Should We Believe Results Obtained from an Internet-Based Cohort Study?

Prepared for the 21st International Conference on Pharmacoepidemiology and Therapeutic Risk Management

Nashville, TN
August 24, 2005

Alicia Gilsenan, *PhD[1], Xiaolei Zhou MS[1], Patricia Tennis PhD[1], Elizabeth Andrews PhD[1], Florence Coste MS[2], Christine Radigue PhD[2]*

1. RTI Health Solutions, Research Triangle Park, NC, United States
2. Sanofi-Aventis, Paris, France.

LEADING RESEARCH…
MEASURES THAT COUNT

Conflict of Interest Statement

- Sanofi-Aventis and RTI Health Solutions employees and consultants contributed significantly to the design and analysis plan for this study.

- Data collection and analyses were conducted by employees of RTI Health Solutions, a not-for-profit research organization.

- The study was fully funded by Sanofi-Aventis.

ATTEMPT Study Objectives

- Describe patterns of smoking cessation
- Explore the influence of weight and craving on the smoking cessation process
- Describe short-term resource use and benefits associated with smoking cessation

Why Choose a Web-Panel Design?

- Increasingly difficult to conduct observational studies using traditional survey methods

- Statistical methods are available that can reduce selection bias due to nonrandom samples

- Prior research has demonstrated results obtained using internet vs non-internet modes for data collection are comparable

- Web-panels are an efficient mode for recruiting

Harris Interactive Web-Panel

- Multimillion-member database of volunteers for periodic market research surveys
- Harris Interactive (HI) panel member recruitment:
  - Online registration site
  - Banner advertisements
- Weighting process
  - Incorporates output of a sample selection bias analysis along with normal demographic characteristics (rim weighting)
  - Propensity score adjustment
- Study sample identification
  - Stratified random sample from HI panel member database

ATTEMPT Study Design

- Prospective, observational, multi-national Internet cohort

- Stratified random sample invited by e-mail to participate in the ATTEMPT Study

- Random sample selected for in-home visit
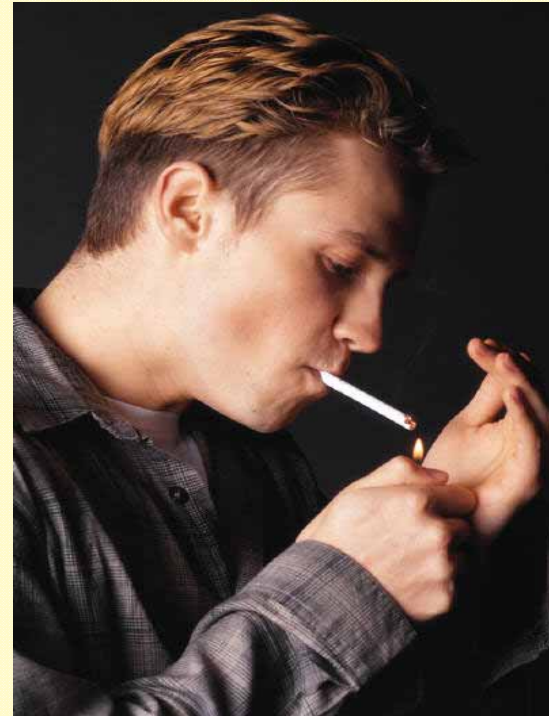
ATTEMPT Inclusion Criteria

- Member of an existing online panel
- Current smokers who smoked at least 5 cigarettes per day
- Intended to quit smoking in the next 3 months
- Between 35-65 years of age

HI Europe

Do you intend to make a serious attempt to stop smoking for good within the next 3 months?

○ Yes
○ No, I don't intend to quit within the next 3 months

PROGRESS ■

RESUME LATER

Data Collection

- Baseline and quarterly follow-up assessments

- 25-minute questionnaire to assess:

  - Demographics

  - Smoking, health conditions, medical resource use

  - Quality of life, productivity, and insurance

- Participants in all countries were provided study weight scale for reporting body weight

ATTEMPT US Year 1 Recruitment

Invited	Responded	Enrolled	Time for Recruitment
23,688	4,692	1,400	8 days

ATTEMPT US Cohort vs. Target Population

- Target Population
  - Smokers aged 35-65 years who were willing to quit

- Online Panel
  - Volunteer panel of pre-identified smokers

- Attempt Cohort Sample
  - Subjects meeting eligibility criteria who completed baseline assessment

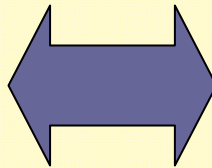Target

Online Panel

ATTEMPT Sample
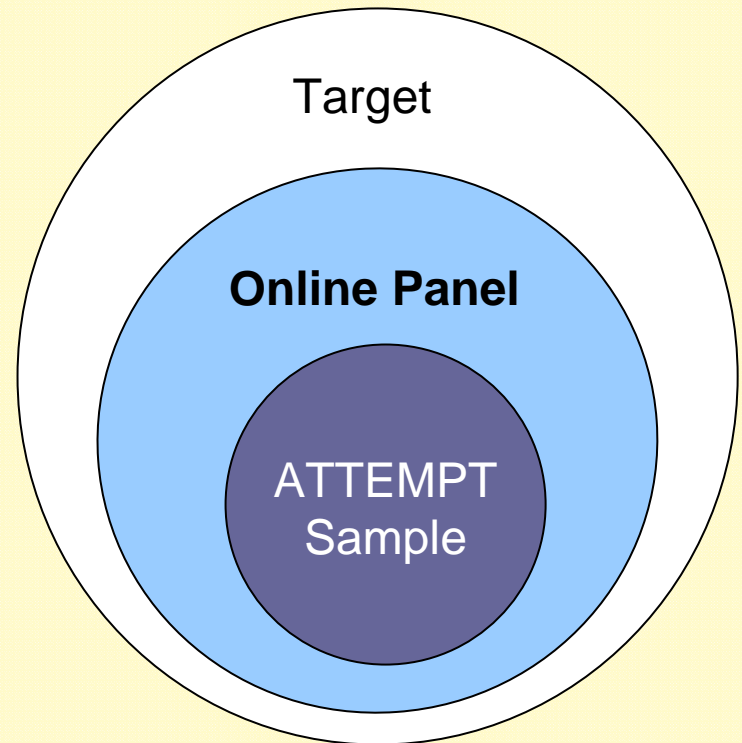
United States

US ATTEMPT
Baseline Year 1
(2003)
(n = 1,400 recruited within 8 days)

- Aged 35-65 years
- Smoked at least 5 cigarettes per day on average
- Indicated willingness to quit in next 3 months
- English speaking

National Health Interview Survey (NHIS)
(2003)
(n = 3,299)

Selected subset of subjects
- Aged 35-65 years
- Current smokers
- Smoked at least 5 cigarettes per day on average

US ATTEMPT vs. NHIS

	US ATTEMPT 2003	NHIS 2003
Mean age and 95% CI (years)	48.6 (48.1, 49.0)	47.4 (47.1, 47.7)
Mean age started smoking* and 95% CI (years)	16.6 (16.3, 16.8)	17.9 (17.7, 18.1)

*ATTEMPT - "How old were you when you FIRST STARTED smoking cigarettes?"

*NHIS - "How old were you when you first started to smoke FAIRLY REGULARLY?"

US ATTEMPT vs. NHIS

The error bars show 95% confidence interval.
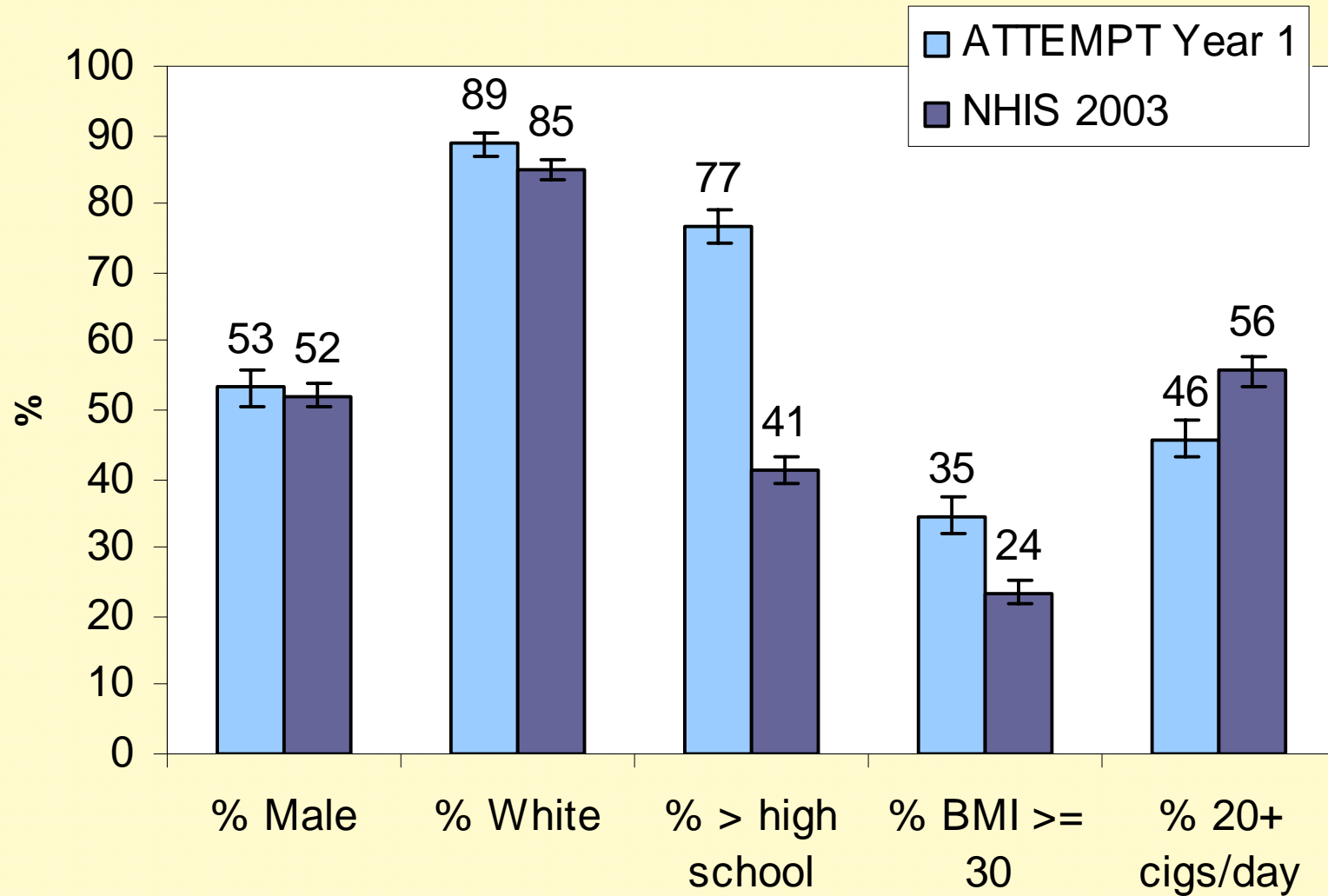
Summary of Demographic and Smoking Comparisons (US)

No meaningful differences found for:

- Age

- Gender

- Race

- Age started smoking

- Smoking consumption (number of cigarettes per day)

Meaningful differences were found for:

- Education – higher in ATTEMPT cohort

- Body Mass Index (BMI) – higher in ATTEMPT cohort

How Do Differences in ATTEMPT Cohort Influence Outcome Under Study?

Abstinence Rate by BMI and Education (US)

Characteristic	Abstinence Rate*
BMI	
BMI < 30 (n = 900)	10.3%
BMI ≥ 30 (n = 478)	10.5%
Education	
High school or less (n = 326)	10.7%
Some college (n = 711)	9.1%
College graduate or more (n = 361)	13.6%

Overall abstinence rate = 10.6%

RTI$(h)(s)$™

What Do Differences Between ATTEMPT Cohort and National Data Mean?

For purpose of estimating abstinence rate among US smokers willing to quit (aged 35-65 years):

- BMI differences between ATTEMPT cohort and the general population likely do not impact the abstinence rate estimate.

- Higher education in ATTEMPT cohort may bias the estimate, because abstinence rate varies slightly by level of education.

  - Weighted estimates
  - Include education in multivariate analyses

Influence of Panel Weights

	ATTEMPT Year 1 baseline (US)		NHIS 2003
	Unweighted	Weighted*	
Mean age (year)	48.6	48.7	47.4
% Male	53.3	52.1	52.1
% White	88.7	85.2	84.9
% Some college or higher	76.7	48.8	41.2
% BMI ≥ 30	34.7	34.7	23.5

Weighting factors: age, gender, education, race, propensity score to account for Internet vs. non-Internet user differences

Should We Believe Results from this Internet Survey?

- Were measures taken to reduce selection bias of sample?

- Were study sample characteristics similar to national estimates?

- Were results valid?

- What are the limitations?

Conclusions

- Rigorous sampling methodology was employed and weights were available to minimize selection bias.

- Most ATTEMPT cohort characteristics were similar to NHIS sample with the exception of education and BMI.

- Self-reported weight was highly correlated with observed weight (data not shown).

- Comparisons to national data can guide the analysis and interpretation before inferences are drawn beyond the actual sample population.

- Credible results can be obtained using the Internet.