CESSATION/EDUCATION MEETING - JULY 9

CESSATION

Questions

Should we do a big federal program or encourage people to use private programs?

- obviously costs less to let private do it
- if we actually can increase demand for programs, private will most likely respond to that
- we can also create demand by going after employers who buy coverage
- by educating, we don't risk supplanting current state or private cessation programs (ec talk – offer a public good)
- Republican Congress likes priv. vs. public bureacracy
- Possible Problem – companies may try to hook people on the programs so they can make more money (disincentive to actually cure them?)
- we may want to expand Medicaid or Medicare to cover cessation, but need to do cost #'s

How much does it cost to quit?

- there was a number quoted for nicotine replacement cigarettes as $65 a month
- still looking for more #'s

Does cessation work?

- the approximate success rate of cessation programs is 10 percent
- if we spend on research first...we may get more in return
- Access to cessation programs does not equal results. Most people quit because of will power. We need to change attitudes and getting people to want to quit.

How effective is Massachusetts's and California's programs?

- they are comprehensive...we got some info from Mass today via fax

What about Youth Cessation?

- it is presently rare and there is a definite need for it
- tough to study because tough to get teens into labs
- addiction looks similar to adult addiction after 2–3 years
- treatment methods for kids should be different (group therapy no good)
- school based education mixed w/ cessation may work

POSSIBLE STRATEGY

There is an overlap with education and cessation, so we can educate/encourage people to quit smoking, as well as try to prevent adolescents from starting. We should also spend money on researching how to effectively stop smoking, and maybe transfer that money to implementing

the programs once we determine what's best.

EDUCATION

ASSIST (Mark Manley)

ASSIST is a 17-state tobacco control demo run by the National Cancer Institute. It costs an average of $1.2 million per state. ASSIST is most effective in setting up anti-smoking infrastructure and building coalitions and networks among businesss, state and local governments, and interest groups. It gives the movement a voice in major meetings and makes sure that the issue remains on the table. It currently does not fund much more than general staff things. Some states choose to use other resources to fund more extensive programs, most notably Massachusetts and California, which fund massive anti-smoking campaigns with excise taxes. (MA is an ASSIST state, CA isn't.) The results seem promisi, cutting consumption rates by an average of 7 percent. (Massachusetts has a drop of about 28 percent...but the cigarette tax may have a lot to do with this)

EDUCATION CAMPAIGN (CDC guy)

1- $500 million is a reasonable number for a nationwide campaign
   - if Mass. was implemented nationwide, it would cost at least $600 million

2- Campaign management - national, state, and local should all work together
   - may be easier to buy media nationwide (kids may repond better to this too)
   - follow up and drive it home with local events & schools, etc.
   - schools, media, community all complement each other
   - the event sponsership replacement provision will primarily go to small venues

DRAFT (July 9, 1997)

SMOKING CESSATION & EDUCATION
Workgroup Consensus: Highlights

Scope of the Problem:

- There are approximately 50 million smokers, and about 20 million would like to quit. The settlement provides substantial funds to help them do so.

- There is a direct relationship between cessation of tobacco use and public education, therefore, public education will be treated as an integral component of any approaches designed to reduce the use of tobacco products.

- Cessation and education strategies must take into account that smoking is an addiction, therefore, it should not be anticipated that success rates for cessation treatments will be comparable to those for more acute processes such as antibiotics for infections. Instead, cessation programs should be regarded in the same light as other chronic conditions such as diabetes, and their success should be held to similar standards.

Settlement Funds Available: In addition to funds specified for cessation and education activities, we should consider crossover with other funding streams, i.e., "Teams' Fund" ($1.8 billion), and Public Health Trust Fund ($25 billion):

Funding Mechanisms/Decisionmaking:

- Mechanisms of administration of settlement funds (e.g., government versus nonprofit entity versus combination of different mechanisms separating control to different pots of money as an accountability feature).

- Need for investment, decisionmaking and priority-setting mechanisms.

- Federal programs (NIH ASSIST, CDC IMPACT, ungirded by the funded state and local programs(including school-based programs) can provide infrastructure for new activities--broader program implementation, permitting local control and input, tailored to local needs. Need to look at states that spend more per capita and have more effective programs (e.g., California and Massachusetts).

- Tribes - the settlement treats tribes like states, but the formula is based on tribal population as a percentage of state population, thus not providing adequate funds for successful program implementation.

Spending Priorities:

- A lot is known about education and cessation program effectiveness (see attachments). There is an issue about whether to use funds to invest in areas (education and assistance) that create demand for cessation services/products or on service delivery or programs that are or could/should be provided by others (particularly the private sector). In areas where we do fund services, those services should be targeted on certain subpopulations.

- Need to develop effective cessation programs for youth (controversial, e.g., use of nicotine replacement products).

- Some portion of cessation and education money needs to go to teach clinicians (nurses and doctors) and managed care plans as to how to encourage smoking cessation.

- There is some evidence that although it costs more to provide cessation services to more individuals, after a certain point there is an economy of scale, and costs per individual begin to decrease so that the overall program is more cost-effective (i.e., the higher the investment, the more return you probably will see per dollar invested)

Research Needs: Necessary crossover with Settlement's research funding.

- Need for market analysis for private sector delivery of cessation programs/products--government does not necessarily need to supplant current market demand. In addition, need analysis of insurance plan cessation programs, reimbursement, incentives. Currently, all insurance companies have some sort of limit on cessation programs (e.g., in the form of co-pays and/or limits on the number of visits).

- Need to characterize why it is so hard to get people into intensive treatment (lack of access when they are ready? too complicated to enter the system?).

- Need market research on nicotine replacement market (one company spends $120 M on PR alone for product, profits must be much higher). Specific concern that minorities and lower-income people cannot afford these techniques.

Current HHS Public Education Activities on Tobacco Control

Media Campaigns

- Through its Media Campaign Resource Center for Tobacco Control, CDC maintains a large inventory of counter-advertising materials (TV, radio, print, outdoor) developed by the federal government, national organization, and states. However, there are no funds available at the national level for paid placement of these ads. Instead, CDC negotiates legal rights to these materials and promotes their use, either as public service or paid placements, to states and nonprofit organizations. ***Annual budget: $500,000***

- As part of its national support of ASSIST, NCI makes available to states a modest pool of funds for paid placement of selected ads from Massachusetts (an ASSIST state that subsequently launched a large excise-tax-supported tobacco control program). ***Annual budget: $500,000*** *(included in the total for state-based programs)*

- The three nationwide state-based tobacco control programs (ASSIST, IMPACT, and SmokeLess states) allow for paid media placement, but individual states vary widely in their ability to pay for media. In general, because of very modest media budgets, states use paid media for highly focused public policy issues rather than for broad public health education. ***Annual budget: $4-5 million*** *(included in the total for state-based programs)*

- The only substantial budgets for mass media efforts are in states with excise-tax-funded programs (California, Massachusetts, Arizona, Oregon, Maine) or with other special appropriations (Maryland, New York). ***Annual budget: $50 million***

- Through the Prevention Center at the Columbia School of Public Health, CDC is supporting a panel of marketing experts to advise CDC on effective media strategies for preventing tobacco use, to develop a national media plan, and to develop a marketing strategy for enlisting private-sector support of the campaign. However, no funds are currently available for funding actual media placements. ***Annual budget: $100,000***

Other Communication Activities

- The Secretarial Initiative to Prevent Tobacco Use Among Teens and Preteens presents a number of specific activities, planned or underway, that make use of mass media and/or interpersonal communication. Examples include: a coordinated entertainment industry strategy to deglamorize tobacco use; a national campaign targeted to parents and caregivers; a media literacy education program aimed at teachers and youth leaders; national diffusion of effective school-based programs; and a national youth summit on tobacco control. Substantial additional funds have been requested in FY 99 to support and expand these activities, but current agency funding levels are very modest. ***Annual budget: $2-3 million*** *(not including state infrastructure costs to deliver programs)*

CDC Office on Smoking and Health
July 9, 1997

Smoking Cessation
Office on Smoking and Health, CDC; July 9, 1997

Four major issues on cessation were discussed by the subcommittee, as indicated below. To put the settlement dollars into context, in 1990, the cessation market (services and products) was $316 million. With the advent of nicotine replacement therapy (NRT) in 1992, the cessation market increased to nearly $1 billion ($820 NRT and $170 cessation services). In 1996, the NRT market was $660 million. There is some evidence that the cessation services market has eroded further since 1992. This is in contrast to a $46 billion market for cigarettes.

What is the relative effectiveness of smoking cessation interventions compared to other health interventions; i.e., is cessation a worthwhile place to spend the money?

- Smoking cessation is a critical component of comprehensive efforts to reduce tobacco use.
- Nicotine addiction is a chronic disease, and should be treated as such by the health care system.
- Cessation interventions include both clinical and non-clinical interventions.
  - Efforts must be made to increase interest in quitting (thereby increasing demand for services).
  - Media attention to smoking issues (cessation, prevention, and protection of non-smokers), as well as policy interventions such as clean indoor air regulations and excise tax increases, complement clinical activity to increase people's interest in quitting and quit attempts.
- The AHCPR smoking cessation guideline, an evidence-based guideline, shows that effective smoking cessation interventions exist.
- These proven interventions need to be disseminated; it is estimated that widespread implementation of the AHCPR smoking cessation guidelines could double cessation rates.
  - Given that about 1.3 million of the 50 million smokers in the United States quit each year, this could result in an additional 1.3 million successful quit attempts each year.
- Clinical interventions for smoking cessation are more cost-effective than commonly provided (and covered) screening procedures as well as the treatment for hypertension and hypercholesterolemia.
- A variety of effective cessation services need to be available and accessible to the smoker interested in quitting, such as access to clinical interventions of various intensities and formats, nicotine replacement therapy, and telephone hotlines/helplines.

Would payment for smoking cessation services just shift payment for services from the private sector (managed care and other insurers) to the settlement money?

Overall, coverage of cessation services is low. In addition, smokers are more likely to be socioeconomically disadvantaged and therefore less likely to have insurance plans that cover these services.

- Large managed care plans, particularly group-model HMOs, are the most likely to provide cessation services. In 1995, however, a survey of 105 larger HMOs showed that although 2/3 provided some level of coverage for cessation services or products, most had restrictions on this access.

- Indemnity insurance plans and self-insured corporations are least likely to provide coverage of cessation services and products.

- Currently only 6 states' Medicaid programs cover the cost of over-the-counter nicotine replacement therapy.

- Medicare does not pay for smoking cessation interventions or NRT.

Even if the money does not supplant money already being used for cessation services, can we realistically cover smoking cessation services for all smokers?

- There was not great support among subcommittee members for the settlement money to be used to fully fund cessation services for all smokers. However, it was noted that although full coverage of cessation services increases cost, it also increases the number of quitters by a comparable degree (e.g. 50% increase in cost results in 50% more ex-smokers).

- There was support for trying to supplement existing services, such as by providing matching funds for insurer and managed care plans that provide cessation services.

- There also was support for more complete funding of cessation interventions for underserved populations.

What is a good way to spend the money allocated to smoking cessation?

- Market analysis of cessation services to determine how are such services being paid for, who is buying the services, and who is being left out.

- Broad dissemination and adoption of the AHCPR smoking cessation guideline (provision of brief advice to quit to all tobacco users, recommendation for NRT use by all smokers unless contra-indicated, and provision of more intensive services for individuals interested in using these services), including training of health care providers in these interventions.

- Reduction or elimination of financial barriers to accessing cessation services and products (by providing incentives for insurance coverage of these services, by ensuring Medicare/Medicaid coverage of these services, and by funding these services for those who are not covered by other mechanisms).

- Incentives for health care systems to establish tobacco use as a vital sign (AHCPR guideline) and to develop office systems to support the provision of cessation services.

- Continued research into effective interventions, including updating the cessation guideline on a regular basis, as well as non-clinical interventions such as media-based cessation interventions, teen cessation interventions, etc.

- Evaluation of the impact of the institutionalization of cessation interventions in the health care system.

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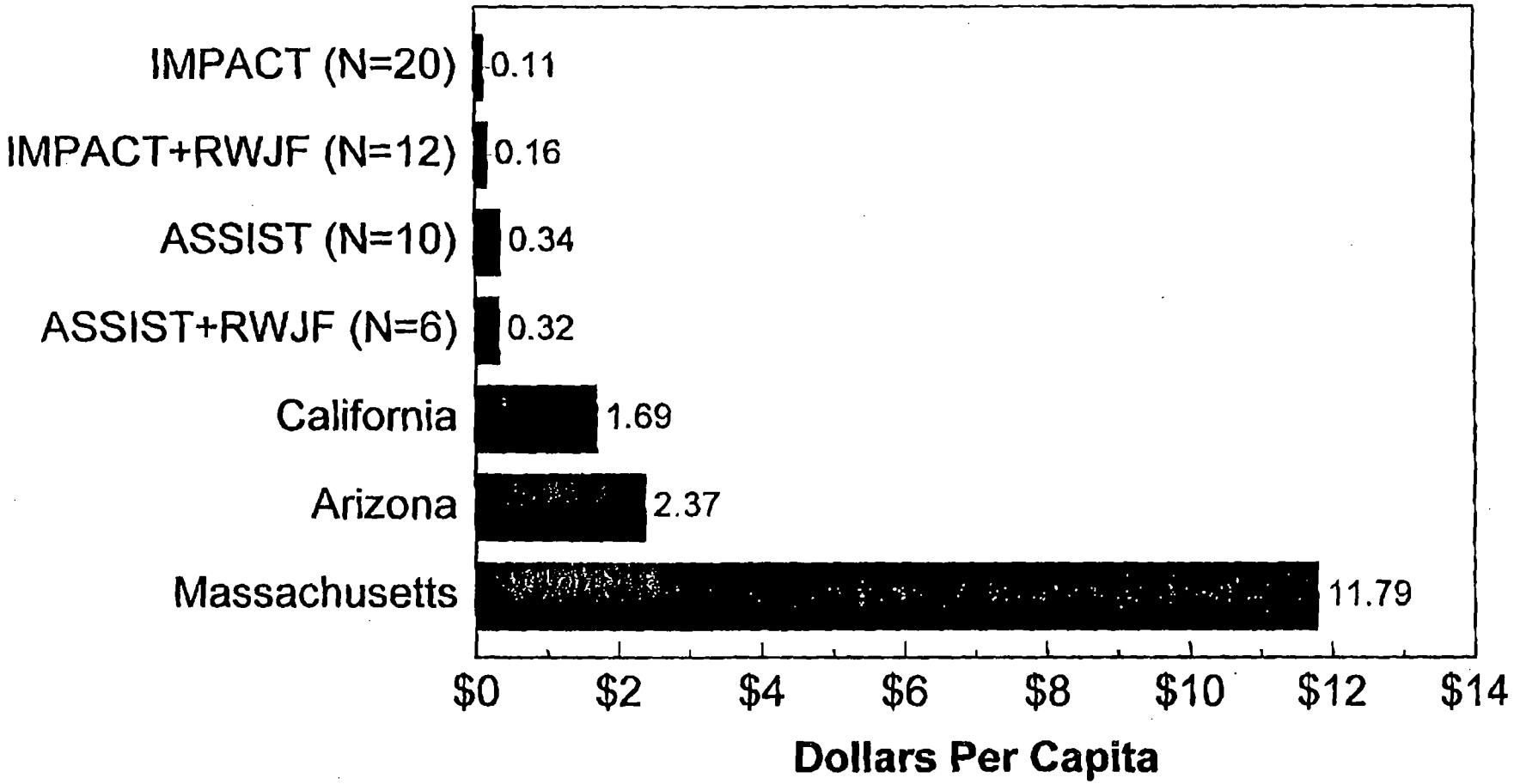
Per Capita Spending on Tobacco Prevention and Control -- FY1995



*Proposed Spending for FY97

MAKING THE CASE FOR SMOKING CESSATION

Evidence from the AHCPR Smoking Cessation guideline suggests that tobacco use presents a rare confluence of circumstances:

1) a highly significant health threat

2) a disinclination among clinicians to intervene consistently

3) the presence of effective, preventive interventions

- 50 million Americans smoke - 20 million of those want to quit <u>each</u> year
- Direct health costs of smoking are $50 billion annually - - every 1 million smokers who quit represents <u>$1 billion less spending on direct health costs</u> and about the same savings in indirect costs.
- Currently 1.3 million smokers quit on their own each year - AHCPR Smoking Cessation guideline will, conservatively, <u>double</u> the quit rate annually.
- This translates into an additional savings in the health care sector of $1.3 billion annually
- Approximately 1 million young people start smoking each year. Best case scenario - prevention campaign would reduce that number by 50%
- Widespread implementation of the AHCPR Smoking Cessation guideline will more than *<u>double</u>* the return on our investment

NATIONAL CESSATION CAMPAIGN

- While we need to target both smokers and clinicians using an integrated, comprehensive approach - a 5 year national campaign focusing on cessation, the AHCPR initiative focuses on the clinician and his/her contact with smokers..

- At the clinical level, with the objective of changing attitudes and practice to recognize and treat smoking as a *chronic* disease, similar to diabetes and hypertension.

- At the consumer level to educate and empower patients to better understand their disease and how to overcome their addition.

- Clinicians are in the most influential position to help patients and have direct access to the smoking population. They have a window of opportunity to identify and treat patients who smoke. Seven out of ten smokers see their physician annually.

- There are myths and misperceptions that keep clinicians from intervening and treating nicotine addition in their patients - from pessimism about a smoker's ability to change his/her lifestyle, to not knowing what does and doesn't work to help people quit.

- There are 3.8 million health care providers in the nation.

- The National Cancer Institute projects that if 100,000 physicians were to help 10% of their patients quit each year, the number of smokers in the U.S. would drop by an additional 2 million. Even greater cessation would occur if other types of health care clinicians would also intervene with their patients who smoke.

CESSATION IS A GOOD INVESTMENT

- AHCPR guideline is the only guideline that provides evidence-based recommendations on what works and doesn't work for smoking cessation treatment.

- Compared to other preventive interventions, smoking cessation is extremely cost effective.

SEE TABLE 8

- The more intensive the intervention, the lower the cost per quality of adjusted life years (QALY) saved - suggesting that greater spending on interventions yields more net benefits (Fiore, et al).

- Cost to implement the AHCPR Smoking Cessation Guideline is $8.1 billion in the first year - with a savings of $2.6 billion in the first year. → all smokers

→ #2.5 – 1/3 try to quit each year.

- Therefore, the funds that are tentatively set aside for the Public Health Trust Fund are inadequate - they provide only about one-tenth to one-fifth of an approximately applied cost of reimbursement.

- If 20 million smokers try to quit <u>each</u> year - providing $500 each would cost $10 billion - considerably more than the $1.5 billion in the public health trust fund.

IMPLEMENTATION OF SMOKING CESSATION INITIATIVES

- In a recent survey, only 17% of managed care plans knew what percentage of their members smoke; only 15% could identify those members and only 18% have analyzed the financial impact of smoking to their organizations. (Pinney & Associates)

TABLE 8

COMPARISON OF SMOKING CESSATION COST-EFFECTIVENESS RATIOS WITH OTHER MEDICAL INTERVENTIONS

SELECTED INTERVENTIONS		
Intervention	Source	Cost-Effectiveness Ratio
Cholestyramine/low cholesterol diet (versus diet) for men aged 35-39 & 290/dL	Oster, *et al*. (1987)	102,033
Annual mammography & breast exam for women 40-49	Eddy, *et al*. (1988)	61,744
Hypertension screening for asymptomatic men age 40	Littenberg, *et al.* (1990)	23,335
Beta-blockers for low-risk myocardial infarction survivors	Goldman, *et al*. (1988)	16,897
3-vessel coronary artery bypass graft surgery (versus medical management)	Weinstein, *et al.* (1980)	12,350
PTCA (versus medical management) for men age 55 with severe angina	Wong, *et al.* (1990)	7,395
AHCPR Guideline, Combined Smoking Cessation Interventions	Cromwell, *et al.* (1996)	2,875
One time cervical cancer screening for women age 65+	Fahs, *et al.* (1992)	2,053
Pneumonia vaccination for people age 65+	Sisk, *et al.* (1983)	1,769
Polio immunization for children age 0-4	Sisk, *et al.* (1983)	<0

- Providing technical assistance for managed care organizations that serve populations with high incidence of smoking or who have made smoking cessation a priority.

Phase IV: Evaluation

- Evaluate efficacy of smoking cesstion interventions
- Conduct needs assessment for clinics treating underserved populations and consider supplemental funding
- Managed care utilization survey (similar to Pinney's)
- Provide results to physicians so they can see immediate impact
- Direct-to-consumer survey on perceptions of smoking, cessation ,etc.
- Provider survey (attitudes and assessment)
- Evaluate emerging populations of smokers (college students, etc.) to assess smoking cessation needs

Cost:

Option 1 $100 million over 5 years ($20 million per year) -- drawing $50 million from the public education campaign (item C) and another $50 million from item #4

Option 2 $50 million over 5 years ($10 million per year) -- splitting item #4 with prevention (100 million total budget)

Educate the medical community about the guideline, its specific recommendations and provide tools that can help them with effective smoking cessation strategies for their patients.

- Educate medical and health schools to look at smoking status as a **vital sign**, teach proper counseling skills, referring, etc.

- Launch campaign (AHCPR's Two-Three Campaign) to target clinicians with smoking cessation prompts and interventions for patients, follow-up and referral strategies, etc.

- Develop or fund one-stop-shopping community clinics that specialize in smoking cessation and provide diagnosis, treatment, support and follow-up for at risk populations

- Internet web site, chat rooms to ask the doctor, etc.

- Exhibits

Phase III: Implementation

- Develop and disseminate tools that can be used in the clinical setting:

  Software programs
  Physician education kits
  Patient education kits, including special populations
  Patient incentives/giveaways as motivators
  Audio/visual aids

- Train-the-trainer programs

- CE/CME seminars

- Offer matching federal grants as incentive to managed care to implement AHCPR-sponsored Smoking Cessation guideline

SMOKING CESSATION CAMPAIGN FUNDING STRATEGIES

Phase I: Federal Funding for Smoking Cessation

- Matching grants to managed care plans, physician groups, and other providers and plans to implement and/or evaluate the efficacy of smoking cessation interventions.
- Provide direct funding to Community Health Centers and other direct providers of care to populations served by HHS.
- Provide matching grants to states to implement and/or evaluate smoking cessation interventions in the Medicaid population.

Phase II: Education and Training

- Continuous updating of the AHCPR guideline as new treatments are proven effective
- Research and evaluate the efficacy of new treatments
- Educate managed care organizations about the benefits of cessation to begin to implement the guideline into their programs
- Educate the medical community about the guideline, its specific recommendations and provide tools that can help them with effective smoking cessation strategies for their patients.

CAMPAIGN FUNDING

Phase II: Education and Training

- Continual updating of the guideline as new treatments are proven
- Research and evaluate new treatments that work (spray, antidepressants, etc.)
- Educate managed care organizations about the benefits of cessation to begin implementing the guideline into their programs.

Guiding Principles for Public Education in Tobacco Control

Public education efforts, including mass media campaigns, grassroots promotions, and other community tie-ins, are needed to denormalize and deglamorize tobacco use among young people, as well as to provide smoking cessation motivation and assistance to adults and to foster public support for smoke-free environments. Whereas a youth-only strategy may inadvertently position tobacco use as a "forbidden fruit," a strategy that includes counter-tobacco messages for all ages and populations can have a powerful impact on reducing the demand for tobacco products in society at large.

Evidence of Efficacy

- Analysis of multi-faceted youth tobacco use prevention programs shows that comprehensive education efforts, combining media, school-based, and community-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
- The Fairness Doctrine campaign of 1967-1970, the only sustained nationwide education effort to date, documented that an intensive mass media campaign can produce significant declines in youth and adult smoking.

Successful Campaign Characteristics

- To be effective over the long run, a national education campaign must be comprehensive, intensive, and sustained. (Note: "Campaign" is used here in its broadest sense as a counter-marketing effort that includes media-based and non-media-based approaches.)
- It must mimic national marketing campaigns, including those of the cigarette companies themselves: continued message variation, pulsed media placement patterns (based on seasonality and audience media habits), promotional tie-ins, and ongoing communications measurement and tracking.
- The campaign should be theory-based, drawing on the extensive literature on psychosocial risk factors for initiating, continuing, and stopping tobacco use.
- The campaign should maximize use of existing high-quality media materials produced by the government, voluntary agencies, and a number of individual states. A large collection is currently available through CDC's Media Campaign Resource Center for Tobacco Control.

Message Content and Appeals

- There is no single "best" motivator for preventing or reducing tobacco use. Campaign messages for both youth and adults should feature a variety of appeals (fear, humor, satire, testimonials, etc.) and executional styles.
- Messages should address tobacco control as both an individual behavior change issue and an environmental/public policy issue.
- Especially for the youth audience, the campaign should use nonauthoritarian appeals that avoid direct exhortations not to smoke.
- Smoking cessation messages for adults should increase motivation to quit and offer tips and referral information.
- Clean indoor air messages should focus on the health hazards of ETS exposure, particularly on infants and children, steps that individuals can take to reduce exposure, and actions that communities can take to enforce existing laws and regulations.

Exposure Levels

- On a per-capita basis, the Massachuesetts media program would cost over $600 million nationally but still fail to adequately target the ethnic diversity of the U.S.
- It is estimated that an annual budget of about $150 million is needed for a year-round broadcast campaign to

- ieve necessary message reach and frequency against a general teen (ages 12-17) audience -- to expose about 75% of U.S. adolescents to each campaign message 6 or more times. This amount is for national broadcast media buys only and does not include costs for production, other media placements, or state and community programs and the infrastructure to deliver them.
- Substantial additional resources -- even beyond $500 million annually -- are needed to reach different demographic and developmental segments of youth, to reach adults with cessation and ETS messages, to communicate messages through non-broadcast media-based channels, and to conduct a variety of non-media-based education efforts.

Message Formats

- The mass media component of the campaign should feature a mix of TV, radio, print, and outdoor advertising that complement and reinforce each other.
- The campaign should also explore the various alternative media options available (e.g., movie trailers, Internet, other computer resources, video games, materials for schools and community groups). This consideration is especially important in view of today's increasingly fragmented media market.
- Campaign planners should explore the need for new and/or tailored materials for at-risk populations (e.g., ethnic groups, people with diabetes, etc.).

Source Identification of Messages

- Planning and implementation of the multi-media campaign should be tightly coordinated; however, messages should appear to be coming not from one monopolistic source, but rather from a variety of sources.
- Highlighting a single theme, tagline, identifier, or sponsor for the campaign may increase the likelihood that young people, in particular, will discount or discredit the messages.

Media and Non-Media Strategies

- Just as tobacco marketing increasingly has moved away from traditional mass media advertising toward targeted promotional activities, tobacco counter-marketing campaigns should consider a combination of media advertising and grassroots promotional approaches.
- The current Secretarial Initiative to Reduce Tobacco Use Among Teens and Preteens contains four strategies in addition to a paid counter-advertising campaign:
  1. Promoting positive alternatives to tobacco use through sports and other youth-centered activities -- including establishing a national "branding" campaign for a tobacco-free lifestyle.
  2. Empowering young people to address tobacco use among their peers.
  3. Deglamorizing tobacco use through a coordinated entertainment industry strategy.
  4. Involving parents and families in addressing tobacco use among young people.

National vs. State Campaigns

- A national media campaign can deliver message reach and frequency at greatest cost efficiencies. Nationally originated messages can have a powerful influence on the public's perceived tobacco control "agenda" and set an overall supportive climate for state and local tobacco control efforts.
- State and local campaigns are necessary for optimizing the behavior and policy change objectives of the national campaign. They should focus not on developing new creative materials, but on local media selection to reach at-risk populations (e.g., ethnic newspapers), for local tagging of messages, where appropriate (e.g., providing statewide toll-free telephone numbers), and for community education tie-ins to the national campaign (e.g., local radio promotions, local TV and radio talk shows, community T-shirt exchanges, referrals to local cessation services).
- Costs for state and local counter-marketing activities are considerable, perhaps equivalent to the costs for a year-round national media campaign.

Tobacco Use Prevention and Control Intervention
Importance of State-wide Programs

Need for State-wide Programs

Effective implementation of tobacco use prevention and control requires a concerted, coordinated, and synergistic effort at the national, state, and community levels. The foundation for a nationwide infrastructure has been developed through the ASSIST and IMPACT programs. These programs serve as "delivery systems" to link individual states and local communities across the nation with federal agencies (CDC, NCI, FDA, SAMHSA), national media campaigns, and research institutions. This nationwide infrastructure also should extend to include partnerships with state departments of education, national organizations, private industry and others. The resources proposed in the settlement agreement will expand and sustain long-term funding of such state-based tobacco control efforts.

Evidence of Efficacy

Efforts to reduce tobacco use in the United States have shifted from primarily focusing on smoking cessation for individuals to populations-based interventions that emphasize primary prevention and reducing the health risks of exposure to environmental tobacco smoke. Interventions are targeted to both youth and adult tobacco users; youth and adult non-users; and the social and environmental factors that encourage and support the use of tobacco. Programs based upon these principles have been demonstrated to reduce per-capita consumption in Massachusetts, California, and the ASSIST states.

Key Program Components

The majority of tobacco control interventions focus on six key components:

- Prevention, including the restriction of minors' access to tobacco products;
- Treatment of nicotine addiction;
- Reduction of exposure to environmental tobacco smoke;
- Counter-advertising and promotion;
- Economic incentives; and
- Product regulation

Funding to state programs will sustain and expand support for the following activities:

- Developing state tobacco prevention and control plans;
- Building and strengthening coalitions to ensure community participation in the development of tobacco prevention and control programs;
- Establishing state health department infrastructure to include staffing, data collection and analysis, resource development, training, technical assistance, media campaigns, educational programs, cessation programs, enforcement, promotion and implementation of public health policies, fostering leadership and coordination, and applied research;
- Conducting surveillance and evaluation activities; and
- Funding local programs, including county governments, community organizations and schools.

Current ASSIST and IMPACT awards provide minimal funding for school-based prevention efforts. Schools are key partners, and should adopt curricula that have demonstrated effectiveness in reducing tobacco use behaviors. School-based tobacco use programs also should be integrated into comprehensive school health education programs. Finally, any school-based program must be an integral part of community-wide strategies, and likewise, any community-based efforts in tobacco use prevention and control should incorporate school initiatives into overall strategies.

The Secretary's Initiative to Reduce Tobacco Use Among Teens and Pre-Teens

Reducing teen tobacco use has been identified as a Secretarial priority for interagency action. The primary aim of this Initiative is to contribute to the achievement of the President's goal of reducing tobacco use among young people by 50% in seven years. The Initiative focuses on strategies to reduce the demand for tobacco products among young people. A nationwide infrastructure of state and community-based programs is essential to effective implementation of the Initiative.

The Secretary's Initiative represents an interagency effort involving ACF, FDA, HRSA, IHS, NIH, and SAMHSA, with CDC serving as the lead. It builds on the strengths and organizational missions of the collaborating agencies and will utilize the delivery systems and community-based mechanisms already in place through these agencies to deliver tobacco demand reduction programs. Key action areas addressed in the Secretary's Initiative are:

- Promoting positive alternatives to tobacco use through sports and other youth-centered activities;
- Empowering young people to address tobacco use among their peers;
- Deglamorizing tobacco use through a coordinated Entertainment Industry strategy;
- Implementing a paid counter-advertising campaign to change social norms about tobacco use; and
- Involving parents and families in addressing tobacco use among young people.

Challenges of Tobacco Control in a Post Settlement Environment

While the proposed settlement can produce important and sweeping changes in the national environment related to tobacco, much will still remain to be done at the state and local level. There would also be a need for enforcement of federal legislative mandates, or effort to pursue actions beyond these mandates that more specifically address local needs. Ultimately, tobacco prevention and control is and will remain a local issue, requiring local control and refinement. The proposed state tobacco prevention and control infrastructure will be the critical component enabling this type of local response and control.

Smoking Cessation: Summary
Office on Smoking and Health, CDC; July 7, 1997

- Smoking cessation is a critical component of comprehensive efforts to reduce tobacco use. Smoking cessation has major and immediate health benefits for people of all ages.

- 70% of all smokers want to stop smoking completely. Effective smoking cessation strategies have been identified, but expanded diffusion of these strategies is needed.

- The 1996 Agency for Health Care Policy and Research (AHCPR) guidelines review evidence on smoking cessation interventions. The results clearly showed that a variety of smoking cessation interventions are effective:
  - Simple advice to quit by a clinician (30% increase in cessation)
  - Individual and group counseling (doubles cessation rates)
  - Telephone hotlines/helplines (40% increase in cessation)
  - Nicotine replacement therapy (NRT) (up to double the cessation rates)

- Studies have shown that providing brief advice to quit smoking during routine office visits, follow-up visits about smoking, and prescribing NRT are more cost effective than commonly utilized screening tests and treatment of risk factors such as hypertension or hypercholesterolemia.

- In a 1995 survey of 105 larger HMOs, two-thirds reported offering some level of smoking cessation program or product as a covered member service; however, there were often restrictions on the use of the benefit. Indemnity plans and corporations who self-insure their health insurance benefits generally do not cover smoking cessation services.

- Currently, only six states' Medicaid programs cover the cost of over-the-counter NRT. Medicare does not pay for smoking cessation interventions or NRT.

- A cost analysis of the AHCPR guidelines estimated that cost per smoker would range from $34.04 for simple advice to quit to $271.81 for individual intensive counseling plus nicotine gum.

- Paying for smoking cessation behavioral intervention and NRT increases use of these services. One study found that the increased costs of full coverage were commensurate with increases in cessation (e.g., 50% increase in cost = 50% increase in cessation).

- Longitudinal follow-up of adult smokers have shown that making more than one quit attempt approximately doubles the rates of successful quitting. Successful ex-smokers typically have attempted to quit but relapsed several times prior to quitting permanently. Therefore, restrictions on coverage of services needs to be carefully considered.

- Cessation services can be institutionalized through dissemination of the AHCPR guidelines, development of office systems to assess tobacco use as a vital sign with appropriate follow up, reimbursement for treatment, accountability for and measurement of cessation efforts.

- Current research indicates that adolescent smokers frequently try to quit but are usually unsuccessful, have withdrawal symptoms similar to adults, are hard to recruit and retain in formal cessation programs, and are not responsive to programs developed to date.

Smoking Cessation: Background Information
Office on Smoking and Health, CDC; July 7, 1997

Introduction

Smoking cessation is a critical component of comprehensive efforts to reduce tobacco use. Smoking cessation has major and immediate health benefits for men and women of all ages. For example, persons who quit smoking before age 50 have 1/2 the risk of dying in the next 15 years compared with continuing smokers (1990 SGR). 70% of all smokers want to stop smoking completely (MMWR 1996); however, nicotine is an addictive substance (1988 SGR), and only 2.5% of smokers stop smoking permanently each year (MMWR 1993). Effective smoking cessation strategies have been identified, but expanded diffusion of these strategies is needed.

What works for smoking cessation?

In 1996, the Agency for Health Care Policy and Research (AHCPR 1996) produced an evidence-based guideline that evaluated smoking cessation interventions available at the time. The results clearly showed that a variety of smoking cessation interventions are effective:

- Simple advice to quit by a clinician (30% increase in cessation)
- Individual and group counseling (doubles cessation rates)
- Telephone hotlines/helplines (40% increase in cessation)
- Nicotine replacement therapy (NRT) (up to double the cessation rates)

The guidelines also noted the following:

- The efficacy of intervention increases with intensity of intervention.
- Cessation treatments (both pharmacotherapy and counseling) should be provided as paid services; providers should be reimbursed for delivering smoking cessation interventions.

Intensive services (e.g., NRT plus behavioral counseling) have been proven to be effective with more heavily addicted smokers (Silagy 1994, Tang 1994)

What is the cost of providing smoking cessation interventions?

- Group Health Cooperative has implemented a behavior modification support program provided either through a series of brief proactive phone calls or via group meetings. This intervention may include a recommendation for NRT use (about 60% of participants used NRT).

- The total cost of the program was $150 for the behavior change intervention and $67 for the NRT; since not everyone used NRT, the average cost of delivery of the more intensive intervention was $192.

- Some plans reimburse for services that are provided in the community (as opposed to services provided through the plan). For example, one plan reimbursed on average $165-185 for cessation services provided through community channels.
  A cost analysis of the AHCPR guidelines estimated that cost per smoker would range from $34.04 for simple advice to quit to $271.81 for individual intensive counseling plus nicotine gum (AHCPR, unpublished and confidential data).

What is the cost-effectiveness of smoking cessation interventions?

- Studies have shown that providing brief advice to quit smoking during routine office visits, follow-up visits about smoking, and NRT were more cost effective than treating mild or moderate hypertension, drug therapy for hypercholesterolemia, PAP tests, zidovudine therapy for asymptomatic HIV infection, and breast and colon cancer screening (Cummings 1989, Oster 1986, Tsevat 1992, Sofian 1995).

- The AHCPR-commissioned study on the cost effectiveness of implementing the AHCPR smoking cessation guidelines also showed that more intensive interventions are more cost-effective than briefer interventions. The cost per year of life saved (at 5% discount) ranged from $1582.19 for intensive group counseling without NRT to $6830.84 for minimal counseling (<3 minutes) and nicotine gum (AHCPR, unpublished and confidential data).

What works regarding smoking cessation in children and adolescents?

Three out of four teens who smoke have made at least one serious, yet unsuccessful, effort to quit (NCHS, 1992). Current research indicates that adolescent smokers frequently try to quit but are usually unsuccessful, have withdrawal symptoms similar to adults, are hard to recruit and retain in formal cessation programs, and are not responsive to programs developed to date. Few adolescent cessation programs have been developed, and even fewer have been studied and evaluated (SGR 94, IOM 94). Nicotine replacement therapy may have a role in helping adolescents quit tobacco use. FDA has not approved it for use in those persons under age 18; however, there are isolated programs throughout the country that are either prescribing or distributing the nicotine "patch" and reporting high success rates in adolescents (Florida, State Dept of Health; Stotts C, unpublished and confidential data).

What is the current status regarding provision of smoking cessation interventions?

- Managed care plans and insurers tend to restrict access to cessation services, suggesting that their primary concern is about controlling drug and program utilization and cost, rather than getting smokers to quit.

- In a 1995 survey of 105 larger HMOs, two-thirds reported offering some level of smoking cessation program or product as a covered member service (Corporate Health Policies Group 1995). However, indemnity plans are least likely to cover preventive services (Schlauffler 1993). In addition, over half of corporations self-insure for their employees' health insurance benefits; few corporations include coverage for smoking cessation services in their health insurance benefit designs (Schlauffler 1993).

- Only 17% of the HMOs know what percentage of their members smoke, only 15% can identify those members who smoke, and only 18% have analyzed the financial impact of smoking to their organization.

- In 1995, over half (64%) of plans provided some coverage for the nicotine patch, but only about half covered it for all of their members. Also, the patch was covered as a standard drug benefit (treated like any prescription drug) by only 36% of plans that covered it. Since NRT has gone over-the-counter, it appears that fewer plans cover the patch, although a formal survey has not been done.

- In many cases, procedures were burdensome to receive coverage (e.g., completion of a smoking cessation program in order to be reimbursed or restrictions on the number of times the benefit could be used). In some cases, reimbursement was only provided if the individual stayed quit for a certain amount of time (e.g., six months).

- Nicotine gum was covered by fewer plans but fewer restrictions were placed on its use.

- In 1995, only about half of the plans offered a behavioral smoking cessation program in house; staff and group model plans were much more likely to provide these than network or IPA model plans (yet network and IPA models predominate the managed care market). While most plans do refer members to outside programs, only 32% of those who refer cover any portion of the cost of those programs.

- Currently, only six states' Medicaid programs cover the cost of over-the-counter NRT.

- Medicare does not pay for smoking cessation interventions or NRT.

<u>Does paying for smoking cessation interventions improve cessation rates?</u>

- Paying for smoking cessation behavioral intervention and NRT increases use of these services.

- One study found that quit rates were somewhat lower among persons who received full coverage for the services compared with those who had only partial coverage. However, because more individuals used the services when they were fully covered, full coverage had a higher overall impact on the population of smokers: a 50% increase in number of persons who quit. Full payment for the intervention and NRT also increased the cost by 50%; therefore, any increase in cost appears to be offset by a comparable increase in overall impact (Curry, unpublished and confidential data)
- Some plans only reimburse for cessation services if an individual stays quit for a certain amount of time (e.g., six months).

Is there a point of diminishing returns in providing smoking cessation services (e.g. should benefits only be allowed for a finite number of quit attempts)?

- Nicotine addiction should be viewed as a chronic disease. As with other chronic diseases, there may not be full patient compliance, and there may be remissions and relapses. However, for other chronic diseases, coverage is not restricted only to those who are fully compliant with treatment or to those put into permanent remission by the first course of treatment.

- Establishing a cut point for providing services does not make sense. Longitudinal studies have shown that the number of previous unsuccessful quit attempts was unrelated to success in quitting (Cohen 1989). One study suggests, in fact, that previous quit attempts may increase success rates (Hymowitz, unpublished and confidential data). Successful ex-smokers typically have attempted to quit but relapsed several times prior to quitting permanently (Cohen 1989, Fiore 1995).

- We do not know very much about how soon after an unsuccessful quit attempt a smoker will make another attempt. When smokers are asked when their last quit attempt was, the mean is about 3 years earlier (Gallup 1993). However, smokers often do not remember quit attempts that were of short duration that occurred more than few months previously (Pierce, 1994).

- We also do not know what effect the offer of more widely available treatment will have on quit attempts, particularly among highly dependent smokers. Clearly, greater access to NRT has resulted in greater utilization.

What is the data on the OTC patch use and use of adjunctive cessation assistance?

- Utilization data on OTC patch and gum suggest a more than doubling in utilization due to OTC availability of NRT (Walsh American 1995; Nielsen 1996).

- It has been estimated that with the OTC gum and patch, 175,000 to 350,000 additional smokers will quit each year (Walsh America 1995; Nielsen 1996).

- Utilization of the Committed Quitters program (free tailored message program available to all purchasers of Nicorette and Nicoderm CQ) has been modest (less than 10% of purchasers)

- A randomized trial conducted by SmithKline Beecham on the Committed Quitters program demonstrated a significant boost in efficacy over use of Nicorette alone (36% v. 24% 28-day cessation at 6 weeks). (Shiffman, unpublished and confidential data)

How can smoking cessation interventions be institutionalized?

- Broad dissemination and adoption of the AHCPR smoking cessation guideline

- Establishment of tobacco use as a vital sign (asked at every visit)

- Provision of brief advice to quit to all tobacco users and referrals for more intensive services for individuals who express an interest in accessing such services

- Establishment of office systems to support assessing tobacco as a vital sign, providing brief advice to quit, and following up with referrals for more intensive services

- Broader access to (and reimbursement for) effective treatment

- For Medicaid, inclusion of cessation in managed care and other contracts

- For Medicare, coverage of smoking cessation intervention, including NRT

- Accountability within the health care system for aggressive cessation efforts, e.g., stronger requirements from HEDIS and other managed care report card systems

- Proper measurement of the performance of institutionalized cessation efforts based on penetration of the smoker population and reductions in prevalence, not simply whether coverage or a program exists.

From: NICOLE LAWRENCE
To: cessmoke1, cessmoke2, kidsmoke, researchsmoke
Date: 7/14/97 2:49pm
Subject: Tobacco Meetings

There will be a meeeting of the tobacco settlement subcommittees tomorrow, July 15, 1997 at 9:00a (research), 10:15 (cessation & Ed) and 11:30a (health investiments) in the HP Conference Room 441/443E of the Humphrey Building.

If you are unable to attend personally you can attend via conference call.
If you have to call from a nongovernment phone call 1-800-545-4387 and give the conference ID number. This is a meet me call and you must call the number given at the scheduled time. Do not call before the schedule time, because you will be told to call back.

9am - 10:00a S/C on Research
Conference ID# M20529
Access # 32321
Conference # 700-991-1610
If you call from a non governement phone call 1-800-545-4387

10:15a - 11:15a S/C on Cessation and Public Education
Conference ID# M18939
Access # 39235
Conference # 700-991-1632

11:30a - 12:30p S/C on Health Investments
Conference ID# M47441
Access # 54257
Conference # 700-991-1236

If you have any questions please call me at 202-690-6052.

CC: rgibson

Chris - some of Fed share / Medicaid
→ same manner for research

- some of cessation / education fund
→ need to research

Week from next Monday —

A. Having a presidential commission —

- how to structure -

- guidance —

- participation —

- Congressional role -

- How we avoid having trust fund replace the approp —
- triggers - if approps don't exceed previous year, trust fund doesn't kick in.

X Consultation (and more w/appropriators)

Vanus - NIH - what does it mean to limit to tobacco-related research —

X CA - investigators submitted applications rejected w/o tobacco

7/2/97

Cessation/education

Jennings
HHS
ACHPR
COL

- 50 million
- 70% say they want to quit

- Only 100% enroll in

Smith-Kline-Beecham — 11% have tried nicotine replacement pr

Drug Kanerow — brief intervention — 40 sec. talk with a clinician —

AHCPR — every person who tries to quit should have nicotine replacement.

- chair of panel — Dr. Mike Fiori. —
will have JAMA article on c/E of smoking cessation programs.

AHCPR - guidelines - insurance coverage was as low as 11%. —

- Inpatient to
- herbal / acupuncture
- no control verifying. —

3 treatment elements important — "contribute independently to a successful outcome.

(1) Nicotine replacement

(2) Social support

(3) Skill training — spend your time where people don't smoke, e.g. museum
— eat carrots

plans are covering 3-600 persons.

Chris - what is success rate?

- how many chances

- what is c/E ratio —

Michael ①

Every State has funded tobacco programs
HHS (ASSIST) or CDC

79000 in MI to 2 million in NY

Educ.
Counter Ad/pt.
Work w/ coalitions

② Media campaigns

- haven't had nationwide campaign for 25 years

except CA, MA, OR, ME, AZ just passed laws

Results hard to tease out. —

tax
paid media
referendum

NCI - ASSIST - 5 year demo, 17 states, average 1.2 million —

Mark? - State, local coalitions.

- excise tax
- ad restrictions
- indoor air

more cost-effective than smoking cessation.

per capita expenditures: 5¢/capita to over $1/capita...

local vs. national

Sharon FDA study - targeted to 12-17 year olds only studied - frequency and reach

$100 million - annual education campaign - focused exclusively on broadcast media kids see 1 per week.

Alan - ONDCP - 160 million 9-17
4 exposures week
90% effective reach.
- over next 4½ months - studying what works - similar in spending to

Chris — state substitution?

Mark — need to tailor to state. —
need state and local control of
media dollars — run risk
of replacing what's normally
going on. —

local lobbyist activities —

— Education funds go to non-profit programs.
do we want that. —

Outreach — questions about how we do these meetings —

— tomorrow want to give us a draft of proposal

— 3 kinds of mtgs which for — different constituencies Donna / Bruce / V.P. —

— needs to talk to Donna she envisions mtg — but there are lot of meetings that may be open

Donna + Icoop/Kessler — mtg closed to press

Donna — is back Monday — here what else we're doing —

½ - ¾ — public meeting —

range of people talk —

preference — would commit to Tuesday —

1