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TTURCs ADDRESS BARRIERS TO SMOKING CESSATION TREATMENT

By Prabhu Ponkshe

Until recently, quitting tobacco use was seen as a personal challenge and not as an item on the policy agenda. However, as health care expenses have escalated, and resources have become tighter, the economic impact of the consequences of smoking have forced a broader, population consideration of the need for cessation. In addition, the effects of environmental tobacco smoke on the health of the public changed focus from an individual problem to a public health issue. Quit-lines and other programs have brought increased attention to cessation from policy makers. Rapid growth in clean indoor air regulations and hikes in tobacco taxes have increased the demand for cessation products and services.

There are plenty of barriers to treatment. The addictive nature is obviously the first barrier. So is the popular belief that quitting is more difficult than dealing with potential health consequences of prolonged use. There are institutional barriers as well. How is treatment going to be financed? Should the individual pay for it? Does it work? Is it worth it? Is it cost-effective? What is the insurance industry's role in cessation? Should the tobacco industry pay for it? Do smokers want to be treated? Is preventing youth smoking better than treating adults?

As we make progress in the science of cessation, here is what is happening in the politics and policy of cessation:

- In Arkansas, Gov. Mike Huckabee (R) announced recently that the state Medicaid program will start covering the cost of smoking cessation programs.
- In Louisiana, a jury recently decided that cigarette-makers should pay for cessation programs. The New Orleans jury decided that U.S. cigarette makers must pay more than \$590 million into a court-administered fund to finance smoking cessation programs for 5 to 10 years.
- In New York City, a high tax on tobacco products and a strong smoke-free law, combined with tobacco cessation and youth prevention campaigns, have resulted in an 11 percent drop in smoking rates.
- In Minnesota, smoking rates among adults insured by Blue Cross/Blue Shield of Minnesota have fallen by 15.6 percent between 1999 and 2003. Blue Cross claims that the investment made in cessation programs is paying off.

The policy debate gains momentum as we make progress in understanding the science of addiction and cessation. As this occurs there is a parallel increase in policies related to treatment. This issue of the Networker focuses on how several of the TTURCs are addressing some questions related barriers to treatment.

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Barriers to Quitting Smoking: The Cost of Treatment

By Gloria Meyer

Smokers encounter multiple barriers in making a quit attempt. One of them is the cost of smoking cessation medications, which typically vary in price from \$3.50 to \$11.00 a day. It is logical that these medications would be covered by insurance since quitting smoking has been estimated to save \$1,623 a year in healthcare costs for each quitter. However, private insurers have been reluctant to cover and employers reluctant to purchase coverage for preventative measures, including smoking cessation. Coverage through Medicaid varies from state to state, and Medicare does not yet cover smoking cessation treatment. Various studies are now underway to determine the extent and effect of insurance coverage for smoking cessation treatments.

A University of Wisconsin Transdisciplinary Tobacco Use Research Center (TTURC) policy research study, supported by the Robert Wood Johnson Foundation (RWJF), focuses on insurance coverage provided by state employers. "In many markets, states and other public employers serve as leaders influencing insurance coverage," said Marguerite Burns, M.A., UW-TTURC policy researcher. "By examining what state employers are doing and the results they are having we can, hopefully, provide information that may lead public and private employers to provide greater coverage of smoking cessation."



When examining this issue, the first question asked is "Are states providing coverage of evidence-based smoking cessation treatments?" The answer is "the coverage is spotty at best." In one study, published in August in *The American Journal of Public Health*, Burns surveyed 45 state employers to ascertain the amount of insurance coverage provided for smoking cessation medication, and whether coverage applied to all or some state employees. Only 7 states were fully consistent with the U.S. Public Health Service guidelines by providing smoking cessation treatment coverage for all state employees. An additional 10 states provided coverage for at least some of their state employees. A total of 29 states provided insurance coverage for one or more of the recommended treatments for some employees.

A second question is "Are the benefits being used?" Preliminary findings from Wisconsin state employees (a more education population than average) indicate that less than 15 percent of smokers are using the benefit annually. Benefit use is greater among smokers who are aware of it.

"One conclusion we can draw is that smokers are not aware of insurance coverage of smoking cessation medications," said Burns. "More awareness may result in greater usage."

In a survey of Wisconsin insurers, conducted by the intervention department of the Center for Tobacco Research and Intervention and supported by the State of Wisconsin, researchers found that the provision of smoking cessation coverage has increased from 56 percent in 2002 to 74 percent in 2004. However, many benefits have barriers which decrease use. For example, the benefit can be used only once, there's no coverage for combination therapy, or coverage is contingent on a successful quit attempt.

Fortunately, tobacco cessation treatments are available and effective, and more medications are being developed to treat tobacco dependence. However, the inability of tobacco users to afford these treatments remains a barrier to reducing smoking prevalence. Cost-benefit studies now underway in a number of institutions may provide the data needed to build the case for insurers and employers, showing that providing smoking cessation coverage is in their best interest.

Smokers May Face Challenges to Obtaining Genetically Tailored Treatment

by Megan Kasimatis

Emerging research of genetically tailored treatment for smoking cessation may lead to individualized treatment approaches that can improve outcomes for smokers who are trying to quit. However, these research advances raise important questions regarding the willingness of physicians to adopt innovative approaches to treatment of tobacco dependence in the clinical setting.

The Transdisciplinary Tobacco Use Research Center (TTURC) at the University of Pennsylvania is currently addressing these concerns through the work of Alexandra Shields, Ph.D., and the TTURC's RWJF-funded policy project. This project aims to facilitate the translation of new scientific knowledge into public policy and clinical practice in a socially and ethically responsible manner.

Shields led a multi-disciplinary research team that recently conducted a national survey of primary care physicians' attitudes toward genetic testing for the purpose of tailoring treatment. The goal of this study was to identify and anticipate issues likely to arise in translating new genetic research into clinical practice. Shields used focus groups to develop credible scenarios and identify key concerns physicians may have about offering a new genetic test to their patients who smoke.



The study surveyed 1,120 primary care physicians identified through the American Medical Association. While 75% of these physicians reported having some formal training in clinical genetics, only 4% had a genetics rotation in residency and fewer than 16% reported a clinical rotation in genetics during medical school.

Physicians were randomly assigned to receive a survey including a scenario in which the new test was presented as a genetic test or one in which the new test was presented as a serum protein test. Survey results indicate a very high level of willingness to adopt a new test (genetic or serum test) for tailoring smoking treatment. However, merely describing a new test to tailor smoking treatment as "genetic" poses a significant barrier to physician adoption. Describing a new test as genetic resulted in an 11% reduction in adoption of the test. Based on national estimates of those who smoke on a daily basis, this 11% reduction in adoption scores would translate into 3.9 million smokers who would not be offered a new genetic-based treatment for smoking.

Physicians who were current or former smokers themselves and physicians who routinely prescribed pharmacological treatment to their patients and who routinely referred patients to smoking cessation programs were significantly more likely to offer the new genetic test to their patients. These results indicate that a specific group of physicians exist who, through personal experience or through experience with patients, have a greater appreciation for the difficulties involved in quitting smoking.

This study has important implications for the translation of research advances in genetically tailored treatment to clinical practice. Study results suggest that as advances in genetically tailored treatment continue to emerge, efforts must simultaneously be made to address primary care physician's knowledge of and comfort with clinical genetics.

Results from this study appear in an article titled "Barriers to Translating Emerging Genetic Research on Smoking into Clinical Practice: Perspectives of Primary Care Physicians," which is currently in press at the Journal of General Internal Medicine.

“Safer” Cigarettes: Barriers to Better Health—or Segues to Cessation?

by Jeanne Mettner

Although 22 million smokers try to quit smoking each year, only 3 to 5 percent are successful in quitting for a full year. In addition, smokers report multiple quit attempts before they achieve long-term success. “A lot of people are interested in quitting smoking, but it’s really trying to sustain abstinence that’s the challenge,” says Dorothy Hatsukami, Ph.D., director of the University of Minnesota (UMN). “For some people, the thought of quitting completely can be an overwhelming and seemingly unattainable goal.”

When cigarette smokers are (for whatever reason) unable to consider smoking cessation as a lifestyle modification step, they may turn to alternative approaches in their attempt to become healthier. One such approach is the use of potentially reduced-exposure tobacco products (PREPs). At the UMN TTURC, researchers are exploring whether this approach actually reduces toxicity exposure. The findings could shed light on the effect of this approach on smoking cessation efforts—specifically, whether such strategies stand in the way of quitting smoking entirely. “If consumers are using such tactics under the erroneous perception that they are making a healthier move, then these strategies may, in some instances, be serving as a barrier to smoking cessation,” says Hatsukami. “More research needs to be conducted to determine if this is the case.”

One marketing tactic that tobacco manufacturers have pursued in response to consumers’ concerns about the toxicity of cigarettes is the introduction of potential reduced-exposure products (PREPs). An example of such a product is *Omni*, a product that (per its manufacturer, Vector Tobacco) purportedly reduces exposure to NNK (a potent lung carcinogen) by 53% and pyrene by 15-20%, according to machine-determined methods. But limited research has been conducted to support the validity of these claims.



Dorothy Hatsukami,
Ph.D.

“Clearly, potentially reduced-exposure tobacco products do not confer the benefits that manufacturers are implying through their advertisements,” says Hatsukami. “Smokers may be getting the wrong message—that these products are a ‘healthier, safer’ alternative to regular cigarettes—and that kind of erroneous information may breed misperceptions that deter a smoker from quitting entirely.”

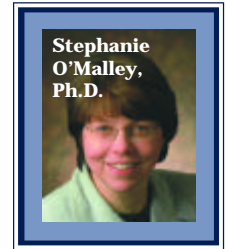
In June 2004, Hatsukami released the results of a UMN TTURC study, in which researchers examined the amount of exposure to NNK and pyrene when smokers switched to the *Omni* cigarette or medicinal nicotine. They observed significant but modest reductions in biomarkers of NNK (21%) and only a 5% reduction in biomarkers of pyrene. Both measurements were much lower than those indicated on *Omni*’s now-deactivated web site. Exposure to carbon monoxide remained the same as before the switch was initiated.

It remains unclear whether the extent of the reductions observed had an effect on disease-risk reduction. Moreover, Hatsukami’s study did not systematically assess the consumer perception piece of the equation—that is, whether participants themselves viewed the product as safer and/or would pursue it as an alternative to smoking cessation. Regardless, the findings do help illustrate that some concern may be warranted.

Naltrexone: A Quitter's Answer to Watching the Waistline?

By Pem McNerney

If there is one thing worse than trying to quit smoking, it's trying to quit smoking and not gain weight. In fact, some people, particularly women, smoke in an effort to prevent weight gain. Their worries about gaining weight can be a barrier to treatment.



Stephanie O'Malley, Ph.D., at Yale University, is trying to address this treatment barrier. In her recent TTURC study, she has found that low dose naltrexone in combination with the nicotine patch reduced weight gain in those who were successful in quitting smoking. The study also showed that naltrexone helps weight concerned smokers in their quit attempts.

"This suggests that low dose naltrexone may provide a novel strategy for addressing the needs of weight concerned smokers," said O'Malley.

O'Malley has a long history of working with naltrexone. Naltrexone, an opioid antagonist, was approved by the FDA for the treatment of alcohol in part due to O'Malley's research. Her initial TTURC-funded clinical trial of naltrexone was complemented by work done by other TTURC researchers.



Novel approaches to cessation medication are only useful if people are willing to pay for them. Susan Busch, Ph.D., and Tracy Falba, Ph.D., conducted a "Willingness to Pay" survey to measure consumer value of the attributes of a new smoking cessation treatment. Results from the survey suggested that there would be a market for new smoking cessation treatments if they were effective and were not associated with increased weight gain. People who were employed, women, and the obese were among those with a higher willingness to pay for such cessation treatments. These results will be of value to smokers, employers, businesses that manufacture and market smoking cessation treatments, and insurers who make decisions about coverage of smoking cessation benefits.

A new approach to analyze data from clinical trials that informs use of naltrexone in smoking cessation treatments was developed by Joel Dubin, Ph.D., Assistant Professor of Epidemiology and Public Health, who also helps head the Statistics Core with Robert Makuch, Ph.D., Professor of Epidemiology and Public Health (Biostatistics) and the Child Study Center. In particular, using graphical methods, including the event chart and event history graph, Dubin shows that researchers who are evaluating pharmacotherapies from trials aimed at aiding smoking cessation can better investigate trial adverse events and associated outcomes, such as participant dropout, and more clearly report these findings to the Food and Drug Administration. Traditional methods of reporting this kind of data involved the development of detailed tables of information that were sometimes difficult to read and interpret. Further work is being pursued to synthesize the information from these graphs with the modeling of this typically complex data.

O'Malley says the transdisciplinary approach towards naltrexone will help make the case that it is an effective smoking cessation aid for which there is a market. "The fact that we have so many people from so many disciplines working on this means that this project will have significantly greater impact when it is published," O'Malley said. "The economic analysis demonstrates that prevention of weight gain is a highly valued outcome of new treatment methods. Generally, we focus exclusively on whether a drug can help people quit or not. But the side effects of treatment, such as prevention of weight gain, in and of themselves, can prompt treatment seeking."



TTURCs Round 1: Selected Highlights

University of Southern California

- Findings indicate that personality characteristics such as depression and hostility are risk factors for smoking among Caucasian but not Asian youth. Smoking among Asian youth appears more dependent on social context.
- Findings in China and California indicate that social influence interventions were more effective in preventing progression to higher levels of smoking than preventing experimentation among never-smokers.
- Adolescents have a 90 percent greater chance of becoming smokers within a year of their parent or guardian losing their jobs, than young people whose families haven't suffered this blow.

University of California, Irvine

- Animal studies indicate that youths are more receptive to the rewarding effects of nicotine (including the first exposure) than adults, making cigarette addiction more likely to occur during adolescence.
- Results reveal that prior smoking changes the effect of nicotine on the brain's metabolic activity.
- Finding indicates that teens diagnosed with ADHD may turn to smoking as self-medication.

University of Minnesota

- Modified tobacco products, particularly the Omni cigarette, were found to reduce carcinogen uptake compared with brand tobacco. Exposure to toxins in modified products are significantly greater than from medicinal products.
- Effects of nicotine replacement and bupropion show significant reductions of carcinogen uptake compared to brand tobacco. Improvements were observed for some cardiovascular risk factors and respiratory symptoms.
- Members of the UMinn TTURC were involved in U.S Congressional Hearings providing oral and written testimony on reduced exposure/risk products in the National Asso. of Attorney Generals meeting examining consumer protection issues associated with PREPs and in the State of Massachusetts meeting examining ingredient exposure.

University of Wisconsin

- Findings on smoking motives suggest that people who are genetically unable to detect a bitter taste are more likely to smoke than others. For such "non-tasters," taste is an important motive for their smoking.
- Findings indicate that withdrawal is highly individual and for some people symptoms may persist for months. The longer symptoms persist, the more likely a person is to relapse back to smoking.
- Smoking appears to serve as an emotional filter, thus, when smokers quit they show large increases in the range and variability of their emotions and they react more strongly to environmental events such as stressors.

Brown University (New England Family Study)

- Offspring of mothers who smoked a pack or more per day during pregnancy had a higher risk for developing nicotine dependence compared to children whose mothers didn't smoke during pregnancy.
- Multiple socioeconomic forces accumulate across the lifespan, leading to increased risk for smoking initiation, progression to regular smoking and difficulty quitting.
- Experiencing a depressive episode in one's lifetime does not necessarily predict failure in cessation treatment.

Yale University

- A new radiotracer was developed to examine the effects of nicotine on the brain and help determine if nicotine acetylcholine receptor levels are altered in Alzheimer's disease, alcoholism, major depression and schizophrenia.
- Low doses of the drug naltrexone reduce that amount of weight gained by successful quitters.
- Results indicate that there is a market for new smoking cessation treatments, such as naltrexone, if they are more effective and if they can help people avoid weight gain while quitting.

University of Pennsylvania/Georgetown University

- Published the first study to document genetic influences on adolescent smoking progression.
- Found that the genetic variation in the mu opioid receptor predicts response to nicotine replacement therapy.

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