

***LESSONS LEARNED ABOUT HEALTH  
DISPARITIES AND BIOBEHAVIORAL  
MECHANISMS OF TREATMENT EFFICACY***

***OR***

***SMOKING CESSATION IN PERSONS  
LIVING WITH HIV/AIDS (PLWHA): WHAT  
WORKS?***

***RAY NIAURA, PHD***

# Outline

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- Problem:
  - Smoking risks
  - Does quitting improve health?
  - Smoking prevalence in PLWHA
- Does smoking cessation treatment work?
- Does treatment work for PLWHA?
- Positive Paths & Aurora
- Complexities

# SMOKING CESSATION BENEFITS THE US POPULATION

*The* NEW ENGLAND JOURNAL *of* MEDICINE

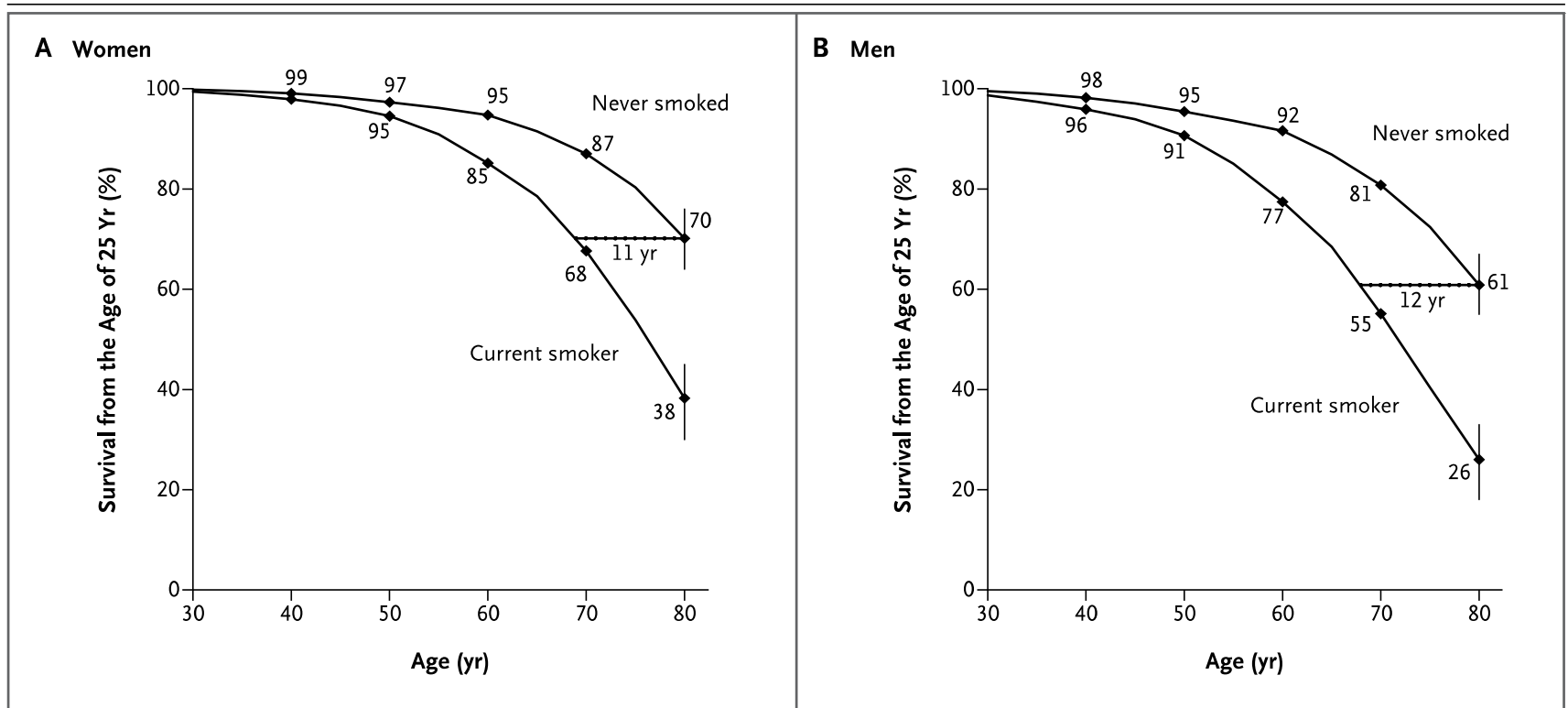
SPECIAL ARTICLE

## 21st-Century Hazards of Smoking and Benefits of Cessation in the United States

Prabhat Jha, M.D., Chinthanie Ramasundarahettige, M.Sc.,  
Victoria Landsman, Ph.D., Brian Rostron, Ph.D., Michael Thun, M.D.,  
Robert N. Anderson, Ph.D., Tim McAfee, M.D., and Richard Peto, F.R.S.

**N Engl J Med 2013;368:341-50.**

# SMOKING CESSATION BENEFITS THE US POPULATION



**Figure 2. Survival Probabilities for Current Smokers and for Those Who Never Smoked among Men and Women 25 to 80 Years of Age.**

The vertical lines at 80 years of age represent the 99% confidence intervals for cumulative survival probabilities, as derived from the standard errors estimated with the use of the jackknife procedure. Survival probabilities have been scaled from the National Health Interview Survey to the U.S. rates of death from all causes at these ages for 2004,<sup>13,16</sup> with adjustment for differences in age, educational level, alcohol consumption, and adiposity (body-mass index).

# SMOKING CESSATION BENEFITS THE US POPULATION

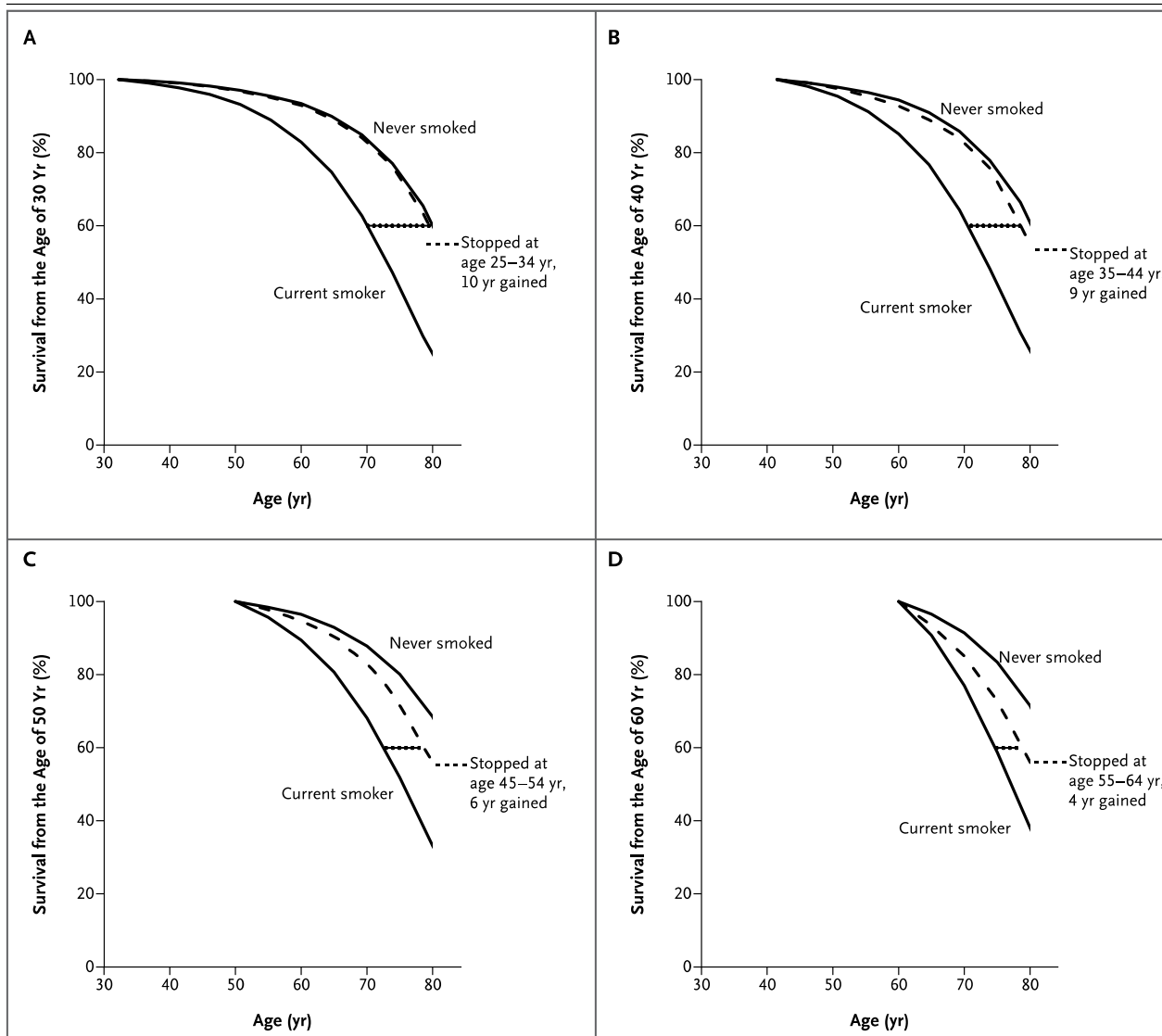
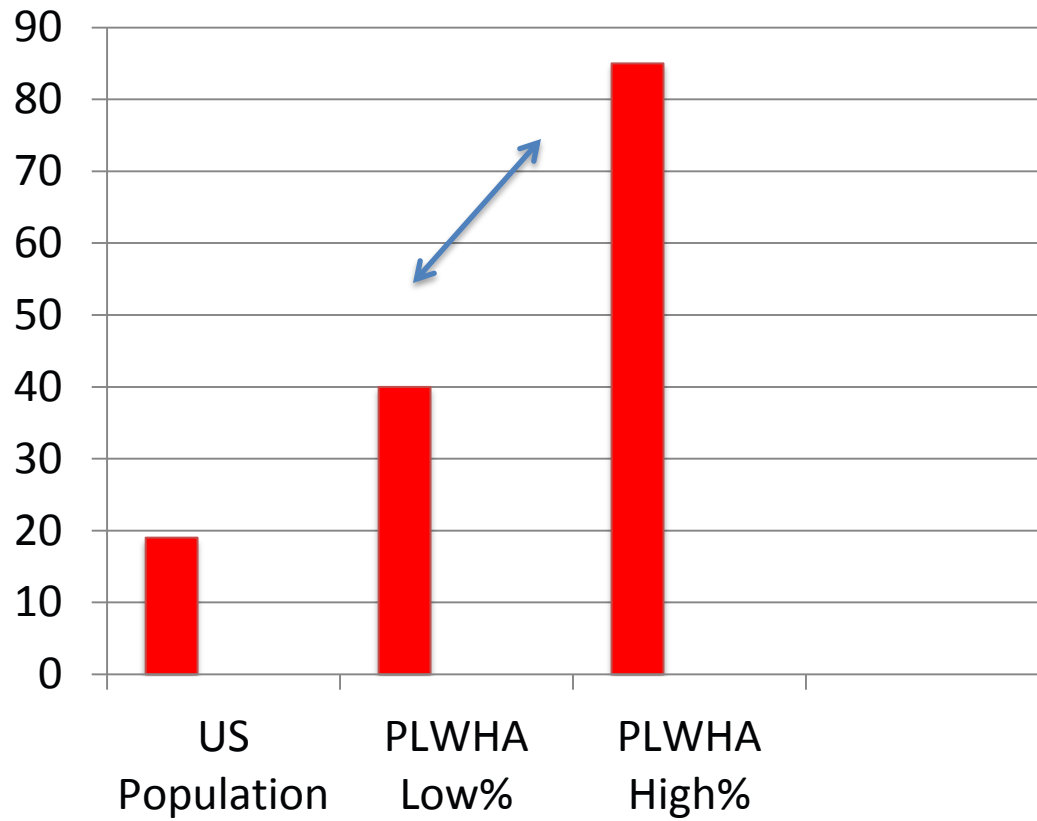


Figure 3. Effect of Smoking Cessation on Survival to 80 Years of Age, According to Age at the Time of Quitting.

# Smoking prevalence in PLWHA



Low and high estimates

# Smoking risks in PLWHA: Smoker vs. Nonsmoker

## Mortality Attributable to Smoking Among HIV-1–Infected Individuals: A Nationwide, Population-Based Cohort Study

Marie Helleberg,<sup>1,7</sup> Shoaib Afzal,<sup>2</sup> Gitte Kronborg,<sup>3</sup> Carsten S. Larsen,<sup>4</sup> Gitte Pedersen,<sup>5</sup> Court Pedersen,<sup>6</sup> Jan Gerstoft,<sup>1</sup> Børge G. Nordestgaard,<sup>2,7</sup> and Niels Obel<sup>1</sup>

<sup>1</sup>Department of Infectious Diseases, Copenhagen University Hospital, Rigshospitalet, Copenhagen; <sup>2</sup>The Copenhagen General Population Study, Copenhagen University Hospital, Herlev; <sup>3</sup>Department of Infectious Diseases, Copenhagen University Hospital, Hvidovre; <sup>4</sup>Department of Infectious Diseases, Aarhus University Hospital, Skejby; <sup>5</sup>Department of Infectious Diseases, Aalborg University Hospital, Aalborg; <sup>6</sup>Department of Infectious Diseases, Odense University Hospital, Odense; and <sup>7</sup>Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

**Background.** We assessed mortality attributable to smoking among patients with human immunodeficiency virus (HIV).

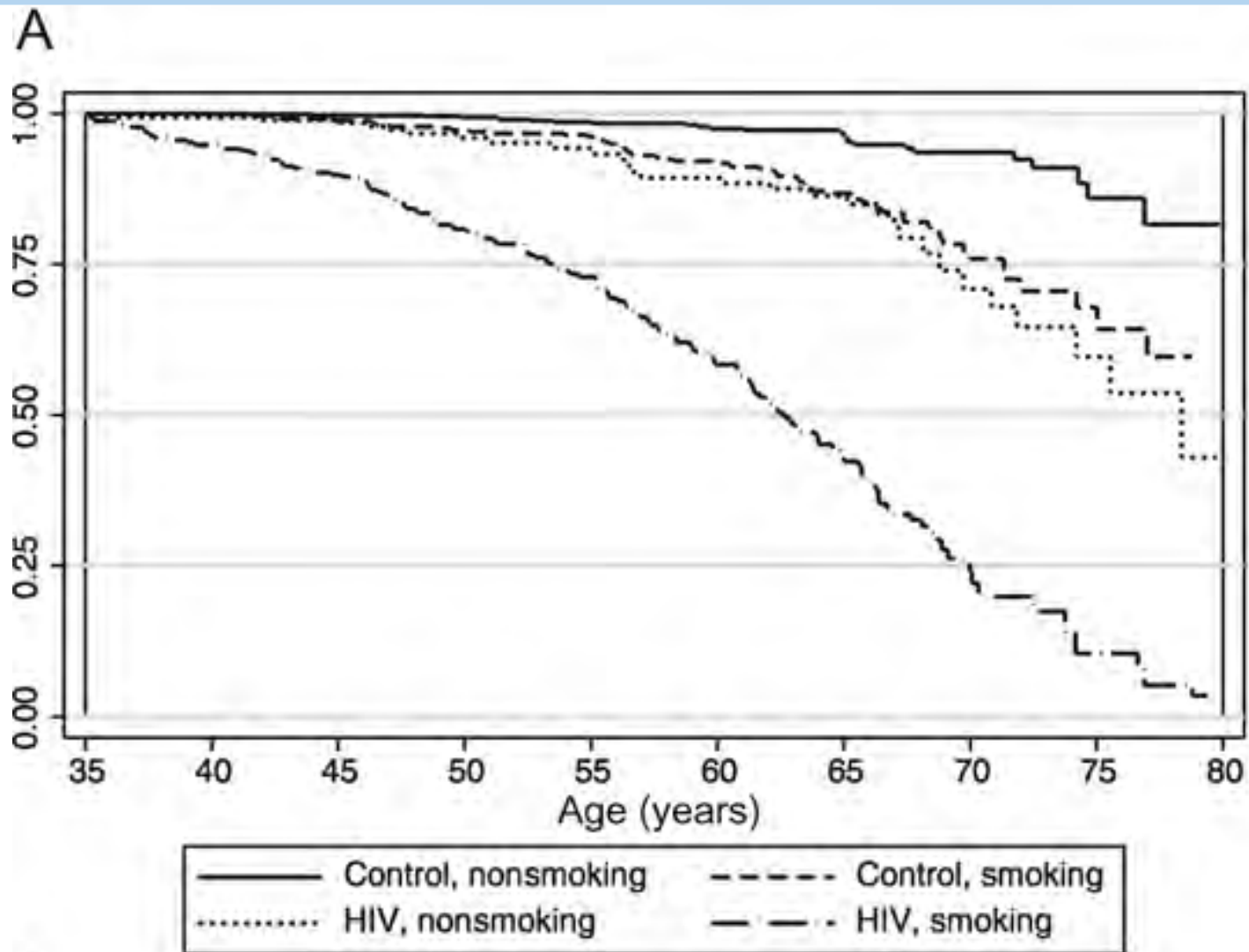
**Methods.** We estimated mortality rates (MRs), mortality rate ratios (MRRs), life expectancies, life-years lost, and population-attributable risk of death associated with smoking and with HIV among current and nonsmoking individuals from a population-based, nationwide HIV cohort and a cohort of matched HIV-negative individuals.

**Results.** A total of 2921 HIV patients and 10 642 controls were followed for 14 281 and 45 122 person-years, respectively. All-cause and non-AIDS-related mortality was substantially increased among smoking compared to nonsmoking HIV patients (MRR, 4.4 [95% confidence interval {CI}, 3.0–6.7] and 5.3 [95% CI, 3.2–8.8], respectively). Excess MR per 1000 person-years among current vs nonsmokers was 17.6 (95% CI, 13.3–21.9) for HIV patients and 4.8 (95% CI, 3.2–6.4) for controls. A 35-year-old HIV patient had a median life expectancy of 62.6 years (95% CI, 59.9–64.6) for smokers and 78.4 years (95% CI, 70.8–84.0) for nonsmokers; the numbers of life-years lost in association with smoking and HIV were 12.3 (95% CI, 8.1–16.4) and 5.1 (95% CI, 1.6–8.5). The population-attributable risk of death associated with smoking was 61.5% among HIV patients and 34.2% among controls.

**Conclusions.** In a setting where HIV care is well organized and antiretroviral therapy is free of charge, HIV-infected smokers lose more life-years to smoking than to HIV. The excess mortality of smokers is tripled and the population-attributable risk of death associated with smoking is doubled among HIV patients compared to the background population.

**Keywords.** HIV; smoking; mortality; population attributable risk; non-AIDS related mortality.

# Smoking risks in PLWHA: Smoker vs. Nonsmoker





# Smoking risks in PLWHA: Smoker vs. Nonsmoker

**Table 3. Number of Life-Years Lost and Population-Attributable Risk of Death Associated With Smoking and With HIV Among Individuals in the Danish HIV Cohort and the Copenhagen General Population Study (Controls)**

Factor	Lost Life-Years (Age 35–80 y) Years (95% CI)	PAR, %
HIV among never smokers		
(never smoking HIV patients vs never smoking controls)	5.1 (4.4–5.8)	0.3
Smoking among controls		
(smoking controls vs never smoking controls)	3.6 (3.1–4.0)	34.4
Smoking among HIV patients		
(smoking HIV patients vs never smoking HIV patients)	12.3 (11.5–13.0)	61.5

Abbreviations: CI, confidence interval; HIV, human immunodeficiency virus; PAR, population-attributable risk.

# Smoking risks in PLWHA: Current, former, never

## Smoking-Related Health Risks Among Persons With HIV in the Strategies for Management of Antiretroviral Therapy Clinical Trial

Alan R. Lifson, MD, MPH, Jacqueline Neuhaus, MS, Jose Ramon Arribas, MD, Mary van den Berg-Wolf, MD, Ann M. Labriola, MD, Timothy R.H. Read, MBBS, for the INSIGHT SMART Study Group

(Am J Public Health. 2010;100: 1896–1903. doi:10.2105/AJPH.2009.188664)

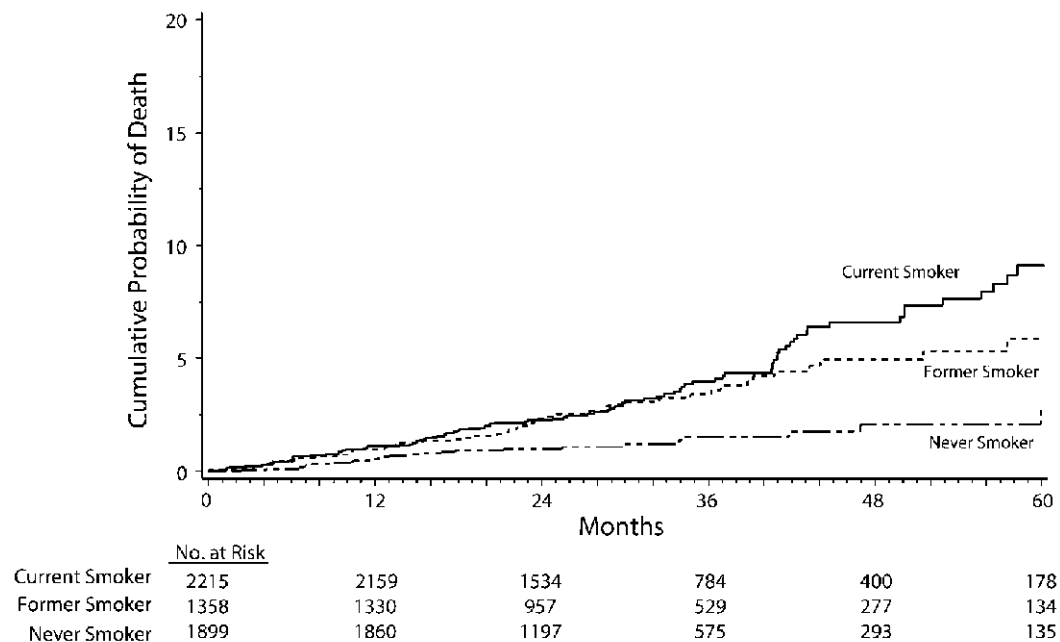


FIGURE 1—Cumulative probability of death (all-cause mortality) by months of follow-up, among current, former, and never smokers: Strategies for Management of Antiretroviral Therapy clinical trial, 2002–2006.

# Smoking risks in PLWHA: Current, former, never

## Smoking-Related Health Risks Among Persons With HIV in the Strategies for Management of Antiretroviral Therapy Clinical Trial

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(Am J Public Health. 2010;100: 1896–1903. doi:10.2105/AJPH.2009.188664)

TABLE 2—All-Cause Mortality and Specific Clinical Events by Smoking Status at Baseline: Strategies for Management of Antiretroviral Therapy Clinical Trial, 2002–2006

Clinical Event	Never Smokers		Former Smokers		Current Smokers	
	Nb.	Rate <sup>a</sup> (95%CI)	Nb.	Rate <sup>a</sup> (95%CI)	Nb.	Rate <sup>a</sup> (95%CI)
All-cause mortality	25	0.5 (0.3, 0.7)	47	1.2 (0.9, 1.5)	95	1.5 (1.2, 1.8)
AIDS-related disease	43	0.9 (0.6, 1.1)	34	0.9 (0.6, 1.2)	86	1.4 (1.1, 1.7)

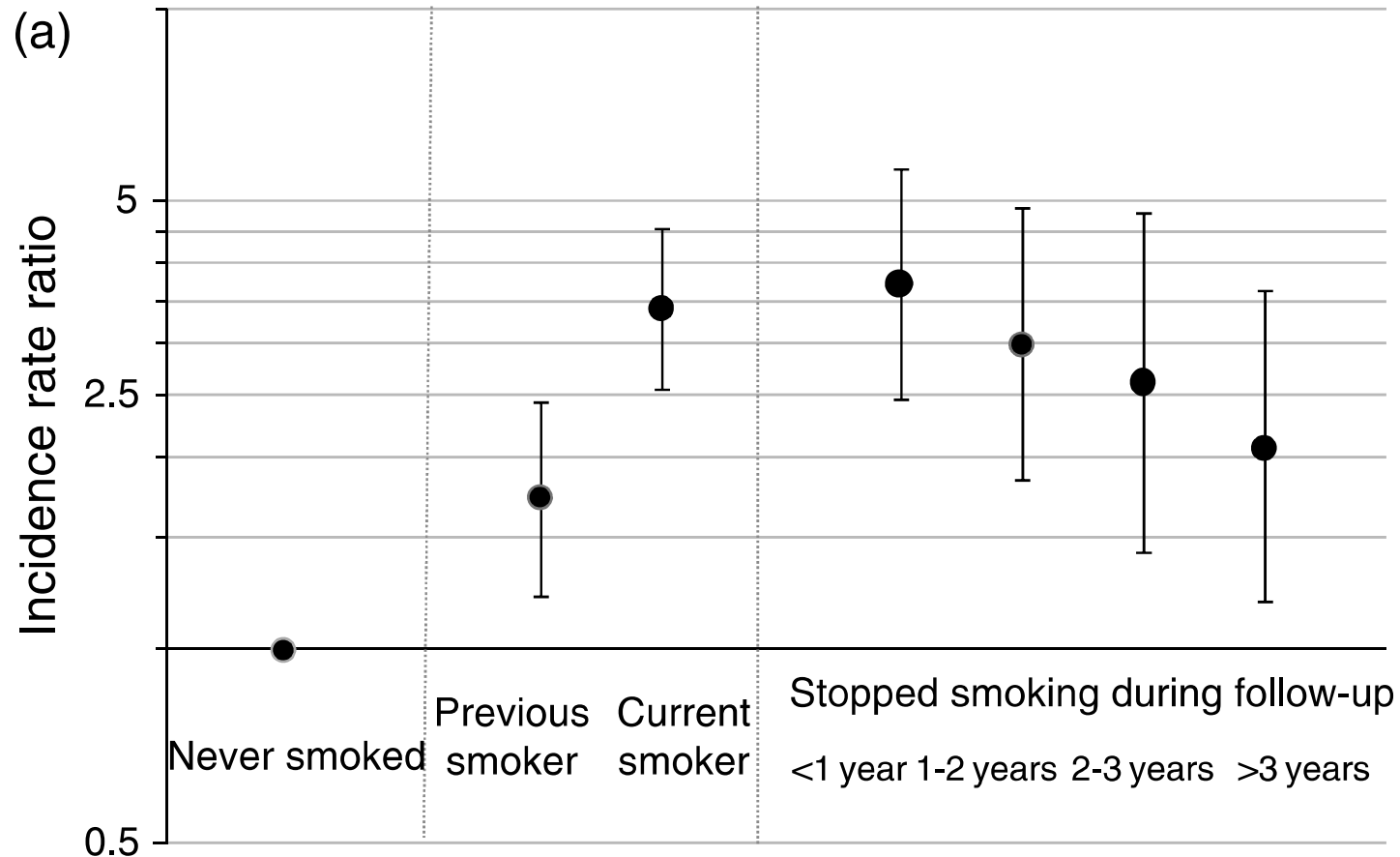
## ORIGINAL RESEARCH

### Rates of cardiovascular disease following smoking cessation in patients with HIV infection: results from the D:A:D study\*

K Petoumenos,<sup>1</sup> S Worm,<sup>2</sup> P Reiss,<sup>3</sup> S de Wit,<sup>4</sup> A d'Arminio Monforte,<sup>5</sup> C Sabin,<sup>6</sup> N Friis-Møller,<sup>2</sup> R Weber,<sup>7</sup> P Mercie,<sup>8</sup> C Pradier,<sup>9</sup> W El-Sadr,<sup>10</sup> O Kirk,<sup>2</sup> J Lundgren<sup>2</sup> and MG Law<sup>1</sup> for the D:A:D Study Group<sup>†</sup>

<sup>1</sup>AHOD, National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, Sydney, NSW, Australia, <sup>2</sup>Copenhagen HIV Programme (CHIP), Copenhagen University, Copenhagen, Denmark, <sup>3</sup>ATHENA, HIV Monitoring Foundation, Academic Medical Center, Amsterdam, The Netherlands, <sup>4</sup>Saint-Pierre Cohort, CHU Saint-Pierre Hospital, Brussels, Belgium, <sup>5</sup>Hospital San Paolo, University of Milan, Milan, Italy, <sup>6</sup>UCL Medical School, Royal Free Campus, London, UK, <sup>7</sup>Division of Infectious Diseases, University Hospital, Zurich, Switzerland, <sup>8</sup>INSERM E0338 & U593, ISPED, Université Victor Segalen Bordeaux 2, Bordeaux, France, <sup>9</sup>Nice Cohort, CHU Nice Hôpital de L'Archet, Nice, France and <sup>10</sup>Harlem Hospital and Columbia University, New York, NY, USA

# DOES QUITTING SMOKING IMPROVE HEALTH IN PLWHA?



# SMOKING CESSATION BENEFITS IN PLWHA: CAUSES AND EFFECTS?

Can we be sure that quitting smoking improves health and survival in PLWHA (independently or because it slows progression of HIV/AIDS) ?

Epi studies cannot easily rule out selection effects: Quitting is not random (unknown variables).

“To find out what happens when you change something, it is necessary to change it.”

*Box, G. E. P., Hunter, W. G., and Hunter, J. S. (1978). Statistics for Experimenters. New York: Wiley.*

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# Smoking cessation: what works?

## SMOKING CESSATION: WHAT WORKS? BEHAVIORAL THERAPIES

**Table 6.18. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for various types of counseling and behavioral therapies (n = 64 studies)<sup>a</sup>**

Type of counseling and behavioral therapy	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No counseling/behavioral therapy	35	1.0	11.2
Relaxation/breathing	31	1.0 (0.7–1.3)	10.8 (7.9–13.8)
Contingency contracting	22	1.0 (0.7–1.4)	11.2 (7.8–14.6)
Weight/diet	19	1.0 (0.8–1.3)	11.2 (8.5–14.0)
Cigarette fading	25	1.1 (0.8–1.5)	11.8 (8.4–15.3)
Negative affect	8	1.2 (0.8–1.9)	13.6 (8.7–18.5)
Intratreatment social support	50	1.3 (1.1–1.6)	14.4 (12.3–16.5)
Extratreatment social support	19	1.5 (1.1–2.1)	16.2 (11.8–20.6)
Practical counseling (general problem-solving/skills training)	104	1.5 (1.3–1.8)	16.2 (14.0–18.5)
Other aversive smoking	19	1.7 (1.04–2.8)	17.7 (11.2–24.9)
Rapid smoking	19	2.0 (1.1–3.5)	19.9 (11.2–29.0)



## SMOKING CESSATION: WHAT WORKS? PHARMACOTHERAPIES

**Table 2** Estimated effect sizes and abstinence rates at five months (or longer) after the quit day of FDA-approved medications relative to placebo<sup>a</sup>

Medication	Number of arms	Estimated odds ratio (95% CI)	Estimated abstinence rate (95% CI)
Placebo	80	1.0	13.8
<b>Single agents</b>			
Varenicline (2 mg/day)	5	3.1 (2.5–3.8)	33.2 (28.9–37.8)
Nicotine nasal spray	4	2.3 (1.7–3.0)	26.7 (21.5–32.7)
Long-term nicotine gum (> 14 weeks)	6	2.2 (1.5–3.2)	26.1 (19.7–33.6)
Nicotine inhaler	6	2.1 (1.5–2.9)	24.8 (19.1–31.6)
Bupropion SR	26	2.0 (1.8–2.2)	24.2 (22.2–26.4)
Nicotine patch (6–14 weeks)	32	1.9 (1.7–2.2)	23.4 (21.3–25.8)
Nicotine patch (> 14 weeks)	10	1.9 (1.7–2.3)	23.7 (21.0–26.6)
Nicotine gum (6–14 weeks)	15	1.5 (1.2–1.7)	19.0 (16.5–21.9)
<b>Combination therapies</b>			
Nicotine patch (> 14 weeks) + nicotine gum or spray	3	3.6 (2.5–5.2)	36.5 (28.6–45.3)
Nicotine patch + bupropion SR	3	2.5 (1.9–3.4)	28.9 (23.5–35.1)
Nicotine patch + inhaler	2	2.2 (1.3–3.6)	25.8 (17.4–36.5)

<sup>a</sup>Meta-analysis results from the Fiore et al. (2008) Public Health Service Clinical Practice Guideline. Eighty-three studies generated the estimates in the entire analysis, which contained some agents not reported on here (e.g., nortriptyline, clonidine).

## SMOKING CESSATION: WHAT WORKS? PHARMACOTHERAPIES

Drug	Comparison	# Trials	N	RR (95% CI)
NRT	Placebo/no treatment	111	40,000	1.58 (1.50-1.66)
Varenicline (Chantix)	Placebo	10	4,443	2.13 (2.01-2.66)
Bupropion (Zyban)	Placebo/no treatment	36	11,140	1.69 (1.53-1.85)
Varenicline	Bupropion	3	1,622	1.52 (1.22-1.88)

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## **SMOKING CESSATION: WHAT WORKS FOR PLWHA?**

**Table 1. Smoking cessation intervention trials for HIV+ smokers**

<b>Author (year)</b>	<b>Design</b>	<b>Interventions</b>	<b>N</b>	<b>Follow-up</b>	<b>Outcome- quit</b>
<b>Cui (2011)</b>	NR	<u>Varenicline</u>	N=36	3 mo ( <u>bcv</u> )	15/36 (42%)
<b>Elzi (2006)</b>	NR	Counseling + NRT;	N=34	12 mo ( <u>sr</u> )	13/24 (38%)
<b>Ferketich (2013)</b>	NR	No tx control NRT <u>Varenicline</u>	N=383 N=228	3 mo ( <u>bcv</u> )	27/383 (7%) OR: 2.75 V>NRT
<b>Humfleet (2013)</b>	R	Counseling + NRT; Internet + NRT; Self-help + NRT;	N=209	12 mo ( <u>bcv</u> )	14/69(20.4%) 15/58(25.6%) 14/73(19.7%)
<b>Ingersoll (2009)</b>	R	NRT + self-help; NRT + MOT	N=18 N=22	3 mo ( <u>bcv</u> )	9/40 (22%) – overall, ns group difference
<b>Lloyd-Richardson (2009)</b>	R	NRT + MOT; NRT + Standard care	N=232 N=212	6 mo ( <u>bcv</u> )	21/232 (9%) 21/212 (10%)
<b>Moadel (2012)</b>	R	Group treatment; Standard care	N=73 N=72	3 mo ( <u>bcv</u> )	14/73 (19.2%) 7/72 (9.7%)
<b>Pedro-Clotet (2006)</b>	NR	Bupropion	N=21	12 mo ( <u>sr</u> )	8/21 (38%)
<b>Tornero (2009)</b>	NR	<u>Varenicline</u>	N=22	6 mo ( <u>bcv</u> )	5/21 (24%)
<b>Vidrine (2011)</b>	R	Cell phone counseling; Standard care	N=236 N=238	3 mo ( <u>bcv</u> )	21/236 (8.9%) 7/238 (2.9%)

**NR: nonrandomized; R: randomized; bcv: biochemical verification; sr: self-report; MOT: motivational intervention;**

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## SMOKING CESSATION: WHAT WORKS FOR PLWHA?

- Not many studies
- NRT + ↑ Behavioral Tx  
**NOT** > NRT + ↓ Behavioral Tx
- Group or Cellphone Counseling > Standard Care

## Motivation and patch treatment for HIV+ smokers: a randomized controlled trial

**Elizabeth E. Lloyd-Richardson<sup>1,2</sup>, Cassandra A. Stanton<sup>3</sup>, George D. Papandonatos<sup>4</sup>,  
William G. Shadel<sup>5</sup>, Michael Stein<sup>3</sup>, Karen Tashima<sup>6</sup>, Timothy Flanigan<sup>6</sup>, Kathleen Morrow<sup>1</sup>,  
Charles Neighbors<sup>7</sup> & Raymond Niaura<sup>3</sup>**

Department of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Centers for Behavioral and Preventive Medicine, The Miriam Hospital, Providence, RI, USA,<sup>1</sup> Department of Psychology, University of Massachusetts Dartmouth, North Dartmouth, MA, USA,<sup>2</sup> The Warren Alpert Medical School of Brown University, Transdisciplinary Research Group, Butler Hospital, Providence, RI, USA,<sup>3</sup> Center for Statistical Sciences, Brown University, Providence, RI, USA,<sup>4</sup> RAND Corporation, Pittsburgh, Pennsylvania, PA, USA,<sup>5</sup> The Miriam Hospital, The Warren Alpert Medical School of Brown University, Providence, RI, USA<sup>6</sup> and Columbia University, Center on Addiction and Substance Abuse, New York, NY, USA<sup>7</sup>

*Lloyd-Richardson EE, Stanton CA, Papandonatos GD, Shadel WG, Stein M, Tashima K, Flanigan T, Morrow K, Neighbors C, Niaura R. Motivation and patch treatment for HIV+ smokers: a randomized controlled trial. Addiction 2009 Nov;104(11):1891-900.*



## Positive Paths:

- A Motivational Intervention for Smoking Cessation among HIV+ Smokers
- RCT designed to assess whether adding a motivational enhancement intervention to nicotine replacement therapy (NRT) would increase cessation compared to NRT + usual care

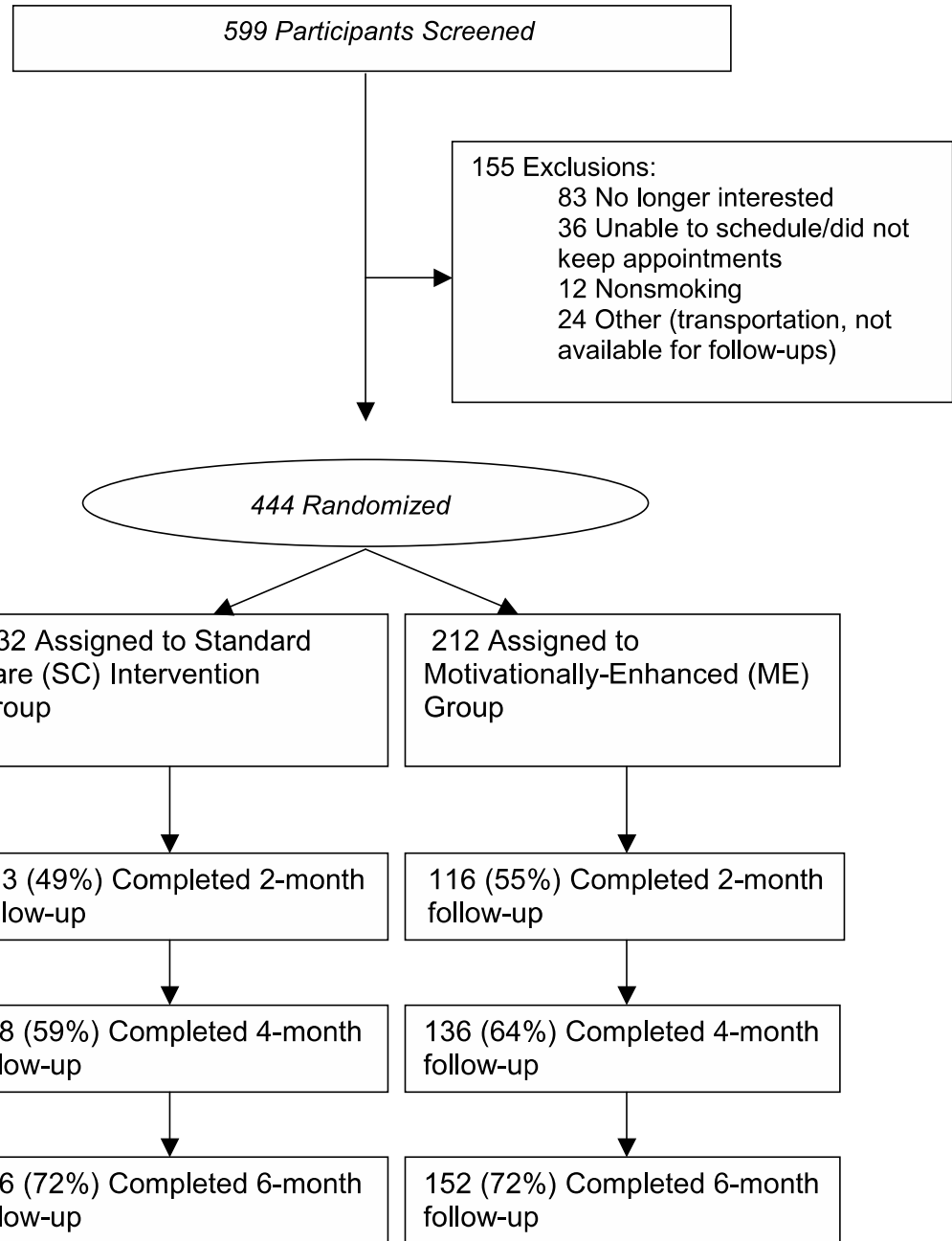
## Baseline Characteristics (N=444)

- Mean age 42 years;
- 63% male;
- 52% European American, 16% Hispanic, 18% African American;
- 78% unemployed;
- 46% single
- Cigarettes per day: 18
- Previous patch use: 68%
- FTND: 5.91

# Intervention

- **Standard of Care:** Two brief sessions (3-4 mins) including assessment of quitting plans, self-help quitting materials
- **Motivational Enhancement:** 4 intervention sessions (30mins: feedback with CO measurements, personal responsibility for change, goal setting, empathy and self efficacy reinforcement) plus quit day phone call
- *All study subjects:* brief cessation advice from their physician and 8 weeks of nicotine patches if they set a quit date

## Study Design and Flow



## Two interventions

# Treatment Outcome

**Abstinence rates (%) using Intent-to-Treat (ITT) Analyses:  
2-month, 4-month, and 6-month differences by treatment arm.**

ITT Abstinence Rates (%)	Time		
	2m	4m	6m
All	12	10	9
Motivation	12	9	9
Standard	13	10	10
p-value	0.72	0.76	0.76

- Note: Abstinence based on 24-hour biochemical verification of self-reported 7-day quit status.
- Column p-values test between-condition differences at each time point.

# Treatment Outcome: Response Prediction

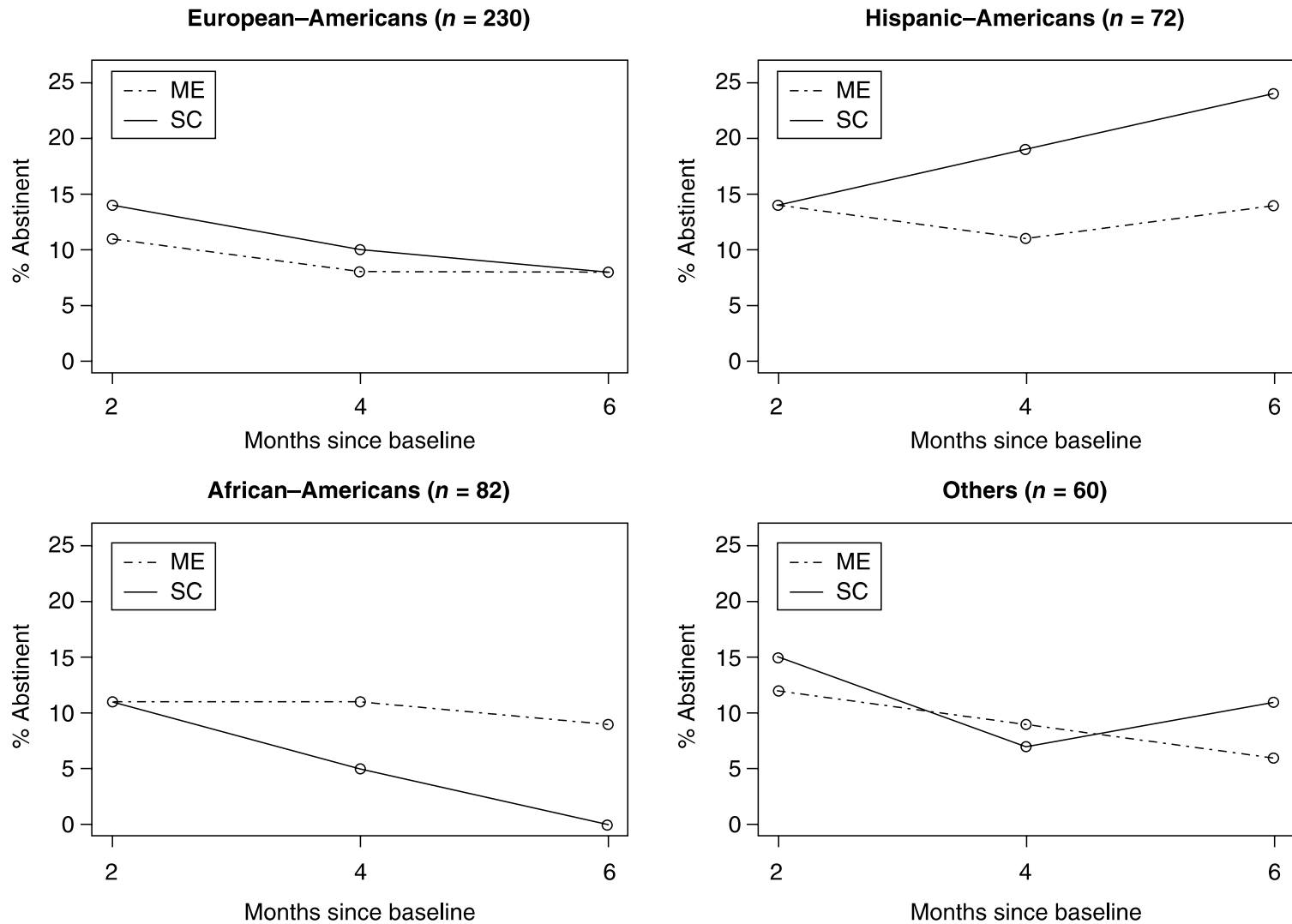
TABLE 2. Predictors of 6-month Smoking Abstinence Excluding Change in Mediators ( $N = 412$ ).

Adjusted Odds Ratios	Value	LCL	UCL	<i>p</i>
Intercept <sup>a</sup>	0.08	0.05	0.14	< .000
Hispanic American versus European American	2.84	1.27	6.34	.010
African American versus European American	0.13	0.02	1.01	.051
Other versus European-American	0.99	0.34	2.90	.990
Baseline self-efficacy	1.50	1.04	2.17	.029
Baseline decisional Balance	0.88	0.60	1.28	.500
NRT-related Contacts	1.35	1.03	1.76	.028

*Note.* LCL = 95% lower confidence limit; UCL = 95% upper confidence limit; NRT = nicotine replacement therapy.

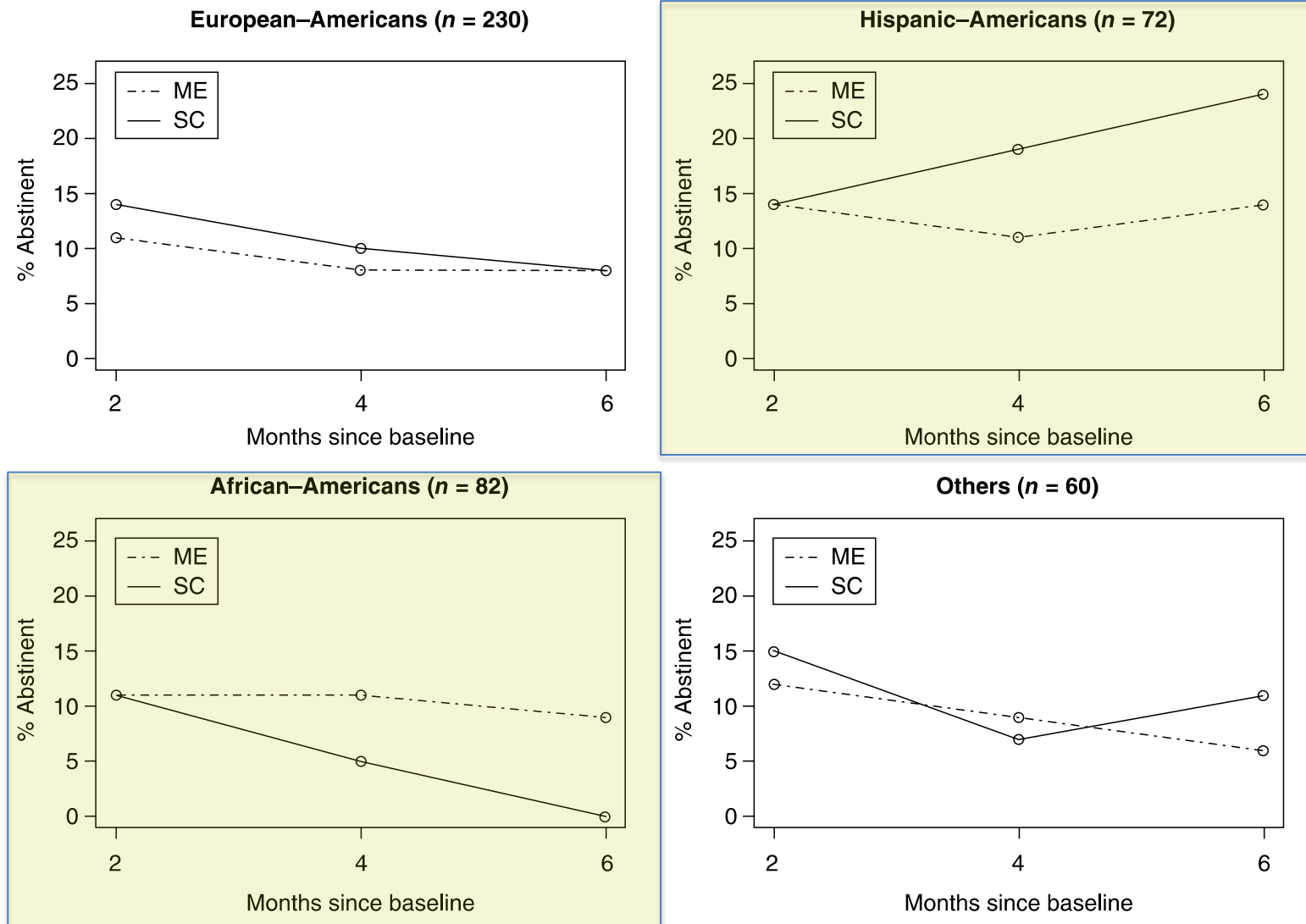
<sup>a</sup>Intercept gives the baseline odds for European Americans.

# Treatment Outcome: Response Prediction



**Figure 2** Intent-to-treat (ITT) quit rates over 2-month, 4-month and 6-month follow-up by study condition and race/ethnic group. ME: motivationally enhanced treatment; SC: standard care treatment

# Treatment Outcome: Response Prediction



**Figure 2** Intent-to-treat (ITT) quit rates over 2-month, 4-month and 6-month follow-up by study condition and race/ethnic group. ME: motivationally enhanced treatment; SC: standard care treatment



## Treatment effects: Conclusions

- 73% of participants set a quit date; 68% used the patch.
- No treatment group differences.
- *Failure* to use NRT predicted smoking at six-month follow-up.
- Significant differences in quit rates by race: Hispanic-Americans receiving SC more likely to be quit at six-months than ME.
- No African-American participants in SC remained quit at 6-month follow-up.

## Treatment effects: Conclusions

- Brief and frequent contacts focused on NRT as effective at improving cessation outcomes compared to a time-intensive motivational counseling approach.
- Are culturally-sensitive interventions that target key psychological measures and increase access and compliance with NRT needed to support smoking cessation efforts among PLWHA?

# Treatment Outcome: Mediation

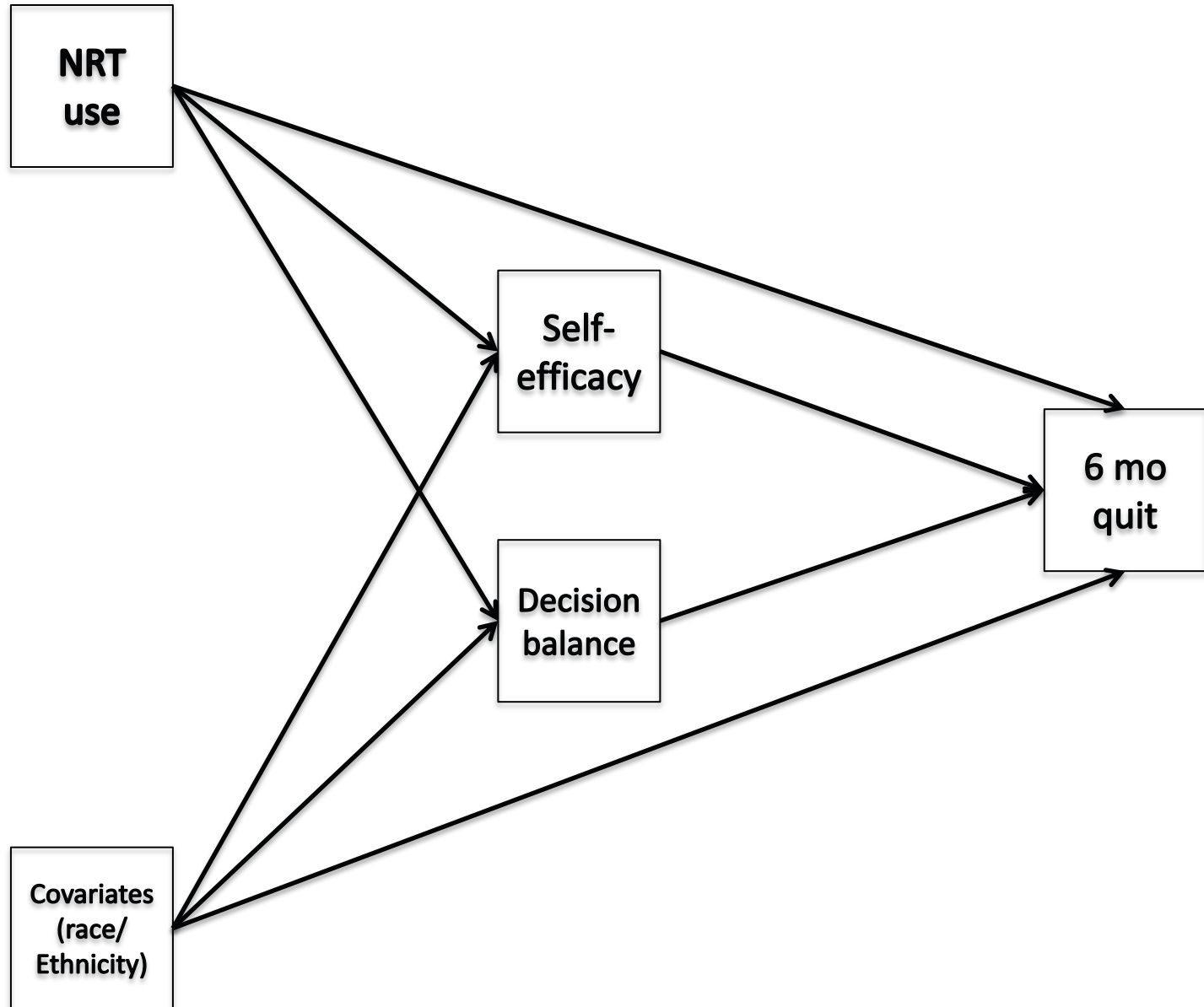
AIDS Education and Prevention, 21, Supplement A, 65–80, 2009

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## MEDIATORS OF THE RELATIONSHIP BETWEEN NICOTINE REPLACEMENT THERAPY AND SMOKING ABSTINENCE AMONG PEOPLE LIVING WITH HIV/AIDS

Cassandra A. Stanton, Elizabeth E. Lloyd-Richardson,  
George D. Papandonatos, Marcel A. de Dios, and Raymond Niaura

## Treatment Outcome: Multiple Mediation Model



# Treatment Outcome: Mediation Predictors of Change in Self-efficacy

TABLE 3. Predictors of 6-Month Change in Self-Efficacy ( $N = 412$ )

Regression Coefficient	Value	LCL	UCL	<i>p</i>
Intercept <sup>a</sup>	0.49	0.31	0.66	< .001
Hispanic American versus European American	0.35	-0.01	0.71	.058
African American versus European American	0.35	0.01	0.69	.045
Other versus European American	0.02	-0.38	0.42	.933
Baseline self-efficacy	-0.26	-0.40	-0.13	.001
Baseline decisional balance	0.05	-0.08	0.19	.428
NRT-related contacts	0.19	0.10	0.28	< .001

*Note.* LCL = 95% lower confidence limit; UCL = 95% upper confidence limit; NRT = nicotine replacement therapy.

<sup>a</sup>Intercept gives the baseline odds for European Americans.

# Treatment Outcome: Mediation

## Predictors of Change in Decisional Balance

TABLE 4. Predictors of 6-month Change in Decisional Balance ( $N = 412$ )

Regression Coefficient	Value	LCL	UCL	<i>p</i>
Intercept <sup>a</sup>	-0.03	-0.16	0.09	.592
Hispanic American versus European American	0.09	-0.16	0.35	.474
African American versus European American	0.01	-0.23	0.26	.924
Other versus European American	-0.22	-0.51	0.06	.131
Baseline self-efficacy	0.03	0.06	0.12	.539
Baseline decisional balance	-0.61	-0.70	-0.53	< .001
NRT-related contacts	0.08	0.01	0.15	.017

*Note.* LCL = 95% Lower Confidence Limit; UCL = 95% Upper Confidence Limit. NRT = nicotine replacement therapy. <sup>a</sup>Intercept is the baseline odds for European Americans.

# Treatment Outcome: Mediation

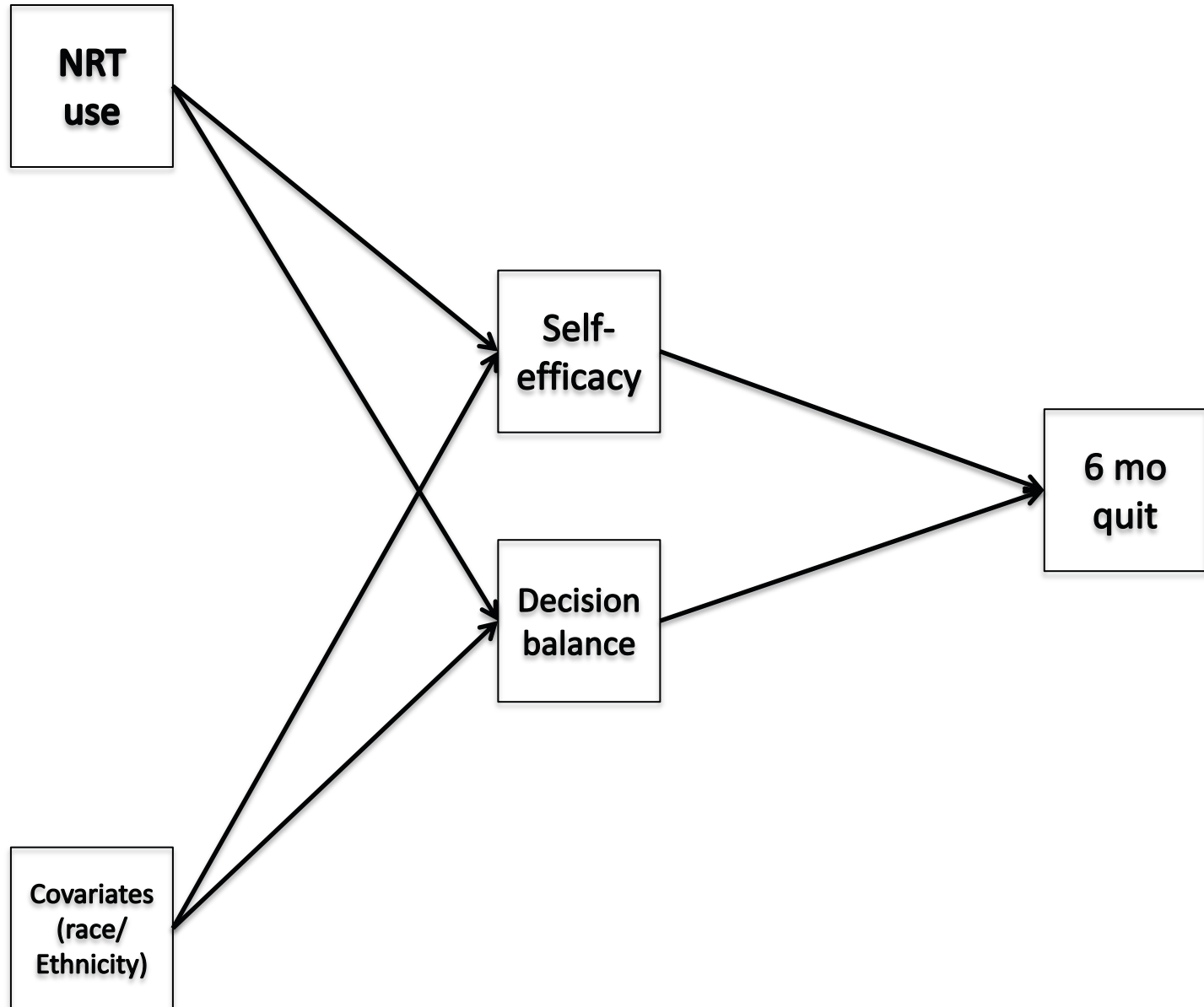
## Change Predictors of Smoking Outcome

TABLE 5. Predictors of 6-month Smoking Abstinence Including Change in Mediators (N = 412).

Adjusted Odds Ratios	Value	LCL	UCL	p
Intercept <sup>a</sup>	0.01	0.00	0.04	< .000
Hispanic American versus European American	0.76	0.15	3.89	.743
African American versus European American	0.11	0.00	5.98	.275
Other versus European American	0.39	0.06	2.69	.342
Baseline self-efficacy	4.96	2.25	10.93	.001
Change in self-efficacy	9.77	4.68	20.37	< .001
Change in self-efficacy				
African-American versus European American	0.01	0.00	0.21	.003
Baseline decisional balance	1.30	0.63	2.66	.477
Change in decisional balance	2.80	1.41	5.55	.003
NRT-related contacts	0.84	0.49	1.46	.541

*Note.* Intercept = Baseline Odds for European-Americans; LCL = 95% Lower Confidence Limit; UCL = 95% Upper Confidence Limit; NRT = nicotine replacement therapy. <sup>a</sup>Intercept is the baseline odds for European Americans.

## Treatment Outcome: Multiple Mediation Model





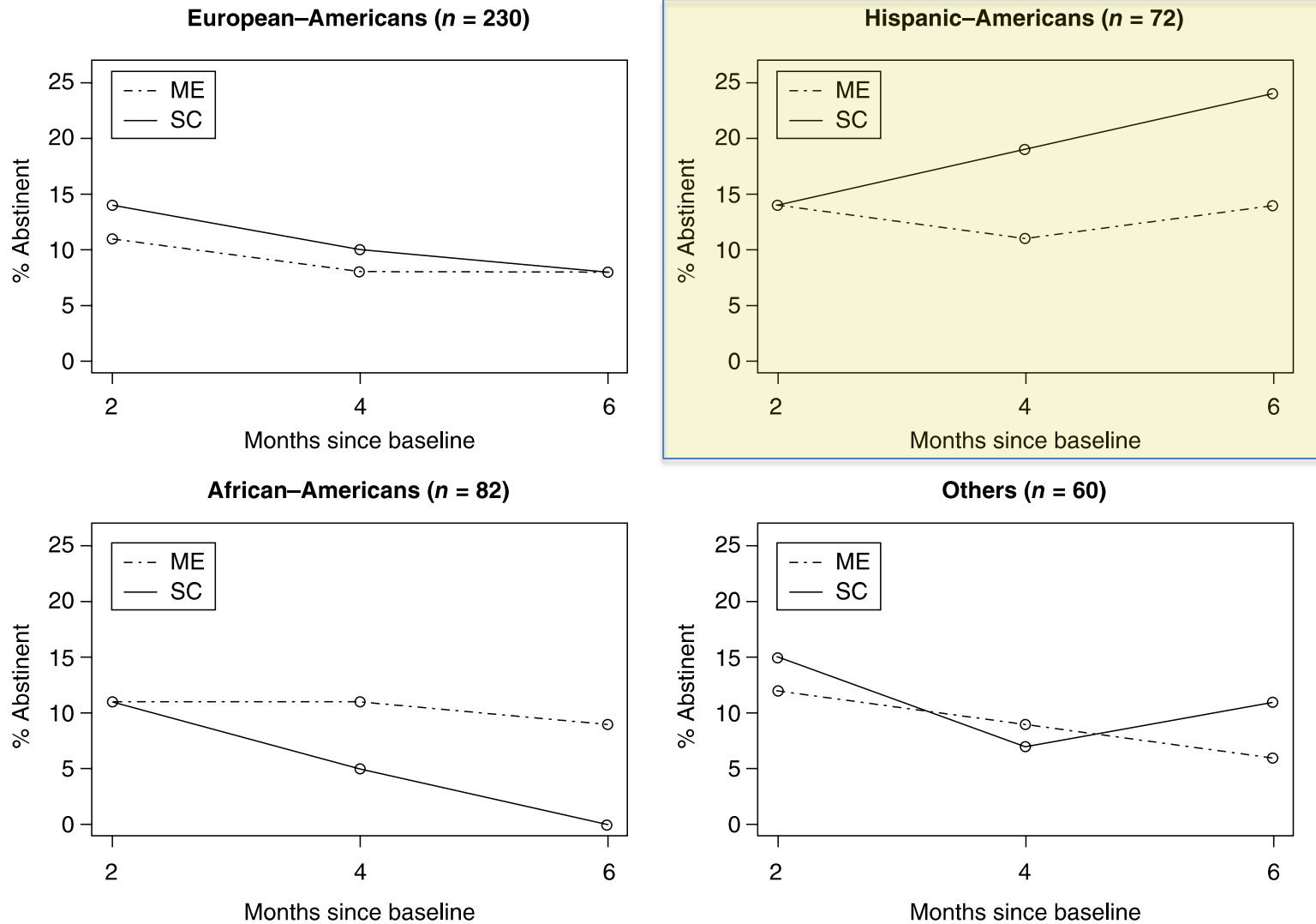
## Treatment Outcome: Mediation

- Using a Baron & Kenny (1986) approach for establishing mediation, abstinence improved significantly with increases in self-efficacy and decisional balance; the association of NRT contacts and abstinence was no longer significant once changes in these mediators were taken into account.
- Longer periods of patch compliance may improve self-efficacy to resist temptations and prevent relapse.
- Success experiences (supported by increased time on the patch) contribute to a sense of confidence that translates to behavior change (the ability to resist temptations and avoid relapse).

## Treatment: What's Next?

- Are *culturally-sensitive* interventions that target key psychological measures and increase access and compliance with NRT needed to support smoking cessation efforts among PLWHA?

# Treatment Outcome: Response Prediction



**Figure 2** Intent-to-treat (ITT) quit rates over 2-month, 4-month and 6-month follow-up by study condition and race/ethnic group. ME: motivationally enhanced treatment; SC: standard care treatment

# PROYECTO AURORA

- Culturally targeted and individually tailored smoking cessation intervention for Latinos with HIV.



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# WHY FOCUS ON LATINOS?

- Latinos are the largest ethnic minority group in the US.
- Latinos accounted for 20% of all new HIV and new AIDS cases in 2010, a rate approximately 3 times higher than that of non-Hispanic Whites.
- According to our pilot data at Aurora study clinics, 53% of Latinos with HIV were smokers.
- Despite Latinos generally being lighter smokers than non-Hispanic Whites, they are not necessarily more successful at quitting.

# PROYECTO AURORA

- NIDA funded randomized clinical trial to develop and test the first culturally tailored smoking cessation intervention for HIV+ Latinos/Hispanics.
- Project Aurora's Focus
  - Develop an intervention that addresses the needs and unique cultural characteristics of Latinos living with HIV/AIDS
  - Test the efficacy of this intervention
  - Explore mediators and moderators of treatment adherence, cessation, patch use, retention, and tobacco use/dependence.
  - Evaluate the main effect of acculturation on smoking quit rates in the two treatment conditions

# CULTURE TAILORED COMPONENTS

- Conducted focus groups
- Intervention Development
  - Involvement of social support
  - Interventionist (bilingual Hispanic) training and experience
  - Screening and integration of cultural factors
    - Acculturation
    - Religion/Spirituality
    - Family
    - Hispanic Values
  - Use of culturally specific intervention materials (pamphlets, videos, etc.).



# AURORA TREATMENT CONDITIONS

## Standard Care Intervention

- Brief physician advice
- Standard smoking cessation self-help booklet
- Set quit date
- Nicotine patches
  
- Two short sessions
- Follow-up call on Quit Date

## Culturally Targeted Intervention

- Brief physician advice
- Culturally targeted smoking cessation self-help booklet and tailored videos
- Set quit date
- Nicotine patches
- 
- Four behavioral skills-based counseling sessions with Intervention Coordinator
- Two booster phone calls, plus phone call on Quit Date
- Option to bring a social support person to sessions and receive free patches for the support person as well

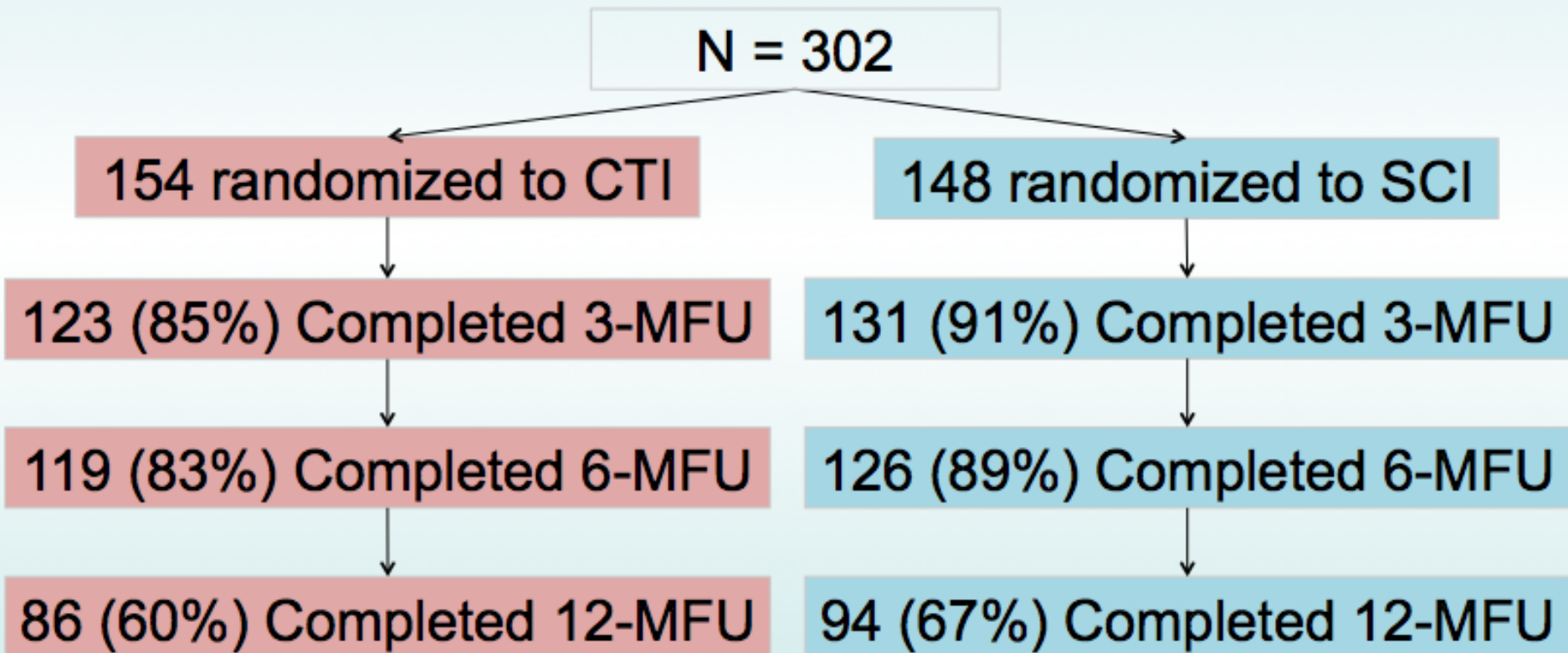
# AURORA

## Results

302 HIV+ Latinos participated (64% male). Over half of the sample was not born in the US (51%), was of Puerto Rican origin (56%), had less than a high school education (57%), and were never-married (53%). Mean age was  $45 \pm 8$  years. Retention at follow-up is depicted in **Figure 1**. Those who did not receive or try the patch during the intervention were more likely to drop out than those who did try the patch ( $p = 0.004$ ).

# AURORA: RESULTS

**Figure 1. Participant retention at 3, 6, and 12 months by treatment condition**



# AURORA: RESULTS

**Table 2. Bivariate analysis of 24-hour and 7-day abstinence at 3, 6, and 12 months (ITT)**

	3 Month Follow-Up			6 Month Follow-Up			12 Month Follow-Up		
	CTI	SCI	<i>P</i>	CTI	SCI	<i>P</i>	CTI	SCI	<i>P</i>
<b>24 hour PPA, <i>N</i> (column %)</b>									
Abstinent	20 (13)	24 (16)	0.427	17 (11)	19 (13)	0.630	11 (7)	10 (7)	0.895
Non-abstinent	134 (87)	124 (84)		137 (89)	129 (87)		143 (93)	138 (93)	
<b>7 day PPA, <i>N</i> (column %)</b>									
Abstinent	16 (10)	18 (12)	0.626	13 (8)	16 (11)	0.485	10 (6)	10 (7)	0.927
Non-abstinent	138 (90)	130 (88)		141 (92)	132 (89)		144 (94)	138 (93)	
<b>Participants with 24 hour quit attempts*, <i>N</i> (column %)</b>									
No quit attempts	31 (20)	24 (16)	0.350	20 (13)	20 (14)	0.803	20 (13)	18 (12)	0.508
At least one	71 (46)	74 (50)		76 (49)	83 (56)		52 (34)	60 (41)	
Unknown	52 (34)	50 (34)		58 (38)	45 (30)		82 (53)	70 (47)	

\*Counts of patients with at least one quit attempt (24 hour periods of abstinence) at any point during the study.

## AURORA: RESULTS

**Table 3. Logistic regression predicting odds of 6-month abstinence among HIV+ Latinos**

Effect	OR Estimate <i>*p</i> < 0.05	95% Wald CI	
		Upper	Lower
NRT Patch Use <u>during</u> Intervention ( <i>vs. never received + never tried</i> )	8.763*	1.956	39.254
Foreign-Born ( <i>vs. US-Born</i> )	2.745*	1.056	7.136

## AURORA: CONCLUSIONS

No differences in 3-, 6-, or 12-month abstinence rates between the culturally tailored vs. standard care condition.

Intervention approaches that include **cessation medication adherence strategies** are critical to delivering effective cessation services to this population.

# LESSONS LEARNED

- Small number of RCT's, variable results.
- Adding BT to NRT does not improve outcomes.
- BT delivered via group or phone shows promise.
- Differences: Populations, settings, implementation barriers, patient engagement (interventions?)
- Adherence to medication is quite important (interventions?)
- Tailoring – no solid evidence (yet).

# COMPLEXITIES

## Tailoring – To what?

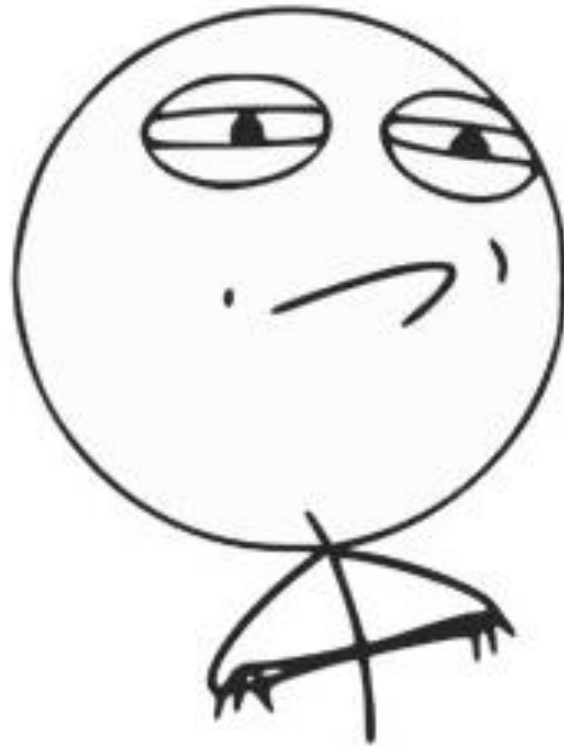
- Race/ethnicity/culture/subculture/microculture
- HIV/AIDS unique needs (what are they, compared to other chronic illnesses?)
  - Reprieve of death sentence (ART; other advances)
  - Low SES (education; income; employment)
  - Social and welfare needs (housing; access to health care; social support)
  - Psychiatric and other medical comorbidities
  - Drug/alcohol use/risky behaviors
  - Sexual orientation/sexuality
  - Low health literacy/knowledge/awareness
  - Complicated treatment regimens (e.g., many meds)



A white analog clock with a black dial and hands. The text "It's Challenge Time" is written across the clock face in a blue, bubbly, sans-serif font. The words are stacked vertically: "It's" at the top, "Challenge" in the middle, and "Time" at the bottom. The clock's numbers are visible in the background.

It's  
Challenge  
Time

**CHALLENGE ACCEPTED**



THANK YOU