

# SAMPLING DESIGN:TOTAL EXPOSURE STUDY

---

Bettie L. Nelson  
December 4, 2003

With material from Bob Johnson's (VCU)  
presentations at the Investigator's Meetings

Presented at the PM/MDS KoP  
meeting, December 2003

1

# Overview

---

- ☐ Target Population
- ☐ Sampling Scheme
- ☐ Stratification Variables
- ☐ Monitored Concomitant Variables
- ☐ Sample Size

# Target Population

---

The target population is U.S. adult (age 21 yrs or older) smokers and, by comparison, non-smokers.

## Sampling Scheme

---

- ❑ Volunteer sample with purposeful targeting of subpopulations.
- ❑ Subjects were to be recruited from populations surrounding diverse sites across the continental U.S.
- ❑ Key demographics were to be *represented in the sample* by way of stratification and monitoring.

# Stratification Variables

---

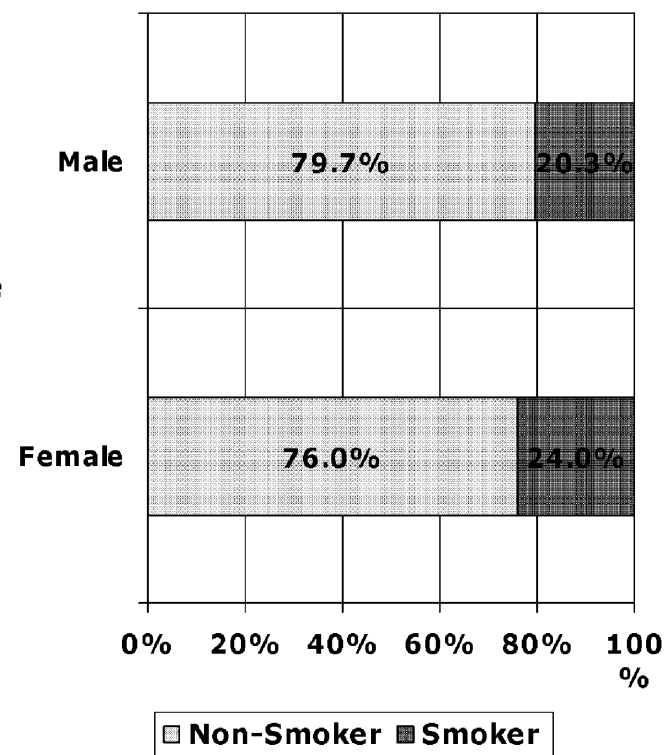
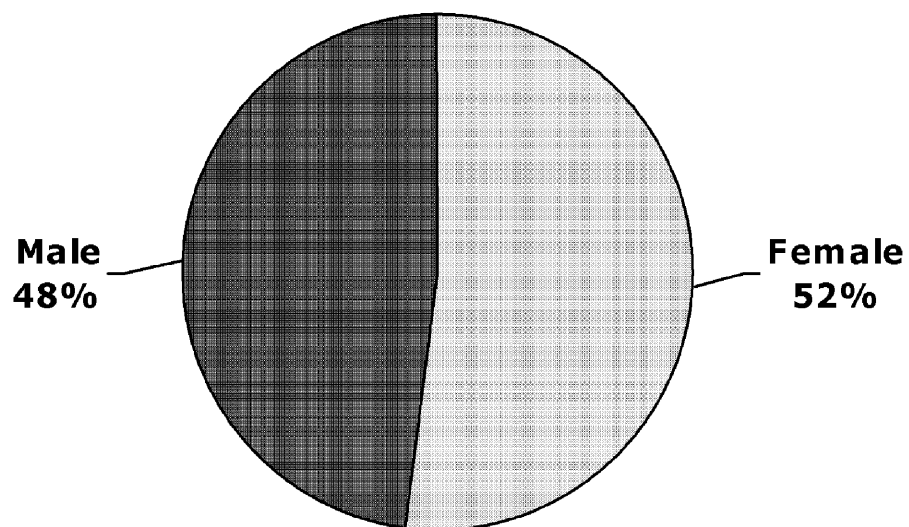
- ☐ FTC Tar Delivery Categories
- ☐ Gender (2 levels)
- ☐ Age (3 levels)
- ☐ Body Mass Index (2 levels)

## FTC Tar Delivery Categories

---

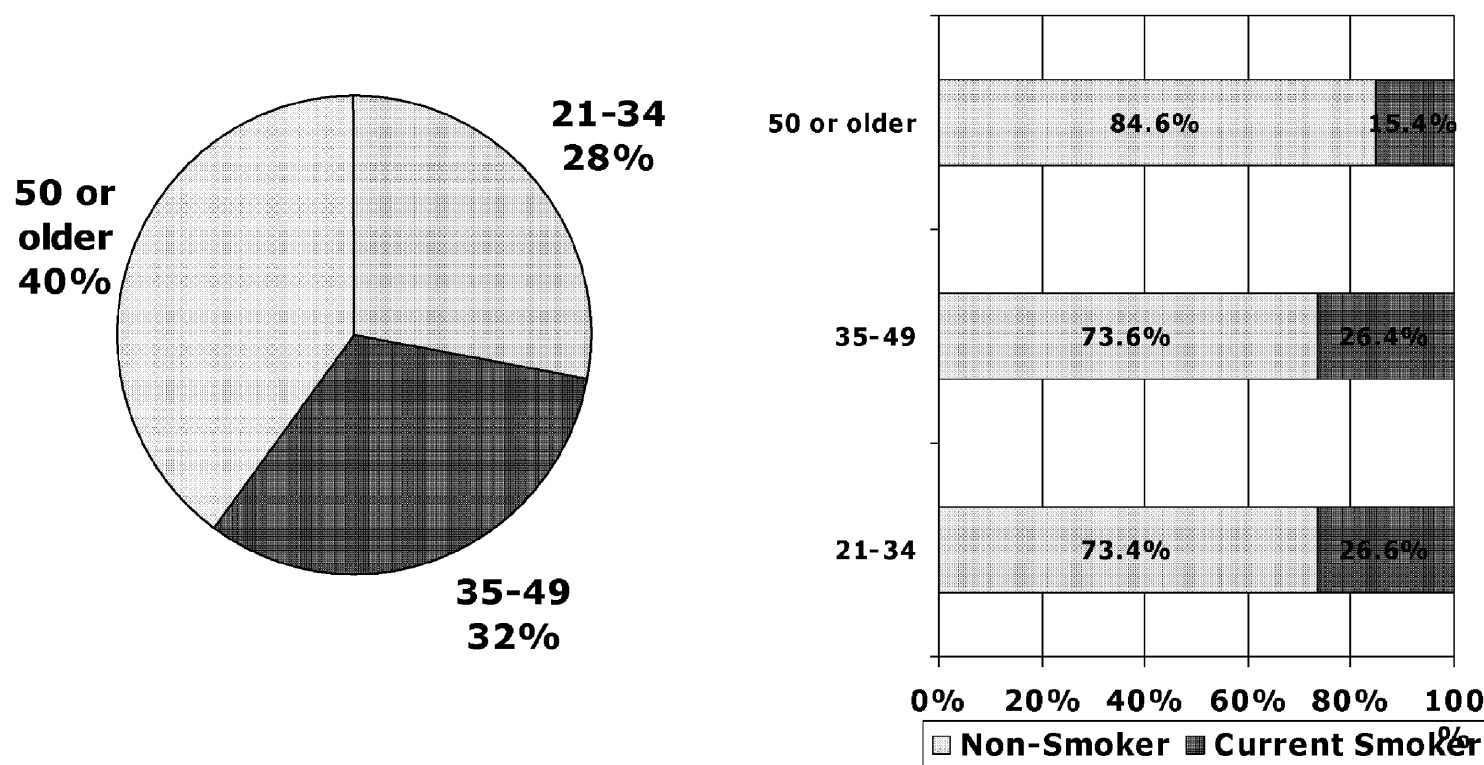
- ☐ 0 – 2.9 mg
  - ☐ 3.0 – 6.9 mg
  - ☐ 7.0 -12.9 mg
  - ☐  $\geq 13.0$  mg
- and
- ☐ Non-smokers

# GENDER - BRFSS



Presented at the PM/MDS KOP Source: BRFSS, 2000  
meeting, December 2003

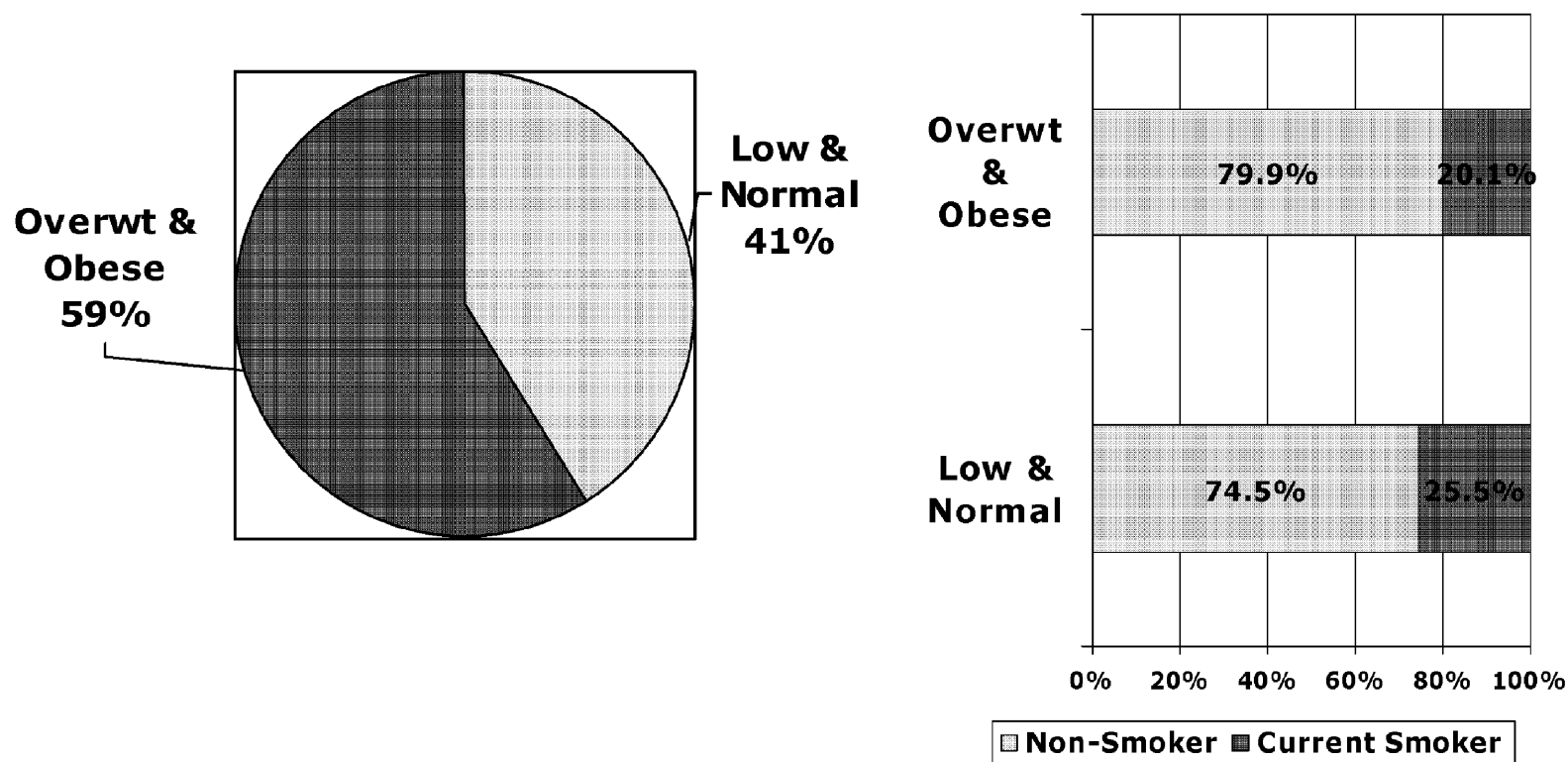
# AGE - BRFSS



Presented at the PM/MDS KoP  
meeting, December 2003



# BODY MASS INDEX (BMI) - BRFSS



Presented at the PM/MDS KoP  
meeting, December 2003

## Distribution of U.S. Population across Gender, BMI, and Age Stratification Cells

| Gender | BMI                      | 21-34  | 35-49  | ≥ 50   | Total   |
|--------|--------------------------|--------|--------|--------|---------|
| Female | Low & Normal (<25)       | 8.00%  | 7.88%  | 9.50%  | 25.38%  |
|        | Overweight & Obese (≥25) | 5.24%  | 8.03%  | 12.04% | 25.31%  |
| Male   | Low & Normal (<25)       | 5.78%  | 4.65%  | 5.46%  | 15.89%  |
|        | Overweight & Obese (≥25) | 8.66%  | 11.75% | 13.00% | 33.41%  |
| Total  |                          | 27.68% | 32.31% | 40.00% | 100.00% |

Source: BRFSS, 2000

## ... by Smoking Status

| Gender          | BMI                       | 21-34  | 35-49  | ≥ 50   | Total  |
|-----------------|---------------------------|--------|--------|--------|--------|
| Current Smokers |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 2.06%  | 2.14%  | 1.70%  | 5.90%  |
|                 | Overweight & Obese (≥ 25) | 1.23%  | 1.93%  | 1.44%  | 4.60%  |
| Male            | Low & Normal (<25)        | 1.83%  | 1.62%  | 1.19%  | 4.64%  |
|                 | Overweight & Obese (≥ 25) | 2.29%  | 2.98%  | 1.93%  | 7.20%  |
| Sub-Total       |                           | 7.41%  | 8.67%  | 6.26%  | 22.34% |
| Non-Smokers     |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 5.94%  | 5.74%  | 7.81%  | 19.49% |
|                 | Overweight & Obese (≥ 25) | 4.01%  | 6.11%  | 10.60% | 20.72% |
| Male            | Low & Normal (<25)        | 3.95%  | 3.02%  | 4.27%  | 11.24% |
|                 | Overweight & Obese (≥ 25) | 6.37%  | 8.77%  | 11.07% | 26.21% |
| Sub-Total       |                           | 20.27% | 23.64% | 33.75% | 77.66% |

# Monitored Concomitant Variables

---

- ☐ Race
  - White, Non-Hispanic
  - Non-white or Hispanic
- ☐ Income
  - < \$20k, \$20k-<\$50k, \$50k or more
- ☐ Education
  - Less than high school
  - High School diploma or equivalent to some college
  - Four years or more of college

# Sample Size, continued

**Table 4:** Power, Effect Sizes, Sample Sizes, and Associated Means Differences for Two-Sided t-tests  
Adjusted for 5% Experimentwise Error.

| Power             | Effect Size (ES) | Sample Size per Tar Group | Difference in Means [ES $\times$ StdDev] |                           |                           |                             |                           |                            |                            |
|-------------------|------------------|---------------------------|--|---------------------------|---------------------------|-----------------------------|---------------------------|----------------------------|----------------------------|
|                   |                  |                           | Nicotine Equivalents (NE)                | NE per Cigarette (NE/C)   | Carboxy-Hemoglobin (COHb) | COHb per Cigarette (COHb/C) | Log (NE)                  | Log (NE/C)                 | Log(COHb) and Log(COHb/C)  |
| 80%               | 0.140            | 1200                      | 1.30                                     | 0.069                     | 0.414                     | 0.027                       | 0.079                     | 0.072                      | 0.081                      |
|                   | 0.153            | 1000                      | <b>1.42</b>                              | 0.075                     | <b>0.453</b>              | <b>0.029</b>                | 0.087                     | 0.079                      | 0.088                      |
|                   | 0.171            | 800                       | 1.59                                     | <b>0.084</b>              | 0.506                     | 0.033                       | 0.097                     | <b>0.088</b>               | 0.099                      |
| 90%               | 0.158            | 1200                      | <b>1.47</b>                              | 0.078                     | <b>0.468</b>              | <b>0.030</b>                | 0.090                     | 0.081                      | 0.091                      |
|                   | 0.173            | 1000                      | 1.61                                     | <b>0.085</b>              | 0.512                     | 0.033                       | 0.098                     | <b>0.089</b>               | 0.100                      |
|                   | 0.193            | 800                       | 1.79                                     | 0.095                     | 0.571                     | 0.037                       | 0.109                     | 0.099                      | 1.035                      |
| Target Difference |                  |                           | 1.50 <sup>*</sup>                        | <b>0.083</b> <sup>†</sup> | <b>0.470</b> <sup>‡</sup> | <b>0.030</b>                | <b>0.095</b> <sup>§</sup> | <b>0.088</b> <sup>**</sup> | <b>0.095</b> <sup>††</sup> |

\* This corresponds to an effect size of 0.160. A sample size of 915 would be required to meet this target.

† A NE difference of 1.5 corresponds to NE/C difference of 0.083 (based on an average of 18 cigarettes per day). This corresponds to an effect size of 0.169. A sample size of 820 would be required to meet this target. For reference, a 10% difference in NE/C corresponds to 0.09.

‡ This corresponds to an effect size of 0.159. A sample size of 926 would be required to meet this target.

§ This corresponds to an effect size of 0.167. A sample size of 840 would be required to meet this target.

\*\* A NE difference of 1.5 corresponds to Log(NE/C) difference of 0.088. A 10% difference in NE/C corresponds to a Log(NE/C) difference of 0.095.

†† This corresponds to an effect size of 0.164. A sample size of 871 would be required to meet this target.

Presented at the PM/MDS KoP  
meeting, December 2003

# Sample Size

---

- Total sample size = 5000 subjects
  - 1000 subjects per tar group and non-smoker group
  - 83-84 per stratification cell

# TES RECRUITMENT RESULTS

---

- As of November 24, 2003
  - 4,665 subjects recruited
    - 1969 – Males; 2696 – Females
  - 39 sites across the continental US

# Geographic Site Distribution

---

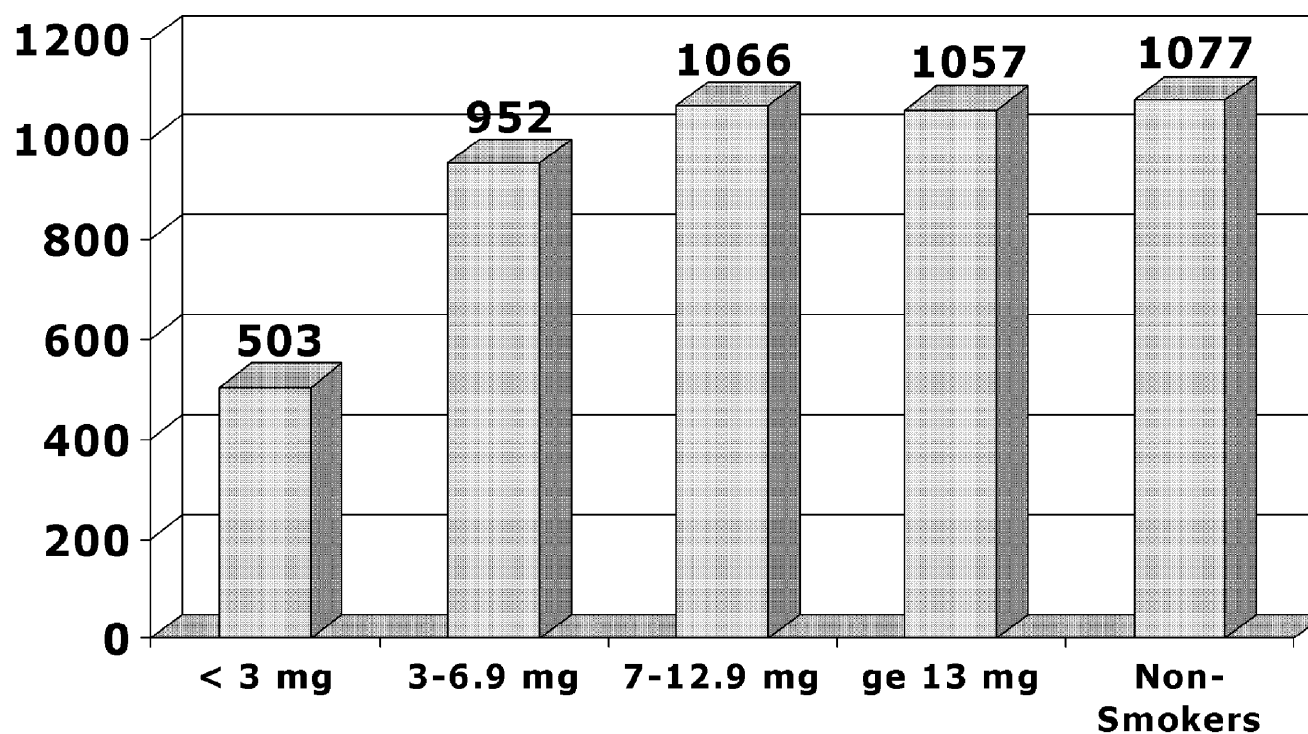


---

Presented at the PM/MDS KoP  
meeting, December 2003



# Number Of Subjects Recruited



Presented at the PM/MDS KoP  
meeting, December 2003

# Number Of Subjects Recruited by Selected Sites

---

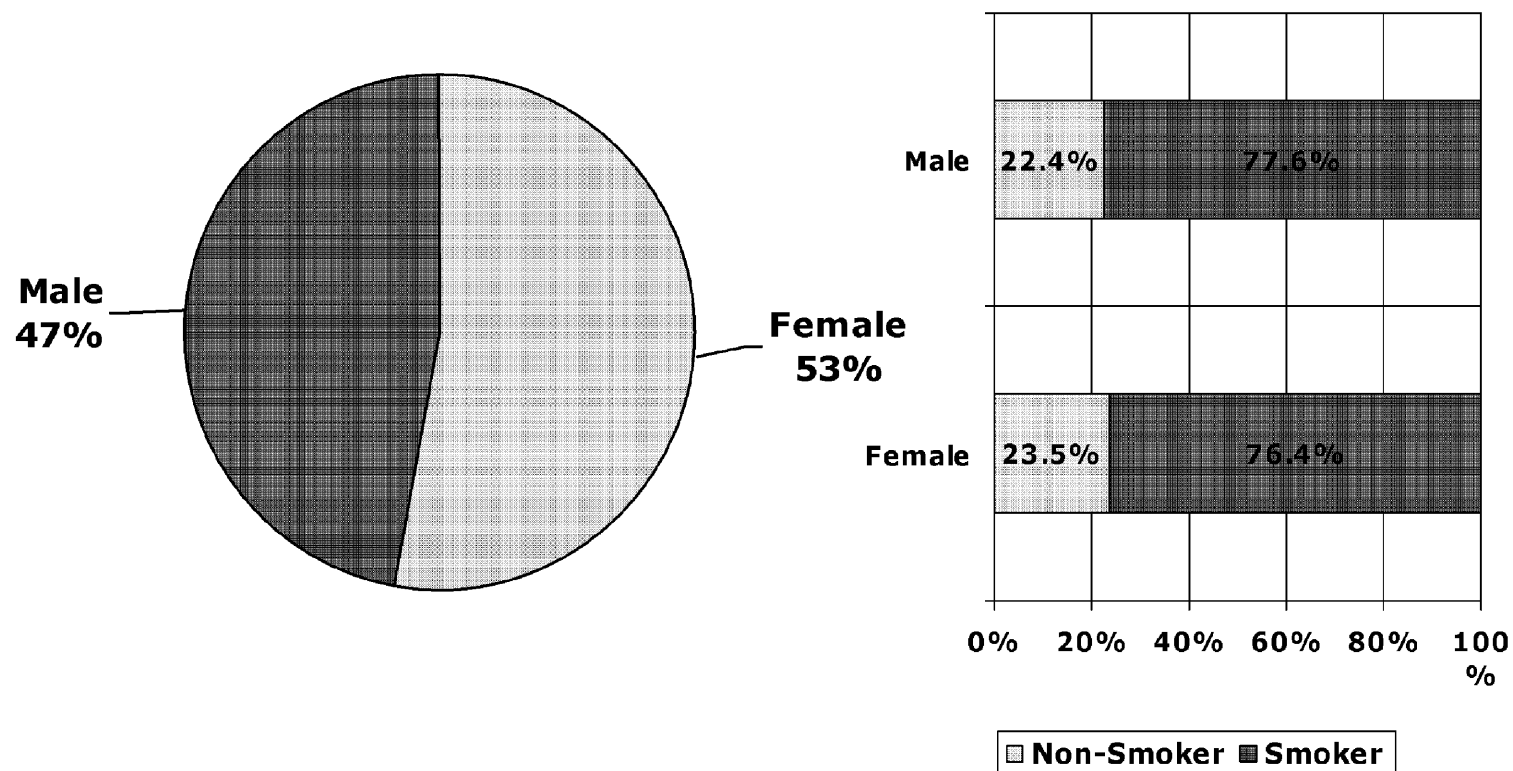
## ☐ Top 5 Highest

- Lawrenceville, NJ (265)
- Raleigh, NC (194)
- Atlanta, GA (193)
- San Diego, CA (183)
- Cincinnati, OH (163)

## ☐ Top 5 Lowest

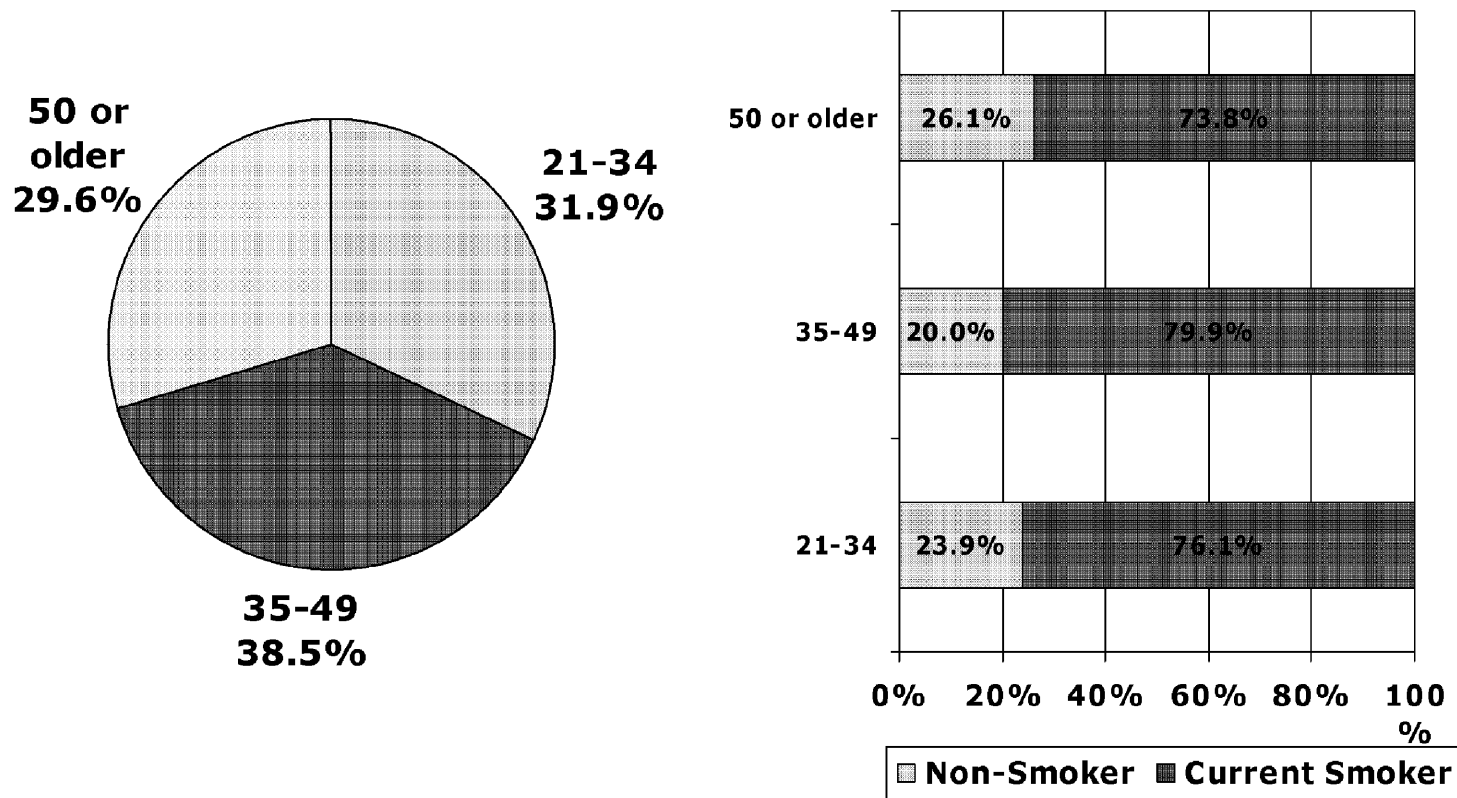
- Newton, MA (22)
- Spokane, WA (45)
- San Antonio, TX (48)
- Omaha, NE (48)
- Jackson, MS (49)

# GENDER – TES



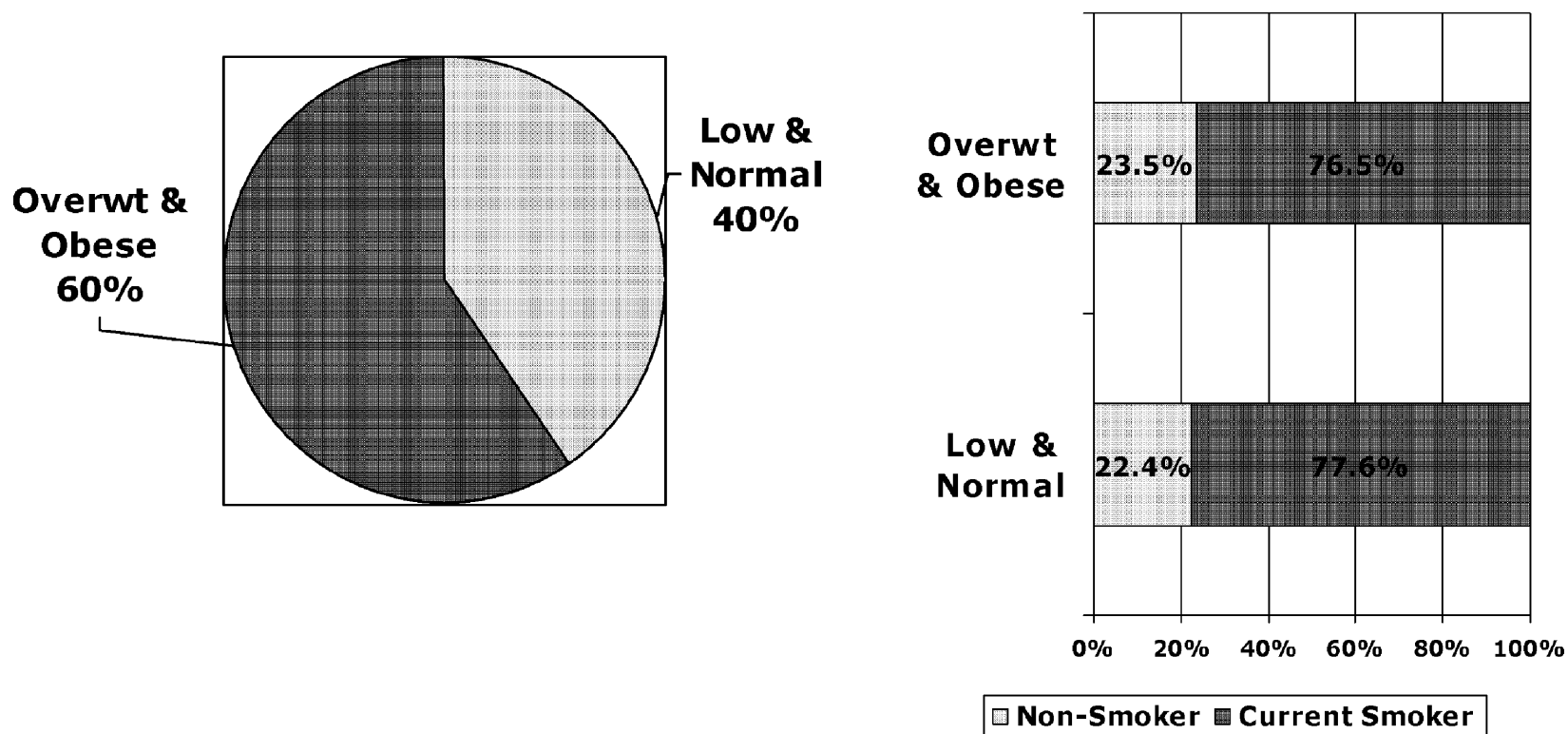
Presented at the PM/MDS KoP  
meeting, December 2003

# AGE - TES



Presented at the PM/MDS KoP  
meeting, December 2003

# BODY MASS INDEX (BMI) - TES



Presented at the PM/MDS KoP  
meeting, December 2003

# Enrollment Stratification

---

| Tar Group        | BMI             | Males     |           |         | Females   |           |         | Sub-Total | TOTAL |
|------------------|-----------------|-----------|-----------|---------|-----------|-----------|---------|-----------|-------|
|                  |                 | 21-34 yrs | 35-50 yrs | 50+ yrs | 21-34 yrs | 35-50 yrs | 50+ yrs |           |       |
| Lt 3.0 mg        | < Normal        | 14        | 29        | 28      | 16        | 52        | 48      | 187       |       |
|                  | Normal or above | 24        | 69        | 49      | 27        | 74        | 73      | 316       | 503   |
| 3-6.9 mg         | < Normal        | 30        | 45        | 26      | 97        | 122       | 85      | 405       |       |
|                  | Normal or above | 50        | 87        | 69      | 99        | 144       | 108     | 557       | 962   |
| 7-12.9 mg        | < Normal        | 83        | 68        | 42      | 95        | 94        | 65      | 447       |       |
|                  | Normal or above | 89        | 92        | 95      | 129       | 122       | 92      | 619       | 1066  |
| Ge 13 mg         | < Normal        | 92        | 92        | 38      | 76        | 84        | 43      | 425       |       |
|                  | Normal or above | 94        | 138       | 85      | 118       | 123       | 74      | 632       | 1057  |
| No Smoking       | < Normal        | 60        | 42        | 38      | 107       | 95        | 81      | 423       |       |
|                  | Normal or above | 85        | 100       | 116     | 104       | 123       | 126     | 654       | 1077  |
| <b>Sub-Total</b> |                 | 621       | 762       | 586     | 868       | 1033      | 795     |           | 4665  |

Note: Targeted 83-84 subjects per cell

## Distribution of TES Sample across Gender, BMI, and Age Stratification Cells

---

| Gender | BMI                      | 21-34  | 35-49  | ≥ 50   | Total   |
|--------|--------------------------|--------|--------|--------|---------|
| Female | Low & Normal (<25)       | 8.38%  | 8.58%  | 6.90%  | 24.87%  |
|        | Overweight & Obese (≥25) | 10.22% | 12.56% | 10.14% | 32.93%  |
| Male   | Low & Normal (<25)       | 5.98%  | 5.92%  | 3.69%  | 15.58%  |
|        | Overweight & Obese (≥25) | 10.42% | 10.42% | 8.87%  | 26.62%  |
| Total  |                          | 31.92% | 38.48% | 29.60% | 100.00% |

## ... by Smoking Status

| Gender          | BMI                       | 21-34  | 35-49  | ≥ 50   | Total  |
|-----------------|---------------------------|--------|--------|--------|--------|
| Current Smokers |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 6.09%  | 7.54%  | 5.17%  | 18.8%  |
|                 | Overweight & Obese (≥ 25) | 8.00%  | 9.90%  | 7.44%  | 25.34% |
| Male            | Low & Normal (<25)        | 4.69%  | 5.02%  | 2.87%  | 12.49% |
|                 | Overweight & Obese (≥ 25) | 5.50%  | 8.27%  | 6.39%  | 20.16% |
| Sub-Total       |                           | 24.28% | 30.73% | 21.87% | 76.79% |
| Non-Smokers     |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 2.29%  | 2.20%  | 1.74%  | 6.23%  |
|                 | Overweight & Obese (≥ 25) | 2.23%  | 2.64%  | 2.70%  | 7.57%  |
| Male            | Low & Normal (<25)        | 1.29%  | 0.90%  | 0.81%  | 3.00%  |
|                 | Overweight & Obese (≥ 25) | 1.82%  | 2.14%  | 2.49%  | 6.45%  |
| Sub-Total       |                           | 7.63%  | 7.88%  | 7.74%  | 23.25% |



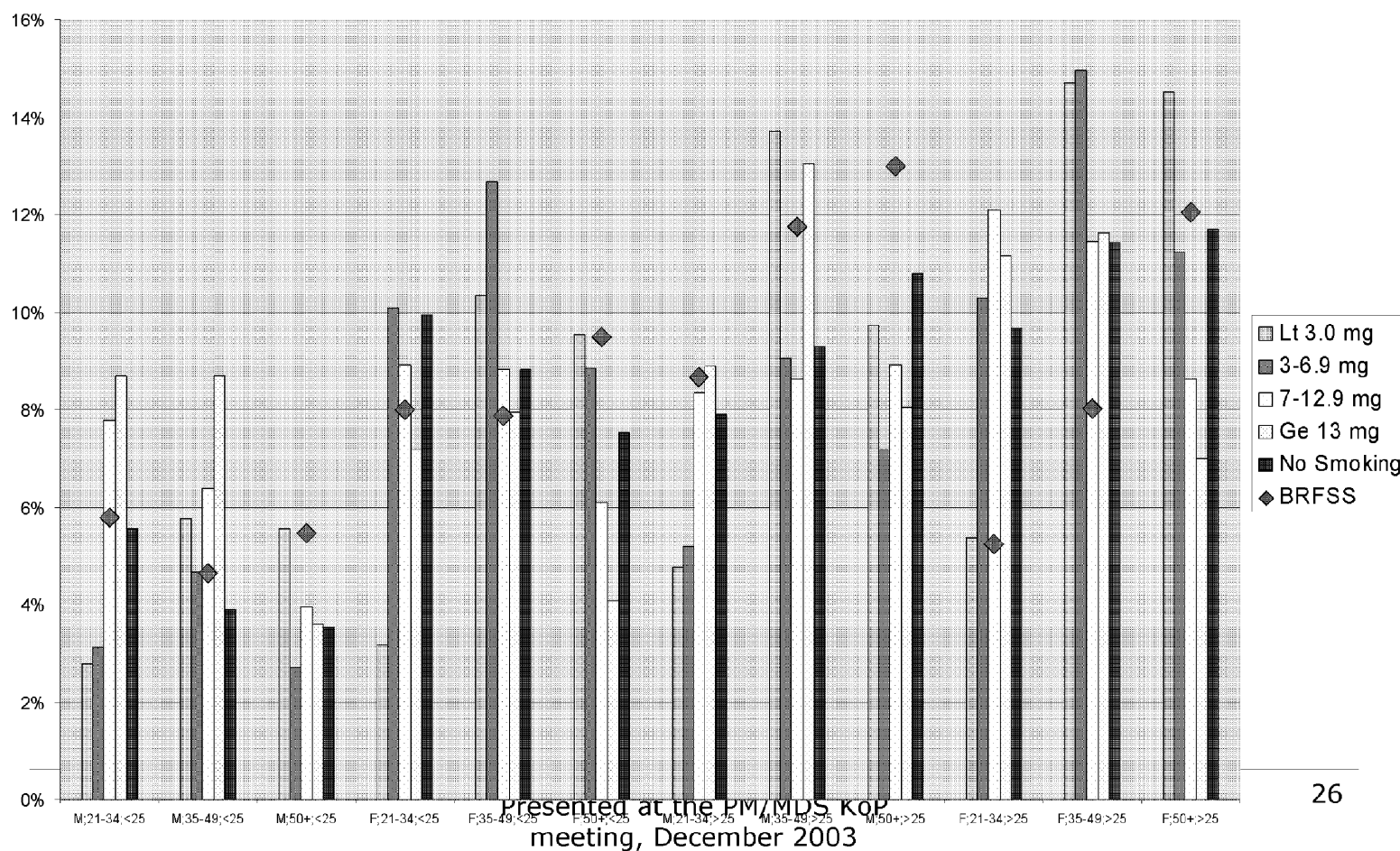
## Default Weights for Tar Groups and Non-Smokers Based on Observed Sample Sizes (weights for each group sum to 1)

|            |                 | Males     |           |         | Females   |           |         |
|------------|-----------------|-----------|-----------|---------|-----------|-----------|---------|
| Tar Group  | BMI             | 21-34 yrs | 35-50 yrs | 50+ yrs | 21-34 yrs | 35-50 yrs | 50+ yrs |
| < 3.0 mg   | < Normal        | 0.0278    | 0.0577    | 0.0557  | 0.0318    | 0.1034    | 0.0954  |
|            | Normal or above | 0.0477    | 0.1372    | 0.0974  | 0.0537    | 0.1471    | 0.1451  |
| 3-6.9 mg   | < Normal        | 0.0312    | 0.0468    | 0.0270  | 0.1008    | 0.1268    | 0.0884  |
|            | Normal or above | 0.0520    | 0.0904    | 0.0717  | 0.1029    | 0.1497    | 0.1123  |
| 7-12.9 mg  | < Normal        | 0.0779    | 0.0638    | 0.0394  | 0.0891    | 0.0882    | 0.0610  |
|            | Normal or above | 0.0835    | 0.0863    | 0.0891  | 0.1210    | 0.1144    | 0.0863  |
| ≥ 13 mg    | < Normal        | 0.0870    | 0.0870    | 0.0360  | 0.0719    | 0.0795    | 0.0407  |
|            | Normal or above | 0.0889    | 0.1306    | 0.0804  | 0.1116    | 0.1164    | 0.0700  |
| No Smoking | < Normal        | 0.0557    | 0.0390    | 0.0353  | 0.0994    | 0.0882    | 0.0752  |
|            | Normal or above | 0.0789    | 0.0929    | 0.1077  | 0.0966    | 0.1142    | 0.1170  |

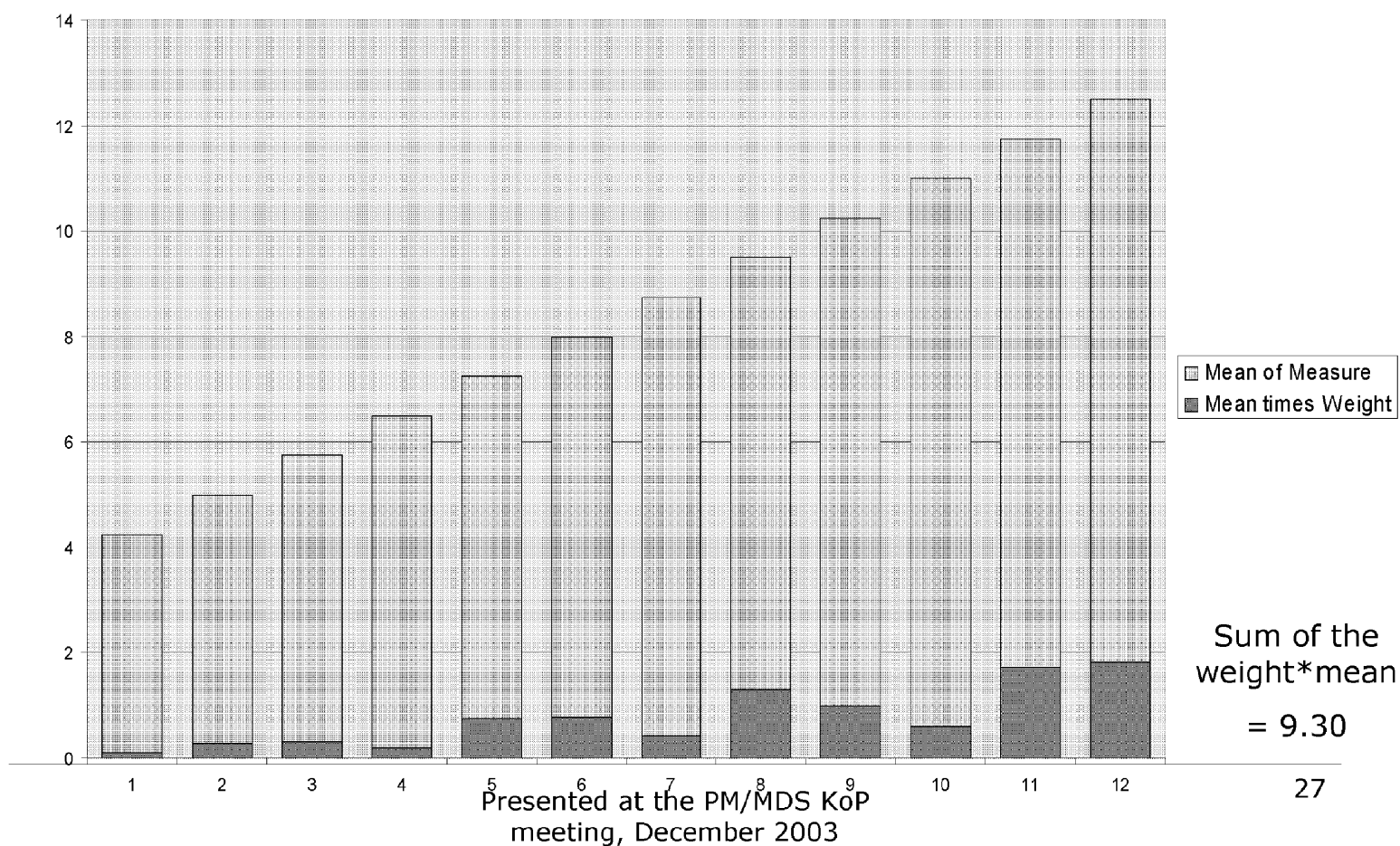
Presented at the PM/MDS KoP  
meeting, December 2003

25

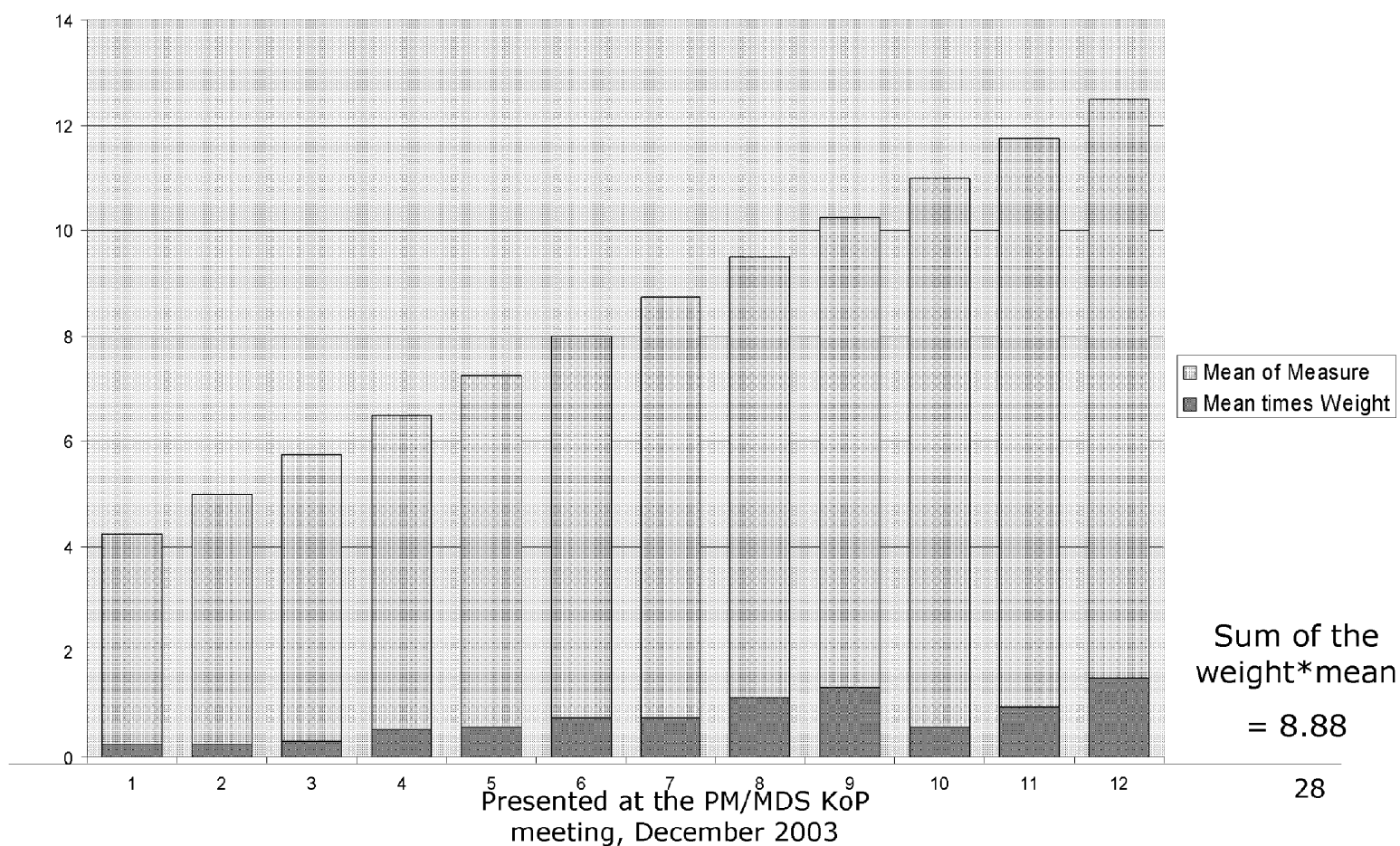
# Default Weights for Tar Groups and Non-Smokers and BRFSS: Standard Weights



# Means of a Measure for each Stratum and the Mean times the Default Weight for Tar Group 7-12.9 mg



# Means of a Measure for each Stratum and the Mean times the Standard (BRFSS) Weight for Tar Group 7-12.9 mg



## Weighted Means of Measure by Tar Group

---

| Tar Group  | Weighted Means |
|------------|----------------|
| Lt 3.0 mg  | 9.299          |
| 3-6.9 mg   | 9.147          |
| 7-12.9 mg  | 8.801          |
| Ge 13 mg   | 8.694          |
| No Smoking | 9.065          |
| BRFSS      | 8.875          |

---

Presented at the PM/MDS KoP  
meeting, December 2003

# SAMPLING DESIGN:TOTAL EXPOSURE STUDY

---

Bettie L. Nelson  
December 4, 2003

With material from Bob Johnson's (VCU)  
presentations at the Investigator's Meetings

Presented at the PM/MDS KoP  
meeting, December 2003

1

## Overview

---

- ☐ Target Population
- ☐ Sampling Scheme
- ☐ Stratification Variables
- ☐ Monitored Concomitant Variables
- ☐ Sample Size

---

Presented at the PM/MDS KoP  
meeting, December 2003

2

## Target Population

---

The target population is U.S. adult (age 21 yrs or older) smokers and, by comparison, non-smokers.

---

Presented at the PM/MDS KoP  
meeting, December 2003

3



## Sampling Scheme

---

- ☐ Volunteer sample with purposeful targeting of subpopulations.
- ☐ Subjects were to be recruited from populations surrounding diverse sites across the continental U.S.
- ☐ Key demographics were to be *represented in the sample* by way of stratification and monitoring.

---

Presented at the PM/MDS KoP  
meeting, December 2003

4

## Stratification Variables

---

- ☐ FTC Tar Delivery Categories
- ☐ Gender (2 levels)
- ☐ Age (3 levels)
- ☐ Body Mass Index (2 levels)

---

Presented at the PM/MDS KoP  
meeting, December 2003

5

## FTC Tar Delivery Categories

---

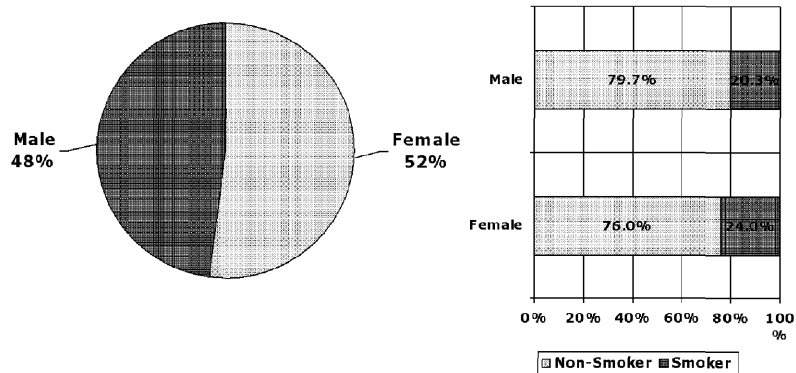
- ☐ 0 – 2.9 mg
  - ☐ 3.0 – 6.9 mg
  - ☐ 7.0 – 12.9 mg
  - ☐  $\geq 13.0$  mg
- and
- ☐ Non-smokers

---

Presented at the PM/MDS KoP  
meeting, December 2003

6

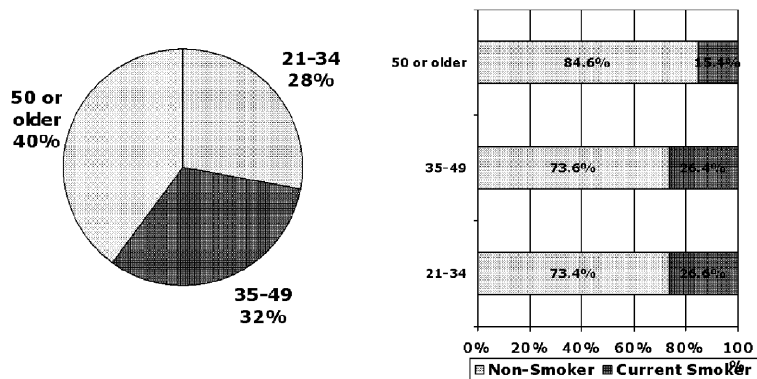
## GENDER - BRFSS



Presented at the PM/MDS Source: BRFSS, 2000  
meeting, December 2003

7

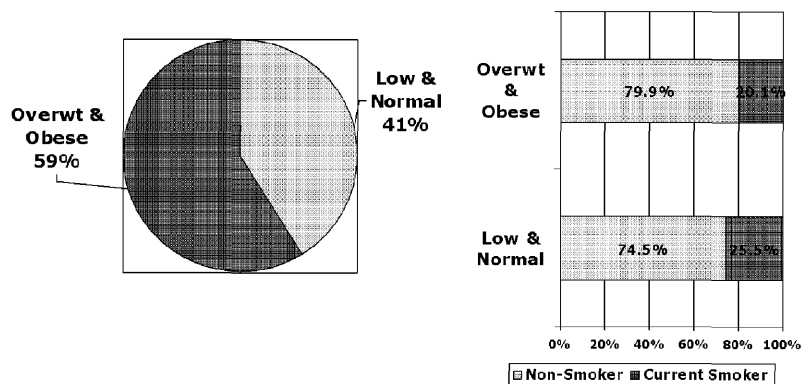
## AGE - BRFSS



Presented at the PM/MDS KoP  
meeting, December 2003

8

## BODY MASS INDEX (BMI) - BRFSS



Presented at the PM/MDS KoP  
meeting, December 2003

9

### Distribution of U.S. Population across Gender, BMI, and Age Stratification Cells

| Gender | BMI                      | 21-34  | 35-49  | ≥ 50   | Total   |
|--------|--------------------------|--------|--------|--------|---------|
| Female | Low & Normal (<25)       | 8.00%  | 7.88%  | 9.50%  | 25.38%  |
|        | Overweight & Obese (≥25) | 5.24%  | 8.03%  | 12.04% | 25.31%  |
| Male   | Low & Normal (<25)       | 5.78%  | 4.65%  | 5.46%  | 15.89%  |
|        | Overweight & Obese (≥25) | 8.66%  | 11.75% | 13.00% | 33.41%  |
| Total  |                          | 27.68% | 32.31% | 40.00% | 100.00% |

Source: BRFSS, 2000

Presented at the PM/MDS KoP  
meeting, December 2003

10

... by Smoking Status

| Gender          | BMI                       | 21-34  | 35-49  | > 50   | Total  |
|-----------------|---------------------------|--------|--------|--------|--------|
| Current Smokers |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 2.06%  | 2.14%  | 1.70%  | 5.90%  |
|                 | Overweight & Obese (≥ 25) | 1.23%  | 1.93%  | 1.44%  | 4.60%  |
| Male            | Low & Normal (<25)        | 1.83%  | 1.62%  | 1.19%  | 4.64%  |
|                 | Overweight & Obese (≥ 25) | 2.29%  | 2.98%  | 1.93%  | 7.20%  |
| Sub-Total       |                           | 7.41%  | 8.67%  | 6.26%  | 22.34% |
| Non-Smokers     |                           |        |        |        |        |
| Female          | Low & Normal (<25)        | 5.94%  | 5.74%  | 7.81%  | 19.49% |
|                 | Overweight & Obese (≥ 25) | 4.01%  | 6.11%  | 10.60% | 20.72% |
| Male            | Low & Normal (<25)        | 3.95%  | 3.02%  | 4.27%  | 11.24% |
|                 | Overweight & Obese (≥ 25) | 6.37%  | 8.77%  | 11.07% | 26.21% |
| Sub-Total       |                           | 20.27% | 23.64% | 33.75% | 77.66% |

Presented at the PM/MDS KoP  
meeting, December 2003

11



## Monitored Concomitant Variables

---

- ☐ Race
  - White, Non-Hispanic
  - Non-white or Hispanic
- ☐ Income
  - < \$20k, \$20k-<\$50k, \$50k or more
- ☐ Education
  - Less than high school
  - High School diploma or equivalent to some college
  - Four years or more of college

---

Presented at the PM/MDS KoP  
meeting, December 2003

12

## Sample Size, continued

**Table 4.** Power, Effect Sizes, Sample Sizes, and Associated Means Difference for Two-Sided t-tests  
Adjusted for 5% Experimentwise Error

| Power             | Effect Size (ES) | Sample Size per Tar Group | Difference in Means [ES $\times$ StdDev] |                         |                           |                             |                    |   |
|-------------------|------------------|---------------------------|--|-------------------------|---------------------------|-----------------------------|--------------------|---|
|                   |                  |                           | Nicotine Equivalents (NE)                | NE per Cigarette (NE/C) | Carboxy-Hemoglobin (COHb) | COHb per Cigarette (COHb/C) | Log (NE)           | Log (NE/C) and Log(COHb/C)                  |
| 80%               | 0.140            | 1200                      | 1.30                                     | 0.065                   | 0.414                     | 0.027                       | 0.079              | 0.081                                       |
|                   | 0.153            | 1000                      | 1.42                                     | 0.075                   | 0.453                     | 0.019                       | 0.087              | 0.088                                       |
|                   | 0.171            | 800                       | 1.59                                     | 0.084                   | 0.506                     | 0.033                       | 0.097              | 0.099                                       |
| 90%               | 0.158            | 1200                      | 1.47                                     | 0.078                   | 0.468                     | 0.030                       | 0.090              | 0.091                                       |
|                   | 0.173            | 1000                      | 1.61                                     | 0.085                   | 0.512                     | 0.033                       | 0.098              | 0.100                                       |
|                   | 0.193            | 800                       | 1.79                                     | 0.095                   | 0.571                     | 0.037                       | 0.109              | 0.105                                       |
| Target Difference |                  |                           | 1.50 <sup>*</sup>                        | 0.083 <sup>†</sup>      | 0.470 <sup>‡</sup>        | 0.030                       | 0.055 <sup>§</sup> | 0.088 <sup>**</sup> and 0.095 <sup>  </sup> |

<sup>\*</sup> This corresponds to an effect size of 0.160. A sample size of 915 would be required to meet this target.

<sup>†</sup> A NE difference of 1.5 corresponds to NE/C difference of 0.083 (based on an average of 18 cigarettes per day). This corresponds to an effect size of 0.165. A sample size of 820 would be required to meet this target. For reference, a 10% difference in NE/C corresponds to 0.09.

<sup>‡</sup> This corresponds to an effect size of 0.159. A sample size of 956 would be required to meet this target.

<sup>§</sup> This corresponds to an effect size of 0.167. A sample size of 840 would be required to meet this target.

<sup>\*\*</sup> A NE difference of 1.5 corresponds to Log(NE/C) difference of 0.088. A 10% difference in NE/C corresponds to a Log(NE/C) difference of 0.095.

<sup>||</sup> This corresponds to an effect size of 0.164. A sample size of 871 would be required to meet this target.

Presented at the PM/MDS KoP  
meeting, December 2003

13

## Sample Size

---

- Total sample size = 5000 subjects
  - 1000 subjects per tar group and non-smoker group
  - 83-84 per stratification cell

---

Presented at the PM/MDS KoP  
meeting, December 2003

14

## TES RECRUITMENT RESULTS

---

□ As of November 24, 2003

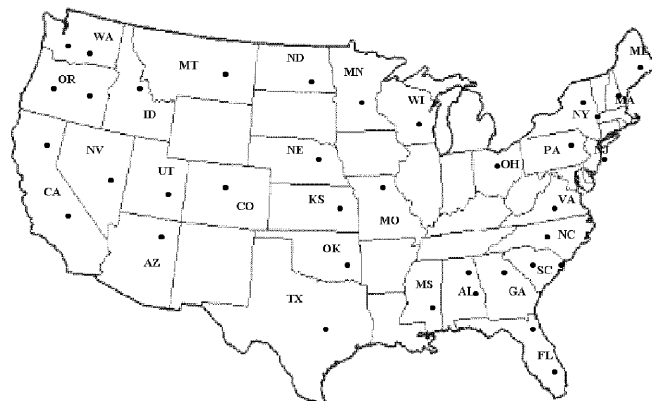
- 4,665 subjects recruited
  - 1969 – Males; 2696 – Females
- 39 sites across the continental US

---

Presented at the PM/MDS KoP  
meeting, December 2003

15

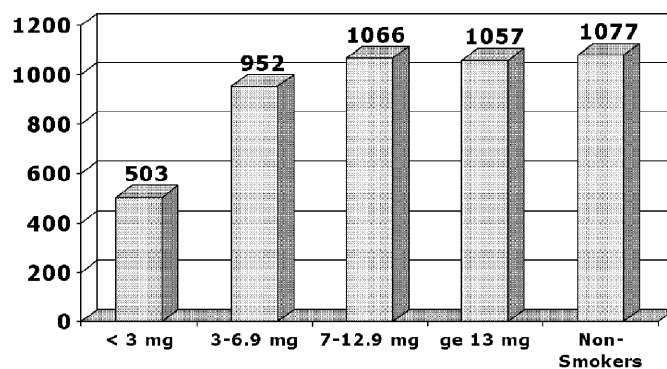
## Geographic Site Distribution



Presented at the PM/MDS KoP  
meeting, December 2003

16

## Number Of Subjects Recruited



Presented at the PM/MDS KoP  
meeting, December 2003

17

## Number Of Subjects Recruited by Selected Sites

---

### ☐ Top 5 Highest

- Lawrenceville, NJ (265)
- Raleigh, NC (194)
- Atlanta, GA (193)
- San Diego, CA (183)
- Cincinnati, OH (163)

### ☐ Top 5 Lowest

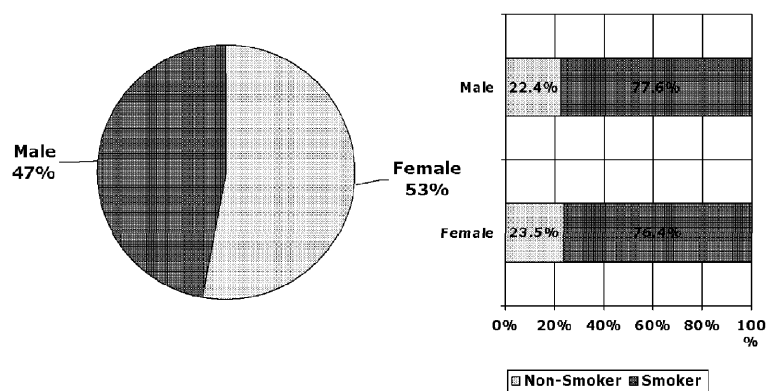
- Newton, MA (22)
- Spokane, WA (45)
- San Antonio, TX (48)
- Omaha, NE (48)
- Jackson, MS (49)

---

Presented at the PM/MDS KoP  
meeting, December 2003

18

## GENDER – TES

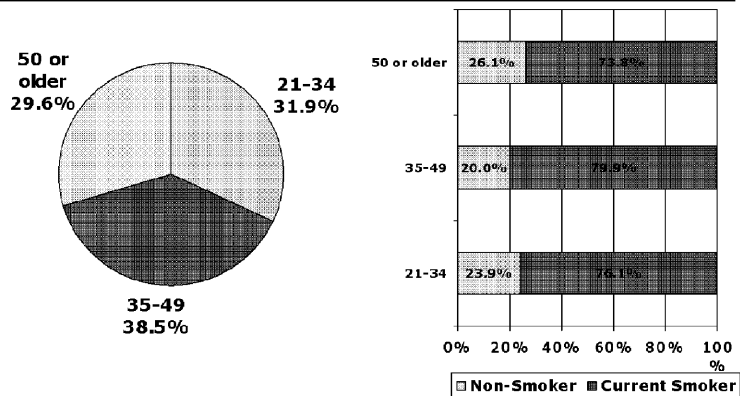


Presented at the PM/MDS KoP  
meeting, December 2003

19



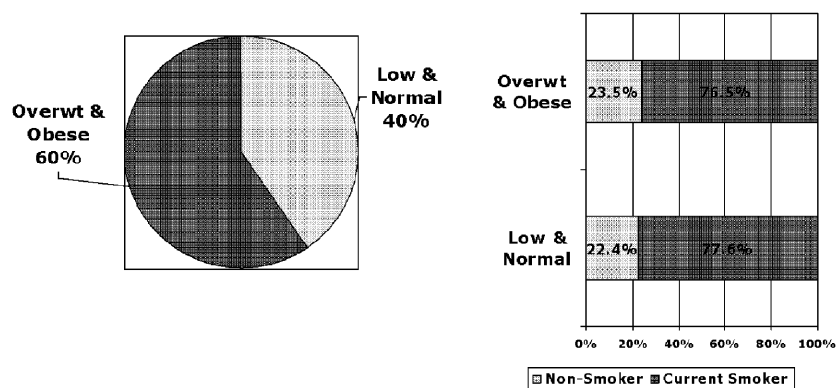
## AGE - TES



Presented at the PM/MDS KoP  
meeting, December 2003

20

## BODY MASS INDEX (BMI) - TES



Presented at the PM/MDS KoP  
meeting, December 2003

21

## Enrollment Stratification

| Tar Group  | BMI             | Males     |           |         | Females   |           |         | Sub-Total | TOTAL |
|------------|-----------------|-----------|-----------|---------|-----------|-----------|---------|-----------|-------|
|            |                 | 21-34 yrs | 35-50 yrs | 50+ yrs | 21-34 yrs | 35-50 yrs | 50+ yrs |           |       |
| Lt 3.0 mg  | < Normal        | 14        | 29        | 28      | 16        | 52        | 48      | 187       | 503   |
|            | Normal or above | 24        | 69        | 49      | 27        | 74        | 73      | 316       |       |
| 3-6.9 mg   | < Normal        | 30        | 45        | 26      | 97        | 122       | 85      | 405       | 962   |
|            | Normal or above | 50        | 87        | 69      | 99        | 144       | 108     | 557       |       |
| 7-12.9 mg  | < Normal        | 83        | 68        | 42      | 95        | 94        | 65      | 447       | 1066  |
|            | Normal or above | 89        | 92        | 95      | 129       | 122       | 92      | 619       |       |
| Ge 13 mg   | < Normal        | 92        | 92        | 38      | 76        | 84        | 43      | 425       | 1057  |
|            | Normal or above | 94        | 138       | 85      | 118       | 123       | 74      | 632       |       |
| No Smoking | < Normal        | 60        | 42        | 38      | 107       | 95        | 81      | 423       | 1077  |
|            | Normal or above | 85        | 100       | 116     | 104       | 123       | 126     | 654       |       |
| Sub-Total  |                 | 621       | 762       | 586     | 868       | 1033      | 795     |           | 4665  |

Note: Targeted 83-84 subjects per cell

Presented at the PM/MDS KoP  
meeting, December 2003

22

### Distribution of TES Sample across Gender, BMI, and Age Stratification Cells

| Gender | BMI                      | 21-34  | 35-49  | ≥ 50   | Total   |
|--------|--------------------------|--------|--------|--------|---------|
| Female | Low & Normal (<25)       | 8.38%  | 8.58%  | 6.90%  | 24.87%  |
|        | Overweight & Obese (≥25) | 10.22% | 12.56% | 10.14% | 32.93%  |
| Male   | Low & Normal (<25)       | 5.98%  | 5.92%  | 3.69%  | 15.58%  |
|        | Overweight & Obese (≥25) | 10.42% | 10.42% | 8.87%  | 26.62%  |
| Total  |                          | 31.92% | 38.48% | 29.60% | 100.00% |

Presented at the PM/MDS KoP  
meeting, December 2003

23

### ... by Smoking Status

| Gender                 | BMI                              | 21-34  | 35-49  | > 50   | Total  |
|------------------------|----------------------------------|--------|--------|--------|--------|
| <b>Current Smokers</b> |                                  |        |        |        |        |
| Female                 | Low & Normal (<25)               | 6.09%  | 7.54%  | 5.17%  | 18.8%  |
|                        | Overweight & Obese ( $\geq 25$ ) | 8.00%  | 9.90%  | 7.44%  | 25.34% |
| Male                   | Low & Normal (<25)               | 4.69%  | 5.02%  | 2.87%  | 12.49% |
|                        | Overweight & Obese ( $\geq 25$ ) | 5.50%  | 8.27%  | 6.39%  | 20.16% |
| Sub-Total              |                                  | 24.28% | 30.73% | 21.87% | 76.79% |
| <b>Non-Smokers</b>     |                                  |        |        |        |        |
| Female                 | Low & Normal (<25)               | 2.29%  | 2.20%  | 1.74%  | 6.23%  |
|                        | Overweight & Obese ( $\geq 25$ ) | 2.23%  | 2.64%  | 2.70%  | 7.57%  |
| Male                   | Low & Normal (<25)               | 1.29%  | 0.90%  | 0.81%  | 3.00%  |
|                        | Overweight & Obese ( $\geq 25$ ) | 1.82%  | 2.14%  | 2.49%  | 6.45%  |
| Sub-Total              |                                  | 7.63%  | 7.88%  | 7.74%  | 23.25% |

Presented at the PM/MDS KoP  
meeting, December 2003

24

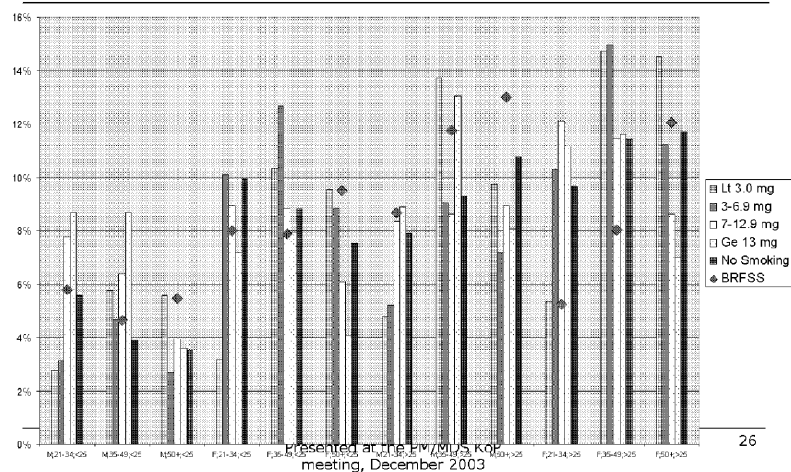
Default Weights for Tar Groups and Non-Smokers  
Based on Observed Sample Sizes  
(weights for each group sum to 1)

| Tar Group  | BMI             | Males     |           |         | Females   |           |         |
|------------|-----------------|-----------|-----------|---------|-----------|-----------|---------|
|            |                 | 21-34 yrs | 35-50 yrs | 50+ yrs | 21-34 yrs | 35-50 yrs | 50+ yrs |
| < 3.0 mg   | < Normal        | 0.0278    | 0.0577    | 0.0557  | 0.0318    | 0.1034    | 0.0954  |
|            | Normal or above | 0.0477    | 0.1372    | 0.0974  | 0.0537    | 0.1471    | 0.1451  |
| 3-6.9 mg   | < Normal        | 0.0312    | 0.0468    | 0.0270  | 0.1008    | 0.1268    | 0.0884  |
|            | Normal or above | 0.0520    | 0.0904    | 0.0717  | 0.1029    | 0.1497    | 0.1123  |
| 7-12.9 mg  | < Normal        | 0.0779    | 0.0638    | 0.0394  | 0.0891    | 0.0882    | 0.0610  |
|            | Normal or above | 0.0835    | 0.0863    | 0.0891  | 0.1210    | 0.1144    | 0.0863  |
| ≥ 13 mg    | < Normal        | 0.0870    | 0.0870    | 0.0360  | 0.0719    | 0.0795    | 0.0407  |
|            | Normal or above | 0.0889    | 0.1306    | 0.0804  | 0.1116    | 0.1164    | 0.0700  |
| No Smoking | < Normal        | 0.0557    | 0.0390    | 0.0353  | 0.0994    | 0.0882    | 0.0752  |
|            | Normal or above | 0.0789    | 0.0929    | 0.1077  | 0.0966    | 0.1142    | 0.1170  |

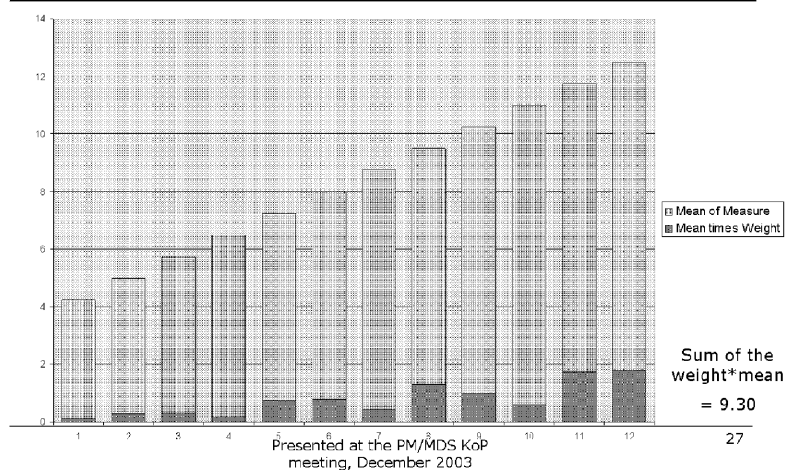
Presented at the PM/MDS KoP  
meeting, December 2003

25

# Default Weights for Tar Groups and Non-Smokers and BRFSS: Standard Weights

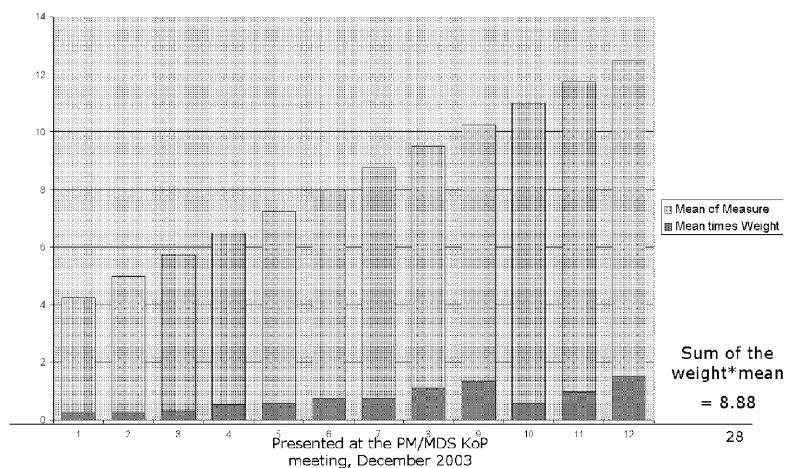


Means of a Measure for each Stratum and the  
Mean times the Default Weight  
for Tar Group 7-12.9 mg





Means of a Measure for each Stratum and the  
Mean times the Standard (BRFSS) Weight  
for Tar Group 7-12.9 mg



## Weighted Means of Measure by Tar Group

---

| Tar Group  | Weighted Means |
|------------|----------------|
| Lt 3.0 mg  | 9.299          |
| 3-6.9 mg   | 9.147          |
| 7-12.9 mg  | 8.801          |
| Ge 13 mg   | 8.694          |
| No Smoking | 9.065          |
| BRFSS      | 8.875          |

---

Presented at the PM/MDS KoP  
meeting, December 2003

29