
IARC Overview & Communications Plan

September 1996

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Presentation Outline

- What is IARC?
- Prior publications on tobacco
- Current research on tobacco
- Potential impact
- Communications plan

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International Agency for Research on Cancer (IARC)

- Leading international cancer research agency
- Funding from 16 Nations
 - U.S., Germany, Japan largest supporters
- Affiliated with W.H.O.
- Located in Lyon, France

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IARC's Mission

"...to conduct research on the causes of human cancer and to develop strategies for cancer control."

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Previous IARC Publications on Tobacco

- 1986 IARC Monographs on the Evaluation Of
The Carcinogenic Risk of Chemicals To
Humans: Tobacco Smoking
- 1987 Environmental Carcinogens: Methods of
Analysis and Exposure Measurement:
Passive Smoking
- Since 1977 38 Publications related to ETS published
by IARC affiliated authors

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IARC's 1986 risk classification - active smoking

Conclusions:

"There is *sufficient evidence* that inhalation of tobacco smoke as well as topical application of tobacco smoke condensate cause cancer in experimental animals.

"There is *sufficient evidence* that tobacco smoke is carcinogenic to humans.

"The occurrence of malignant tumours of the respiratory tract and of the upper digestive tract is causally related to the smoking of different forms of tobacco (cigarettes, cigars, pipes, *bidis*). The occurrence of malignant tumours of the bladder, renal pelvis and pancreas is causally related to the smoking of cigarettes."

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Conclusion on ETS

"Several epidemiological studies have reported an increased risk of lung cancer in nonsmoking spouses of smokers, although some others have not. In some studies, the risk of lung cancer in nonsmokers increased in relation to the extent of spouses' smoking. Each of the studies had to contend with substantial difficulties in determination of passive exposure to tobacco smoke and to other possible risk factors for the various cancers studied. The resulting errors could arguably have artefactually depressed or raised estimated risks, and, as a consequence, each is compatible either with an increase or with an absence of risk. As the estimated relative risks are low, the acquisition of further evidence bearing on the issue may require large-scale observational studies involving reliable measures of exposure both in childhood and in adult life."

IARC, 1986

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IARC's Tobacco Agenda

"...tobacco and cancer will remain a focus of the Agency's epidemiological work since it is now generally agreed that in developed countries approximately 30 to 35% of all human cancers are related to tobacco consumption and worldwide, one in seven cancers can be attributed to smoking. The question to which extent passive smoking constitutes a health risk has not yet been unanimously solved. The Agency is involved in a multi-centre case-control study in European countries, to be completed in 1995."

IARC Proposed Program (1996-1999) and Budget (1996-1997)
Governing Council, Lyon, France
April 27-28, 1995

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Current IARC Research on ETS

- Multicenter study on ETS
- Risk classification on ETS

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Multicenter Study on ETS

- Begun in 1988
- Examines lung cancer risk for nonsmoking women living with smokers
- Relies principally on questionnaires
- Initially included cities in Asia, North America and Europe
- Currently narrowed to 10 cities in 7 European countries

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Multicenter Study Cities

- 10 Cities in 7 Countries

- Portugal -- Lisbon & Vila Nova
- United Kingdom -- Oxford
- France -- Villejuif
- Spain -- Barcelona
- Italy -- Turin & Padua
- Sweden -- Stockholm
- Germany -- Wuppertal & Bremen

- Principal investigators in Sweden and France are committed anti-smokers

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Multicenter Study -- Possible Outcome

- **What?** A relative risk for spousal nonsmoker exposure to ETS
- **When?** From first quarter 1997
- **Where?** Published in a peer review journal
 - > European Journal of Cancer
 - > The Lancet
 - > British Medical Journal
- **How?** Probable media event organized by the journal and/or IARC and W.H.O. to publicize results
- **After?** Individual study center results may then be published separately

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Risk Classification of ETS

- Proposed title: ETS and Tobacco-Related Nitrosamines
- Drafted by an expert international working group:
 - Biostatistics, toxicology, epidemiology and pharmacology
- IARC staff is the secretariat for the working group
- Observers from government and industry participate
- Based on a review of all peer review and government publications on ETS
- Announcement of classification scheduled October 1997
- Written publication will follow

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IARC'S Risk Classification System

- **Group 1** **Known carcinogen**
 - asbestos, benzene, tobacco products, vinyl chloride

- **Group 2A** **Probable carcinogen**
 - formaldehyde, cadmium

- **Group 2B** **Possible carcinogen**
 - DDT, chloroform, carbon tetrachloride

- **Group 3** **Not classifiable**
 - cholesterol, cyclamates

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Potential Impact - Multicenter Study

■ Media reaction

- Major story in Europe
- News in other parts of the world
- Renewed allegations of “excess deaths” due to ETS exposure

■ Government reaction

- In Europe a demand for tougher smoking restrictions in public places
- Possibly increased demands for new regulation outside Europe

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Potential Impact - Risk Classification

■ Government reaction

- Health ministries initiate new regulations restricting or banning smoking in public
- Basis for W.H.O. worldwide campaign?
- Confirm other classifications of ETS by the EPA and, upcoming, SCOTH report

■ Media reaction

- Worldwide news
- "Debate closed on ETS" (depending on the classification)
- Demands for severe restrictions or bans on public smoking

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Response to IARC

- Scientific
- Corporate affairs

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Scientific Response

- Monitor developments
- Maintain dialogue
- Assess prior publications by IARC
 - Look for precedents on ETS -- Is there bias?
 - Establish criteria for study design -- Is there a double standard?
 - Confounders, bias, exposure
 - What basis is there for the interpretation -- Do the data support the conclusions?
- Participate in risk classification working group
- European Independent Scientific Panel
- Original research on exposure and confounders

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Corporate Affairs Response

- Hospitality and workplace allies
- Endorsement of Good Epidemiological Principles
- E.U. campaign
- Media background briefings
- Simulations in Europe and Asia
- Industry communications plan

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Research

- **Personal monitoring studies to measure actual nonsmoker exposure to ETS**
 - **ETS exposure is minimal**
 - **Lowest in the workplace, then public places and the home**
 - **Nonsmokers overestimate perceived exposure**
 - **Reported nonsmokers are misclassified**

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Personal Monitoring Study Centers

- U.K. Published November 1994
- Sweden Published July 1996
- Other European sites
 - Spain, Germany, France, Portugal, Italy, Switzerland and Czech Republic
- Asian sites
 - Hong Kong, Malaysia and Beijing
- Australia

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Confounder Studies

- To identify possible confounders that may play a role in health end points traditionally associated only with ETS
- Italy and Germany
- “Paper studies” relying on national health statistics and
- Clinical observation studies
- Similar to the Matanoski paper published July 1996

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Recent Publications by IARC Staff

- A series of literature reviews on ETS scientific publications
- A study validating the use of questionnaires which are relied upon in most of the ETS epidemiology
- Establish an acceptable rate for smoker misclassification (1.5%)
- What does the subject and timing these publications suggest?
 - IARC is building a defense for the design and outcome of the multicenter study

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ETS Literature Reviews by IARC Authors

- 1993 "Environmental Tobacco Smoke and the Risk of Lung Cancer in Adults"
- 1994 "Exposure to Environmental tobacco smoke and Adult Nonneoplastic Respiratory Diseases"
- 1994 "Exposure to Passive Smoking During Childhood and Cancer Risk: The Epidemiological Evidence"
- 1994 "Exposure to Environment Tobacco Smoke and Risk of Lung Cancer: The Epidemiological Evidence"

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IARC Communications

Industry Communications Plan

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Objective

- Manage initial (2-3 days) Media Response to IARC
 - Rapidly
 - Efficiently
 - Consistently

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How This Gets Done

■ Establish Regional Co-ordination Teams

- EU -- lead
- Europe (non-EU)
- Canada
- Latin America
- U.S.A.
- Asia
- Japan
- Australia

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Europe Coordination Team

- **E.U. Level:**

- **Management Team**
- **Scientific Assessment Team**
- **Europe Communications Support**

- **Country Level:**

- **In-Market Response Teams**

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Management Team

- **Members**

- **CA Heads from:**

- **B.A.T., PM, RJR, Rothmans, Imperial, Reemtsma**

- **Team Leader among CA Heads**

- **1 Legal Representative (SH&B)**

- **1 Scientific Coordinator**

- **Operations based at Burson Marsteller / London**

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Management Team

■ Responsibilities

- Plan activation
- Strategic analysis and decision making
- Refine and approve communications materials
- Legal approval
- Spokesperson for select major EU media
- Coordination with Scientific Assessment Team

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Scientific Assessment Team

■ Members

- A principal Europe-based scientist from member companies
 - Team leader/Scientific coordinator reports to Management Team

■ Operations based at Burson Marsteller / London

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Scientific Assessment Team

■ Responsibilities

- Evaluate Multicenter Study
 - Preliminary analysis
 - Comprehensive analysis
- Act as spokespersons as-needed
- Provide additional scientific information as needed

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Europe Communications Support

■ Members

- Communications Executives from each member company
- Team Leader will liaise with Management Team

■ Location to be determined

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Europe Communications Support

■ Responsibilities

- Liaison with E.U. NMAs
- Liaison with Non-E.U. regional coordinators
 - E.U., Europe (Lead), Europe, other, Canada, Latin America, U.S.A., Asia, Japan, Australia
- Distribute communications materials to market/regions
 - Holding statement (prior distribution)
 - Press release
 - Preliminary and comprehensive study analysis
 - Additional materials as needed
- Screen/evaluate media inquiries and implement or recommend responses to Management Team
- Liason with non-EU regional teams

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In-Market Response Teams

■ Members

- Company executives/NMAs/CDITs
 - Spokesperson(s) to be identified

■ Responsibilities

- Prepare local response plan
- Identify liaisons with European response center
- NMAs liaise with country company representatives
- Respond to local inquiries based on pre-determined local plans
- Country company representatives communicate with company-specific Management Team members as needed

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