

The Scientific and Public Health Foundation for Tobacco Harm Reduction

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Inveterate Smokers^{1,2,3}

Smokers Unable or Unwilling to Quit Smoking and Nicotine

- Use cigarettes as a convenient, inexpensive source of nicotine
- As many as 24 million in the US⁴
- Up to half will die from smoking

¹ Rodu & Cole, Nature 370: 184, 1994; Technology 6: 17-21, 1999.

² Broadstock, New Zealand Health Technology Assessment, 2007.

³ Gartner et al, Lancet 369: 2010-14 2007.

⁴ Rodu & Cole, International J Cancer 97: 804-06, 2002.

Conventional Smoking Cessation Ineffective Behavioral Therapy

US National Cancer Institute Manual for Physicians - Counsel Patients to:

- "Keep your hands busy - doodle, knit, type a letter"**
- "Cut a drinking straw into cigarette-sized pieces and inhale air"**
- "Keep a daydream ready to go"**

Source: How to help your patients stop smoking. NIH Pub. No. 93-3064, 1993

Conventional Smoking Cessation Inadequate Use of Nicotine

- **Temporary – 6 to 12 weeks**
- **Expensive – per unit and per box**
- **Very Low Dose – unsatisfying for smokers**
- **7% Success* – "Efficacious", "Modest"**

*J. Hughes et al. Meta-analysis in Tobacco Control, 2003.

Tobacco Harm Reduction

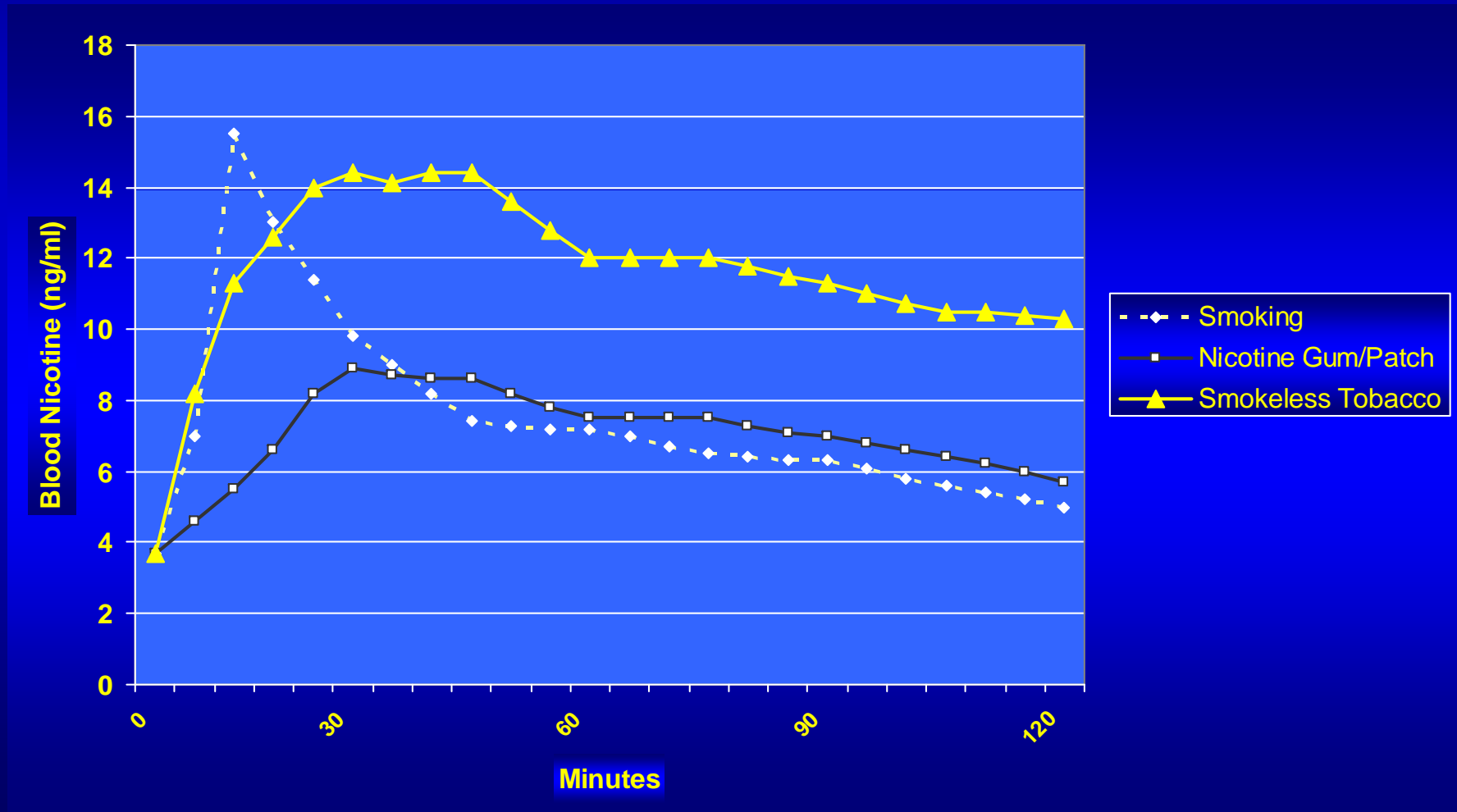
Permanent Nicotine Maintenance

Smokeless Tobacco

- Modern products are socially acceptable
- Nicotine levels comparable to smoking
- Population-based evidence from Sweden – and the U.S. – that smokeless works
- Vastly safer than smoking (>98%)

Nicotine Concentration from Smokeless Tobacco

(Adapted from N Benowitz. NEJM 319: 1318-1330, 1988)



Similarity of Nicotine and Caffeine

	<u>Nicotine</u>	<u>Caffeine</u>
Source	Plant alkaloid	Plant alkaloid
CNS	Stimulant Enhances Concentration Enhances Performance Sense of Well Being Mood Elevation	Stimulant Enhances Concentration Enhances Performance Sense of Well Being Mood Elevation
Addiction	Psychic Dependence Tolerance Withdrawal	Psychic Dependence Tolerance Withdrawal

Similarity of Nicotine and Caffeine

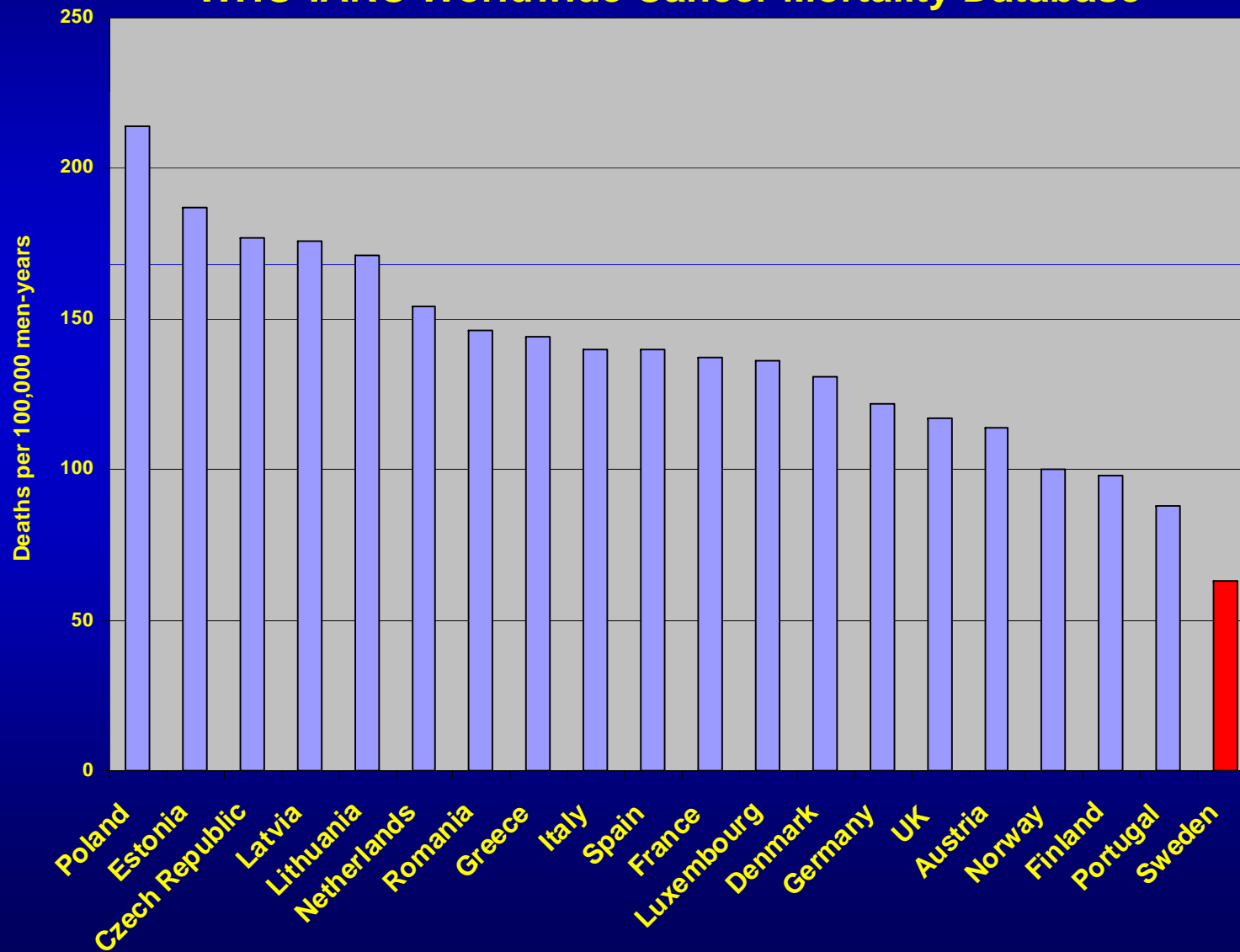
	<u>Nicotine</u>	<u>Caffeine</u>
Cardiovascular		
Temporary:	Increased Heart Rate Increased BP Vasoconstriction	Increased Heart Rate Increased BP Vasoconstriction
Causation:		
Cancer	Definitively No	Definitively No
Lung Disease	Definitively No	Definitively No
CV Disease	Not likely	Not likely

Tobacco Use: Swedish Men Past 50 Years

- Europe's **highest** per capita consumption of smokeless tobacco
- **Lowest** cigarette consumption in Europe
- **Lowest** lung cancer mortality rate in Europe
- **Lowest** percentage of smoking-related deaths among developed countries
- Among the **lowest** oral cancer mortality rate in Europe

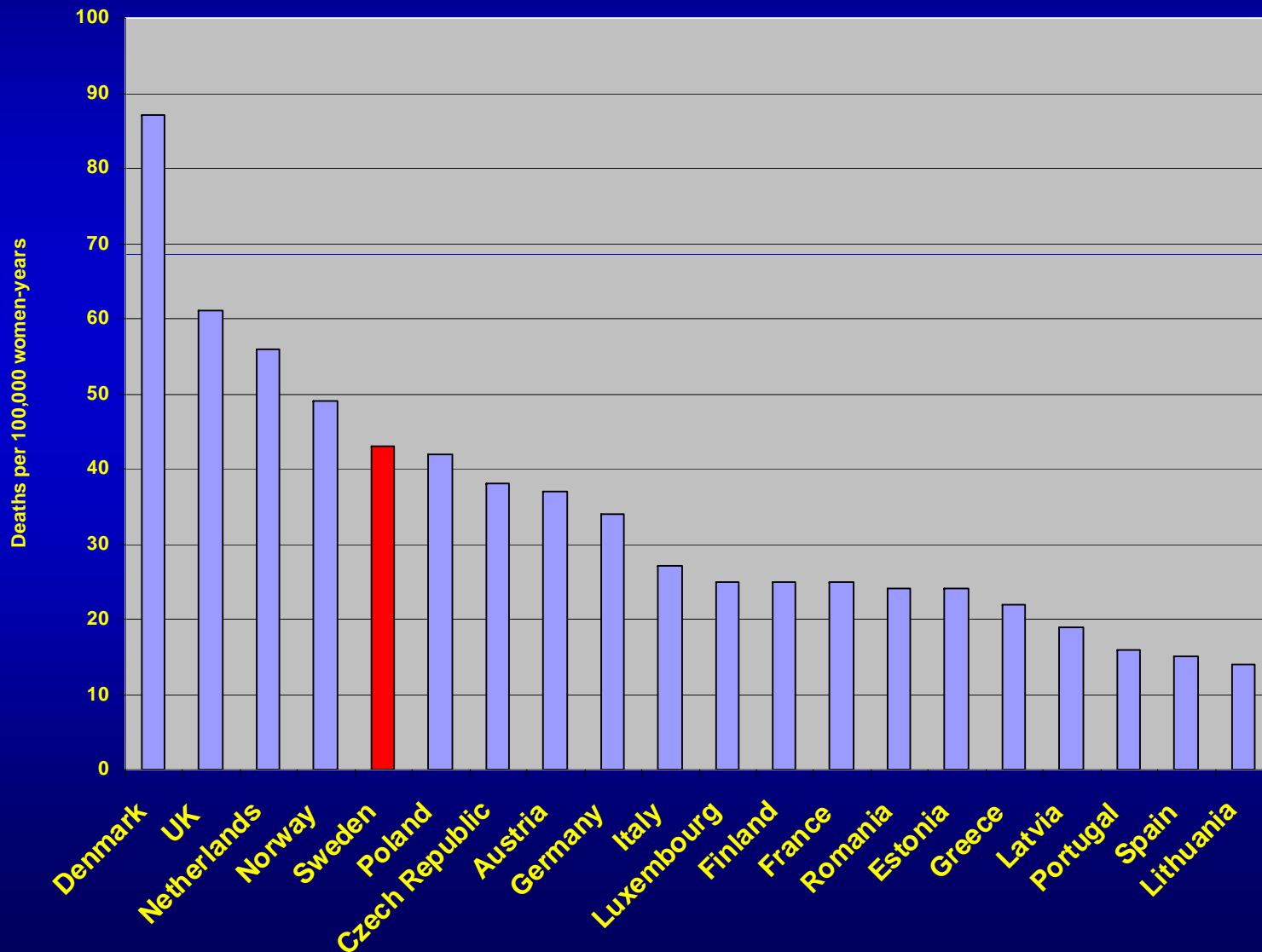
Lung Cancer Deaths, Men Age 40+, Europe 2002

WHO-IARC Worldwide Cancer Mortality Database



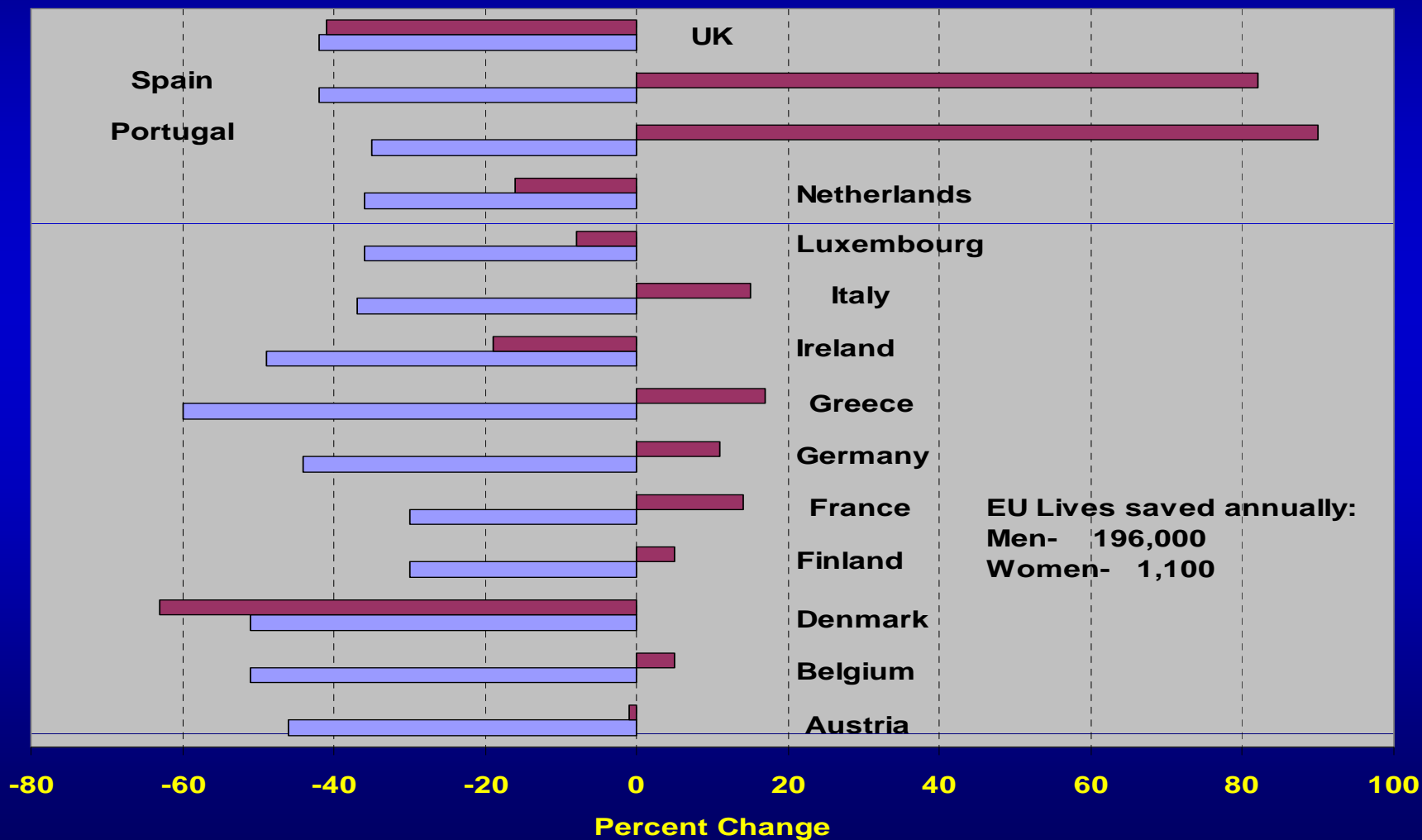
Lung Cancer Deaths, Women Age 40+, Europe 2002

WHO-IARC Worldwide Cancer Mortality Database



EU Smoking Deaths at Swedish Rates

Rodu and Cole. European J Epidemiology 19: 129-131, 2004

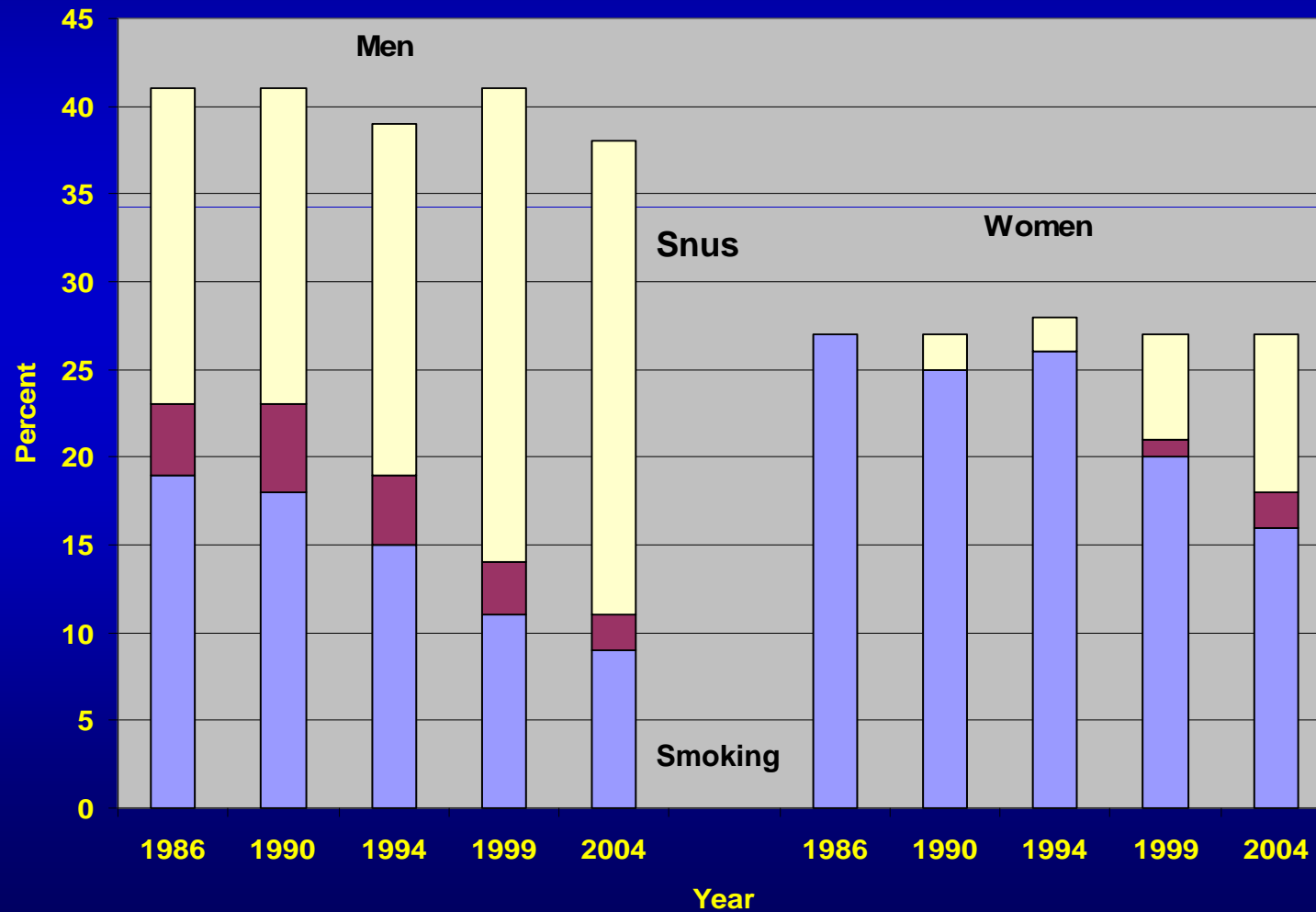


Tobacco Use Patterns in Northern Sweden

- WHO MONICA Study
- Northern Sweden -Norbotten & Västerbotten Counties; 1986, 1990, 1994, 1999, 2004
- Population surveys- stratified by age/gender
- Our Population
Men and women age 25-64
- Moist snuff (US) = Snus (Sweden)

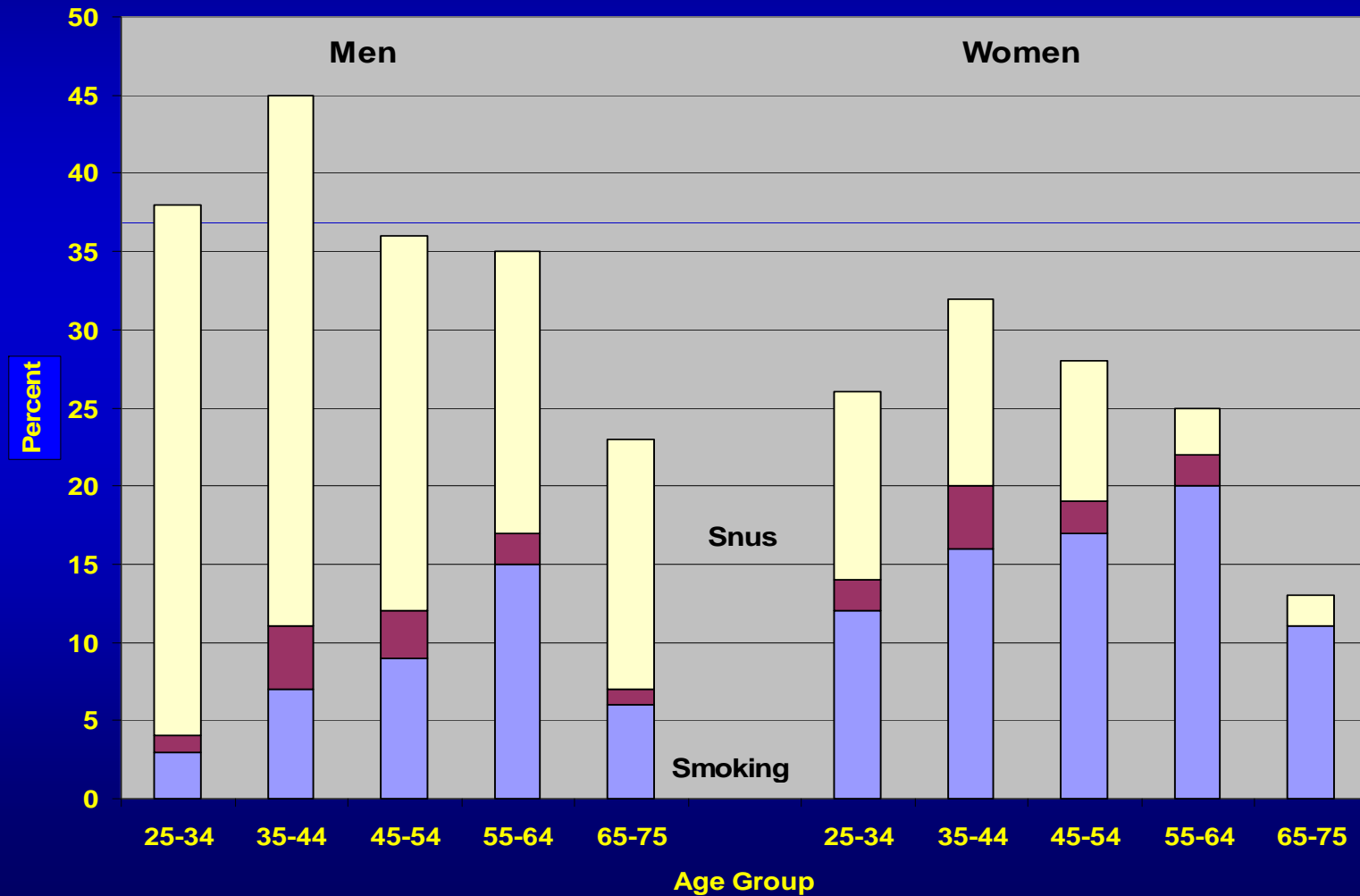
Tobacco Use in Northern Sweden

From Rodu et al, JIM 2002; Stegmayr et al, Scand J PH 2005



Tobacco Use Northern Sweden, 2004

From Stegmayer, Eliasson and Rodu. Scand J PH 33: 321-324, 2005



Other Studies of Swedish Tobacco Use

“...using snus, Swedish male smokers may increase their overall chances of abstinence” (by about 50%) – Gilljam and Galanti, *Addiction*, 2003

“For every snus user who takes up smoking, four smokers quit by switching to snus” – Swedish National Board of Health and Welfare Report, 2005

Snus use “associated with smoking cessation...” “...widely used, non-medical form of NRT” – Furberg et al. *Tobacco Control*, 2005

“The patterns observed in our study are in line with those of Rodu et al...” – Furberg et al. *Addiction*, 2006

“Use of snus in Sweden is associated with...an increased likelihood of stopping smoking.” – Ramström and Foulds. *Tobacco Control*, 2006

Smokeless Tobacco as a Smoking Cessation Method in the U.S.

2000 National Health Interview Survey

- Asked about 12 methods used in last quit attempt, including medications and switching to smokeless tobacco
- Former Smoker – method successful
- Current Smoker – method not successful
- Not a clinical trial, but real-world experience among smokers
- Our study – men only
- Nationally representative

B Rodu and CV Phillips, Harm Reduction Journal 5: 18, 2008

Smokeless Tobacco for Smoking Cessation Men in the U.S., 2000

<u>Method</u>	<u>Attempted*</u>	<u>Former* (%)</u>	<u>Current* (%)</u>
All	39,252	23,981 (61)	15,261 (39)
Nicotine Patch	2,881	996 (35)	1,885 (65)
Bupropion	1,060	308 (29)	752 (71)
Nicotine Gum	964	323 (34)	641 (66)
Nicotine Inhaler	98	27 (28)	71 (72)
Nicotine Spray	14	0 (0)	14 (100)
<u>Switch to ST</u>	<u>359</u>	<u>261 (73)</u>	<u>98 (27)</u>

*Numbers in thousands

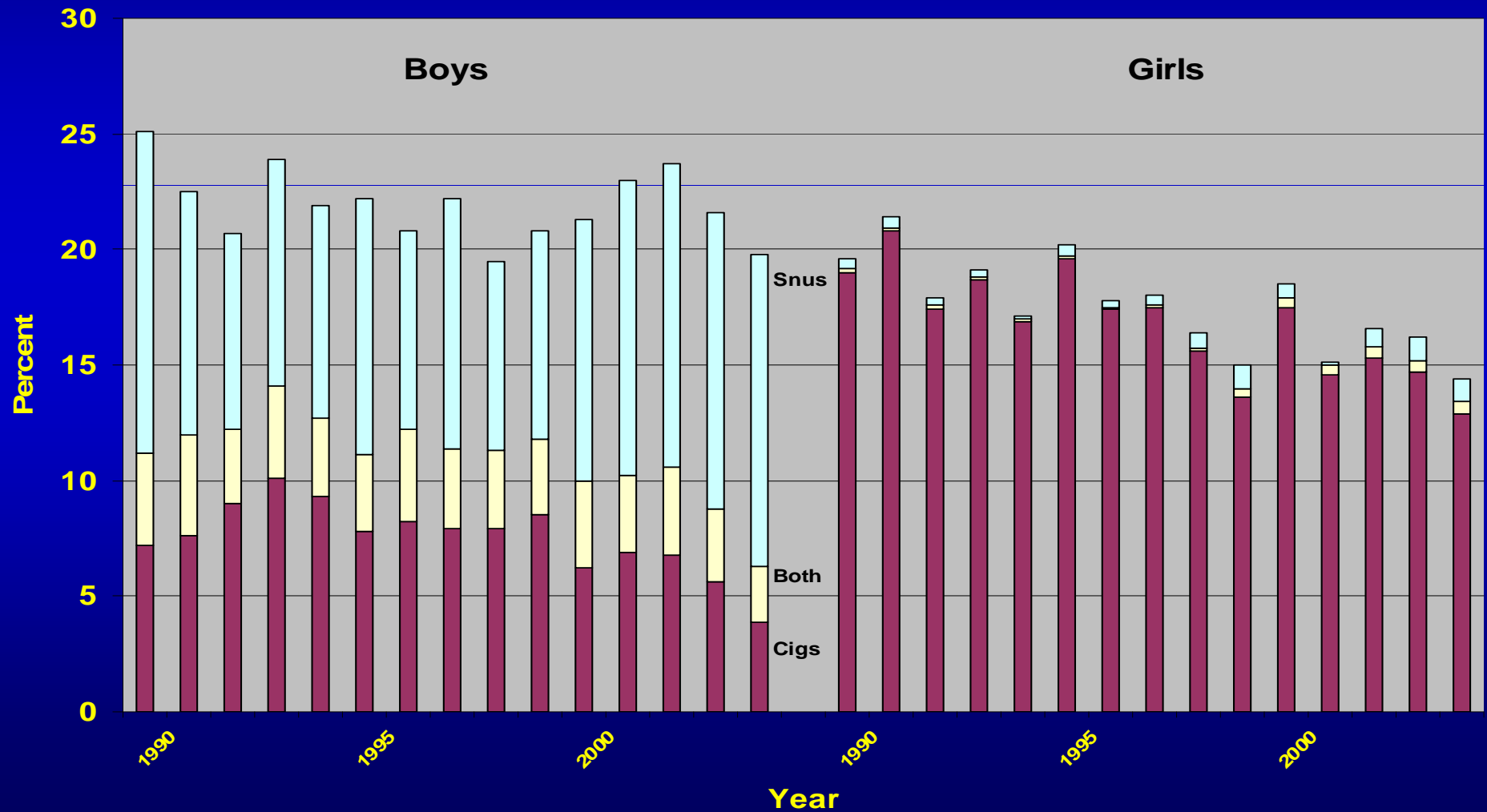
Rodu and Phillips, Harm Reduction Journal 5: 18, 2008

The Gateway Speculation: Will Snus Use Cause Swedish Children to Smoke?

- **Major Argument for:**
 - Sustaining the ban in the EU
 - Opposing harm reduction in the US
- **Swedish Council for Information on Alcohol and Other Drugs**
 - Tobacco Use Data from 1989-2003, nationally representative
 - 15-16 year old Swedish Schoolchildren
 - 5,600 surveys per year

Regular Tobacco Use in Swedish Boys and Girls Age 15-16 years, 1989-2003

From B Rodu et al. Tobacco Control 14: 405-408, 2005.



Other Swedish Gateway Conclusions

- “...in Sweden, the use of snus served not as a gate to smoking but as a way to give it up.” – Ramström, *Nicotine & Tobacco Research* 5: 261, 2003
- Snus use “inversely associated with initiation” - Furberg et al, *Tobacco Control* 2005
- “Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker...” – Ramström and Foulds, *Tobacco Control* 2006
- “The Swedish data...do not support the hypothesis that...snus is a gateway to future smoking.” – SCENIHR Report, 2007

Oral Cancer: The Risks and The Determinants

- **The Risks (with and without alcohol):**
 - Smoking**
 - ”Western” smokeless tobacco products**
 - Chewing tobacco, moist snuff, dry snuff**
 - ”Eastern” smokeless products**
- **The Determinants in Smokeless Tobacco:**
 - Tobacco-specific nitrosamines (TSNAs)**
 - Other Contaminants**

Smoking/Alcohol and Oropharyngeal Cancer

<u>Risk Factor</u>	<u>OR/RR</u>
Smoking 20-30+ pack-years	5-10
Heavy Alcohol Use 5+ drinks per day	4-8
Smoking + Heavy Alcohol	10-20

Adapted from: Lewin et al. Cancer 82: 1367-1375, 1998
Blot et al. Cancer Res 48: 3282-3287, 1988

Western Smokeless Tobacco Use and Head/Neck Cancer

Rodu and Cole. Oral Surgery 93: 511-515, 2002

- **Comprehensive Review of Western Products**
Data from 21 studies (20 case-control)
Range from 1957 to 1998
Last full review in 1986 (10 studies)
- **Methods**
Pooled relative risks (Mantel-Haenszel
Summary ORs)
Specific anatomic sites
SLT type: Chewing tobacco, moist snuff, dry
snuff, unspecified

Smokeless Tobacco and Head/Neck Cancer

Rodu and Cole. Oral Surgery 93: 511-515, 2002

<u>SLT Type</u>	<u>RR (95%CI)</u>	<u>Studies</u>	<u>Cases/Controls</u>
Chewing tobacco	1.2 (1.0-1.4)	8	3145 / 5245
Moist snuff	1.0 (0.8-1.2)	5	2846 / 4926
Dry snuff	5.9 (1.7-20)	4	391 / 1340
Unspecified	1.9 (1.5-2.3)	7	1428 / 3681

Strengths and Limitations of the Review

- **Strengths**

- Large numbers of cases and controls**

- **Limitations**

- Many studies lack control of confounding by**

- Smoking- positive and negative**

- Alcohol - positive only**

- Lack of clarity regarding anatomic sites**

Smokeless Tobacco and Oral Cancer

Relative Risks

Smoking	~10
Alcohol Abuse	~4

American Smokeless Tobacco*

Chewing tobacco	1.2 (1.0 – 1.4)
Moist snuff	1.0 (0.8 – 1.2)
Dry Snuff	5.9 (1.7 – 20)

Incidence Rate in Long-term ST users (At RR=4):
26 per 100,000 person-years (py)

*Over 20 epidemiologic studies, reviewed in: B Rodu, P Cole. Oral Surgery 93: 511-515, 2002.

Smokeless Tobacco and Oral Cancer

Incidence Rate: 26 per 100,000 person-years (py)

Mortality Rate:

American ST Users	12 per 100,000 py
American Automobile Users	15 per 100,000 py

Swedish ST Users	Even Fewer
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Smokeless Use and Oral Cancer

Recent Studies Showing No Risk

- **Swedish**

Case-referent	Cancer, 1998
Case-control	Int J Cancer, 1998
Case-control	Acta Oto-Laryngol, 2005
Follow-up	Lancet, 2007

- **American**

Follow-up	Am J Epidemiol, 2002
Follow-up	Cancer Cause Contr, 2005
Follow-up	Cancer Cause Contr, 2005 (ACS)

Smokeless Tobacco and Cancer Risk

Waterbor et al. J Cancer Educ 2004: 19: 17-28

– Oral Cancer:

The scientific evidence: not decisive.

“Many brochures overemphasize the risk of oral cavity cancer, reaching beyond the scientific data.”

SLT Use in the West and the East

What Explains the Difference in Risk?

	<u>Western</u>	<u>Eastern</u>
<u>Determinants</u>		
Manufacturing	Centralized	Local
Process controls	High	Low
TSNA's	Very Low	Variable
Other contaminants	Low	Unknown
Additives	Few	Betel, areca, lime
<u>Risks</u>	Very Low	High

Tobacco/Alcohol Use and Oral Cancer in India

From Znaor et al. Int J Cancer 105: 681-686, 2003

Odds Ratios in Men¹

<u>Tobacco</u>		<u>No Alcohol</u>	<u>Alcohol</u>
Neither		Ref	2.6
Smoking		2.5	4.8
Quid	Without Tobacco	3.4	4.4
	With Tobacco	9.3	24
Smoking and Quid Use		8.5	16

¹ Adjusted for age, region and education.

Smokeless Tobacco and Other Cancers

Waterbor et al. J Cancer Educ 2004: 19: 17-28

- Pharynx and larynx cancer. (The scientific evidence: no relationship)**
- Lung cancer. (Evidence: inadequate)**
- Stomach cancer. (Evidence: not persuasive)**
- Kidney cancer. (Evidence: no association)**
- Esophagus cancer. (Evidence: not persuasive)**
- Pancreas cancer. (Evidence: inconclusive)**
- Breast cancer. (Evidence: none)**
- Bladder cancer. (Evidence: none)**

Smokeless Tobacco Use and Pancreas Cancer

Four Recent Studies

		Relative Risk
• Cancer Epi Biom Prev, 2004	(U.S.)	1.4
• Int J Cancer, 2005	(Norway)	1.6
• Lancet, 2007	(Sweden)	2.1
• Cancer, 2007	(US)	0.5

Unresolved Technical Issues:

Poor control of confounding (family hx, alcohol, smoking)

Selective exclusions

Much lower than risk among smokers

Smokeless Use and CV Diseases

10 Relevant Studies

No Risk
Case control

Snus and:
Myocard Infarct

J Int Med, 2007
Epidemiology, 2005
J Am Coll Cardiol, 1999
Br Med J, 1992
Stroke, 2003
J Int Med, 2007
Eur J CV Prev Rehab 2005
Am J Epidemiol, 2002

Follow-up

Stroke
Myocard Infarct
Coron Heart Dis
Cardiovasc Dis

Low Risk
Follow-up

RR=1.4 CV Disease
HR=1.2 CV Disease

Am J Publ Health, 1994
Canc Cause Contr, 2005 [ACS](#)

Tobacco Use and Weight Gain Among Men in the MONICA Study

<u>Tobacco Use</u>	<u>Avg Gain (lbs, 9 yrs)</u>	
Nonusers (Referent)	7.0	
Consistent Smokers	5.1	
Smokers Who Quit Tobacco	15.0	p < 0.05
Smokers Who Switched to Snus	7.9	
Consistent Snus Users	6.8	
Snus Users Who Quit Tobacco	11.2	p < 0.05

Adapted from B. Rodu et al, Journal of Internal Medicine 255: 102-107, 2004.

Growing Discussion about Tobacco Harm Reduction

- 2002 Royal College of Physicians Report

Consumption of smokeless 10 to 1,000 times less hazardous than smoking

Manufacturers may market products as harm reducing; they may find support in the public health community

- 2004 Cancer Epidemiology Biomarkers Prevention, NCI Funded

Smokeless products at least 90% safer than smoking

“... raises ethical questions concerning whether it is inappropriate and misleading for government officials or public health experts to characterize smokeless tobacco products as comparably dangerous with cigarette smoking.”

Growing Discussion about Tobacco Harm Reduction

- 2006 Addictive Behaviors, NCI Funded

“...4 million [American] smokers would switch to the low-carcinogen smokeless tobacco.”

- 2006 American Council on Science and Health (www.acsh.org)

”....there is a strong scientific and medical foundation for tobacco harm reduction, which shows great potential as a public health strategy to help millions of smokers.”

Policy Recommendations

Endorsed by the American Council on Science and Health

- **Discontinue the campaign of misinformation about smokeless tobacco**
 - Federal agencies – e.g. Surgeon General**
 - Remove “This product is not a safe alternative to cigarettes”**
 - Health organizations – e.g. ACS, Mayo Clinic**
- **Revise regulatory restrictions on NRT products**
 - Higher doses, Better flavors, Lower costs**
 - Longer duration**
- **Establish rational state excise tax policies based on risk**
 - Kentucky, 2005**

Harm Reduction Journal 3: 37, 2006

Policy Recommendations

Endorsed by the American Council on Science and Health

- **Acknowledge that smokeless tobacco use is vastly safer than smoking**
All American cigarette manufacturers have done this –
It is time for the public health community to act
Federal legislation regulating tobacco should not prohibit cross-category comparisons
- **Communicate to smokers through a cigarette pack insert**
Smokeless has risks, but cigarettes are far more dangerous
Quitting tobacco is ideal, but switching to smokeless can greatly reduce risks to smokers and those around them

Harm Reduction Journal 3: 37, 2006

Growing Discussion about Tobacco Harm Reduction

- **2007 Royal College of Physicians Report**

Makes the case for harm reduction strategies to protect smokers... Smokers smoke predominantly for nicotine,...nicotine itself is not especially hazardous,...provided in a form that is acceptable and effective as a cigarette substitute.

Harm reduction

- a fundamental component of many aspects of medicine and... everyday life...
- has not been applied to smoking.
- controversial, and challenge many current and entrenched views in medicine and public health.
- has the potential to save millions of lives, and deserves consideration.

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For More Information

www.smokersonly.org