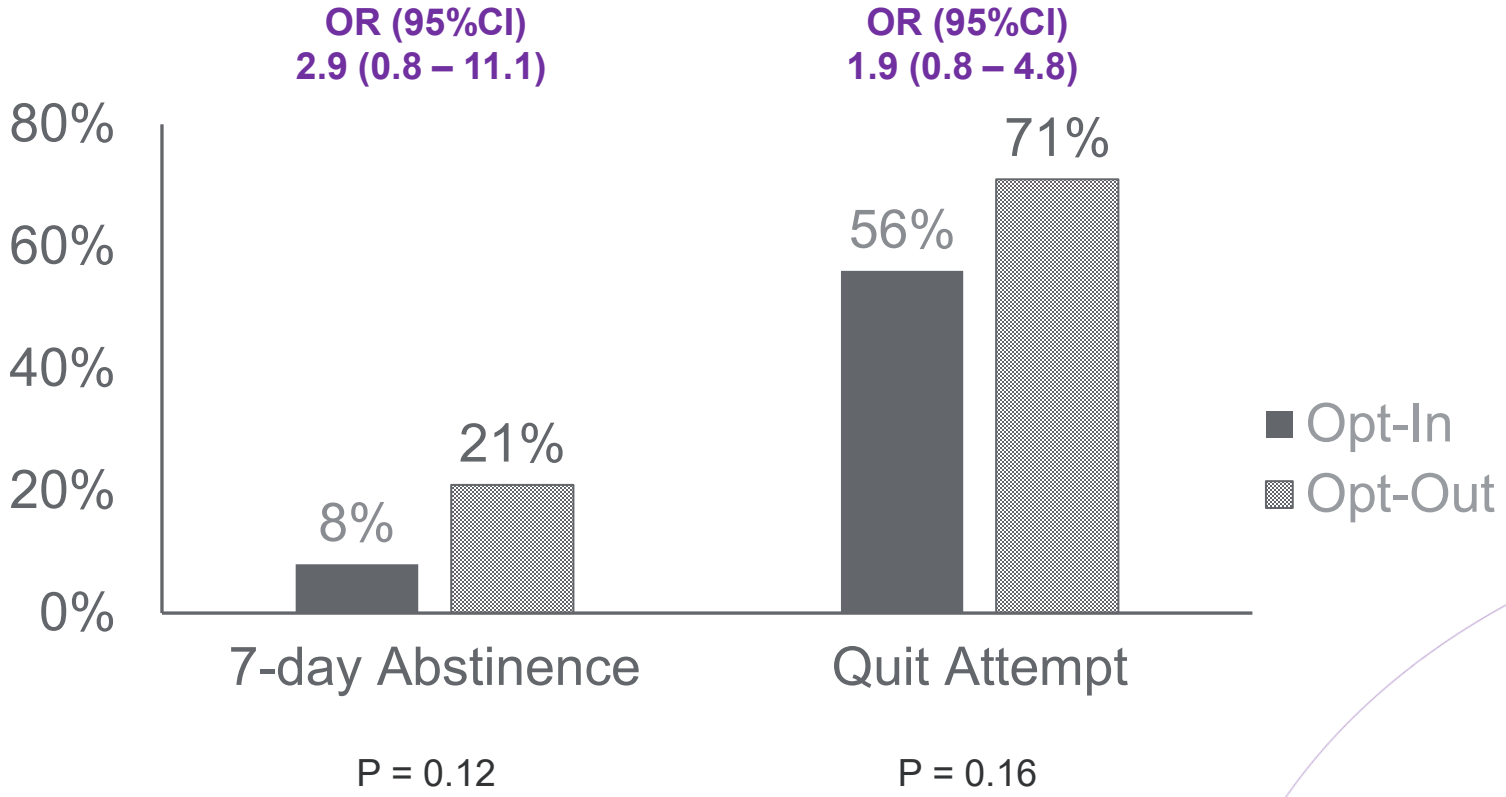
Secondary outcomes – abstinence and quit attempts



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Discussion

- Simple change to health care system
- Preliminary data but effect appears profound
  - Increase in referrals and treatment
  - Trend towards more abstinence
- Plan is to follow-up with multi-site study

Health **E**lectronic **R**ecord, an **O**pt in versus **O**pt out Approach

- Cluster RCT in primary care nurses
- Type 1 hybrid effectiveness/implementation study
- Funded by VA HSR

Study design

- Compared an opt-in vs. opt out approach for smoking cessation treatment among Veterans
- VA nurses were randomized (by team) to:

Opt-in arm

- Encourages referral to Quitline or text messaging
- Patient must **fill out a form** to be referred

Opt-out arm

- Encourages referral to Quitline or text messaging
- Patient is **automatically referred** unless they fill out form to opt-out

HERO

How was data collected?

- Electronic Health Records
- Post-visit survey
- Population Survey

Outcomes

- Referral to treatment
- Engagement with treatment
- Abstinence (smoke free) at the end of the study

Treatment

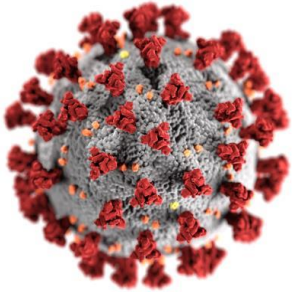
- NYS Quitline
  - One proactive call
  - Unlimited reactive calls
- Text messaging – Agile Health – Kick Butts
  - Not required to set a quit date initially
  - 2 weeks of motivational enhancement messages
  - 6 months of messages after quit date

Study timeline

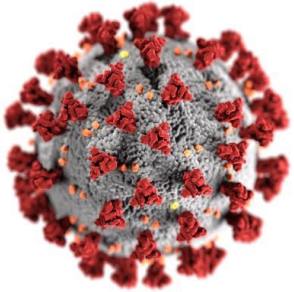
Start intervention

2020

Study timeline



Study timeline

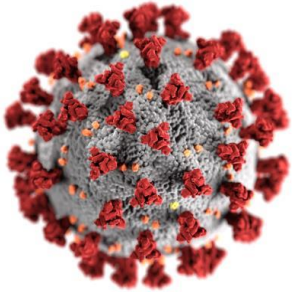


Start intervention

2020

2021

Study timeline



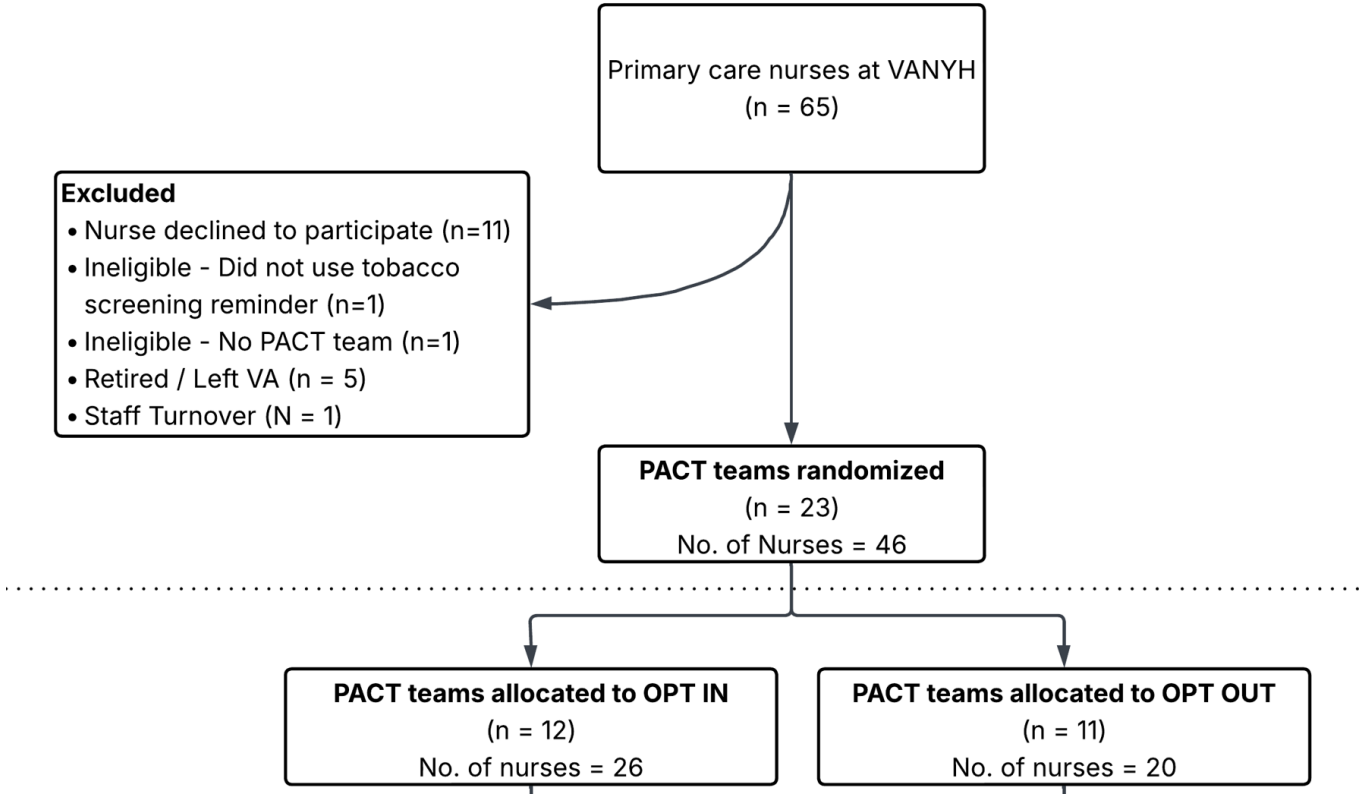
Start intervention

End intervention

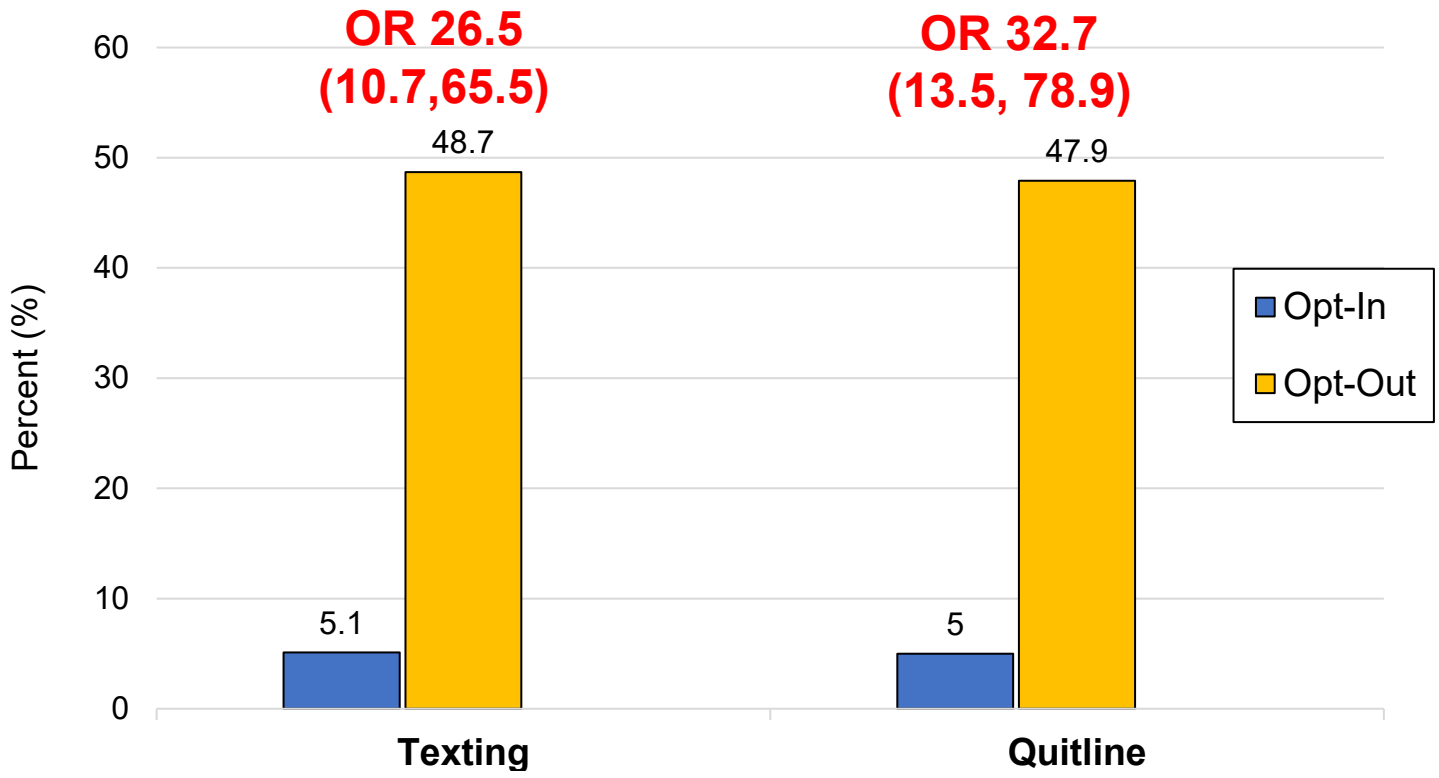
2020 2021 2022 2023

Results

Overview of study enrollment



Referred to treatment



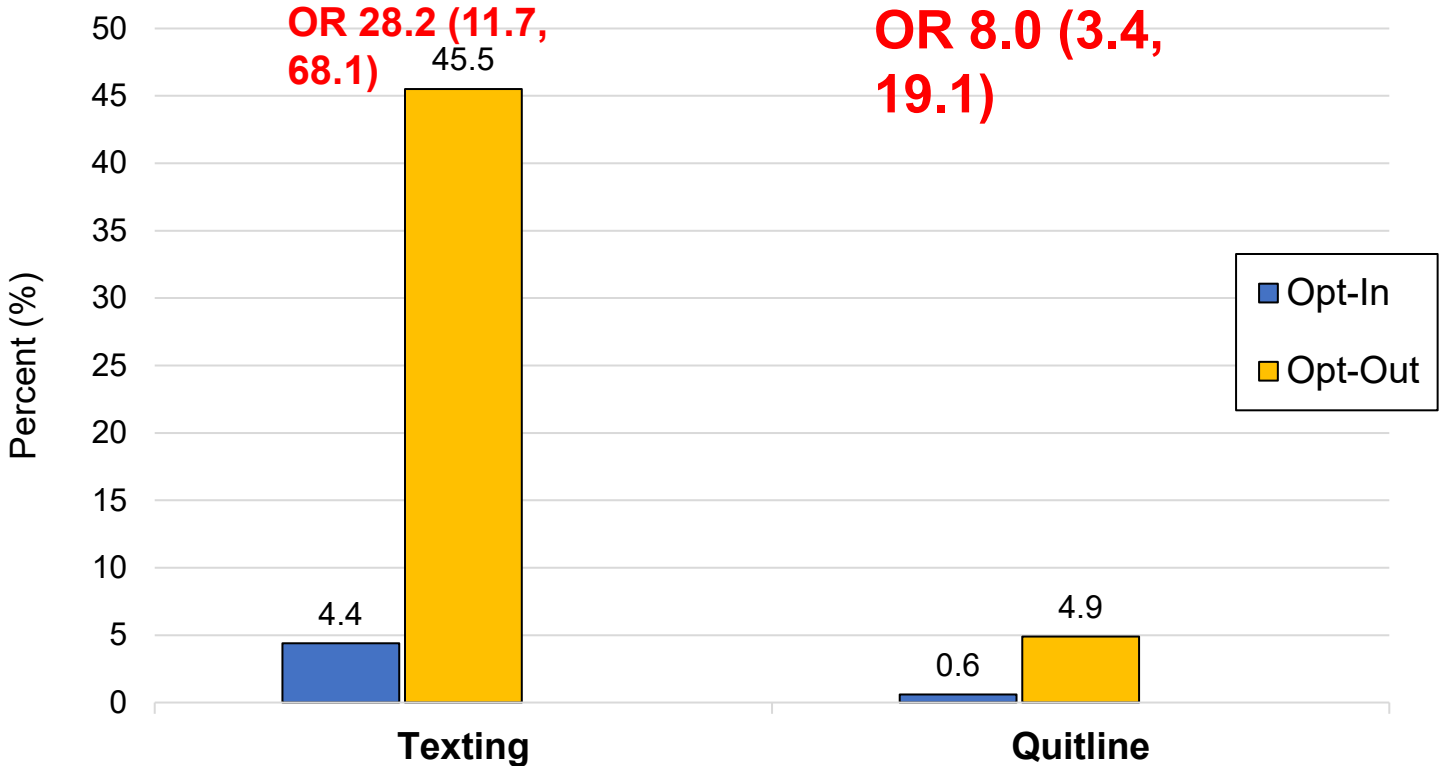
Results summary

Referral ✓

Engagment

Abstinence

Engaged with treatment



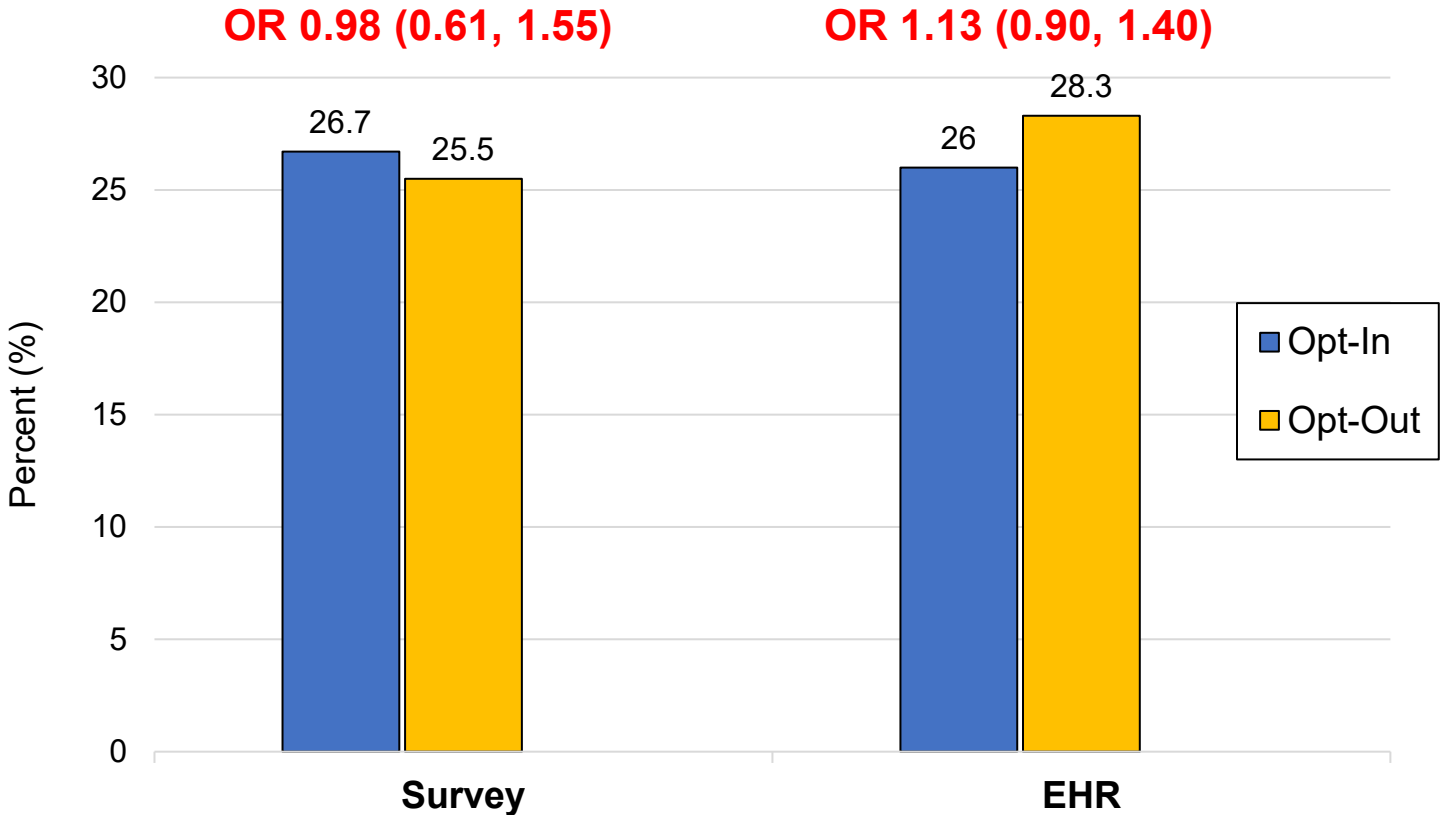
Results summary

Referral ✓

Engagment ✓

Abstinence

Abstinent from smoking



Abstinent from smoking

Outcome	Opt-In Arm N (%)	Opt-Out Arm N (%)	Adjusted OR (95% CI)
Patient Survey	99/385 (25.7%)	63/247 (25.5%)	0.98 (0.61, 1.55)
EHR	244/939 (26.0%)	300/706 (28.3%)	1.13 (0.90, 1.40)

Results summary

Referral ✓

Engagment ✓

Abstinence ✗

Patient perceptions

Post-visit question	*OR (95% CI)*
• RN said goal is to refer all smokers	1.19 (0.58, 2.44)
• I was strongly encouraged to receive a referral	1.33 (0.79, 2.24)
• I felt forced to receive the referral	1.06 (0.69, 1.63)
• How was the overall quality of discussion with RN	0.97 (0.64, 1.47)

Conclusions

- Opt-out approach was
  - Outstanding for text messaging referral and engagement
  - Outstanding for Quitline referral, just OK for engagement
- Opt-out approach did not affect abstinence rates
- No effect on patient perception of visit

So why didn’t it work?

- Opt-out approach works for “low burden” choices
- Intervention only targeted the nurse
- Treatment was low at the opt-out visit – only 15% got meds and 2/3 not the most effective

Limitations

- Single hospital
- VA has extremely high baseline rate of offering tobacco treatment
- Abstinence measured by self-report and by EHR, both of which have limitations

Next step

HERO II resubmitted to VA

- 4 facilities
- Type II hybrid effectiveness/implementation
- Provider will also have an opt-out for meds
- Equity-focused audit and feedback

THANK YOU

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