VA in the Vanguard:

Building on Success in Smoking Cessation

Proceedings of a Conference Held
September 21, 2004
in San Francisco, California

Stephen L. Isaacs, J.D., Editor
Steven A. Schroeder, M.D., and Joel A. Simon, M.D., M.P.H.
Conference Organizers

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PREFACE

Lawrence Deyton, M.S.P.H., M.D.*

Veterans who use the VA health care system smoke and use tobacco at a rate significantly higher than that of other Americans. The VA health care system is the largest provider of integrated health care in the United States, serving nearly five million veterans in fiscal year 2004. Learning how to continue to improve smoking and tobacco use cessation for the men and women veterans who use the VA health care system presents exciting opportunities as well as interesting challenges. Smoking cessation continues to be a high priority for the VA, not only because of the extraordinary impact of this preventable cause of disease and death on those who have served our nation, but also because the VA health care system is a natural national laboratory in which to demonstrate the impact of improved policies and programs to promote smoking and tobacco use cessation.

There exists a rich history of smoking cessation policies and programs in the VA. This history is embedded in the context of factors such as provision of tobacco products during military service, controversies over smoking as a perceived personal freedom for veterans and the VA health care system's core health mission, and the challenges of implementing national policies in a time of rapid system change. In order to assess where we are in VA smoking and tobacco use cessation and to continue to improve these activities, in September 2004 the VA Public Health Strategic Health Care Group, in a collaboration with the University of California at San Francisco Center for Smoking Cessation Leadership and the San Francisco VA Medical Center, convened a dialogue, *VA in the Vanguard,* for a thoughtful discussion of clinical best practices in smoking and tobacco use cessation with special emphasis on the populations served by the VA. Under the leadership of Dr. Steven Schroeder and Dr. Joel Simon, approximately 80 policy, research, and clinical leaders convened. The meeting was designed to catalyze an exchange of experience and ideas for future directions. As you will see by these proceedings, the meeting was very successful.

I hope that these proceedings will provide a roadmap for the VA's smoking and tobacco use cessation policies and programs, and stimulus for those outside of the VA health care system. I strongly believe that what we learn in the VA can and should be exported to other large health care delivery organizations and those concerned with attacking the most preventable cause of disease and death in our country – smoking and tobacco use. The VA is already a leader in this important public health arena. I am proud to work with the doctors, nurses, psychologists, pharmacists, social workers, and

other professionals who lead the VA's smoking and tobacco use cessation activities and honor their service to those who have served our nation.

Finally, I would like to thank Dr. Steven Schroeder, Dr. Joel Simon, Dr. Kim Hamlett-Berry, Mr. Stephen Isaacs, and Ms. Elissa Kessler for their wonderful leadership in the development of the conference and the proceedings that have followed.

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INTRODUCTION

Steven A. Schroeder, M.D.* and Joel A. Simon, M.D., M.P.H.†

In the fall of 2003, we were approached by leaders at the Public Health National Prevention Program at the Department of Veterans Affairs (VA) headquarters to organize a national conference of smoking cessation experts to advise and inform the effort to drive down smoking prevalence rates among patients served by the VA. Because smoking had long been a part of the military culture, smoking prevalence rates have historically been higher among veterans than among other segments of the American population. Complicating smoking cessation efforts within the VA have been institutional barriers, high rates of mental illness and substance abuse, budgetary constraints, and competing priorities. Our charge was to convene a conference that would explore the history of smoking cessation efforts in the VA, review the state of the art in smoking cessation, assess barriers to translating research into programmatic innovations, and chart a course for VA efforts for the immediate future.

On September 21, 2004, an historic meeting was held in San Francisco, California, bringing together for the first time approximately 90 national experts in smoking cessation with policy leaders from the VA Central Office, the VA Center for Health Promotion and Disease Prevention, and many local VA facilities. Experts were drawn both from within the VA system and from the broader U.S. tobacco control community. The conference was organized around five content areas: (1) past and present smoking cessation policy within the VA; (2) best practices for treating tobacco addiction in medical settings; (3) smoking cessation in U.S. minority populations; (4) smoking cessation among patients with mental illness in general and specifically, post-traumatic stress disorder (PTSD); and (5) the potential of telephone quitlines to aid in smoking cessation.

The format for the meeting was designed to encourage the active participation of the attendees. Prior to the meeting, all participants were sent the draft papers that now appear in their final form in these *Proceedings*. Each author, a national leader in the designated field, summarized the state of the art for his or her topic area in a five-minute presentation that was then followed by a five- to ten-minute commentary by an expert discussant, which in turn was followed by a much longer discussion among the attendees. The format worked well and resulted in a spirited discussion with broad

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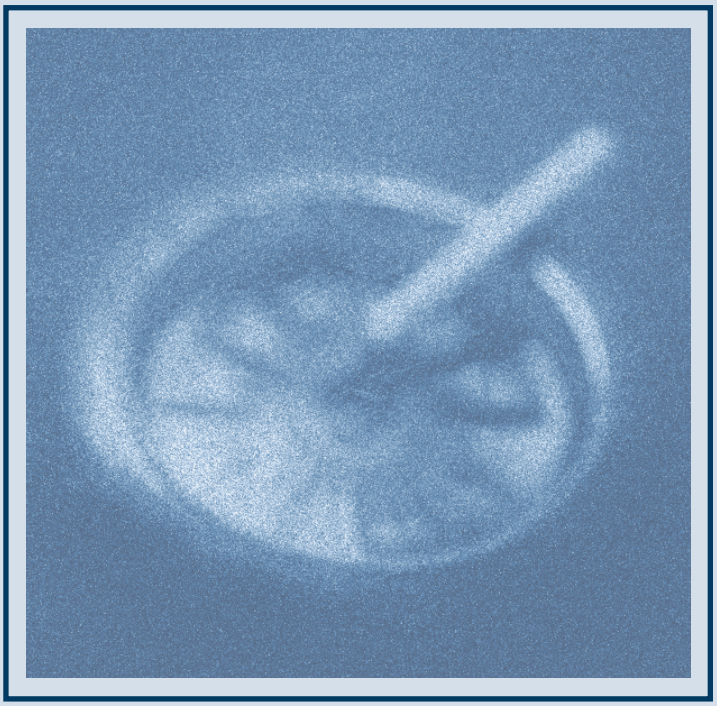
audience participation. At the end of the meeting, conference participants also left written comments, thoughts, and suggestions with us.

The participants reached a general consensus regarding five areas that deserve attention as the VA intensifies its already outstanding efforts to reduce smoking among veterans:

- The importance of making smoking cessation a high priority within the VA and allocating the resources necessary to insure that smoking cessation treatment is provided routinely and that proven pharmacologic interventions are available at no cost to smokers who want to quit.
- The need to integrate smoking cessation efforts into relevant services (e.g., weight management, blood pressure control, and diabetes management) that the VA already provides and to use "teachable moments," such as hospital admissions, to encourage quitting.
- The utility of having mental health providers deliver evidence-based smoking cessation counseling and drug therapy in conjunction with their treatment of psychiatric illness, substance abuse disorder, and post-traumatic stress disorder. This proposed expansion of the scope of practice for mental health providers would require a modest investment of time and money, but would have the advantage of unifying treatment in the related areas of mental health and addiction medicine.
- The need to make use of the research opportunities afforded by the VA's Computerized Patient Record System, including refining and standardizing smoking-related computer clinical reminders and performance measures across VA sites nationally.
- The potential benefit that telephone quitlines might provide to VA patients who often live great distances from VA sites, may be reluctant to participate in face-to-face or group counseling sessions, and for whom the anonymity of telephonic care might be especially attractive.

These *Proceedings*—which contain the papers, discussions, and distilled suggestions of the conference participants—provide a state-of-the-art assessment of what does and does not work in smoking cessation, with a special emphasis on the VA patient population. At the end of the book, we have included a summary of next steps that might be taken to assure that the VA remains in the vanguard of smoking cessation efforts in the US. Although the conference was sponsored by and focused on the VA, we believe that the insights it produced will have broad applicability to non-VA health care providers and policy-makers.

We wish to thank the sponsors of this event at the VA, in particular Lawrence Deyton, M.S.P.H., M.D., Chief of Public Health for U.S. Department of Veterans Affairs, and Kim Hamlett-Berry, Ph.D., Director of the Public Health National Prevention Program in the VA Public Health Strategic Health Care Group, as well as Diana Nicoll, M.D., Ph.D., for stimulating the creation of this project; Elissa Keszler for her superb organizations skills; and Stephen Isaacs for his outstanding editing. It is our hope that this conference, as captured in these *Proceedings*, will result in more veterans being able to quit smoking.



TOPIC ONE

Smoking Cessation Policy in the VA

Smoking Cessation Policy in the VA Health Care System: Where Have We Been and Where Are We Going?

Kim Hamlett-Berry, Ph.D.*

The VA system provides medical care to nearly five million veterans, who comprise an older, more financially disadvantaged population, with a greater number of medical and psychiatric co-morbidities than the general U.S. population. Organized into 21 administrative regions, or VISNs, the Veterans Health Administration offers integrated health care services through 158 hospitals, 42 residential rehabilitation centers, 854 outpatient clinics, and 206 counseling centers for post-traumatic stress disorder. Since 1969, the VA has pursued policies to reduce smoking among veterans and to establish VA facilities as smoke-free—policies that have met with some resistance from members of Congress and some veterans' groups. Since 2002, the VA Public Health Strategic Health Care Group has had responsibility for the National Smoking and Tobacco Use Cessation Program. It has developed a variety of approaches to increase veterans' access to effective smoking cessation therapies.

The prevalence of smoking among veterans in the care of the Department of Veterans Affairs (VA) health care system is approximately 43 percent higher than that of the comparable U.S. population, based on age- and gender-adjusted comparisons.[1] In examining the current rates of smoking and smoking-related illnesses among veterans in the care of the VA health care system, it is important to consider the context of the larger historical relationship between tobacco use and military service in the United States. While the practice of providing cheap and readily available tobacco to troops dates back as early as the Civil War, this practice and the culture of high rates of tobacco use in the military were most common during World Wars I and II and the Korean War. As a result, many of the veterans of these conflicts and those that followed became smokers while serving in the military and went on to develop smoking-related illnesses.

The Culture of Tobacco Use in the Military

During World War I and World War II, the image of the American soldier smoking was a familiar one. Many Americans who may have never smoked prior to their military service began smoking while in the service. "Smoke 'em if you've got 'em" was a common command and in many cases was even encouraged as it was thought to help keep soldiers alert and awake, or to help them cope with the tedium of waiting while on watch and the stress of combat. There

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was also governmental support and encouragement of this practice in the form of inclusion of cigarettes in K-rations and provision of cigarettes in care packages sent to soldiers overseas. Cigarettes such as Lucky Strikes were provided for free, and tobacco companies made it a patriotic duty to contribute free cigarettes, leading to high rates of nicotine addiction in an entire generation. This was reflected in one of the most popular cultural icons of the time for service members, the cartoon "Willie and Joe," created by the Pulitzer Prize-winning cartoonist, Bill Mauldin. Willie and Joe were described as the "everyman of the World War II American Army," and images of smoking soldiers were commonly featured in this very popular cartoon series in the Stars and Stripes newspaper that was circulated to U.S. military stationed throughout the world.

At home, cigarette ads of that era often featured images of U.S. military members smoking their cigarettes. An ad for Camels featured a young infantryman exclaiming, "In this man's Army, the cigarette is Camel. They are first with me on all counts." The importance of tobacco use was so prevalent among troops that General John J. Pershing once said, "You ask me what we need to win the war? I answer tobacco as much as bullets."[2] Staging areas in the European theater of operations in World War II were named after cigarette brands such as Camp Lucky Strike, Camp Old Gold, and Camp Phillip Morris.[3] The confluence of these factors all led to high rates of nicotine addiction and smoking-related illnesses among what has been termed "America's Greatest Generation."

Arguably, cigarette smoking was viewed very differently in the culture of the United States prior to the 1964 Report of the U.S. Surgeon General, but the support of smoking within the military culture was even greater. Even in the years following the Surgeon General's initial report, high rates of smoking were prevalent in active military populations. The initiation of smoking while in the military has been common in both times of war and peace. It has been widely acknowledged in the military that many young soldiers, sailors, and Marines first started smoking or tobacco use during initial "boot camp" training. Prior to the change in policy in 1987 that banned all tobacco use at training commands, giving or denying a "smoking break" was a reward or punishment commonly used by drill instructors or company commanders.[4,5]

In 1996, as part of a national policy to decrease tobacco use and the rates of smoking-related illness, the Clinton administration extended this policy to the entire U.S. military and eliminated the practice of making available very low, subsidized prices for tobacco to U.S. service members. Administration efforts and policies also focused on recovery of federal government costs associated with the treatment of smoking-related illnesses, including care provided for military personnel and dependents and veterans. In September 1999, the Department of Justice (DOJ) sued the tobacco companies seeking recovery under three federal statutes: the Medical Care Recovery Act (MCRA) to recoup taxpayer dollars spent on health care costs associated with smoking-related illnesses for veterans, military personnel, and federal employees; the Medicare Secondary Payer (MSP) provision of the Social Security Act to recoup costs of care of elderly covered by Medicare payments; and the civil provisions of the Racketeer Influenced and Corrupt Organizations Act (RICO). On September 28, 2000,

federal district court judge Gladys Kessler dismissed the portion of the DOJ suit that related to the medical cost recovery claims, leaving only the RICO counts to go to trial, beginning in September 2004.[6]

Tobacco continues to play a significant role even in current military deployments as seen in news stories of U.S. Marines reporting battlefield shortages of cigarettes and smokeless tobacco during the most recent war in Iraq.[7] Higher rates of smoking continue to be a significant concern for the military. The 2002 Department of Defense (DoD) Survey of Health Related Behaviors Among Military Personnel showed the first increase in smoking among DoD personnel in 20 years. Between 1980 and 1998, cigarette smoking declined from 51 percent to 30 percent, but then increased to 34 percent in 2002.[8] Also, while not having initiated smoking before the age of 18 years is typically a protective factor for being a nonsmoker, this is not true of men and women who serve in the military. Serving in the military is a risk factor for smoking even for those who have not initiated smoking prior to the age of 18.[9] It is not surprising that given the higher rate of smoking among military populations, management of tobacco use and treatment of smoking-related illnesses is one of the major clinical challenges in the treatment of veterans in the care of the VA health care system.

The VA Health Care System

The Department of Veterans Affairs houses the nation's largest integrated health care system. It includes 158 hospitals, 132 nursing homes, 42 residential rehabilitation treatment programs, 854 outpatient clinics, and 206 counseling centers for the treatment of post-traumatic stress disorder. In the late 1990s, the Veterans Health Administration (VHA) underwent a dramatic reorganization and restructuring, shifting from a system with a primary focus on acute inpatient care and medical specialization to one grounded in ambulatory and primary care. In addition, there was also a major change in the operational and management structure of the VHA,[10] which is now organized into 21 administrative regions, known as Veterans Integrated Service Networks (VISNs). Federal funds to support health care services are distributed to these regional networks, each of which has oversight responsibility for the health care facilities in its region. The size of these geographic regions varies greatly. For example, VISN 3 (NY/NJ Veterans Healthcare Network) includes facilities in the greater New York City area and southern New York, while VISN 23 (VA Midwest Health Care Network) includes all of the health care facilities in the states of Minnesota, North and South Dakota, Iowa, and Nebraska.

As opposed to other Federal programs, such as Medicaid or Medicare, the VA health care system is a direct service provider rather than an insurer or payer for health care services. It provides a full range of outpatient and inpatient health care services with an emphasis on prevention and primary care. This range of services includes: preventive services, including immunizations and screening; primary health care; diagnosis and treatment; home health care; hospice and palliative care; urgent and emergent care; and pharmaceuticals. In addition, some veterans are eligible for services such as nursing home care, residential rehabilitation, adult day

care, and limited dental services. VA health care is generally available to all enrolled, honorably discharged veterans of the U.S. Armed Forces. Once a veteran has enrolled for care, he or she is then assigned to one of 8 priority groups, with 1 being the highest priority for enrollment. The priority groups are categorized according to whether the veteran has a service-connected disability and whether his or her income meets the VA Means Test threshold. Priority is given to veterans who are receiving care for conditions or disabilities related to military service or who have low income, few assets, and no health insurance.[11]

In 2003, the VA provided care for 4.8 million veterans out of a total national population of 26 million veterans. The veterans who receive care in the VA represent an older, more financially disadvantaged population with a greater number of medical and psychiatric co-morbidities. It is estimated that the VA is used by 75 percent of all disabled and low-income veterans nationally. Approximately 60 percent of veterans who receive VA medical care have no private or Medigap insurance,[12] two-thirds earn below $20,000 a year, and more than one-third are 65 or older.[13] Therefore, for many veterans, the VA health care system serves as a "safety net" provider. In addition, many of the demographics that characterize the population being cared for in the VA also characterize those with higher rates of smoking, namely patients with lower socioeconomic status, higher rates of psychiatric disorder, and higher rates of other substance abuse.

Over the past four decades, the smoking cessation policies and programs of the VA health care system have changed in accordance with the changes of hospitals, clinics, and health care systems across the country. But the VA has also had the additional mission and challenge of developing policies and clinical programs that are responsive to the needs of a veteran population that has a much higher rate of smoking, in addition to higher rates of other medical and psychiatric co-morbidities. All this has taken place in the paradoxical context of a political climate and culture that has often depicted access to and use of tobacco as a personal freedom to be protected, increasing research on the adverse health effects of smoking as the leading cause of preventable death and disease, and the VA health care system as it has been undergoing major changes in its organization and mission.

The History and Background of the VA's Smoke-Free Policy

One of the VA's earliest policies on smoking was issued in June 1969, five years after the Surgeon General's report that outlined the initial public health message that smoking was a cause of lung cancer and therefore hazardous to health.[14] The VA's circular, *Policy on Smoking in Medical Centers*, stated that "in view of the established fact that cigarette smoking is directly related to considerable excess morbidity and mortality, and that cigarette smoking constitutes one of the nation's major preventive health problems," the Public Health Service, VA, and DoD would all agree to develop measures to discourage cigarette smoking in all their medical care facilities.[15]

In 1969, these measures included educating staff about the health hazards of cigarette use, about cessation, and about the influence of their behavior as health care workers on patients;

environmental measures to discourage smoking and reinforce non-smoking by banning the distribution of free cigarettes; restricting the sales of cigarettes in hospitals or clinics to canteens; discouraging smoking by health care professionals while in the presence of patients; and restricting smoking to waiting areas, patient day rooms, staff lounges, private offices, and other designated areas. Medical centers were encouraged to "aggressively initiate and continue smoking cessation activities aimed to high risk patients and to all patients who wish to stop or modify their smoking behavior." Medical service personnel were also encouraged to "avoid the use of cigarettes when making formal appearances (this particularly includes TV and movie appearances)." It is interesting to note that this policy states that these requirements "may be interpreted in accordance with the local situation," giving medical centers some leeway in their interpretation and implementation of even these basic requirements.

This policy was renewed in 1975 with no changes from the 1969 document.[16] Changes to the policy in 1977 and 1978 included the establishment of no-smoking areas in hospitals in such places as elevators and stairwells, patient interview areas, exam rooms, conference rooms and auditoriums, and cafeterias; and making sure that the canteen selling price of all tobacco products was equal to the average community retail price. In 1977, the VA outlined its commitment to "the voluntary reduction and eventual elimination of smoking in its health care facilities."[17, 18] But there was little in the way of increased initiatives to make VA health care facilities smoke-free until the 1980s.

In 1984, the VA's Chief Medical Director at the time, Dr. John Gronvall, noted that the smoking policy had drawn significant criticism from both within and outside the VA system. In a memo to facility directors and regional directors, Dr. Gronvall acknowledged the criticism of the VA's smoking policy by health care professionals who spent much of their time providing care for veterans with smoking-related illnesses. He stated the many of the veterans whom they provided care for were "products of an era and culture that viewed tobacco quite differently than do health care professionals today." He also noted that many veterans of the World War II era had been strongly encouraged to smoke and were now paying the price with a disorder that was difficult to cure with the therapies available.

Dr. Grovnall continued by noting that this dilemma was further complicated by the VA's role as a provider of a continuum of care from acute to long-term care. While some of the veterans affected would be those acutely ill requiring a brief stay, others included those with histories of repeated institutionalizations or chronic medical or psychiatric conditions that meant that a VA facility would be "the only home that they truly have." VA providers were often of a generation that had trained well after the 1964 release of the Surgeon General's report and the cultural shift away from smoking as an acceptable practice. Many of these providers expressed concerns that as a medical system devoted to the treatment and prevention of smoking-related illnesses, the VA's smoke-free policies did not go far enough and were inconsistent with the VA's core health care mission. The tension between these health care providers and veterans who smoked made it difficult to develop a smoking policy that would truly be acceptable to all involved. Dr. Gronvall went on to emphasize the critical role of

smoking cessation efforts at each facility and the VA's potential to help play a prominent role in the national effort to reduce smoking and smoking-related illnesses.[19]

The VA further increased efforts to delineate no-smoking areas to prevent exposures to second-hand smoke in accordance with the smoking regulations published for all Federal government buildings by the General Services Administration (GSA) on December 8, 1986. These included steps to make all VA workplaces not ordinarily used by patients smoke-free and to encourage an aggressive education and smoking cessation program for all facilities.[20] The VA announced steps to collaborate with the American Cancer Society to provide "Fresh Start Clinics" to all employees who wished to stop smoking and to provide support and time off to attend such clinics. Additional efforts were made to provide materials to employees who wanted to try to quit on their own. This policy also acknowledged the concerns about the VA's policy to continue to sell cigarettes in the VA canteens. It was noted that this was a "complex issue" with a long history that was being discussed but did not yield itself to an easy resolution.[20]

In 1988, smoking cessation was identified as an area of "special emphasis" in the preventive medicine areas that should be provided in the care of service-connected veterans as well as those with a disability rating of at least 50 percent.[21] The goals as identified by the VA were: "create a smoke free environment in VA medical centers; elimination of tobacco products from the VA medical centers' canteens; reduction in tobacco use by employees of the VA; and reduction in tobacco use by patients of VA".

Canteen Sales of Tobacco Products

Eliminating the sale of tobacco products in VA medical center canteens became a contentious and political issue locally and nationally. While many felt that the sale of tobacco products was in direct conflict with the mission of a health care system, others, including veterans' service organizations, industry representatives, and members of Congress, fiercely argued that this violated veterans' freedom of choice and placed undue hardship on hospitalized veterans who had bravely served their country and whose tobacco dependence may have been initiated by their military service. The 1988 proposal to eliminate tobacco sales was met with such resistance that a fairly high standard was established before a medical center could even apply for permission to stop selling tobacco products. Medical centers that wished to apply for approval to stop local sales were required to have support from their clinical executive board, local veterans' service organizations, their union, and any "appropriate political constituencies."[22] In addition, medical center canteens seeking approval were required to present a plan that demonstrated that they would be able to generate a net profit without tobacco, as tobacco products had been a major source of profit. Medical centers that could not submit an acceptable plan to generate the required net profit would not be approved. There was significant resistance to even these criteria from veterans' service organizations and members of Congress, particularly some who represented "tobacco states."

Over-the-counter sales of tobacco products in the VA finally ceased October 1, 1991. However, medical centers were still allowed to make provisions for some populations, such as veterans receiving long-term and chronic care who were identified by medical staff as meeting "specific medical criteria" (e.g., patients in hospice, nursing homes, psychiatric inpatients, and spinal cord injury patient populations) and unable to obtain tobacco products elsewhere. (It was also emphasized that it was expected that these would represent rare exceptions and anecdotally, this was typically the case.) Strict provisions were made for identification of these patients and the mechanisms to allow sales to verify that only these patients would receive the items. These patients were then permitted to smoke only in designated areas.[23]

The VA—Finally Smoke-Free?

In 1989, the VA announced a three-phase plan to establish a smoke-free environment in all health care facilities. Phase I sought to establish "no smoking" as the cultural norm with promotional and educational initiatives to advance this goal. It also called for the establishment of designated smoking areas and an emphasis on smoking cessation programs for patients and employees. Phase II included efforts to make all acute care VA facilities smoke-free, as well as efforts to inform patients and employees about the rationale of this initiative and its importance to the VA's health care mission. In addition, resources were developed to help facilities meet this goal. The goal for Phase II was that all facilities (initially defined as all acute care facilities not having American Federation of Government Employee bargaining units) would be smoke-free. This meant that at all acute care facilities at which outdoor smoking shelters were available, no smoking would be permitted indoors. This policy was not yet applicable to patients in long-term care facilities or chronic care facilities, including psychiatry. However, there were clear guidelines about the indoor areas that could be used by these patients. There were also requirements to minimize exposures to smoke by other patients and VA staff, and educational efforts to target cessation efforts for these patients were required as well.

By 1991, all Department of Veterans Affairs medical facilities had been successful in implementing a policy that prohibited indoor smoking by patients, employees, visitors, or volunteers, and as noted earlier, hospital canteens were no longer allowed to sell tobacco products.[3, 24, 25] Outdoor areas or shelters had been established with clear guidance about management and enforcement of the national smoke-free policy. VHA facilities with long-term care facilities and other special programs that had previously been excluded from the VA national smoke-free policy were to put a plan into effect on how to be smoke-free by December 31, 1993. The plan was to include a list of "specific medical criteria supported by a valid, defensible rationale defined by the medical staff under which a patient in the building will be allowed to smoke."[26] These gains had been hard-fought, but the steady efforts of committed VA health care professionals and administrators had ultimately paid off even in the face of challenges by veterans' smoker groups (some reportedly supported by tobacco-industry funding) and some members of Congress. Despite the early concerns and dire warnings of some about the potential impact of smoke-free policies, veteran patients who smoked had not

abandoned the VA, nor had significant numbers of VA medical center employees resigned. Efforts were made to increase education of veterans and employees about the health effects of smoking and the availability of smoking cessation programs. In 1992, to provide assistance to employees who still smoked during the time of transition to smoke-free work environments, each facility was required to provide smoking cessation assistance to employees as part of the Employee Health Program for at least one year following the implementation of the smoke-free policies. Guidance was issued defining effective smoking cessation programs that were consistent with national practices, and facility directors were to reimburse employees who provided "evidence of successful completion of an approved method" of smoking cessation. Reimbursements equaled a co-payment with the employee of 50 percent of the cost of the method or $75, whichever was less.

Resistance to the VHA's Smoke Free Policy

These efforts were complicated in late 1992, when Congress passed Public Law 102-585, the Veterans Health Care Act, which required the VHA to establish "suitable" indoor or outdoor smoking areas that have "appropriate heating and air conditioning." As noted in an insightful 1994 commentary by Dr. Anne Joseph, which was published in the *Journal of the American Medical Association*, and titled, "Is Congress blowing smoke at the VA?" this was seen as a major setback by many to the progress accomplished through the VA's national smoke free policy.[3] In 1991, as noted by Joseph, Representative Staggers (D-WV) and Representative Wise (D-WV) introduced the Veterans Dignity in Health Care Act as an amendment to a broad veterans health care authorization bill. This amendment would have required that the VA make tobacco products available for sale to veterans and provide indoor smoking areas for patients. Representative Staggers argued that aged veterans were unable to go outside to smoke, especially in winter months, and that this was an undue hardship for men who had bravely served. It was also reported that both he and Representative Wise had received campaign donations from political action committees of two major tobacco companies.[3] This campaign was marketed through ads that featured poignant pictures of elderly veterans smoking in VA hospital parking lots.

During hearings on the bill, members of the House of Representatives heard emotional testimony from veterans and veterans' service organizations about elderly patients in wheelchairs being forced to smoke outside in the cold. There was also reluctance to oppose the amendment as it was attached to a bill that promised much needed benefits to many veterans. In addition, other members of Congress reported being lobbied by veterans when they made visits to VA medical centers in their home districts.[27] The measure was strongly opposed by the then Secretary of Veterans Affairs, Edward Derwinski. In an address to the members of the American Legion veterans' service organization in February 1992, he had stated, " If we're to be a reputable medical system, we can't be tolerating smoking. It's just that precise and direct."[28] Other opponents included Secretary of Health and Human Services Louis Sullivan, Surgeon General Antonia Novello, the American Lung Association, the American Heart Association, and the American Cancer Society. Unfortunately, in late 1992, the legislation passed and was enacted by Congress.[3]

One of the requirements of the Veterans Health Care Act of 1992 was a report by the General Accounting Office (GAO) on the feasibility of establishing and maintaining the mandated smoking areas with regard to issues such as the effect on the accreditation of the VA's medical facilities, the funding levels necessary for establishing the areas, and the estimated length of time needed for construction. In its review, the GAO concluded that the VA did face a number of obstacles to implementation, but concluded that they were not "insurmountable." The GAO determined that the estimated costs to establish the smoking areas varied widely, depending on the VA's implementation strategy, with a lower-end estimate of $4 million to a higher-end estimate of $24 million. It was estimated that most facilities would require more than a year for total planning, design, contracting, and construction. Finally, it determined that the change in smoking policies would not affect accreditation as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recognized that laws have precedence over its accreditation standards. As a result, if a standard conflicted with a law, the Joint Commission would not use that standard in determining a health care organization's accreditation.[29]

Still, there was great criticism of this measure, as the VHA had made significant progress in making its health care centers smoke-free. In addition, since there was no increase in appropriations to fund this mandate, the money needed for construction and maintenance of these smoking areas had to come out of existing VA patient care funds. The VA remained clear that its goal was to eliminate smoking in the VA. Given that most VA medical centers had outside smoking shelters as part of smoke-free initiatives already underway, the VA's official position was that outdoor detached smoking areas were preferable and more appropriate than the alternative of an indoor smoking area. The VA issued guidance on the design requirements for the detached smoking areas or shelters and in 1993, directors of facilities that did not have adequate outdoor detached shelters were provided up to $25,000 to upgrade or construct appropriate shelters.[30,31]

In addition, this legislation appeared to adversely affect the VHA's earlier efforts to develop plans to help long-term care clinical settings and inpatient psychiatry settings become smoke-free. Since 1993, the VHA's smoke free guidance has recognized that some facilities still maintain established indoor smoking areas for long-term care patients as well as some psychiatric patients. While there have been clear regulations about the need for separate ventilation systems for these indoor areas, there has been no new guidance on the need for facilities to develop plans to eliminate these indoor facilities (as originally proposed in the 1991 directives that had required elimination of indoor areas by 1993) and to establish alternatives to tobacco use for inpatients in these clinical settings, such as provision of nicotine replacement therapies. Guidance has been less clear about whether indoor smoking facilities could be established in new construction to replace long-term care or inpatient psychiatric units in older facilities if they did not already have long-established indoor areas. (When this question has been raised with the Public Health Strategic Health Care Group national program office, hospital administrators have been advised to contact their regional counsel to determine whether this is allowed under current regulations. They have also been strongly

advised to consider the use of nicotine replacement therapy, or NRT, for these patients during their inpatient stay as a medical alternative to help patients manage their nicotine addiction and prevent withdrawal. This practice has already been adopted at sites such as the inpatient psychiatric unit of the Palo Alto VA Medical Center with apparent success and no reported increase in problem behaviors among patients.)

Smoking Cessation Access Issues—Where Were the Gaps?

In 1995, a VHA directive from the Under Secretary for Health on "Smoking Policies for Patients in VA Health Care Facilities" included language on the importance of a national emphasis on an aggressive educational program to address the benefits of stopping tobacco use along with a strong emphasis on smoking cessation. However, this directive also included new guidance that may have inadvertently provided a conflicting message about the importance of smoking cessation efforts in the VA. First, the directive stated, "Directors are encouraged to conduct their own smoking cessation programs. However, if local programs such as those sponsored by the American Cancer Society, American Heart Association, American Lung Association, and others are available in the community, it would be appropriate to share smoking cessation activities with these programs in order to conserve resources." In addition, this directive also stated that NRT "should only be used in conjunction with a behaviorally based smoking cessation program and then only with patients that have seriously expressed a commitment to quit smoking."[32]

While it is true that conserving resources is always an important goal for any health care system, it is unclear why smoking cessation programs were targeted for fiscal restraints, given the well-established low utilization of smoking cessation programs and the high rates of smoking-related illnesses of veterans in care. At the time of this 1995 directive, the VA health care system was in the midst of dramatic transition away from the traditional emphasis on hospital-based care and medical subspecialization to a system that focused on primary care and prevention. The approach supported by this directive was inconsistent with the new direction of health care in the VA. To some extent, this language appeared to encourage referrals to outside agencies for smoking cessation. Yet it was well known that there was a very high prevalence of smoking among veterans in the care of the VA, with up to one-third being current smokers. And in fiscal year 1992, the VA reported that it had spent more than half a billion dollars on inpatient care of veterans with smoking-related illnesses.[33] Increasing the outreach of existing VHA smoking cessation efforts would appear to have been a highly cost-effective strategy.

Furthermore, in limiting NRT only to those who were willing or able to attend a formal intensive smoking cessation program, the VA greatly limited the number of veteran smokers who would have access to a highly effective therapy for smoking cessation. This requirement also acted to prevent primary care physicians from providing highly effective brief counseling coupled with a prescription for NRT. There were no guidelines as to how providers were to determine whether patients were "highly committed" to stop smoking or why this condition

was added. When asked informally about the rationale for enacting the restriction on prescribing NRT, VHA administrators have given one of two answers as the rationale for the more restrictive policy.

The first has been that this was an evidence-based recommendation at the time, as the research had indicated that NRT was most effective when used in conjunction with an intensive smoking cessation program. However, this same standard was not enforced for many other medications. (For example, while drug treatment of conditions such as depression or high cholesterol levels would be more effective when used in conjunction with behavioral change therapies, these therapies were not required when those medications were prescribed.) The other answer has been that this restriction had been put in place because of possible budgetary concerns. The rationale was that NRT would be too expensive for the system since veteran patients would either be (a) likely to misuse them and request multiple trials, leading to significant increases in pharmacy budgets, or (b) provide them to family members instead, since these therapies were not covered by private insurers.

The period of 1995 through 2000 was characterized largely by smoking cessation oversight issues rather than new policy initiatives. The program office was coping with the enormous challenges of national implementation of the smoking shelters requirement of the Veterans Health Care Act of 1992. This was achieved in consultation with local smoking coordinators who had been designated to provide updates on facilities' progress in complying with the smoke-free policies. In addition, the program office routinely consulted with the VA smoking cessation leaders who made up the field advisory group that later served as the basis for the VA Smoking and Tobacco Use Cessation Technical Advisory Group. In 1999, the VA was also focused on its participation in the federal lawsuit against the tobacco companies to recover costs associated with treatment of smoking-related illnesses. Finally, this was a time of great change across the system, as the VHA was undergoing a major reorganization as it moved from a centralized administration structure to a decentralized administration of regional networks.

A Public Health Approach to Smoking Cessation

In January 2002, the VA Public Health Strategic Health Care Group was assigned responsibility for the National Smoking and Tobacco Use Cessation Program. Oversight of this important public health policy issue was assigned to the Public Health National Prevention Program, as smoking is currently the leading cause of preventable disease and death. This move also reflected the recognition of the public health and medical aspects of smoking and tobacco use as a chronic health condition. The immediate goal for the program was to increase veterans' access to and utilization of evidence-based smoking and tobacco use cessation clinical interventions. In August 2003, the Under Secretary for Health issued a directive stating that "smoking and tobacco use cessation will continue to have a high priority and visibility in the VHA. In support of this goal, the National Smoking and Tobacco Use Cessation Program will implement and place additional emphasis on the following elements:"

- "As part of the VA's commitment to preventable illness, a strong public health educational effort on the health benefits of quitting tobacco use will continue with a strong emphasis on outreach, and an increasing awareness of the availability of the full range of smoking and tobacco use cessation treatment options in VA."
- "VA will provide a Smoking and Tobacco Use Cessation Program that delivers the highest standard of care to veterans who want to quit smoking or tobacco use. In accordance with the evidence-based VA-DoD Tobacco Use Cessation Clinical Practice Guidelines, smoking cessation medications need to be made available to all smokers interested in quitting, regardless of whether or not the patient is willing to attend a smoking cessation program. Current VA and non-VA quality of care measures for smoking cessation assess the extent to which smokers interested in quitting are given medications to help them quit. NRTs need to be made available to veterans who are attempting to quit smoking or other tobacco use as part of routine care in primary care and other clinical care settings where veterans are seeking help with tobacco use cessation."[34]

Increased Access to NRT in the VA

This directive removed the earlier restriction on prescribing NRT and bupropion in order to increase the access of veterans to these highly effective smoking cessation therapies. This was a move that had been strongly supported by the VA Smoking and Tobacco Use Cessation Technical Advisory Group (TAG) advising the national program office. There was significant evidence from the 2002 Cochrane review that NRT, in combination with brief counseling from a primary care provider, was highly effective.[35] The 1999 VA/DoD Clinical Practice Guidelines had previously recommended that primary care providers prescribe NRT or bupropion for patients who wanted to quit smoking, as part of a primary care and preventive approach to cessation.[36] Yet even with the strong support of the VHA leadership, this policy initiative to remove the restriction was a highly controversial one that met with significant resistance.

As part of the process in the VHA, the proposal was presented to the leadership of the Pharmacy Benefits Management (PBM) Strategic Health Care Group, the VISN or the VA administrative regional Chief Medical Officers, and others. As with any VHA directive, it also went through an internal concurrence process with required approval from all the VHA national program offices that would be affected by the change in policy. At each step, concerns about possible problems were raised, discussed, and addressed. In addition, a review of national PBM data by Jonk and colleagues revealed that NRT and bupropion prescriptions over the past four years had been prescribed infrequently and had cost the VA very little (the therapies accounted for approximately one-half of one percent of total national pharmacy expenditures).[37] So the directive was approved, and the restriction on NRT was lifted as of August 2003, by the order of the Under Secretary.

However, resistance to lifting the restriction has continued at the local level at a number of VA Medical Centers, and the policy has continued to generate controversy. While there have

been numerous providers who welcomed the increased access to NRT as part of a population-based approach to smoking cessation, others have voiced strong concerns. Some opposition has come from directors of smoking cessation programs, concerned that primary care providers will be unable to competently provide even brief counseling in smoking cessation or that this policy would effectively eliminate smoking cessation specialty programs. VA providers have reported that their local pharmacies have continued to enforce the restriction on prescribing NRT, effectively blocking primary care providers from prescribing NRT that had, in some instances, been approved by the FDA for over-the-counter use. Others have lifted the restriction, but have limited access by allowing only a one-month course of the medications with a limit of only two prescriptions allowed for a calendar year (despite the evidence that shows that multiple quit attempts are typically needed before a smoker is able to quit). Some local pharmacies have voiced concerns that veterans are likely to misuse NRTs, such as the nicotine patch, by using them while continuing to smoke, while others have expressed concern that the policy change will potentially break pharmacy budgets. (It is interesting to note that at about the same time that the lifting of the pharmacy restriction on NRT was mandated, another unfunded mandate went into effect that allowed VA-eligible veterans who had not been able to get in to see VA providers to get prescriptions from outside providers filled at VA pharmacies. This was a dramatic shift in a pharmacy policy that had strictly prohibited dispensing of pharmaceuticals not prescribed by VA care providers. A number of pharmacists pointed to the coincident timing of these two mandates as contributing to some resistance by VA pharmacists who felt that their budgets would be overtaxed by these two concurrent policy initiatives.)

There are many lessons learned from this policy initiative. First, it illustrates the complexities of policy implementation and oversight in a national health care system. Conceiving, writing, and mandating well-meaning and clinically-sound policies is one thing. Obtaining the buy-in and compliance of 158 hospitals and 854 outpatient clinics is quite another. Even for sites welcoming the new policy, change sometimes came slowly. The mechanisms for implementation do not always match the will of their champions, and communicating change in national policy does not always ensure that those responsible for carrying out the change at the local hospital level will hear about it in a timely manner. Questions need to be asked about what could have been done differently to elicit greater support. For example, pharmacy representatives might have supported this initiative initially if there had funding support to offset any resulting short-term increases in pharmacy budgets. Over the long run, the cost of drugs needed to treat smoking-related illnesses is likely to dwarf the cost associated with prescription smoking cessation products. However, these cost savings may take years to be felt by the system.

Finally, it is also important to note that some pharmacy leaders were at the forefront on this issue. An example is Julie Himstreet, a Pharm. D. who led smoking cessation program efforts at her site at the Roseburg, Oregon, VA Medical Center. She had already worked to develop clinical templates for the Computerized Patient Record System (CPRS) to allow providers to

order immediately an 8-12 week trial of NRT for patients who wanted to stop smoking. Had such a product been included in the national rollout of this policy initiative, perhaps this would have insured greater buy-in and success. An important lesson in policy change may be the importance of providing the tools to make it easier for providers to do the right thing.

Other concerns voiced about this policy initiative appeared to reflect the worry that the integration of smoking cessation into primary care and other clinical areas would mean the end of intensive smoking cessation programs. A few VA providers suggested that instead of integrating smoking cessation across the system, efforts should be directed instead at funding increased numbers of staff to promote intensive smoking cessation programs across the system. It could be argued that this approach would be inconsistent with the vision of the VA as a health care system that is moving away from a specialty care model to one focusing on primary and preventive care in the prevention, management, and treatment of chronic health conditions.

To address these concerns, it was necessary to reassure providers that the integration of smoking cessation in primary care was not being promoted to replace intensive smoking cessation programs, but rather to provide additional treatment alternatives for smokers wanting to quit. While many veterans who were referred to smoking cessation programs in the VA have been successful in quitting, many others are unwilling or unable to attend a smoking cessation program because of transportation difficulties, disabilities, or conflicts with work schedules. Data from the VHA Office of Quality Performance's national surveys and medical record reviews found that more than half of national survey respondents who were referred to programs did not follow-up on the referral. For about 38 percent of the respondents, the referral was probably inappropriate since the smoker reported that they weren't ready to quit (34 percent) or that they had just wanted medication for a quit attempt (4 percent). Approximately 36 percent reported that access was an issue because the program was difficult to get to (19 percent), the times were inconvenient (14 percent), or appointments were not available (3 percent). Finally, 14 percent of veterans who responded to the survey indicated that they did not want to attend a program delivered in a group format.[38]

A Population-Based Approach to Smoking Cessation

The initiative to increase veteran smokers' access to NRT has been part of a broader initiative to adopt a population-based approach across the VA health care system. Another important component of this initiative was the revision of the VA/DoD Clinical Practice Guidelines on smoking cessation. As part of the VHA's commitment to quality care initiatives, the Office of Quality and Performance, in coordination with the DoD, routinely convenes a panel of clinical experts to develop evidence-based clinical practice guidelines (CPGs) for management of a number of diseases or health conditions. These guidelines are then reviewed and approved by the VA/DoD CPG council and are disseminated to VA and DoD health care professionals. The CPGs are made available on the VA Office of Quality and Performance web site. The most recent revision, The VA/DoD Clinical Practice Guidelines on the Management of Tobacco Use

were approved in July of 2004 and represent a marked shift to a population-based approach to smoking and tobacco use cessation within both federal health care systems.

As noted in the introduction to the CPGs, the 2004 version reflects "a more comprehensive approach to the problem of tobacco use among veterans, military personnel, and their families." There are also a number of other changes from the 1999 version, reflecting the progress in tobacco cessation research in the period separating the two works. These include evidence of additional effective counseling strategies, such as telephone counseling; the greater number of effective pharmacologic treatments, as well as better information on the efficacy of combinations of NRT; the availability of NRT as over-the-counter medications; and the strong evidence on the cost-effectiveness of smoking cessation. Together, these findings provide a strong argument that "smoking cessation treatments should not be withheld from patients when other less cost-effective medical interventions are routinely delivered. Furthermore, *access to tobacco treatment should be as easy as purchasing tobacco products*."[39]

The major change to the CPGs is the new emphasis on population health. Previous versions had emphasized encouraging tobacco users to attend a smoking cessation program, since this was regarded as the most effective treatment. However, it was noted that while there were significant advances in cessation treatment, the prevalence of tobacco use in both military and veteran populations had remained high. While cessation programs are available in both systems, they are typically used by only a small proportion of tobacco users. While less effective than smoking cessation programs, primary care-based treatment ultimately means access to a larger portion of the population of smokers. In adopting a population health approach, it is hoped that there will be an increased focus on interventions that will have a broader reach and will help support the efforts of many more tobacco users in quitting.[39]

Toward that end, the CPGs emphasize that "convenient access to counseling and pharmacotherapy is a necessary concomitant of a population health approach." The integration of smoking or tobacco use cessation is encouraged in a broader range of clinical settings, including primary care, pediatrics, and dental clinics, as well as the use of community resources such as telephone quitlines, as younger and healthier populations in the military may visit medical clinics less frequently. Finally, because tobacco dependence is a chronic condition that may require multiple interventions, the updated CPGs also adopt a collaborative treatment approach between the patient and provider to help determine a mutually agreeable treatment plan that is responsive to the needs of the patient.[39] Since these CPGs have just been approved, their impact will not be known for some time.

Co-payment for Smoking Cessation Counseling as a Possible Barrier

When the Public Health Strategic Health Care Group assumed responsibility for smoking cessation policy and programs, one of the first issues was to identify and address any potential barriers to smoking cessation that existed. Given the high prevalence of smoking among

veterans in the care of the VA, the relatively low utilization of smoking cessation programs, and the cost-effectiveness of smoking cessation, any potential barriers to smoking cessation treatment needed to be removed. One potential barrier was the $15 basic co-payment for group and individual smoking cessation counseling (required of certain veterans, either because they did not have service-connected illnesses or injuries, or they did not meet the eligibility for income means testing).

Numerous studies have examined the effects of cost sharing on the utilization of health care services in general and found that the use of medical services is reduced when co-payments are required.[40, 41, 42] There is evidence in both acute care and preventive services that any cost-sharing reduces access to and use of medical care. While cost-sharing can play an important role in reducing inappropriate care, its effects are not desirable when services are underutilized and the goal is to increase use to an appropriate level.[43] It can be argued that given the higher rates of smoking among VA populations and the proven cost-effectiveness of smoking cessation, the VA's goal should be to increase smoking cessation utilization.

There is evidence that co-payments are a barrier to smoking cessation specifically. Both the 2000 PHS Guidelines on Smoking Cessation and the CDC Task Force on Community Preventive Services recommend reduction or elimination of out-of-pocket expenses for smoking cessation services.[44, 45] Literature examining the experience of the private sector has shown that a co-payment for smoking cessation reduces access to and use of services. The Group Health Cooperative in Seattle has conducted large studies of the effectiveness of reducing out-of-pocket costs and found that when compared with enrollees who were offered partial coverage of smoking cessation services, enrollees who were offered full coverage (no co-payment) were four times more likely to use cessation services and four times more likely to quit as a result of using the services.[40] This finding was supported by research of other health care plans that eliminated the co-payment for smoking cessation as well. With elimination of co-payment, the number of smokers who used smoking cessation services increased, access to more effective interventions was increased, and the number who were able to quit increased.[46] Finally, it is known that low-income populations have the highest rates of tobacco use nationally. Many veterans who smoke have low incomes. Unless they meet the level of financial need that would preclude assignment of a co-payment, it is likely that a $15 co-payment for each smoking cessation session (along with a co-payment for NRT or bupropion) would act as a deterrent.

A white paper outlining the issues and proposing elimination of the co-payment for group and individual smoking cessation counseling (while still leaving a co-payment for smoking cessation medications) was presented to the leadership of the VHA in late 2003. It was proposed that smoking cessation counseling instead be considered as a preventive service and moved into the "no co-payment category" of outpatient care. This would be a significant change since the other preventive services for which there is no co-payment include only publicly announced VA health initiatives (such as health fairs), or outpatient visits consisting of

preventive screening and/or immunizations (such as influenza immunizations, pneumococcal immunizations, and screenings for breast, cervical and colorectal cancer).[47] There was general support for this measure by the VHA leadership, although reservations were expressed about whether this measure would also create a precedent. To help address this issue and provide additional support, an economic analysis of the proposed elimination of the co-payment was requested by the Deputy Under Secretary for Health.

The economic analysis was conducted by Ruth Hoffman of the Office of the Assistant Deputy Under Secretary for Health in November of 2003. It examined the cost in the form of lost revenues from the waived co-payments, along with the additional expense of treating participants who would seek out smoking cessation once the co-payment was waived. While the entire economic analysis is beyond the scope of this paper, a general overview is provided as follows: To determine any savings that would result from the policy change, the costs associated with treatment of smoking-related illnesses were calculated. Ms. Hoffman relied upon a 1999 VA analysis of Department of Veterans Affairs health care costs in 1998 for veterans with tobacco-related conditions, such as lung cancer, chronic lung disease, and coronary heart disease. The number of veterans who had been provided care in 1998 for smoking-related conditions was extracted from VA national databases for inpatient and outpatient care encounters. Costs were compiled by diagnosis, totaled, and then multiplied by the smoking-attributable factors from the National Center for Health Statistics for final costs. The costs were then examined in a number of different models that assumed varying degrees of costs associated with treatment of secondary tobacco-related illnesses. Based on the models examined, the Hoffman report concluded that the percentage of total health care costs associated with smoking in the VA health care system could range from 8.31 percent to 23.81 percent. When the relative savings were compared to the costs, it was estimated that "it could take as little as 1.84 years and at the outset, only 5.27 years to recoup the costs associated with the policy change."[48]

As a next step in the internal VHA policy review process, an executive decision memo outlining the literature in support of the proposal to eliminate the co-payment for smoking cessation counseling, along with the economic analysis, was submitted to and approved by the VHA National Leadership Board in March of 2004. A consultation with the Office of the General Counsel resulted in an opinion that this proposal required approval by the Office of Management and Budget as it will require a change in federal regulations outlining the co-payment structure in the VHA. That process is currently underway and the proposal is under review for possible approval after a period of public comment. While it is hoped that the co-payment for smoking cessation counseling can be eliminated in the VA health care system, as it has been in many private health care systems, the process in the federal government is very complex. If the proposed change in the Federal regulations is approved and the co-payment for smoking cessation counseling is eliminated, the Public Health National Prevention Office would then implement a plan to use existing VHA national databases to assess its effects on smoking cessation counseling utilization in our patient population.

Next Steps for the VA in Smoking Cessation Policy and Program Development

The VA health care system has made significant progress in smoke-free policies and smoking and tobacco use cessation since the initial 1969 VHA guidance on discouraging smoking among patients and providers. Some of these developments, such as the adoption of a population health approach seen in the VA/DoD Clinical Practice Guidelines and the removal of previous restrictions on NRT, are relatively recent and their effects will not be known for some time. However, there is still much to be done to increase integration of smoking cessation into routine care and to decrease the rates of smoking and smoking-related illnesses among veterans seen in our system.

There are many resources and opportunities in the VA that have not been fully utilized in this effort. Some of these yet-to-be-explored resources include the use of national databases on patient care utilization and electronic medical records to quantify smoking and tobacco use patterns and the health-related and financial impact of cessation policies and programs. Given the depth and breadth of these resources and the magnitude of the smoking and tobacco use problem in the VA, the potential role of the VA as a national leader in the education and training of the majority of health care professionals practicing in the U.S. today is an avenue that needs to be further explored. Another important resource is the veteran patient population that we serve. Veterans have already provided service to their country in the military, and frequently they are willing to continue to serve through voluntary participation in research trials that will help other veterans. An additional resource is the network of dedicated VA clinicians and researchers in tobacco use cessation. The leaders in this area are also national leaders. As the largest single provider of mental health and substance abuse care, the VA also has the potential to serve as a national laboratory to assist in the development and evaluation of evidence-based interventions for special populations, such as psychiatric and substance use disorder populations that are disproportionately affected by smoking and smoking-related illnesses.

Additional work is needed to continue the earlier work on the development of smoke-free policies to help those VA medical centers that still have separate indoor smoking areas for veterans hospitalized on inpatient psychiatric and long-term care units. These centers need assistance with development of policies and procedures to provide appropriate NRT to these patients and phase out existing indoor smoking areas. There have been significant advances in smoking cessation therapies and pharmacotherapies that were not available when the policies allowing for these areas were originally written. While many VA facilities have successfully made this transition, others have not, reflecting the relative autonomy of individual facilities and regions in the VA's decentralized administration.

There is exciting work underway in the VA to begin to address some of the challenges inherent in meeting the cessation needs of high-risk populations, such as psychiatric and substance abuse populations. Following a limited call for clinical training proposals to the network of VA Mental Illness Research, Education, and Clinical Centers (MIRECCs) last year, funding was

awarded to the VA Puget Sound VA Medical Center/Northwest Network MIRECC and Center of Excellence in Substance Abuse Treatment & Education. This group, under the direction of Dr. Miles McFall, had previously conducted clinical research on the efficacy of tobacco use treatment delivered by mental health providers integrated into psychiatric care of veterans with post-traumatic stress disorder.[49, 50] Dr. McFall and his colleagues found that integrating tobacco use cessation into routine psychiatric care for this veteran population appeared to be superior to the usual practice of referral to a separate smoking cessation program. Based on this work, the group developed a clinical preceptorship for VA mental health professionals on the practice of integrating tobacco cessation treatment into mental health care. The first training of 53 VA health care professionals was held June 3-4, 2004. This group will be followed for more than a year and the participants will be provided with ongoing technical assistance and long-term support as they return to implement the clinical program at their sites.

Communication among this group of trainees will continue through ongoing conference calls, an email group, a website, and, if needed, expert consultations through site visits. The trainees will in turn provide training to their clinical colleagues in their clinical sites and VISNs. As part of the preceptorship, trainees have also been provided with evidence-based, brief intervention manuals and other provider training and patient resource materials. The goal of this preceptorship was broadly defined as "making it easy for providers to do the right thing" to help their patients stop using tobacco. The demand for this initial training was so great that the program has been renewed for two additional years with continued funding for training of an additional group of preceptors.

Some of the challenges that the system faces are also related to its size, as implementation in a national system of 158 hospitals and over 850 clinics can be daunting. What are the steps needed to promote the institutional and cultural shift away from smoking cessation as the sole responsibility of the smoking cessation specialty program to a broader population issue for which all providers assume greater responsibility? As a national health care system, how can the VA begin to integrate the system-wide use of state and/or national telephone quitlines and best coordinate this new and effective technology into existing VA smoking cessation treatment? What will be the treatment needs of our newest veterans, who are coping with the trauma and challenges of recent deployments (such as to Iraq and Afghanistan), given that smoking rates appear to be similar to those of our older veterans in care? [8]

These and other challenges are likely to continue to require ongoing examination and revisions of VA policies and programs as the field of tobacco use cessation continues to change in response to treatment advances, as tobacco continues to play a role in the health of our military populations, and as the landscape of our Federal health care system changes. Collaborations with important government partners in the National Cancer Institute and DoD are beginning to develop a dialogue on how to address these clinical and policy challenges. While the last four decades of smoking cessation policies and programs in the VA health care system have been exciting, rewarding, and sometimes controversial, the next decade is likely to be so as well.

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COMMENTARY ON SMOKING CESSATION POLICY

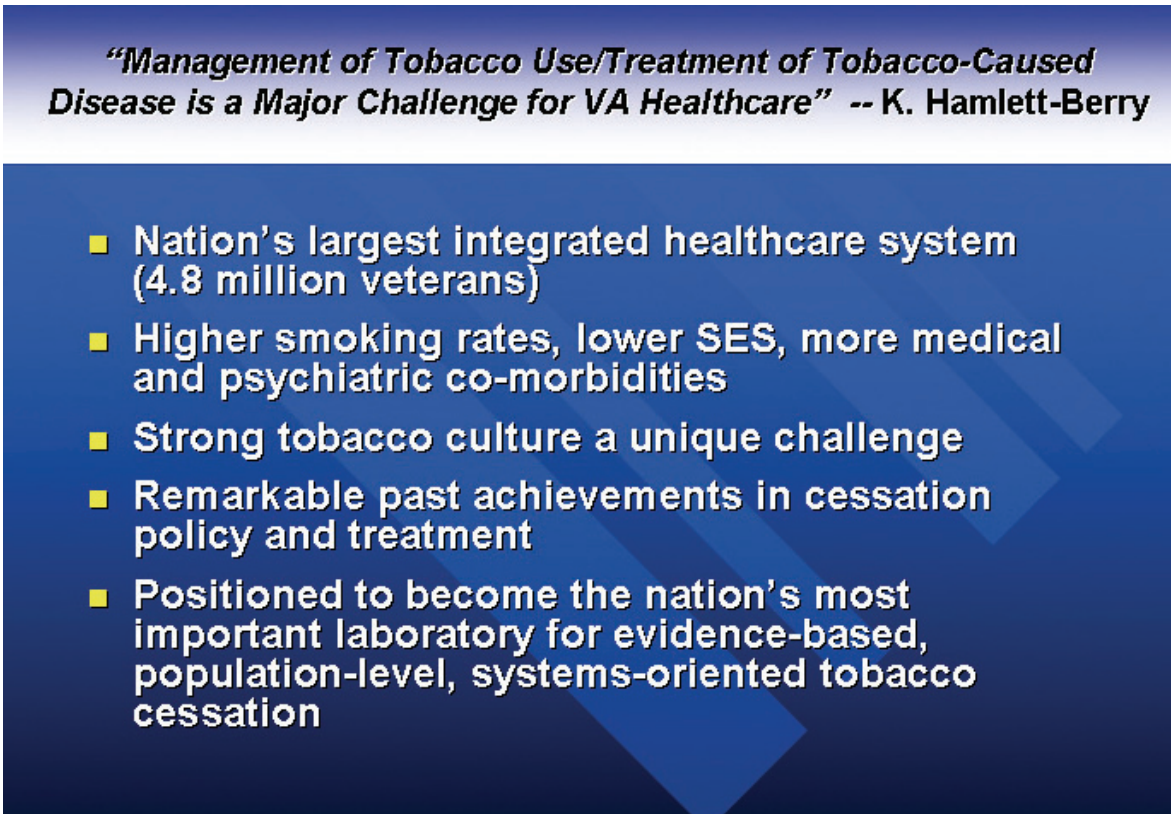
C. Tracy Orleans, Ph.D.*

It is a great pleasure to be here and, especially, to be invited to comment on Dr. Hamlett-Berry's excellent paper, setting the stage brilliantly for the issues to be discussed at this forum.

Dr. Hamlett-Berry makes it clear that the management of tobacco use and treatment of tobacco-caused disease are major challenges to the health care provided by the VA, the nation's largest integrated health care system, responsible for the care of almost five million veterans.

This is not only because of the higher rate of smoking among veterans cared for by the VA, but also because these smokers are poorer, sicker, and more likely to suffer from serious medical and psychiatric co-morbidities. Moreover, veterans have been exposed to one of the strongest, most pervasive cultures of tobacco use of any group in our history—creating powerful institutional and personal barriers to cessation.

Figure 1



Dr. Hamlett-Berry concludes, looking back, that the VA has made substantial progress implementing cessation policies and programs—which is remarkable given this historically strong tobacco culture. From what she has described as the next steps, I think that the VA is on

* The Robert Wood Johnson Foundation

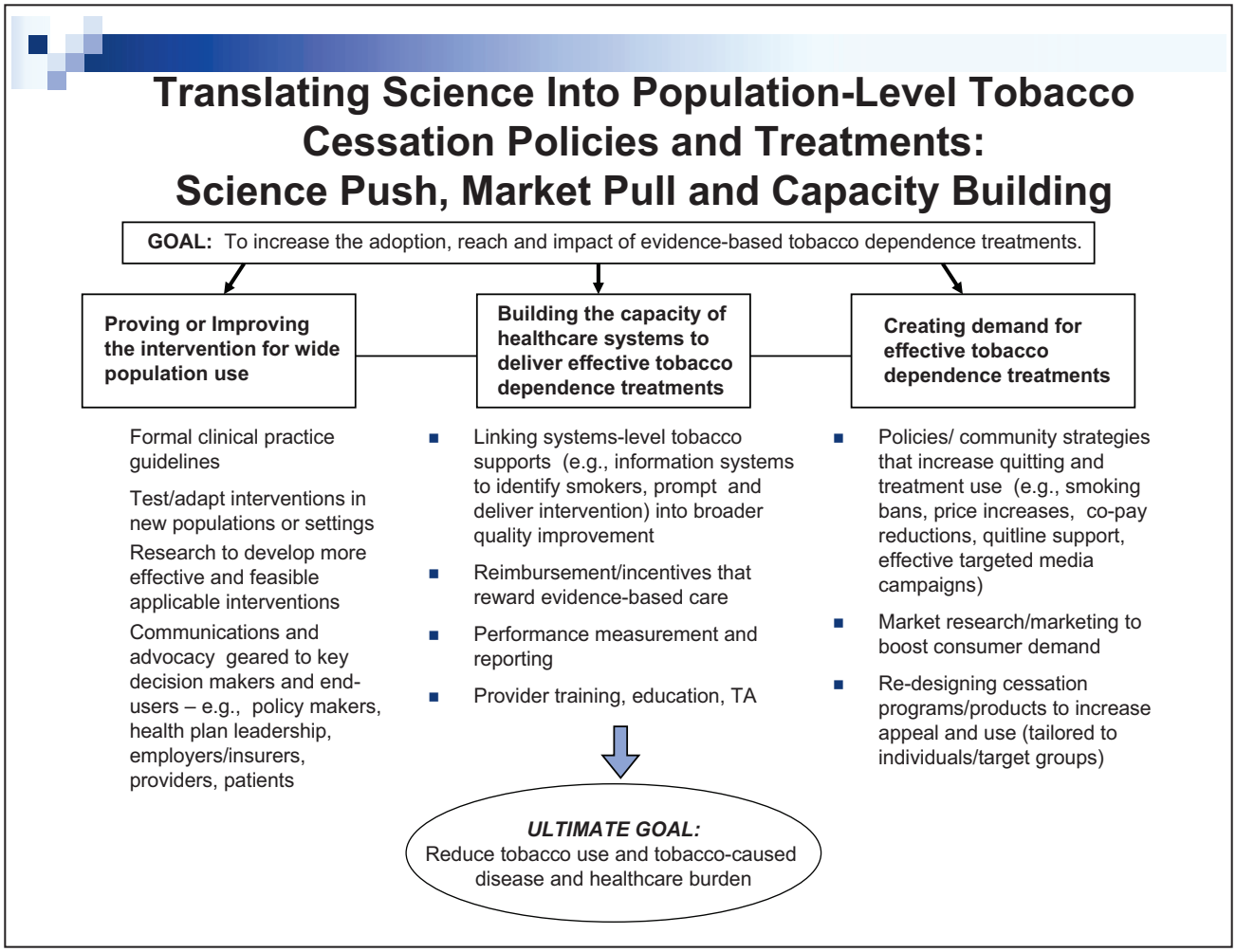
the brink of becoming the nation's most important laboratory for evidence-based, population-level, and systems-oriented tobacco cessation.

Because the history that Dr. Hamlett-Berry presents documents a continuous effort to translate the expanding science base for tobacco control into effective policy and practice, I decided to use this simple push-pull-capacity model (see figure 2) to organize my thoughts and comments.[1]

According to this model, translating science into practice requires working on three fronts:

- Strengthening the *science push* by proving, improving, or communicating evidence-based interventions for wide population use
- Boosting *market pull or consumer demand* for these interventions
- *Building the capacity* of relevant systems and institutions to deliver them.

Figure 2

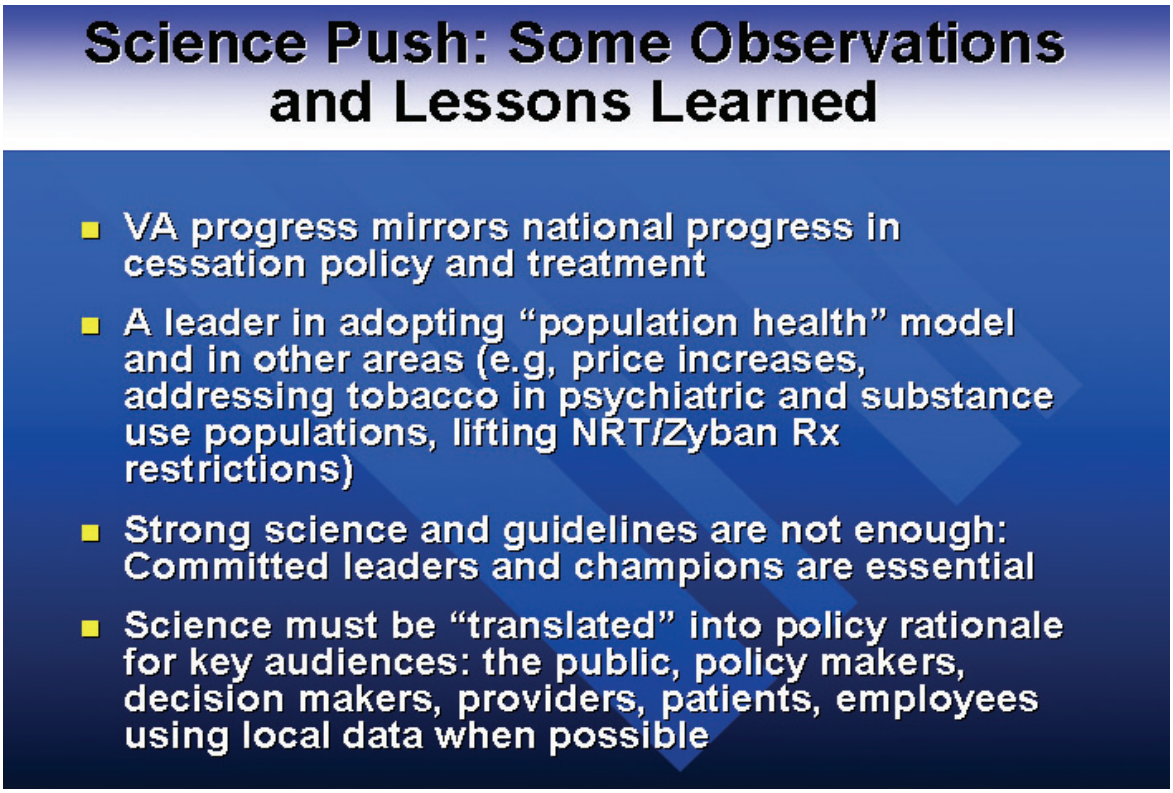


It is not my intent to describe the model, only to use it to highlight some of the accomplishments, challenges, and opportunities that Dr. Hamlett-Berry has described.

Of the many lessons or observations that could be drawn from Dr. Hamlett-Berry's paper about *science push*, I decided on these four "big picture" points (see figure 3):

- I roughed out a timeline comparing the VA's cessation policy developments and milestones against some national benchmarks, such as the JCAHO tobacco ban, the 1996 and 2000 clinic practice guidelines, the first "intentional" tobacco price increases, and NCQA's HEDIS quality measures. What I found was that the VA's progress mirrored broader national efforts fairly closely—which again is remarkable given the strong culture of tobacco use in the VA and in the military, and the VA's greater susceptibility to tobacco industry and Congressional interference. For instance, in the VA and nationally, there was a similar evolution from voluntary to mandatory policies, from limited to comprehensive smoking restrictions and bans, from education to behavioral and pharmacological treatments, and from intensive clinical treatments to lower-intensity, wider-reaching population-based approaches.
- In some cases, VA policies and programs have lagged behind the science and broader efforts—for instance, in its late and reluctant embrace of brief primary care interventions. But I think that the VA was actually a bit ahead of the curve in adopting a population approach, one of the hallmarks of which is that you need both "downstream" individually-oriented treatments *and* "upstream" policy supports for meaningful population impacts. Examples are the VA's early use of tobacco price increases as a cessation tool; its 1991 total smoking ban which *mandated* subsidized treatment for employees (while the JCAHO accreditation standard issued a year later only *encouraged* it); the restriction and treatment of tobacco use in psychiatric units; and the elimination just last year of restrictions that made NRT and Zyban prescriptions conditional on enrollment in a formal cessation program. Similar restrictions still are in place for 20 percent of AHIP (America's Health Insurance Plans) health plans nationally, and 38 percent of California's health plans.
- Another lesson that jumps out from Dr. Hamlett-Berry's "behind-the-scenes" account of VA policy victories is that science and science-based guidelines *alone* are never enough. Committed leadership and champions are essential. As Stephen Isaacs and Steven Schroeder have pointed out, highly credible scientific evidence can persuade policy makers and withstand attack by those whose interests are threatened, but significant policy or social change rarely, if ever, happens without focused, astute, and courageous advocacy.[2]
- Finally, it is generally the case in science-based tobacco control that each major advance has required a careful effort to *translate* the science into a clear *rationale* for a new policy, or a new treatment benefit, or a new performance measure. This translation has to address the top concerns of key decision makers—whether policy makers, insurers, employers, or providers—who are often more interested in economic, administrative, and public relations effects than in health impacts. As with the VA's recent analysis of the economic effects of eliminating cessation treatment co-payments, the most persuasive data are local. As I was reading Dr. Hamlett-Berry's paper, I wondered what kinds of data the VA has collected *in the past* to track the health, behavioral, and economic impacts of its cessation

Figure 3



initiatives, and to design, evaluate, or advocate for new policies and programs—and what mechanisms have been put in place to use the VA's phenomenal electronic medical record, utilization, and quality databases for these purposes *going forward*.

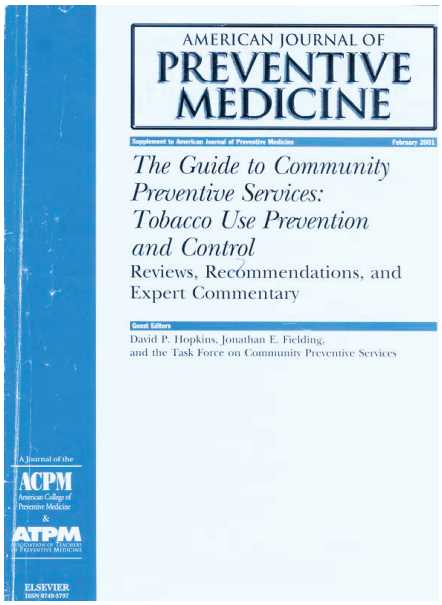
Regarding "market pull," (see figure 4) the Community Preventive Services Task Force of the Centers for Disease Control and Prevention (CDC) found that each of the following policy, community, and environmental strategies was effective in increasing population quit rates and treatment use: unit price increases, smoking bans and restrictions, reducing out-of-pocket treatment costs, telephone quitline support, and mass media campaigns to inform and motivate users to quit.[3]

The first three have been part of the VA's population or public health cessation model. The new VA/DoD guideline calls for greater use of local and state telephone quitlines and other community resources to widen the reach and use of cessation treatments, especially for younger veterans and military personnel who are not in frequent contact with the health care system. Since well-designed mass media campaigns have been vital in drawing smokers to call quitlines for help, I am very interested in learning about the VA's plans for similar quitline marketing strategies.

As Dr. Hamlett-Berry points out, the field and the VA need to find ways to *boost consumer demand* (see figure 5). Cessation programs are increasingly accessible, but still used by only a small proportion of smokers. From past research, it is clear that reducing and even

Figure 4

Market Pull: Population-Level Policies and Interventions that Increase Quitting and Treatment Use/Demand



- Unit price increase (excise tax)
- Smoking bans and restrictions
- Reducing out-of-pocket treatment costs -- expanding coverage
- Telephone quit lines
- Multi-component cessation campaigns

Figure 5

Pull: The Challenge of Boosting Consumer Demand

- Reducing/eliminating out-of-pocket costs is not enough
  - Full (vs. 50%) coverage quadrupled treatment use (10% vs. 2.4%) and population quit rates (2.8% vs. 0.7%) at GHC (Curry et al., 1998)
  - Leaders from private plans lament smokers' low demand for/use of services (AAHP, 2000)
- Many with coverage don't know they have it
  - Only 30% of Health Partners/BCBS of Minnesota enrollees knew of full medication coverage (Boyle et al., 2002)
  - Only 36% of Medicaid enrolled smokers know their state Medicaid program offered any coverage (McMenamin et al., 2004)
- Need creative market research, targeted marketing and product re-design (tailored to target groups/individuals, interactive technology)

eliminating out-of-pocket costs will not be enough. Eliminating co-pays at the Group Health Cooperative quadrupled the number of smokers who enrolled and the health plan's overall quit rate—but the peak enrollment rate was only 10 percent. Coverage, including total coverage, has risen dramatically in private health plans across the country, but there is wide frustration over smokers' limited use of covered services. Part of the problem, documented by growing evidence from health plan enrollees and Medicaid beneficiaries, is that smokers simply don't *know* about these benefits. But uptake is limited even when they do.

Meeting the new VA/DoD guideline goal of widening the use of VA and community cessation resources will require creative marketing research, marketing, and program redesign—to boost the appeal and accessibility of proven treatments. Again, new clinical databases can be harnessed for cost-effective interactive communications—from individually tailored mailings to interactive computer and web-based applications—which bring care to patients, rather than patients to care. Involving veterans' service organizations (the ultimate consumers) in these efforts, and stimulating them to advocate for cessation services and policies, seems essential.

When it comes to expanding the *capacity* of current health care systems to *deliver* effective cessation services, the most important development is the new movement for national healthcare quality improvement unleashed by the Institute of Medicine's patient safety and *Crossing the Quality Chasm* reports.[4] This movement has brought much greater attention to the need for systems change, and has provided a new impetus and vehicle for efforts to improve the delivery of evidence-based care for tobacco dependence.

Both the new VA/DoD guideline and the quality chasm report emphasize the need for systems change (see figure 6). Until recently, most work to understand and improve systems supports for tobacco dependence treatments were fairly siloed, focused on tobacco treatments in isolation, or in the context of other preventive services. This was probably helpful, since systems change research and strategies are currently more advanced for tobacco than for other areas of health behavior change. In fact, the CDC Community Task Force found enough research to issue an evidence-based recommendation for office-based tobacco reminder systems. But the IOM quality chasm reports, including the *Priorities* report that selected tobacco dependence treatment as one of the top 20 targets for national quality improvement, are helping to move systems changes for tobacco cessation from the margin to the center of mainstream health care improvement efforts.[5]

And there is no place where this is more likely to happen than in the VA, which currently has almost unparalleled capacity and leadership for quality improvement. There are two reasons for this (see figure 7):

- First, the VA health care system is kind of the ultimate HMO; it allocates funds on a modified capitation basis, and VA managers know that they are likely to care for their patients for the rest of their lives. This creates an environment where prevention really *can* pay.

Figure 6

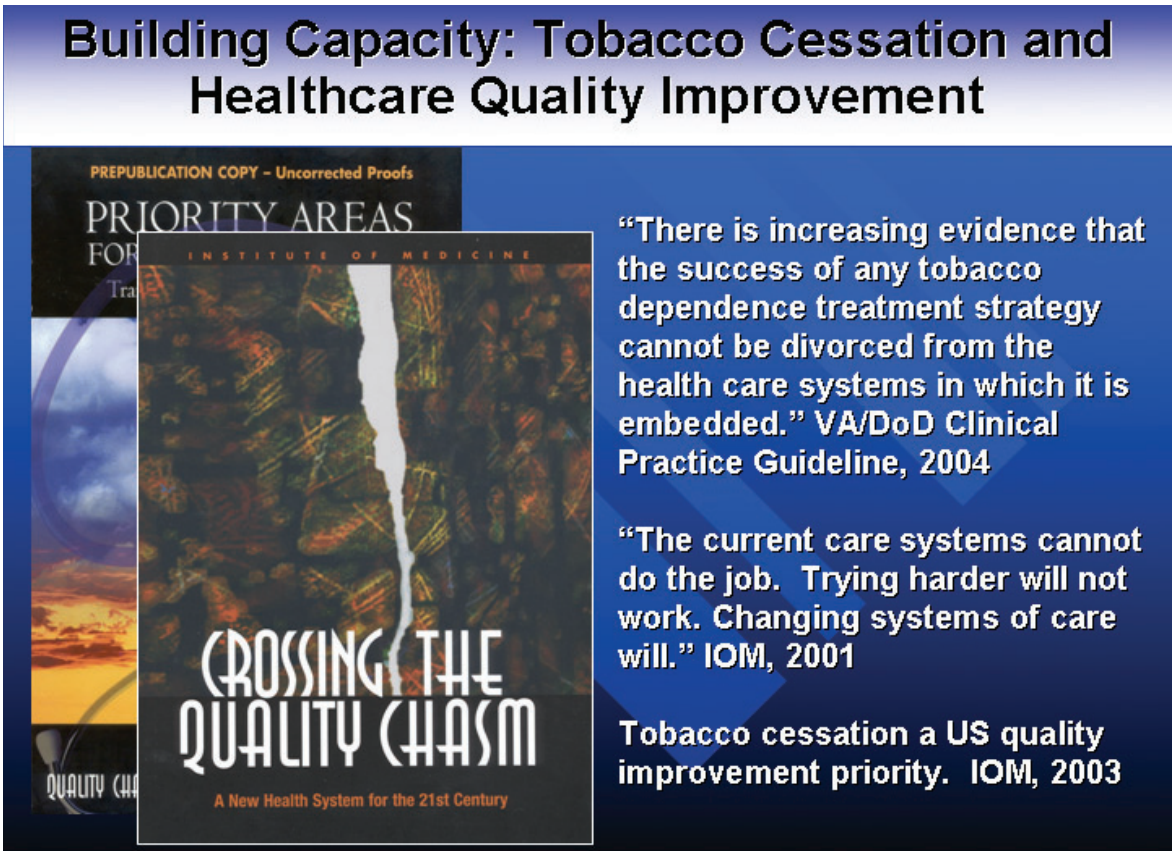
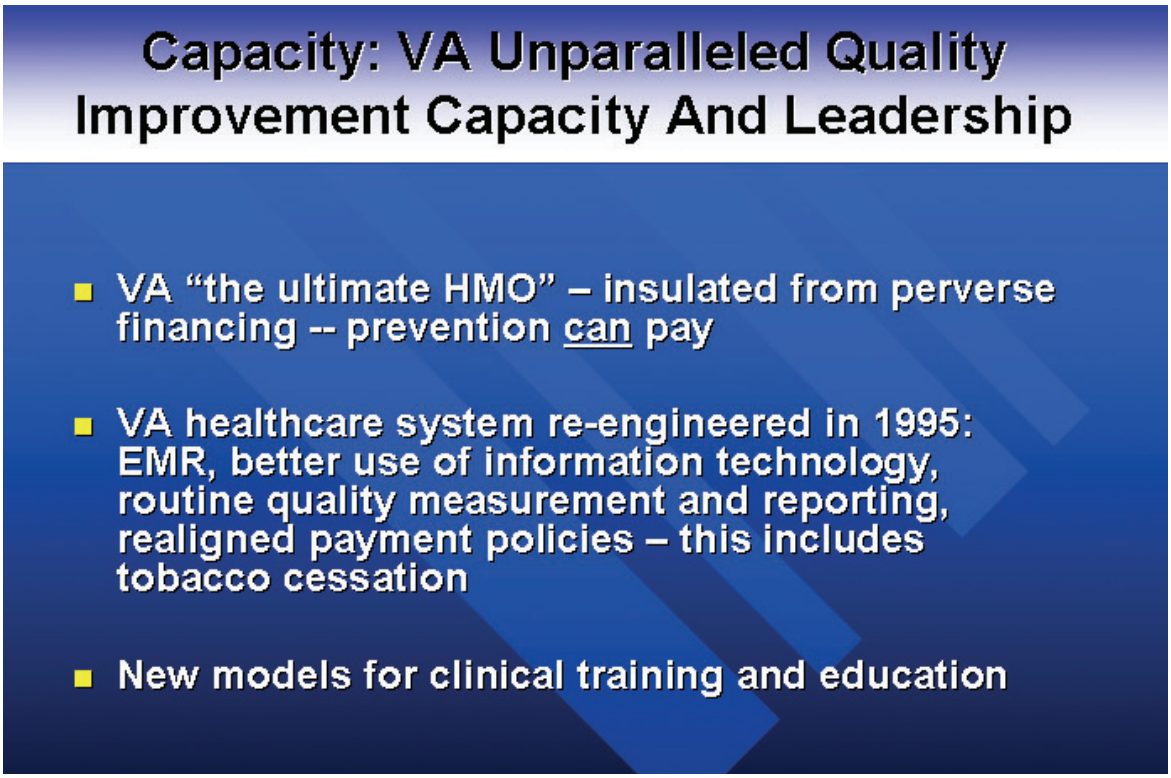


Figure 7



- Second, as Dr. Hamlett-Berry noted, the VA embarked ten years ago on a major systems re-engineering. It implemented a system-wide electronic medical record to prompt and coordinate guideline-based care, and a comprehensive quality measurement and improvement approach that holds regional managers accountable for improving care for a number of priority conditions—including tobacco use.

This makes the VA not only a unique laboratory for quality improvement research and training, but also a unique training ground for twenty-first century health care.

Results of two large national comparisons have found that VA inpatient and outpatient care has improved substantially, including for tobacco. The statistics in figure 8 come from two studies—one by Jha et al. comparing quality of care in the VA and Medicare fee-for-service programs,[6] and the other a recent RAND study by Ashe et al. comparing VA care with care in a national sample.[7] From 2000 through 2003, the VA scored consistently better on delivering guideline-based inpatient and outpatient care for tobacco use and addiction. In 2003, the VA scored even better than HMO settings outside the VA which voluntarily reported their NCQA HEDIS tobacco measures.

Of course, there is still room for improvement. But these findings are *really* exciting.

Figure 8

VA Healthcare Quality Has Improved Substantially – Including For Tobacco

Cessation counseling during admission *(Jha et al., 2003)*	Medicare	VA	
	1997-99	39%	---
	2000-01	38%	62%

	National Sample 2000-01	VA 2000-01	VA 2002	VA 2003
COPD patients counseled at Dx	80%	100%		
Smoking status in chart	45%	94%		
Smokers advised to quit	29%	56%	69%	75%* *(Perlin, 2004)*
Pharmacotherapy Rx *(Ashe et al, personal communication)*	13%	20%**		

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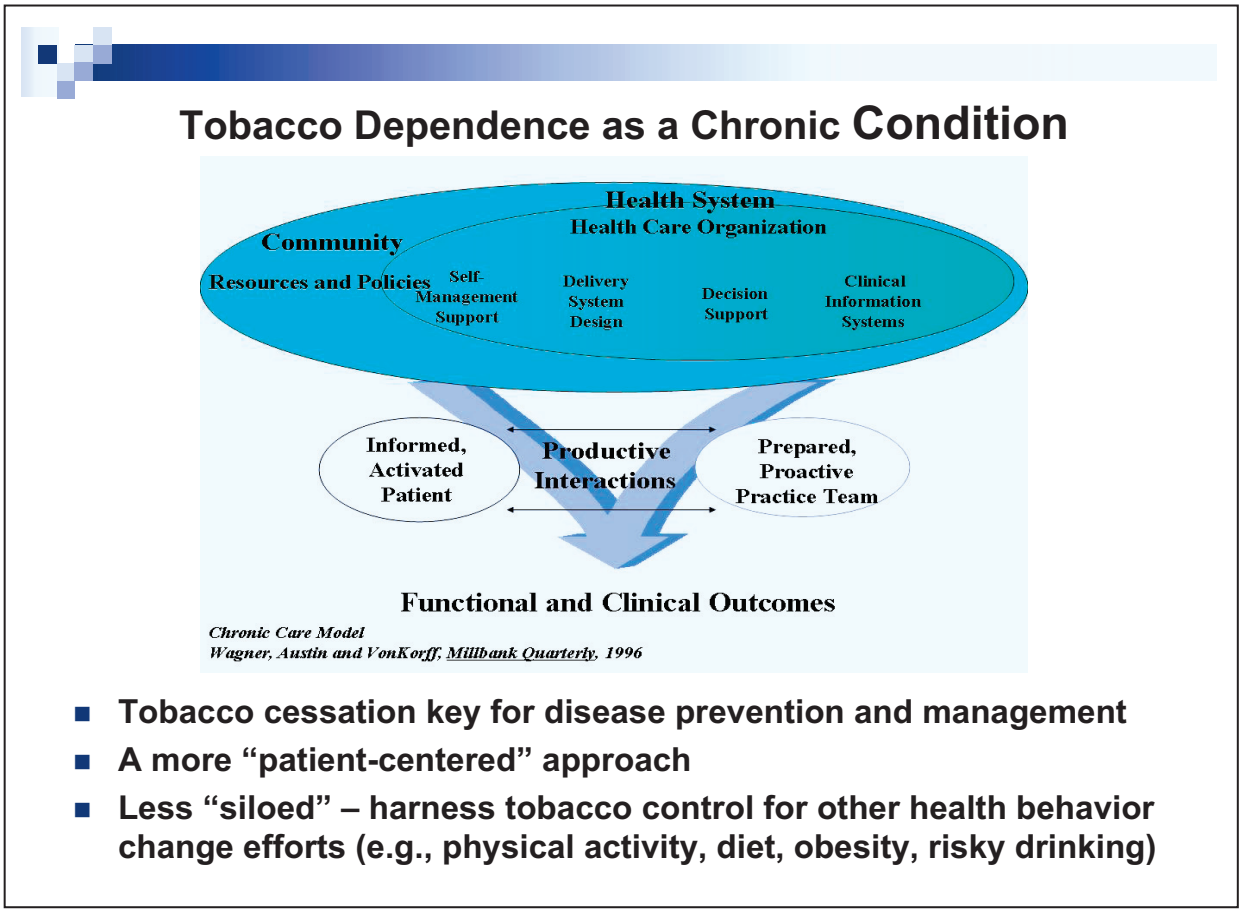
* 2003 HEDIS advice to quit at least once 67-68%; VA advice to quit 3X

**2004 HEDIS pharmacotherapy discussed – 32-37%

Finally, the application of the rapidly spreading chronic care model to tobacco dependence treatment has reinforced the view of tobacco dependence as a *chronic condition* and emphasized the role of tobacco dependence treatment as a critical component of the management of many other chronic diseases, such as heart disease, diabetes, and chronic obstructive pulmonary disease (see figure 9).[8] This, in turn, is helping to move previously *siloed* tobacco dependence treatment into *mainstream* health care improvement efforts.

In closing, another by-product may be to stimulate efforts to harness the chronic care model-type systems supports that already are in place for tobacco as a platform for broader health behavior change efforts—for instance, for physical activity, diet, obesity, and risky drinking.[9] A number of innovative programs, including one at Health Partners, are moving in this direction, both to better serve their patients (most smokers have at least one other behavioral risk factor), and to make their tobacco interventions more efficient—and less vulnerable to pendulum-type funding shifts from one priority health risk (like tobacco) to another (like obesity).[10] This more efficient, holistic approach may be of interest to the VA as well.

Figure 9



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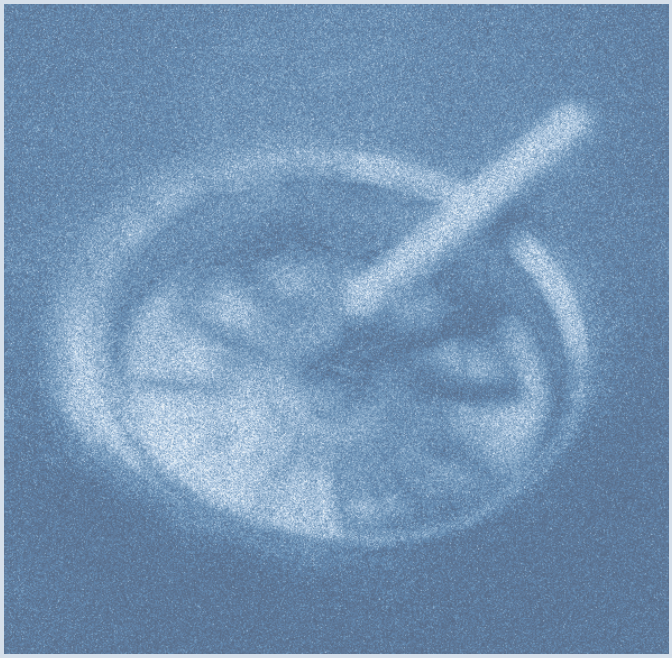

TOPIC TWO

Best Practices

Treating Tobacco Dependence in a Medical Setting: Best Practices

Richard D. Hurt, M.D.*

This article examines behavior treatments and pharmacologic products available to treat nicotine dependence, offers a model of tobacco intervention that can be used by medical institutions, and addresses some major challenges to medical institutions in adopting best practices. State-of-the-art treatment, following the U.S. Public Health Service Guideline, involves four components: behavioral treatment, addictions treatment, pharmacotherapy, and relapse prevention. A workable model of tobacco interventions in medical institutions includes counseling services performed under physician supervision; integration of tobacco dependence treatment into the medical system; provision of a range of interventions; treatment for surgical, cancer, substance abuse, and transplant patients; and ongoing marketing. The biggest challenge may be the lack of institutional support; a champion with credibility with the institution's leadership is essential. Other challenges are lack of time and insufficient training in the 5 A's.

Tobacco, which is indigenous to the Western Hemisphere, was used in the Americas long before Western European explorers reached the New World. However, cigarettes did not become widely used until the late 19th century. In fact, the automated cigarette rolling machine was not invented until 1881. Annual consumption of cigarettes in the United States rose from four billion cigarettes per year in 1905 to more than 100 billion cigarettes just 20 years later.[1] The epidemic of tobacco-caused diseases emerged in the mid-20th century in the United States and the United Kingdom and now has spread throughout the world. While over 400,000 Americans die each year of tobacco-caused diseases, making it the leading cause of preventable death in our country,[2] an estimated ten million tobacco-caused deaths per year are expected to occur worldwide by the year 2030.[3] The cigarette industry responded to the rising death toll attributed to tobacco-caused diseases first by denying the relationship of cigarettes to these diseases, and then by developing a highly sophisticated public relations campaign to deliberately deceive the public.[4]

The first major product change came in the 1950s when filters were added to cigarettes for "health reassurance." In the late 1960s "low-tar low-nicotine" cigarettes were introduced and widely promoted as a safer alternative. Presently low-tar low-nicotine yield cigarettes account for more than 90 percent of the cigarettes sold in the United States. Most smokers are unaware of the ventilation holes, and misperceive light and ultra-light cigarettes as being less harmful than regular filtered cigarettes.[5]

* Nicotine Dependence Center, The Mayo Clinic

The cigarette companies have continued their pursuit of the most efficient delivery system for nicotine that exists, and they have perfected this in the modern cigarette. The cigarette is a highly sophisticated and refined nicotine delivery device which delivers *arterial* blood concentrations of nicotine approaching 80-90 ng/mL within seconds of inhalation. Those who treat patients for tobacco dependence must understand that the nicotine replacement products used in treatment are less efficient at delivering nicotine than cigarettes because of their slow absorption via the venous circulation. More aggressive behavioral treatments, combined with creative use of the available medicines and development of newer and better pharmacologic agents will lead to more effective treatment in the future.

This paper examines the behavioral treatments and pharmacological products available to treat nicotine dependence. It then offers a model of tobacco interventions that can be used by medical institutions, and concludes by addressing some of the major challenges to adopting best practices in medical institutions.

The Policy Context

National Policy: From 4 A's to the U.S. Public Health Service Guideline of 2000

In the 1980s and early 1990s, a great deal of effort was focused on training physicians to provide interventions that would help their patients stop smoking.[6, 7] This led to the development of the 4 A's—Ask, Advise, Assist, and Arrange, later incorporated into the 1996 Agency for Health Care Policy and Research Guideline (AHCPR)[8, 9]—and rather extensive efforts to engage physicians, especially primary care providers, and train them in this brief office intervention. Despite incorporation into the first AHCPR by the late 1990s, it became clear that implementing the 4 A's in physicians' practices was not occurring.[10]

The 2000 United States Public Health Service (USPHS) Clinical Practice Guideline, "Treating Tobacco Use and Dependence," focused on "clinicians" which was more broadly defined to include a full range of non-physician healthcare providers.[11] This update of the 1996 Guideline added a fifth "A"—"Assess"— to make the 5 A's: Ask, Advise, Assess, Assist, and Arrange. It also introduced the 5 R's: Relevance, Risks, Rewards, Roadblocks, and Repetition which are intervention techniques meant to provide motivation. The Guideline pointed out the need to address tobacco dependence in a manner similar to the way healthcare providers address other chronic conditions, such as diabetes, hypertension, and hyperlipidemia, realizing that relapse is common and that repeated follow-up and adjustment may be needed. The Guideline also promoted the identification of tobacco use as another "vital sign" to be assessed at each clinical encounter. It emphasized that even brief interventions are effective in promoting tobacco abstinence and that there is a strong dose-response relationship. The Guideline endorsed the use of pharmacotherapy for every smoker who wants to use it, except in situations where use is contraindicated. It also defined effective behavioral support more clearly and separated it into intra- and extra-treatment spheres.

Intra-treatment behavioral support includes encouragement, empathy, and support of any self-efficacy, i.e., "You stopped smoking before for (hours, days, weeks or months), so I know you can do it again!" Extra-treatment support includes soliciting support from family and friends and telling them how they can be helpful, especially by making the work and home environment smoke-free. Other extra-treatment support can include telephone quitlines or telephone counseling and printed relapse-prevention material, which has been shown to improve chances of long-term smoking abstinence.[12, 13]

Public Policy Changes Regarding Reimbursement

The Guideline also pointed out the need for major healthcare system changes to address the problem of smoking addiction by providing reimbursement for treatment. It noted the obligation of healthcare systems to provide patients with effective interventions that have been demonstrated to be effective. This is certainly the case with the treatment of tobacco dependence.

While reimbursement may not be an important issue within the VA system, it is a major barrier outside of the VA. Budget problems facing the federal government are likely to squeeze the healthcare resources available to the VA system. Thus, an effort needs to be initiated (if it is not already being done) or enhanced (if it is underway) to obtain or maintain the resources to provide tobacco dependence treatment. Many third-party payers are following the lead of BlueCross BlueShield of Minnesota and providing coverage for counseling and pharmacotherapy. In many states, Medicaid provides partial or even full coverage for both. Medicare is presently studying the efficacy of telephone counseling for older smokers and is considering the merits of providing coverage for face-to-face counseling and pharmacotherapy.

Public Policy That Helps Smokers Stop or Never Start

Increased cigarette taxes and smoke-free indoor air are effective policy tools to help smokers stop and continue to abstain from smoking. Members of the healthcare community not only need to be aware of this, but should also be advocates for policies that help their patients abstain from smoking. It has been well established that increasing prices for cigarettes motivates smokers to stop and prevents young people from starting.[14] Likewise, smoke-free indoor air causes continuing smokers to smoke less, helps smokers to stop, and discourages young people from starting.[15] Little wonder that the tobacco industry fights these two issues with such vigor.

State-of-the-Art Treatment

The USPHS Guideline is the roadmap for evidence-based treatments. State-of-the-art treatment involves four components: behavioral treatment, addictions treatment, pharmacotherapy, and relapse prevention.

Behavioral Treatment

Behavioral treatment is a cornerstone for the treatment of tobacco dependence and has been shaped over the past decade or so by new evidence-based techniques such as motivational interviewing.

Motivational Interviewing

In addition to the intra and extra treatment support which are part of the USPHS Guideline, motivational interviewing, as a patient-centered facilitating approach, has been shown to be an effective means of bringing about behavioral changes.[16] Unlike the confrontational style popular during the 1970s and 1980s, motivational interviewing is based on establishing rapport through empathetic, nonjudgmental approval. This opens a dialogue which helps patients resolve the normal ambivalence toward changing their smoking behavior and facilitates change by exploring the importance of change and building self-efficacy. The positive emphasis of motivational interviewing gives the clinician opportunities to support any past success (no matter how brief) that the patient may have had in previous attempts to stop, which helps build self-esteem in most smokers. For those who remain unable to stop, the clinician must avoid being argumentative and be able to maintain rapport until the patient can be re-engaged.

Process of Change

Clinicians should know that stopping smoking is a process that does not begin and end at the same time. For many smokers, preparing to stop and becoming motivated to try to stop smoking can take many years. For others, it can occur with a "teachable moment." The transtheoretical model of the stages of change has been popularized over the years and has proven to be useful for clinicians to conceptualize the *process* of stopping smoking.[17] The contemplation ladder (also a measure of readiness to stop smoking) has also been found to be useful and has been shown to be a stand-alone predictor of long-term smoking abstinence.[18]

"Teachable Moments" in a Healthcare Setting

From a medical perspective, the term "teachable moment" has been used to describe events that motivate patients to change and stop risky health behaviors.[19] Unfortunately, smokers consistently judge the health risks of smoking to be smaller and less well established than do nonsmokers.[20] Furthermore, smokers tend to minimize their own personal risk compared to other smokers, a characteristic that addiction specialists would call rationalization and/or denial.

However, the more severe the health problem, the more likely that the teachable moment will lead to smoking abstinence. A basic health visit is rated very low as a teachable moment. Pregnancy and hospitalization—particularly for a heart attack—rank high as teachable moments; they produce very high smoking abstinence rates especially when a specific tobacco dependence intervention is provided. About 50 percent of smokers who survive a myocardial infarction will achieve long-term smoking abstinence.[21] A key role for the clinician in capitalizing on

any teachable moment is to personalize the health risk by making the patient aware that a symptom (coughing or wheezing) or disease (heart disease, emphysema) is associated with the patient's smoking, and then to personalize the benefits of stopping. For example, it can be pointed out to smokers who have had a myocardial infarction that stopping smoking reduces their risk of having another heart attack to that of a nonsmoker in approximately three years.[21] Although clinicians tend to focus on the negative effects of smoking, more emphasis needs to be placed on the positive effects of stopping.

Individual Counseling versus Group Programs

One-on-one counseling is preferred by most smokers. Since it can be provided at the hospital bedside or in the outpatient clinic, it is easily arranged in most medical settings. Group programs are more difficult to manage because of scheduling and other logistical problems. In smaller population areas (communities of less than 100,000), group programs are often undersubscribed. If group programs can be provided, they are more efficient (requiring less staff) than individual counseling and equally effective. Internet-based interventions such as QuitNet® have great potential and are attractive to younger smokers, but their efficacy has only been shown with the more complex and less widely available "expert" systems. Expert systems allow for individualizing a treatment algorithm based on previous responses by the smoker.[22]

Telephone Quitlines

Telephone quitlines have been shown to be effective and are becoming more widely available.[23] The ability of telephone quitline counseling to reach smokers in a nonclinical setting is substantial, and when provided in the context of good public health policy (i.e., smoke-free work sites and high cigarette taxes), its efficacy can be even better.[24]

Addictions Treatment

Understanding and accepting tobacco (or nicotine) dependence as a true addiction is central to successful treatment of patients. Like alcoholics, smokers use defenses such as rationalization and denial. It is important for clinicians, patients, and families of patients to understand the degree to which these defenses are at work. Also central to the concept of addictions treatment is loss of control. Patients and family members need to understand the biological basis of tobacco dependence and the neurochemical changes that occur in the brain of dependent smokers, which make it difficult to stop. This knowledge often relieves patients and family members. By showing that tobacco use goes beyond a bad habit and a person's being "weak-willed," it allows patients to understand the importance of their treatment program and encourages family members to be more supportive. Patients also need to be informed about the neurobiology of, and expected duration of, nicotine withdrawal symptoms and the urge to smoke.

Pharmacotherapy

Over the past decade, substantial progress has been made in the development of safe and effective pharmacotherapy for treating tobacco dependence.[25] The U.S. Food and Drug Administration (FDA) has approved six products (nicotine gum, patches, nasal spray, inhaler, lozenges, and bupropion) for the treatment of tobacco dependence in the United States, and two additional second-line medications (nortriptyline and clonidine) were included in the 2000 USPHS Guideline.[11] It is encouraging that the number of quit attempts using pharmacotherapy increased from approximately one million in the early 1990s to more than eight million in 1998.[26] Because pharmacotherapy has been established as a cornerstone of treatment of the tobacco-dependent patient, research and development of newer medications is continuing; at least two new non-nicotine products are likely to reach the market in 2006.

Measuring Nicotine Exposure

A first step to the therapeutic use of nicotine replacement products is to determine an individual's level of nicotine exposure. Once this is done, a nicotine replacement dose that approximates the one the individual receives from smoking can be prescribed. However, several factors make this task difficult. Smokers exposed to the same concentrations of nicotine in inhaled tobacco smoke may have marked inter-individual differences in venous nicotine concentrations.[27, 28] Cigarette smoking produces initial arterial nicotine concentrations that are several-fold higher than concomitant venous nicotine concentrations.[29] In addition, nicotine has a short half-life of 120 minutes and, with smoking, tends to have marked peaks and troughs in both the arterial and the venous concentrations.

For these reasons, a non-nicotine biologic measure is needed to estimate nicotine exposure in smokers. Cotinine, the major metabolic product of nicotine, has a half-life of 18 to 20 hours and can be used to quantify an individual's exposure to nicotine. The use of blood nicotine and cotinine concentrations is similar to the manner in which clinicians use fasting plasma glucose and glycosylated hemoglobin to determine glycemic control in patients with diabetes. Plasma glucose is used to determine the "real-time" glucose levels, whereas glycosylated hemoglobin provides an estimate of longer-term glycemic control. Venous nicotine concentrations give an assessment (albeit much less than arterial levels) of acute nicotine exposure, whereas cotinine integrates nicotine exposure over a period of two to three days.

Minor tobacco alkaloids such as nornicotine, trans-3-hydroxycotinine, and anabasine can also be measured in body fluids.[30 31] Anabasine is a tobacco alkaloid that is not a metabolic product of nicotine. Anabasine is present in the urine of tobacco users but not in the urine of patients using nicotine replacement therapy. Anabasine thus can be especially useful in distinguishing abstinent tobacco users who are using nicotine replacement therapy from those who are continuing to use tobacco. The ability to accurately detect tobacco use in the presence of nicotine replacement therapy is very important in some subgroups of patients (see Transplant Patients).

Nicotine Replacement Therapy (NRT)

According to the USPHS Practice Guideline, all patients who attempt to stop smoking should be treated with pharmacotherapy if they request it.[11] Clinical trials have shown that, in general, adding pharmacotherapy to a behavioral intervention doubles the success rate. Because of its demonstrated efficacy in clinical trials, NRT remains a mainstay of pharmacotherapy for the treatment of tobacco dependence. To date, the FDA has approved several NRT products, including nicotine gum, nicotine patches, a nicotine nasal spray, a nicotine vapor inhaler, and most recently, a nicotine lozenge. While nicotine gum, patches, and lozenges are available over the counter, the nasal spray and inhaler are available by prescription only. Physicians who prescribe NRT for tobacco dependence should individualize the dose and duration of treatment and schedule follow-up office visits or telephone calls to monitor the patient's response.

Nicotine Gum. Nicotine gum has been available for many years, and both the 2 mg and 4 mg doses are available as over-the-counter products. Venous nicotine concentrations achieved through the proper use of nicotine gum are relatively low compared with those produced by smoking cigarettes.[32] Nevertheless, nicotine gum is effective in the treatment of tobacco dependence. The 4 mg dose seems to be more effective in smokers who are more dependent[33,34] and is recommended for those who smoke 25 or more cigarettes per day.

Patients should be instructed to bite into a piece of the nicotine gum a few times until a mild tingling or peppery taste indicates nicotine release. The patient then should "park" the gum between the cheek and gum for several minutes before chewing it again. This cycle allows for buccal absorption and should be repeated for about 30 minutes per piece of gum. Because the rapidity of absorption of nicotine is lowered by a more acidic pH, patients should be instructed not to drink beverages or eat while using the gum. When nicotine gum is used as a single agent, most patients should chew a minimum of 10 to 15 pieces per day to achieve initial abstinence.

Nicotine Patch. Nicotine patch therapy, which was introduced in 1991, delivers a steady dose of nicotine for 16 to 24 hours. The once-daily dosing requires little effort on the part of the patient, resulting in high compliance. Nicotine patches are available without a prescription in doses of 7, 11, 14, 21, and 22 mg, which deliver nicotine over 24 hours, and a 15 mg patch that delivers nicotine over 16 hours. In almost every randomized clinical trial performed to date, the nicotine patch has been shown to be effective compared with a placebo, usually with a doubling of the stop rate. Standard-dose nicotine patch therapy begins with a dose of 21 or 22 mg/24 hours or 15 mg/16 hours. Most regimens continue this dose for several weeks before tapering over a period of a few weeks. However, single-patch dosing is not effective in all smokers. In fact, it has been shown that a standard dose (21 or 22 mg/24 hours) of nicotine patch therapy achieves a median serum cotinine level of only 54 percent of the cotinine concentrations achieved through smoking.[27, 35] Lighter smokers with lower baseline cotinine concentrations have higher stop rates, suggesting that their nicotine replacement needs are more adequately met than those of heavier smokers.[36]

Because of the observation that many patients are under-dosed at standard nicotine patch doses, efforts have been made to study the effects of increases in dosage. The limited number of reported studies have yielded mixed results. However, use of higher doses of nicotine patch therapy (that is, more than one patch at a time) can be appropriate for smokers who previously failed single-dose patch therapy, especially if their nicotine withdrawal symptoms were not relieved sufficiently with previous standard therapy.[37] This approach can be especially important for heavy smokers because they will almost certainly be significantly under-dosed with single-dose patch therapy.[27]

High-dose nicotine patch therapy has been shown to be safe and well tolerated in patients who smoke more than 20 cigarettes per day.[27, 38] By employing the concept of therapeutic drug monitoring, the clinician can use venous cotinine concentrations to tailor the nicotine replacement dose so that it approaches 100 percent replacement of the venous cotinine concentrations when smoking. Therapeutic drug monitoring offers a scientific approach to selecting a drug regimen to achieve a targeted blood concentration and thus will optimize the pharmacotherapy. The venous cotinine concentration is used because of its longer half-life and correlation between serum cotinine concentrations and nicotine intake from tobacco or NRT.[39] A baseline cotinine concentration is obtained while the smoker is smoking his or her usual number of cigarettes. An initial nicotine patch dose based on the cotinine level (or cigarettes per day) is prescribed. After the patient reaches steady state (>3 days of nicotine patch therapy and not smoking), the serum cotinine concentration is rechecked. The replacement dose then can be adjusted according to the steady-state cotinine level on NRT and patient symptomatic response (withdrawal symptom relief and/or abstinence from smoking). Percentage replacement for a given dose of nicotine patch therapy can be expressed as follows:

$$\text{Percentage Replacement} = \frac{\text{Steady-state venous cotinine}}{\text{Baseline venous cotinine}} \times 100$$

Table 1. Initial Nicotine Patch Dose, Based on Baseline Venous Cotinine Concentration (While Smoking)

Cotinine (ng/mL)	Nicotine Patch Dose
<200	14-22 mg/day
200-300	22-44 mg/day
>300	>44 mg/day

Table 1 shows the recommended initial dosing of nicotine patch therapy based on venous cotinine concentrations. Higher percentage replacement has been shown to reduce nicotine withdrawal symptoms,[27] but the efficacy for long-term abstinence of such an approach has not been completely established.[27, 40-44] Nevertheless, this concept can be used to titrate more precisely the dose needed to reach higher levels of nicotine replacement in the more severely addicted patient.

Individualizing the nicotine patch dose is warranted because of the marked inter-individual variability of baseline nicotine concentrations among smokers who smoke a similar number of cigarettes per day. There is also some inter-individual variability in steady-state serum cotinine while receiving nicotine patch therapy during abstinence from smoking.[27, 45, 46] Serum cotinine can be drawn at any time of the day for this assessment.[45]

If serum cotinine testing is not available, the replacement dose can be estimated based on the number of cigarettes smoked per day. Table 2 shows the recommended initial dosing of nicotine patch therapy based on the number of cigarettes smoked per day.[47]

Table 2. Initial Nicotine Patch Dose, Based on Number of Cigarettes Smoked Daily

Cigarettes per Day	Patch Dose* (mg/day)
<10	7-14
10-20	14-22
21-40	22-44
>40	44+

**Nicotine patches are available in the following doses: 7, 11, 14, 15, 21, and 22 mg.*

After initiation of nicotine patch therapy on the stop date, the patient should have a follow-up visit or a telephone contact within the first week and periodically thereafter. Abstinence from smoking during the first two weeks of patch therapy has been shown to be highly predictive of long-term abstinence and conversely any smoking at all in the first two weeks predicts treatment failure.[36, 48] Alterations in therapy at follow-up depend on how well the patient is maintaining abstinence from smoking and the relief of withdrawal symptoms. If the patient continues to smoke at all during the first two weeks, the treatment must be changed, either by adding an additional medication (increasing the nicotine replacement dose and/or adding an additional nicotine or non-nicotine product) and/or intensifying the behavioral counseling. Nicotine patch doses should be increased for patients who experience more than just mild nicotine withdrawal symptoms (such as irritability, anxiety, loss of concentration, or craving), or for patients who do not achieve 100 percent replacement based on the second serum cotinine level. Optimal length of treatment has not been determined for any of the medications but the USPHS Guideline calls for 10 weeks of nicotine patch use with the last four weeks utilized for tapering. Our experience suggests that for many patients, especially the severely dependent, longer courses of treatment are necessary. As with other chronic disorders, individualization of medication dose and duration is often required for successful treatment of the condition.

Although the various nicotine patches have quite comparable pharmacokinetic profiles, there are differences between brands that could lead to higher percentage replacement.[49] Thus, measuring cotinine is a more accurate method of assessing the adequacy of nicotine replacement and avoiding "over replacement" if that is of concern, such as in pregnant patients. However, because of the central nervous system tolerance to nicotine that most smokers have, "over replacement" is rare, but when it occurs, nausea and vomiting are the first symptoms of nicotine toxicity.

Side effects of nicotine patch therapy are relatively mild and include localized skin reactions at the patch site. In rare instances, a generalized skin eruption can occur, requiring that nicotine patch therapy be discontinued. Although sleep disturbance is another side effect that has been attributed to nicotine patch therapy, it often is difficult to ascertain whether this is attributable to nicotine withdrawal or to the administration of nicotine during the evening hours. In a sleep study of smokers, the best quality of sleep was observed in those abstinent smokers receiving a 22 mg/24 hour nicotine patch dose.[50] If there is a concern that nicotine patch therapy is causing sleep disturbance, the patch can be removed at night to see if the sleep disturbance resolves.

Shortly after nicotine patches reached the market, the lay press expressed concern that smokers might be at increased risk of myocardial infarction if they continued to smoke while using the patch.[51] This led to hearings at the FDA, which concluded that there is no cause for concern. Subsequent studies have shown no adverse effects of nicotine patch therapy in smokers with a history of coronary disease,[52, 53] nor on lipids or markers of homeostasis in nonsmokers who received nicotine patch therapy.[54]

Nicotine patch doses up to 63 mg/day were not associated with short-term adverse cardiovascular effects in smokers.[55] Standard nicotine patch doses have been shown to reduce exercise-induced myocardial ischemia (assessed by exercise thallium studies) in smokers who were trying to stop smoking.[56] Experimentally, nicotine patch doses of up to 44 mg/day for four weeks have not adversely affected the early patency of coronary artery bypass grafts in dogs.[57] Conversely, transdermal nicotine can *increase* the production of, and response to, nitric oxide in the bypass grafts, which usually would produce beneficial vasodilatation.[57] If there are *any* risks of nicotine patch therapy in smokers with cardiovascular disease, they are trivial compared to the potential benefits of stopping smoking.[58]

Nicotine Nasal Spray. Nicotine nasal spray delivers nicotine directly to the nasal mucosa. It has been found to be effective in randomized clinical trials.[59] This device delivers nicotine more rapidly than other therapeutic nicotine replacement delivery systems and reduces withdrawal symptoms more quickly than nicotine gum.[60, 61] The reduction in withdrawal symptoms may be partially attributable to the rapidity with which nicotine is absorbed from the nasal mucosa and the resulting arterial venous differences in the plasma concentration of nicotine.[28] Each spray contains 0.5 mg of nicotine, and one dose is one spray in each nostril (a total of 1 mg). Recommended dosing is one to two doses per hour, not to exceed five doses per hour or 40 doses per day. When using the nicotine nasal spray as a single agent, most patients initially use 12 to 16 doses per day. The nicotine nasal spray can be used in combination with other nicotine replacement products or with bupropion (Zyban®). The most common adverse side effects are rhinorrhea, nasal and throat irritation, watery eyes, and sneezing, all of which decrease significantly within the first week of use, independent of dose.[62]

Because the nicotine nasal spray is a more rapid delivery device than other nicotine replacement products, there was early concern that the spray could have long-term abuse liability.[63] More recent information indicates that the potential for abuse is low.[64]

Nicotine Inhaler. The nicotine vapor inhaler has been shown to be effective in placebo-controlled trials.[65] This device is a plastic holder into which a cartridge containing a cotton plug impregnated with 10 mg of nicotine is inserted. The device delivers a nicotine vapor that is absorbed through the oral mucosa and although the device is called an inhaler, practically none of the nicotine vapor reaches the pulmonary alveoli, even with deep inhalations. Positron emission tomography studies show that only a small amount of radiolabeled nicotine reaches the upper airway of the lungs, and that most of it is absorbed through the oral pharynx, so the inhaler does not provide high arterial levels of nicotine in the manner of cigarettes.[66-68] When the nicotine inhaler is used as a single therapy, efficacy is increased when more than six cartridges per day are used.[65,69] The recommended initial dose of the nicotine inhaler when used alone is six to 16 cartridges per day. Although this device requires frequent puffing to deliver substantial amounts of nicotine, the puffing mimics some of the behavior of smoking. Because it is a unique delivery device, the nicotine inhaler lends itself to being used in combination with other nicotine replacement products and/or bupropion.

Nicotine Lozenge. The most recent addition to NRT is the nicotine lozenge which is now available in the U.S. as an over-the-counter product.[70] The nicotine lozenge is available in 2 and 4 mg doses, with the latter for use in "high" dependence smokers (i.e., time to first cigarette of the day <30 minutes after arising). Although the method of delivery (transbuccal) is similar to that of nicotine gum, the lozenge is simpler to use and likely will lead to improved patient compliance. Like the other more acute delivery products, it can be used alone or in combination.

Summary. All of the approved NRT products discussed here have been found to be effective in randomized, placebo-controlled trials, usually with a doubling of the stop rate in the active treatment group compared with placebo. These products have proved to be remarkably safe. As the number and availability of such products have increased, the number of attempts to stop smoking by American smokers has increased dramatically.[26] Although all of the nicotine replacement products seem to be equally effective, there is better compliance with nicotine patches, gum, or lozenges, compared to the inhaler or nasal spray. There are, however, no notable differences between the products when used at standard doses, nor in their effects on withdrawal symptom discomfort, perceived helpfulness, and general efficacy.[71] To improve compliance, and therefore efficacy, we generally discuss all of the options and pros and cons of each product. This engages the patient in the product selection. We encourage combination therapy for most patients—using nicotine patch and/or bupropion as the base medication, and supplementing with a more immediate release form of NRT.

Non-Nicotine Products

Bupropion. Bupropion is a monocyclic antidepressant that inhibits the reuptake of both norepinephrine and dopamine.[72] Dopamine release in the mesolimbic system and the nucleus accumbens is thought to be the basis for some of the reinforcing properties of nicotine and other drugs of addiction.[73-75] It does not appear that bupropion works through its

antidepressant activity. Rather, it is hypothesized that the efficacy of bupropion in smoking cessation stems from its dopaminergic activity on the pleasure and reward pathways in the mesolimbic system and nucleus accumbens. Recently, bupropion also has been shown to have an antagonist effect on nicotinic acetylcholine receptors.[76, 77] Thus, its mechanism of action likely is multifactorial.

Sustained-release bupropion has been shown to be effective in a dose-response study with a significant dose-response effect which was detected at all time points.[78] In addition, there was an attenuation of weight gain during the treatment period for those who were continuously abstinent while receiving the 300 mg/day dose (however, the attenuation of weight gain did not persist at one-year follow-up). Bupropion has been shown to be effective in an actual healthcare practice setting with the 300 mg dose outperforming the 150 mg dose, at least for the short term (three months).[79] Treatment with bupropion alone or in combination with the nicotine patch resulted in a significantly higher long-term rate of abstinence from smoking than did use of either the nicotine patch alone or a placebo.[80] Smoking abstinence rates were higher with combination therapy than with bupropion alone, but the differences were not statistically significant. Bupropion appears to be equally effective in smokers with or without a history of depression or in recovering alcoholics and non-alcoholics alike,[81] and has been shown to be effective in African American smokers.[82] A meta-analysis of bupropion SR for smoking cessation estimated a combined odds ratio of 2.54 (95 percent confidence interval, 1.90-3.41) for 6-month or 12-month smoking abstinence compared with placebo.[83]

Treatment with bupropion should be initiated about one week before the patient's stop date, at an initial dose of 150 mg/day for three days, then 150 mg twice a day. The usual length of treatment is six to 12 weeks, but bupropion can be used safely for much longer. As with other antidepressants, a small risk (0.1 percent) of seizures is associated with this medication. Therefore, bupropion is contraindicated in patients who have a history of seizures, serious head trauma (such as a skull fracture or a prolonged loss of consciousness), an eating disorder (anorexia nervosa or bulimia), or concomitant use of medications that lower the seizure threshold. The most common adverse side effects are insomnia and dry mouth. Recent reports from the FDA suggest that treatment-emergent hypertension can occur during treatment with bupropion, especially when it is used in combination with nicotine patch therapy. Therefore, periodic blood pressure measurements during treatment are advised.

Bupropion also has been tested for relapse prevention. Smokers abstinent from smoking at the end of seven weeks of open-label bupropion were assigned randomly to active or placebo bupropion for the remainder of the year.[84] Smoking abstinence rates were significantly higher in the bupropion group compared with a placebo at the end of medication therapy (week 52) and at week 78, but not at 104 weeks. The median time to relapse was significantly longer for subjects who received bupropion compared with a placebo, and there was significantly less weight gain in the bupropion group compared with placebo at the end of treatment and at one year after bupropion was discontinued. As with the dose-response study, the extended use of bupropion for relapse prevention is effective for smokers with or without a history of

depression.[85] This work needs to be replicated, however, as bupropion did not reduce relapse to smoking in smokers who stopped smoking with tailored nicotine patch therapy.[86] Extended release bupropion with once daily dosing is now available but has not been tested for tobacco dependence treatment.

Because of the high prevalence of depression in smokers, clinicians often encounter smokers who want to stop smoking but already are being treated with an antidepressant. The question arises as to whether to discontinue the current antidepressant before starting bupropion, or to simply add bupropion to that regimen. There is no drug-drug interaction to preclude the use of bupropion with either selective serotonin reuptake inhibitors or tricyclic antidepressants. Thus, adding bupropion to a selective serotonin reuptake inhibitor is preferable to discontinuing that medication and using bupropion alone. Although one study showed no serious adverse effects,[87] patients receiving two antidepressants should be monitored carefully. The use of monoamine oxidase inhibitors is a contraindication for use of bupropion. In summary, bupropion has utility in the general smoking population, seems to attenuate the weight gain associated with stopping smoking, and can be used to prevent relapse. It is appropriate to use as first-line monotherapy, but it can also be combined with any of the NRT products.

USPHS Guideline Second-line Drugs

Nortriptyline. Nortriptyline, a tricyclic antidepressant, is recommended as a second-line drug for treating tobacco dependence.[11] Randomized clinical trials have shown a significant effect with active nortriptyline compared with a placebo.[88, 89] In these studies, the maximal dose range was 75 to 100 mg/day, and the length of treatment was eight to twelve weeks. The most common adverse effects were sedation and dry mouth. As with bupropion, nortriptyline produced higher smoking abstinence rates than did a placebo, independent of a history of depression.

Clonidine. Clonidine is a centrally acting alpha-agonist that can be used as a second-line drug.[11] It is available in both oral or transdermal forms. The transdermal form is easier to use, with a recommended dose of 0.2 mg/day for three to 10 weeks. The clonidine patch should be initiated a week before the patient's stop date and changed weekly thereafter. Common side effects include dry mouth and drowsiness, which limit its utility to the point that it is rarely used in clinical practice.

Combination Pharmacotherapies

The USPHS Guideline recommends that combining the nicotine patch with a self-administered form of NRT—nicotine gum, nasal spray, inhaler, or lozenge—may be more effective than a single form of nicotine replacement. This approach should be encouraged if a patient is unable to stop smoking by using a single first-line pharmacotherapy. In fact, this has become common practice in our treatment program, as well as many others across the country.

It is not clear whether the superiority of combination therapy is due to the use of two types of delivery systems or to the fact that two delivery systems tend to produce higher blood nicotine concentrations. The former seems to be the main reason for improved success with combination therapy, but more research is needed. Nicotine patch therapy combined with nicotine gum has been shown to reduce nicotine withdrawal symptoms[90] and to improve abstinence outcomes when compared with placebo gum and nicotine patch therapy alone.[91] Nicotine nasal spray combined with nicotine patch therapy was more effective at the end of treatment (but not at one year) than either one used alone.[92] Nicotine patch therapy for five months, combined with nicotine nasal spray for one year, produced higher rates of abstinence from smoking than did nicotine patch therapy with placebo nasal spray.[93] Treatment with the nicotine vapor inhaler plus the nicotine patch seems to significantly increase smoking abstinence rates beyond that seen with the inhaler plus placebo patch.[94]

Unproved Pharmacotherapies

Anxiolytics, such as buspirone, have not been shown to be effective in helping patients stop smoking.[95, 96] Antidepressants other than bupropion and nortriptyline have been tested and generally have been found to be ineffective in producing long-term abstinence from smoking. Doxepin was reported to be effective in one small clinical trial, which has not been replicated.[97] Fluoxetine has been tested in a large randomized clinical trial and shown to have some efficacy using a nonstandard analysis. However, using an intent-to-treat analysis, there was no main effect in the active versus placebo.[98] Subsequent analyses of the same cohort showed the 60 mg dose of fluoxetine improved both positive and negative mood states after stopping smoking.[99] Fluoxetine was not found to enhance nicotine inhaler therapy.[100] Paroxetine (Paxil®) has been tested in combination with nicotine patch therapy and showed no added value in improving smoking abstinence rates.[101]

The antihypertensive mecamylamine was shown to have efficacy in a small trial of smokers.[102] A larger, unpublished study of a mecamylamine/nicotine patch showed a modest increase in smoking abstinence rates of the combination versus nicotine patch alone or placebo. Despite the theoretical role that dopamine plays as a critical mediator of the reinforcing effects of nicotine, administration of carbidopa/levodopa (a dopamine agonist) in doses used to treat Parkinson's disease showed no efficacy compared with placebo.[103] Finally, naltrexone did not show efficacy compared with placebo in a randomized, clinical trial using naltrexone and the nicotine patch;[104] however, other studies suggest that it may have some short-term effects.[105, 106]

Clinical Decisions about Pharmacotherapy

In our treatment program at the Mayo Clinic, we base our clinical decision making regarding dosing and medication selection on the published literature but also on our clinical experience, which spans 16 years and the treatment of more than 30,000 patients.[107] As has long been recognized by clinicians, there are limitations of standard or fixed dose regimens with most drugs used in clinical practice today. As a result, clinicians use their clinical skills

and knowledge of pharmacotherapy to individualize each patient's drug dose.[108] These same skills and knowledge should be applied to medications used to treat tobacco dependence. Though each of the FDA-approved products has been shown to be effective compared to placebo in randomized clinical trials, we rarely use nicotine gum, nicotine inhaler, nicotine lozenge, or nicotine nasal spray alone. From a practical standpoint, we view nicotine patch therapy or bupropion as the floor on which to begin building pharmacotherapy and will often use either as a stand alone in treating patients with mild tobacco dependence or those who have had initial smoking abstinence with one of these products. Depending on the patient, we may use nicotine patch therapy in combination with bupropion. We then use the shorter acting NRT products as needed by the patient to control intermittent withdrawal symptoms or cravings. Much of this clinical decision making is based on the patient's past experience and the patient's preference. For patients with more severe nicotine dependence, such as those treated in our residential treatment program, we usually use combination therapy and often use three or more products simultaneously.

New Medications

The following medications are at various points in the research process which will ultimately be submitted for FDA approval.

Rimonabant. The endocannabinoid system, while primarily characterized through its interaction with delta THC, is also important in tobacco dependence. To date, two cannabinoid receptors that are widely distributed throughout the body have been identified, but only the CB_1 receptor is found in the brain.[109] Endocannabinoid release in the nucleus accumbens results in reward and reinforcement. The endocannabinoid system is constantly stimulated in smokers, resulting in reward-related behaviors.[110] A CB_1 receptor inhibitor, rimonabant has been shown to block the reinforcing effects of nicotine.[111] Rimonabant has been effective in helping smokers to stop smoking, and also has the very positive attribute of reducing weight gain after a smoker stops smoking in short-term trials.[112]

Nicotine Vaccine. A potential novel approach to treating patients with tobacco dependence is to administer a vaccine which stimulates production of antibodies to nicotine. Such a nicotine vaccine is currently under investigation and has been shown in animal studies to reduce brain nicotine levels.[113, 114] Nicotine is bound by nicotine antibodies in the serum and thus cannot cross the blood-brain barrier. Theoretically, this should reduce the reward and reinforcement produced with smoking. Furthermore, the presence of nicotine antibodies would also theoretically block the effect of smoking a cigarette to alleviate nicotine withdrawal symptoms.[115]

Nicotine Straw®. Another novel approach is orally-ingested nicotine in the form of nicotine bitartrate beads delivered via a straw.[116] A single 8-12 mg dose of nicotine ingested by sipping a beverage through the straw which contains the nicotine bitartrate beads, thus carrying them into the gastrointestinal (GI) tract, produced serum venous nicotine concentrations of 20 ng/mL. Repeated doses produce serum venous concentrations of over 40 ng/mL. These serum

venous nicotine concentrations are considerably higher than those achieved with standard dosing using currently available NRT products.

CYP2A6 Inhibitors. Altering venous nicotine concentrations through manipulation of its metabolism is another but very different pharmacologic mechanism. Genetic variations of CYP2A6, a prominent hepatic enzyme that metabolizes nicotine, have been shown to alter serum nicotine concentrations. People with low CYP2A6 are "slow nicotine metabolizers" and are at lower risk for becoming cigarette smokers to begin with. Smokers who are slow metabolizers smoke fewer cigarettes per day and have venous nicotine concentrations equivalent to normal metabolizers with lower expired air CO levels,[117] indicating less exposure to other toxic chemicals in tobacco smoke. Methoxsalen is a drug that inhibits CYP2A6, so it blocks nicotine metabolism and increases serum nicotine concentrations in patients who take NRT, thus it could potentially increase the efficacy of NRT. Methoxsalen also reduces the smoking rate in continuing smokers because they do not have to smoke as much in order to achieve high nicotine concentrations.

Relapse Prevention

Preventing relapse remains as a key component but perhaps the least well understood element of state-of-the-art treatment for tobacco dependence. Clearly, there is room for improvement in relapse prevention.

Telephone Follow-up Counseling or Face-to-Face Counseling

Follow-up and ongoing support are essential, especially in the first few weeks after the smoker stops smoking. In nicotine patch trials, almost every patient who smokes at all during the first two weeks after the target quit date is considered a treatment failure. Thus, a follow-up visit, or at the very least, a telephone contact should be planned in the first two weeks of treatment. Support groups such as Nicotine Anonymous can provide the reinforcement that many smokers need to maintain smoking abstinence. These twelve-step oriented support groups seem to resonate with smokers who are in recovery from other addictions and have previously used the twelve-step approach.

Self-Help Materials and Longer-Term Pharmacotherapy

While self-help materials have not been shown to be effective in initiating abstinence from smoking, specific self-help materials, such as the National Cancer Institute's *Forever Free*, have been effective in helping smokers to maintain their abstinence.[118] Finally, longer use of pharmacotherapy is useful in some patients in order to maintain newly established smoking abstinence long enough to stabilize the treatment effect. The optimal length of pharmacotherapy has not been established for any of the available medications. Two studies have been published where bupropion has been administered for approximately 12 months to smokers who were abstinent from smoking at the end of a short course of pharmacotherapy. One study showed a delay to relapse and a significant, albeit small, effect on smoking abstinence.[84] The other study

showed virtually no effect of bupropion on preventing relapse.[86] Prolonged nicotine patch therapy (five months) combined with nicotine nasal spray for one year also seems to prevent relapse to smoking.[93]

A Workable Model of Tobacco Intervention in Medical Institutions

Counselor-provided Treatment Services Under the Supervision of a Physician

While many potential models of care can be provided in medical institutions, at Mayo Clinic we adopted a treatment model where services are provided by master's trained counselors under the supervision of a physician. This model has been very successful in the chemical dependency field for over three decades, and after careful analyses, we concluded that it was the most workable one for our institution. Now almost 16 years later, we have found that this is still the best model for our setting and for other medical institutions as well. There are many reasons for this, including the existence in most medical institutions of staff who have counseling skills. Counselors can range from master's trained counselors to nurses to social workers. What is necessary are basic counseling skills and training in other areas such as addictions treatment, pharmacotherapy, and relapse prevention.

Full Integration into the Medical System

To be successful, a tobacco dependence treatment program has to be fully integrated into the medical care system of the host institution. This will vary from institution to institution but fundamentally means recognizing counselors as full members of the health-care team and allowing them the same privileges that other clinicians have. Ordering a counseling service must be as simple for a clinician to order as a chest X-ray. Including tobacco dependence counseling in the existing order system is not only the best way to do it: it is the *only* way to do it.

The counselors should enter a record of their consultations directly into the medical record. This can be placed in a special part of the medical record, but it must be easily accessible so that all can see what the counselor has recommended. The format of the counseling session should be fairly standardized and consistent. This requires the program coordinator or lead counselor to perform periodic chart reviews and directly observe patient consultations of the other counselors. The counselors should be available to see patients at the bedside in the hospital or in the outpatient area promptly (our goal is to see the patient within 48 hours of receiving the referral). For most of the consultations, the counselor travels to the area where the physician is seeing the patient. This increases the potential interaction with the counselor and physician, which enhances the consultation and counseling session itself.

Range of Treatment Services

We consider the following services to be essential in providing comprehensive treatment for patients in a medical institution.

Individual Face-to-Face Counseling at the Bedside or in the Outpatient Setting

Since more people favor individual face-to-face counseling than group counseling, this is a *must* service to provide. The initial counseling session should be long enough to do a thorough interview of the patient and to develop a solid treatment plan. We recommend 45-60 minutes. Whether initial counseling takes place at the bedside or an outpatient area, it should be basically the same.

Carbon Monoxide Testing

Carbon monoxide (CO) testing is an excellent tool to personalize the risks of smoking and the benefits of stopping. CO monitors are small and easily portable. Our counselors take them to the inpatient bedside and the outpatient areas in the clinic. CO of expired air correlates very well with blood carboxyhemoglobin, thus reflecting the potential harmful effect of smoking. We measure CO in almost all patients and do daily measures on residential patients. To personalize the risks and benefits, we furnish the patients with a handout that shows the effects of different CO readings such as: 28 ppm – significant loss of O_2 carrying capability of the blood, 35 ppm – legal limit for eight hours of work exposure, and 50 ppm – "air pollution emergency" alert.

Group Therapy

Although it would be ideal to have a group program available as an option, the use of group therapy will depend upon the expertise of the treatment team and the population being served. In a small population base, it is difficult to engage enough people in order to make the group process effective. We consider six members to be the minimum for an effective group interaction and 10 to 12 to be the maximum for a single group leader.

Residential Treatment

While it represents a small part of our treatment services, we think it is essential that residential treatment be available in a few tertiary care institutions in the country.[119] Provided in a tobacco-free protected milieu, this intensive treatment embraces the four essential elements of state-of-the-art treatment and is modeled after alcoholism and drug dependence treatment. Using an intent-to-treat analysis, one-year smoking abstinence rates are 45 percent. Behavioral treatment centers around group therapy and individual counseling. Residential treatment affords the ability to tailor the pharmacotherapy based on therapeutic drug monitoring. Daily rounds on all patients allow for direct observation of the severity of nicotine withdrawal symptoms, thus allow for modification of pharmacotherapy to alleviate these symptoms. These daily rounds also allow the team to assess how well the patient is accepting and integrating into treatment, thus providing for face-to-face counseling and direction to help the patient to more

fully engage the treatment process. Residential treatment also emphasizes a medical model of tobacco dependence treatment which some patients seem to appreciate, and provides time for a greater in-depth education about tobacco dependence. Residential treatment should be available for patients who have failed treatment repeatedly, as well as for patients at high risk of serious and immediate medical consequences, such as the loss of life or limb or removal from a transplant list.

Follow-Up Visits vs. Telephone Counseling

As recommended by the USPHS Guideline, follow-up visits are absolutely critical to the success of a treatment program. Follow-up counseling can be done face-to-face or by telephone. Depending upon the circumstance, either may be appropriate. However it is done, a follow-up in the first week or two after the initial treatment service is essential. We provide telephone contact to all patients at one month, three months, and six months after the initial counseling session. We also have a telephone quitline which is available at no cost to all of our employees.

Internet Services

While a growing number of Internet services are available, very little research has been done to assess their efficacy. As mentioned earlier, expert systems, which use an algorithm that is tailored to an individual based in part on previous responses, have been shown to be effective, but they are not widely available. At present, we do not offer an Internet-based treatment service but provide interested patients with web-based resources that might provide additional help to them.

Treatment in Special Populations

Some patient populations are readily available to a treatment team in a medical setting, but do not receive services on a regular basis. These patients may be in a highly teachable moment. JCAHO criteria consider it essential to treat tobacco dependence in patients hospitalized for acute myocardial infarction, congestive heart failure, or community-acquired pneumonia, thus extension of treatment to other populations of patient smokers is only logical.

Surgical Patients

Surgical patients should be on the list for tobacco dependence treatment services because stopping smoking improves surgical outcomes.[120] It reduces post-operation respiratory complications, especially if the smoker stops smoking well in advance of surgery.[121, 122] The underlying biological mechanisms for these effects are multifactorial. The alveolar macrophages in smokers are dysfunctional and unable to ingest foreign particles.[123] Smoking impairs wound healing through decreased tissue profusion, thus decreased tissue oxygenation, as well as impairment of neutrophil function. As with other teachable moments, the severity and duration of surgery is related to higher rates of stopping smoking. For example, in patients undergoing abdominal aortic aneurysm surgery, the only factor associated with stopping smoking was the

surgery itself, while in continuing smokers, the death rate was three times that of patients who stopped smoking.[124] Although smokers report increased baseline stress, smoking abstinence at the time of surgery does not affect changes in perceived stress over the perioperative period. In addition, nicotine withdrawal symptoms do not seem to be a clinically significant problem in the perioperative period for most abstinent smokers.[125]

Cancer Patients

Providing tobacco dependence treatment for the large and growing population of cancer surviving smokers is important. Such treatment can be effective especially if provided shortly after the initial diagnosis.[126] Smokers with cancer, especially those with cancers of the head and neck, who stop smoking will improve their general health, decrease the risk of side effects of cancer therapy, and improve overall outcomes. Moreover, stopping smoking decreases the risk of developing tobacco-related second primary cancers. Again, this is particularly true of patients with head and neck cancer.[127] Less work has been done on patients with lung cancer. Given the low long-term survival for lung cancer patients, many physicians feel that since the patients are going to die anyway, why not let them have one of the few pleasurable experiences left to them? We do not subscribe to this philosophy. We believe that what literature is available shows that the side effects from the radiation or chemotherapy are likely exacerbated by continuing smoking and that continued smoking may also interfere with the efficacy of the chemo- or radiation therapy.

Substance Dependent Patients

The importance of treating tobacco dependence in alcoholic and non-nicotine substance abusers is highlighted by this fact: in patients previously treated in an inpatient addiction treatment program, tobacco-caused diseases account for more than 50 percent of all deaths.[128] Not only are the mortality rates higher, but there is a marked decrease in the general and mental health status of smokers with a history of alcohol problems.[129] While not generally available throughout the alcoholism treatment community, successful efforts have been made to treat tobacco as a drug of dependence in some addiction treatment programs (Dr. Zeidonis's paper for this conference goes into more detail about this topic.)[130, 131] For alcoholic patients with a history of major depression, effective interventions have focused on managing negative mood.[132, 133] Thus, a variety of cognitive strategies should be considered in treating tobacco dependence in patients in recovery. In general, alcoholic smokers have more severe nicotine dependence than do nonalcoholic smokers.[134, 135] Studies comparing the efficacy of NRT among alcoholic smokers have produced mixed findings. Recent reports indicate that while individuals with active or recovering alcoholism can achieve short-term success using nicotine patch therapy, long-term success is not as high as it is among nonalcoholics.[134-136] However, these findings may be compromised as the nonalcoholics in these studies were less heavy smokers than their alcoholic counterparts. Thus, when compared to equally heavy smokers with no history of alcoholism, recovering alcoholic smokers have similar six-month stop rates.[137] A recent study of heavy smokers (greater than 30 cigarettes per day) receiving a nicotine patch dose of up to 42 mg per day found that higher doses were somewhat more effective than standard doses and

that there was no difference in nicotine patch efficacy between nonalcoholics and recovering alcoholics.[44] Thus, high dose nicotine patch therapy seems justified for alcoholic patients, since they are likely to be heavier and more dependent smokers—and therefore have a higher risk of mortality from tobacco-caused diseases—than nonalcoholics. Additionally, combinations of NRTs or combinations of nicotine replacement and non-nicotine products such as bupropion seem indicated. Bupropion seems to be effective in smokers, irrespective of their history of depression or alcoholism.[81] Indeed, with such a high mortality rate, recovering alcoholic smokers may well need more intensive behavioral treatment, such as residential treatment.[119]

Transplant Patients

One of the most valuable and expensive procedures available today is heart transplantation. With the scarcity of donors, transplant teams are scrutinizing patients for modifiable factors that will improve long-term success. Even low rates of smoking (usually in patients who were smokers before transplantation) leads to a very high rate of post-transplant vasculopathy and lung cancer.[138] In 1997, with our heart transplant team, we developed a protocol to screen all potential transplant candidates for tobacco dependence. Current smokers are referred for tobacco dependence treatment, including residential treatment if necessary. Potential candidates are not eligible (except in emergency cases) to be on the heart transplant list with less than six months of biochemically confirmed tobacco abstinence. We expect to extend these assessments and treatment options to other transplant programs, such as kidney, liver, and lung transplant patients.

Spit Tobacco Users

As with nicotine delivered from cigarettes, nicotine derived from spit tobacco (ST) acts as a powerful reinforcer with high addiction potential.[139] Long-term ST use is known to increase the risk of oral leukoplakia (white precancerous changes), oropharyngeal cancer, and periodontal disease.[140] ST use may increase the risk for cancer of the esophagus, larynx, stomach, and pancreas.[141-143] ST use may be associated with risk factors for cardiovascular disease, such as high blood pressure and elevated serum cholesterol concentrations.[140, 143-145] Symptoms of nicotine withdrawal have been reported in ST users at a similar frequency and severity as in cigarette smokers.[146, 147] In addition to withdrawal, other signs of significant tobacco dependence are dipping within 30 minutes of awakening and swallowing, rather than spitting, the tobacco juice most of the time.

We recommend treating ST users with many of the same behavioral and pharmacologic approaches used for cigarette smokers, as discussed above. An important aspect of the intervention for ST users is an oral examination. Identification and discussion of identified lesions (which almost all ST users will have) can be a powerful motivator. Clinicians should make the oral examination part of their assessment and treatment of all ST users and other tobacco users as well. Part of the behavioral therapy that is unique to ST users can include the use of non-tobacco oral snuff substitutes such as “Mint Snuff®” [www.mintsnuff.com], “KIKIT®” [www.kikit.net], and “Bacc-Off®” [www.dipstop.com]. Some ST users find that

these products provide the substitute they need to satisfy the oral sensation. Others feel the products are too similar to their tobacco product and wish to avoid their use.

The FDA has not approved any medications specifically for the treatment of ST use. However, our work and that of others suggest the following approach to medication use:[148]

- Nicotine patches should be dosed at levels that achieve 100 percent replacement of nicotine levels achieved during ST *ad lib* use. Initial dosing can be based on the amount of ST used/week as follows:

Cans/pouches used per week	Initial daily nicotine patch dose
<2	14 mg
2-3	21mg
>3	42 mg

- Nicotine gum (2 mg or 4 mg) can be used as needed, in combination with the patch, to provide additional control of withdrawal symptoms and cravings. The nicotine lozenge has not been studied in ST users. Anecdotal experience suggests that this form of NRT may be helpful for this population of tobacco users, too. Generally, supplementing the nicotine patch with the nicotine lozenge on an "as needed basis" seems safe and helpful.
- Based on pilot studies we and others have done, it appears that bupropion SR may be used in the same dosages used for cigarette smokers, either in combination with NRT products or as monotherapy.[149, 150]

Systematic Ongoing Marketing

Sustainable programs require ongoing marketing. Just because a good service is available does not mean it is going to be utilized. Marketing is an essential part of long-term success. It can take the form of presentations, announcements in the institution's newsletter, and publications. When we have done surveys of physicians, we are always surprised to find out that many of our physician staff do not know what services exist. In medical institutions, marketing is targeted toward prescribers or referrers, but there also has to be an effort to reach the ultimate customer—the patient. From the patient's perspective, the most influential source of information is word of mouth, followed by the general reputation of the institution and then by a person having had a good experience as a patient in the institution. Less influential sources are news and media advertising and direct mail. The Internet seems to be a growing source of referrals, especially to our residential program. An accessible, easily navigable, and attractive website is very important.

Challenges

Gaining Institutional Support

Garnering institutional support in a time of restrained resources could be the biggest challenge of all. This requires a high degree of commitment and persistence by the entire team, as well as a deep understanding of the decision-making process of the institution. Having an articulate and energetic champion who has credibility with institutional leadership is essential; in most medical institutions, this should probably be a physician. Assembling a multidisciplinary team (physicians, nurses, administrators) to develop a business plan is a good first step. The plan must be seen as meeting a need for patient care and go well beyond the fact that tobacco dependence treatment is the right thing for the institution to do (which it is). The plan has to have realistic projected costs and benefits. Even though it will benefit employees (and as a result, ultimately reduce health care costs for the institution), the plan must be focused on providing treatment to patients at large. Making the plan fit the institutional culture is also critical. Finally, although several studies show that tobacco dependence treatment is among the most cost-effective services provided in medicine, one can't rely on this to convince institutional decision-makers.[151-153]

Time

Clinicians are very busy and have limited time. For physicians to adopt tobacco treatment services, the services must add value to patient care, be accessible, and not require much of their time. Given the constraints of time, it is highly unlikely that all clinicians will become fully versed in the 5 A's. If we can get clinicians to identify tobacco-using patients (which the system should do for the clinician), personalize the risk of smoking and the benefits of stopping, and then refer them for a counseling session, that may be all we can do. In addition, clinicians and their staffs should know of the availability of telephone quitlines in their area and provide patients with the toll-free number, and encourage the patients to call.

5 A's Training is Taking Place but Not Consistently Across the Country

As more and more tobacco treatment specialists make presentations at general medicine and specialty conferences, the 5 A's are becoming more widely known. They would become even more widely known if more training about them was provided in medical schools and residency programs. The advocates for tobacco dependence treatment have to be involved in these curricula in order to teach young physicians the best practices for treating tobacco dependence. Certainly, in a closed system like the VA, a special effort should be made to train clinicians and residents in effective tobacco dependence treatment and compliance with the 5 A's.

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Best Practices in Tobacco Control: Identifying Effective Strategies for Improving Quality within the Veterans Health Administration

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VA guidelines state that all tobacco users interested in quitting should be offered medication and counseling. Yet despite the availability of smoking cessation programs at nearly every VA medical center, the rate of utilization remains low—among smokers attempting to quit, only 22 percent received treatment for smoking cessation. A systematic review of best practices (those that increase use of medication or counseling within a population of smokers) within the VA examined patient-level interventions, provider-level interventions, and systems-level interventions. The review identified seven effective strategies that could be implemented widely within the VA: (1) recruitment by direct mail; (2) telephone counseling; (3) greater support of tobacco cessation treatment by primary or mental health care providers; (4) improved audit and feedback; (5) smoking cessation programs for hospitalized patients; (6) newer, more challenging performance measures; and (7) removal of co-payment for smoking cessation treatment.

Imagine for a minute that you wrote and are directing a play. You and the cast have spent months perfecting the play. Critics love your play, calling it "powerful," and speak of its "tremendous societal impact." Your theater has several thousand seats, but unfortunately only about 25-50 seats are filled at each performance.

This scenario represents the current state of tobacco control at most places in the Veterans Health Administration (VA) and elsewhere. We have wonderful programs and treatments to help people quit smoking, yet few people use them. And then we wonder why the prevalence of smoking hasn't changed!

This situation is by no means unique to tobacco use. Throughout much of medicine, the last few decades have seen a phenomenal growth in the number of effective treatments available, yet until recently, there has been very little research on how to increase the use of these effective treatments. This can be seen in the low rate of beta-blocker use after a myocardial infarction, of medications or counseling for major depression, and of a wide range of other services that have been proven to be beneficial.[1] The realization that effectiveness alone is not sufficient to change behavior has led to increasing study of how to effect change within the health care system.[2, 3, 4]

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Let's return for a minute to our scenario of the well-designed, but poorly attended play. There are many possible reasons why the turnout is so sparse. Perhaps the subject just does not appeal to the general public. Maybe the ticket prices are too high or the theater is in an inconvenient or even dangerous location. Perhaps the critics' favorable reviews only appeared in obscure publications. To increase attendance, you might consider interventions targeted at the audience, the actors, the ticket agents or critics, or even the location. You might even consider bringing the play to the audience by televising it, decreasing its impact somewhat but reaching a much, much larger audience.

Just as in our hypothetical scenario, one can think about intervening at multiple levels to increase the use of smoking cessation treatments – the patient, the provider, the clinic, or the system.[2] For tobacco control, a patient-level intervention might be to have flyers or posters in the waiting room, encouraging smokers to ask their doctor to help them quit. Having all providers attend an educational seminar on smoking cessation would be a provider-level intervention. The most effective approaches to changing treatment patterns generally intervene at multiple levels.[2, 3, 4] We will now use this multi-level approach to consider "best practices" for tobacco control within the VA.

In a recent article on tobacco control,[5] Schroeder noted that "the Veterans Health Administration is poised to serve as a model health care system for smoking cessation." He noted areas both of excellent performance (e.g., high rates of asking about smoking and advising smokers to quit) and of room for improvement (e.g., low rates of treatment among smokers interested in quitting). This paper provides a systematic review of the smoking cessation strategies and interventions that are being used to improve treatment for smokers using the VA.

Methods

What is a "Best Practice"?

The current VA/Department of Defense (DoD) clinical practice guidelines for smoking cessation[6] state that all tobacco users interested in quitting should be offered medications and counseling. Treatment should occur in the most intensive setting that they are willing to attend, which might be a smoking cessation program, but equally likely might be within routine primary or mental health care. Therefore, we define a best practice as one that increases use of effective treatments (medications or counseling) within a population of smokers.

In choosing this definition of a best practice, we are approaching tobacco control from a public health approach (delivering effective treatment to the entire population of tobacco users), rather than a specialty medical approach (delivering the best approach to people attending a specialized program). We do this because in spite of the availability of intensive smoking cessation programs at nearly every VA medical center,[7, 8] the rate of utilization remains quite low. A national VA survey of about 19,000 smokers showed that among smokers who attempted to quit during the prior year, only 22 percent reported receiving treatment for smoking cessation.[9]

Data Sources

Since there is no single source for information on tobacco control strategies within the VA, we used a multifaceted approach to identifying best practices. Interventions and strategies were identified using three complementary approaches.

Systematic Search for Interventions

We systematically reviewed the following four sources to identify best practices within the VA. Our search terms were "veteran" or "military" and "smoking" or "tobacco."

- *PubMed*—We searched Medline/PubMed, identifying resources during the last 10 years (January 1, 1995-present). We excluded efficacy, effectiveness, and safety studies of specific medications (such as randomized trials of nicotine replacement therapy), as well as studies that did not describe an intervention or program (i.e., descriptive studies of knowledge/attitudes and the predictors of cessation).
- *Research funding*—We searched the NIH (http://www.crisp.cit.nih.gov/) and VA (http://www.hsrd.research.va.gov/research) research funding databases.
- *Abstract presentations*—We searched through all recent abstract presentations from the following annual meetings: Addressing Tobacco in Managed Care, American Public Health Association, Society of Behavioral Medicine, Society of General Internal Medicine, Society for Research on Nicotine and Tobacco, and VA Health Services Research and Development Service.
- *National VA sources of best practice*—We also searched existing best practice repositories on the VA Intranet, including the VA Virtual Learning Center and VA Employee Education System.

Both authors independently reviewed all programs identified as possible best practices. In general, the programs were rated on how important it is that every VA facility be informed of this intervention. In making this determination, we considered both the feasibility and the likelihood of having a population impact.

Survey of VA Smoking Cessation Lead Clinicians

Each VA facility had previously designated a lead clinician for smoking cessation, and we asked these clinicians whether they had published or presented any new or noteworthy programs at their site. We received responses from 122/131 lead clinicians (93 percent). We requested more information from the 25 (20 percent) who said they had written up something, and each write-up was reviewed for possible inclusion.

Expert Opinion

One of the authors (SES) is Chair of the VA's Smoking and Tobacco Use Cessation Technical Advisory Group (described below), and in this role often comes in contact with people starting up clinical or research programs. We also included promising programs brought

to the attention of the Technical Advisory Group, as well as programs started by the VA at the national level.

Best Practices in Tobacco Control within the VA

Patient-level Interventions

There is a wide range of potential interventions at the level of the patient, ranging from the very simple (e.g., posters) to the very complex (e.g., Internet-based cessation programs). In general, the patient-level interventions that have had the biggest effect on health behaviors have been those that "activate" patients, getting them more involved in their own health care.

Printed Materials

Patient education materials for tobacco use cessation are usually minimally effective at best, and are perhaps ideally used to heighten awareness of a program or as a supplement to advice to providers. As an example of an intervention to motivate patients, experts at the Seattle VA (Miles McFall, Ph.D., and Victoria McKeever, Ph.D.) created a brightly colored card to leave out in the waiting room, encouraging patients to ask their doctor (Figure 1). This card has not been formally evaluated; their assessment is that it probably has a low yield, but requires very little effort.

Recruitment of Patients

While unsolicited mailings have generally been at best minimally effective in health promotion, this approach has been used effectively in two studies to recruit smokers within the VA. In a study of a VA telephone quitline, Joseph et al. sent an unsolicited letter to 58,592 patients at five VA Medical Centers in the Midwest.[10] They received calls from 1,506 patients asking for more information about the project, of whom 715 met eligibility criteria and enrolled in the study. Using estimates for the prevalence of smoking at these medical centers, 8.6 percent of all smokers called the number to obtain more information on quitting, and 4.1 percent of all smokers actually participated. These percentages are likely to represent an underestimate, since many factors make recruiting for a research study more difficult (patients must give informed consent, be willing to accept treatment randomization, and complete various surveys). The surprisingly good response probably reflects the nature of the intervention (telephone counseling is popular with patients) and the newness of the program, which was not available at the VA previously.

In recruiting for a multiple intervention study, Velicer et al[11] sent an unsolicited mailing to nearly 34,000 veterans at the Boston VA Medical Center. After eliminating approximately 7,800 who could not be reached or had health or language issues, and 2,664 who were still waiting to be called, they were able to obtain verbal informed consent to participate from 2,915 smokers. They enrolled 2,054 smokers in the study, who gave their written consent. Using a prevalence of smoking of 30 percent, we can estimate that there are 7,046 smokers among

the patients that were reachable. Their approach then resulted in enrollment of 29 percent of all smokers, which is quite a remarkable achievement. Not only did they enroll large numbers, but they also were successful in helping them quit smoking, with over 20 percent abstinence at 20 months follow-up.[12] Therefore, in answering whether or not unsolicited mailings can be an effective strategy, these two studies lead us to conclude that the answer is an unequivocal yes.

My HealtheVet

The VA has invested heavily in information technology, and central to that effort in the future will be the My Health*e*Vet initiative. Building upon the VA's fully integrated electronic medical record, My Health*e*Vet gives veterans web-based access to their own electronic medical record. In addition, it incorporates a wide-range of online health education materials, with a particular focus on chronic disease management and health promotion. There is a comprehensive section on tobacco use cessation, including links to VA and external smoking cessation resources. The integration of this material with the patient's electronic medical record will allow for tailored educational materials in the future. Thus, the information that a smoker views could be tailored to his or her health conditions. Some examples of how this might work:

- A smoker with diabetes and coronary artery disease might view a screen showing his or her specific risk of myocardial infarction, as well as the health benefit he or she could expect from cessation.
- A tobacco user with a history of seizure disorder who wanted information on smoking cessation medications might see a page on nicotine replacement therapy (adapted to what is available on the local VA formulary). In addition, he or she might also see a page indicating why the seizure disorder makes bupropion contraindicated.
- The tobacco use cessation advice given by the primary care provider at a recent visit could automatically be reinforced and augmented. Targeted questions might screen for side effects from recently prescribed smoking cessation medication.

This dynamic tailoring of health information for smoking cessation has not been developed yet. We include it here as an example of what could be done with relatively little difficulty. The hardest part in designing such a tailored system is having access to an up-to-date electronic medical record, and the VA is already doing that.

Web-assisted Tobacco Intervention

There is increasing evidence that web-assisted tobacco interventions are effective in helping smokers to quit.[13] Dr. Leslie Lenert at the San Diego VA Healthcare System is currently testing an Internet-based cessation program specifically tailored to VA users. The program sends pre-scripted e-mail messages to patients who have agreed to quit smoking. The messages come directly from the primary care provider and can be adapted to individual preferences.[14] In addition, this web-assisted tobacco intervention will include a discussion group where VA

users can support each other's quit attempt, in a setting that shares information on their period of military service and other information they choose. Once regional testing of this system is complete, it can easily be incorporated into My Health*e*Vet, so that someone reading the tobacco use cessation health education materials who decides he or she wants to quit can immediately link to a web-assisted tobacco intervention.

The software for web-assisted tobacco interventions has already been developed; research needs to focus on evaluating its effectiveness and in determining how to implement it. The latter issue—how to foster implementation of this approach—is a major one for the VA. Few if any data on the prevalence of Internet access among patients using the VA are currently available, but it is estimated to be in the 20-40 percent range and will certainly increase over the next several years. Implementation plans therefore need to consider a variety of issues and barriers related to computer use, including access, ability (computer skills), and attitudes.

Provider-level and Clinic-level Interventions

The VA/DoD guidelines[6] suggest that there are four levels at which tobacco cessation treatment is routinely delivered – within smoking cessation programs, from individual primary care or mental health providers, via telephone, or during inpatient hospitalizations. Each of these represents an effective venue in which to provide smoking cessation medications and counseling. The challenge for health care systems is to decide how much emphasis to place on each of these approaches and how to maximize the utilization of the approach(es) chosen.

Increasing the Use of Smoking Cessation Programs

We recently completed the Quality Improvement Trial for Smoking cessation (QUITS), a group randomized trial of evidence-based quality improvement[15] to increase adherence to national clinical practice guidelines for smoking cessation.[16] As part of the process evaluation, we conducted a survey of the 20 sites initially participating in the project and another 20 sites participating in a separate VA-funded study of implementing smoking cessation practice guidelines (Guideline Implementation for Tobacco, Dr. Anne Joseph, Principal Investigator). We found that nearly all VA facilities (39/40) in our sample had an on-site smoking cessation program,[7, 8] and for most, this was their preferred approach to smoking cessation treatment.

QUITS used a locally-designed approach to improve tobacco control efforts. Intervention sites were assisted in choosing tobacco control priorities and in creating and implementing a quality improvement plan to achieve these local goals. Most sites developed a strategy to increase use of their on-site smoking cessation program, since the majority of sites restricted smoking cessation medications to patients attending the program. Unfortunately, this intensive effort to increase use of VA smoking cessation clinics was unsuccessful, as patients at the intervention sites were no more likely than those at control sites to report being counseled about smoking cessation, being referred to a program, or actually attending a program.[17]

Given these results, it is important to think about why this approach (locally-designed, evidence-based quality improvement) didn't work. We think there are three main reasons for our lack of benefit. First, all sites were already doing quite well on the existing smoking cessation performance measures, in most cases with more than 90 percent of patients being asked about smoking and more than 90 percent of smokers being advised to quit. In the face of many other competing demands on the time of providers[18] and facilities, staff may have felt there was little incentive to do more than was already being done.

A second reason for the lack of benefit is that while top management at each site endorsed the project, few made it an institutional priority. As a result, the main site contacts also did not consider it a top priority. One of our expert consultants on the study, Dr. Bruce Chernof, Medical Director of HealthNet, advised us in advance that unless the project managers "brought the project home with them at night" and really cared about it, there was little chance of success. As a further example of this, one site had the most comprehensive quality improvement plan and the largest improvement. Just prior to the start of the site's involvement in QUITS, its leadership decided that the current approach to tobacco control was not working, convened a local quality improvement team, restructured care, monitored outcomes, and documented that care had improved. Thus, the site's leaders essentially did the entire study intervention prior to joining the project. In an interview featuring the site as a "best practice," the chief of staff said that he had learned during his time in the military that what the commander cared about always got done, so he made it very clear to everyone that tobacco control was a top priority. Therefore, one very important way to foster change at the clinic and provider level is to ensure that there is strong and unequivocal support from top administration.

The third reason why our intervention had no effect is that it was an unstructured intervention, which we had deliberately designed to be locally determined. Our study design was adapted from the intervention used in the Mental Health Awareness Project.[19] In analyzing why some sites in that study were more effective than others at improving care for depression, Rubenstein et al.[19] found that in supportive environments (high local support and expertise), both locally-designed and expert-designed interventions were likely to be successful. However, when conditions were not optimal, expert-designed interventions fared better than those that were locally-designed. As noted above, our sites had only moderate support. Furthermore, all of our site leaders had expertise in smoking cessation, but few were also expert in quality improvement techniques. Therefore, we might have had more success (although possibly less buy-in) with a more structured, externally-designed intervention rather than a locally-designed one.

Our literature review for this manuscript found two other interventions that were successful either at increasing attendance at a smoking cessation program or in decreasing drop-out rates. In an abstract presentation at the Society of General Internal Medicine, Volpp et al.[20] reported the results of a randomized trial of financial incentives at the Philadelphia VA Medical Center. Smokers in the intervention group were offered $20 for each smoking cessation program

class attended and $100 for completing the program. The incentive group had higher rates of program enrollment (43 percent vs. 20 percent) and program completion (26 percent vs. 12 percent). Longer follow-up was still underway, but financial incentives appeared to be effective among veterans.

At the New Orleans VA Medical Center, patients attending the smoking cessation program complained about having to wait in the pharmacy to pick up their smoking cessation medications. In the VA Virtual Learning Center, Rick Gibson and Sheila Corrigan reported on their experience restructuring care at the New Orleans VA Medical Center so that a pharmacist was available within the smoking cessation clinic to dispense medications.[21] They reported that this change increased patient satisfaction with the program and increased the percentage completing the program from 34 percent to 53 percent.

These last two strategies—financial incentives and use of a clinical pharmacist—are readily available within the VA. The first is perhaps the more difficult one, as a variety of VA regulations make incentive payments difficult to arrange. All VAs have clinical pharmacists on staff, so the main barrier to pharmacists' increased involvement is competing demands on their time. This is not a major barrier for smoking cessation programs, however, as they typically meet only weekly or even less frequently.

Programs to Support Treatment in Primary or Mental Health Care

The vast majority of VA patients see their primary care provider at least once a year, and many have considerably more primary care visits. The main barriers limiting primary care-based treatment have been competing demands on the provider's time[18] and providers' lack of knowledge about and experience with smoking cessation treatment. Several VAs have designed innovative medical record-based systems to support the primary care provider. For example, the Erie, Pennsylvania, VA Medical Center[22] designed a primary care-based program to address concerns about time constraints, staff knowledge and skills, and impact on the pharmacy budget. They modified an existing computerized clinical reminder for smoking cessation in several ways (see Figure 2 for a screen shot). First, the reminder guided the clinician about how to approach the patient and what treatment options were available. Second, the clinician could click on pre-made order sets to automatically generate a prescription for either nicotine patches, nicotine gum, or bupropion. Third, additional check boxes were available in the reminder to automatically schedule telephone follow-up at two weeks and three months and to print out patient education materials. Finally, the reminder also included a hyperlink to the clinical practice guidelines for additional information. Evaluation of the program is still underway, but during the first three months the program resulted in a 400 percent increase in the number of patients given smoking cessation treatment. Since all VAs use the same computer system, this approach could easily be replicated at other facilities.

Andrews et al.[23] examined the effect of education and feedback on providers' compliance with the Public Health Service guidelines in two primary care teams at a southeastern VA Medical Center. The intervention team received a single 90-minute education session and

later received written individual and team-level performance feedback, while the control team received no special training or intervention. Based on chart reviews conducted four to eight weeks after each phase, education had no effect on behavior but audit and feedback led to significant increases in advising smokers to quit, assisting them in quitting (with treatment and/or referral), and in arranging follow-up.

The VA population in general has significantly more physical and mental health problems than the general population and than patients in other health care systems.[24] For many VA patients, the mental health care provider is either the actual or the *de facto* primary care provider. Programs to increase treatment within primary care would in most cases miss these patients. The VA has taken a two-pronged approach to increasing treatment rates within mental health care. First, adherence to smoking cessation guidelines is assessed and reported separately for primary care and mental health care. This has led to dramatic increases in asking mental health care patients about tobacco use and advising users to quit, much as it had done several years earlier for primary care. The second component is a nationwide program (funded by the VA's National Public Health Prevention Program and led by Dr. Miles McFall and Dr. Victoria McKeever) to train selected mental health care providers in smoking cessation techniques and have them go back and train additional people at their respective facilities. In addition, these leaders would work to reduce barriers to treatment at their institutions. The first set of mental health care providers attended a two-day training session in June 2004 and is now reporting monthly on its progress. The training will be held again next year, allowing another set of providers to participate. Dr. McFall and Dr. McKeever are currently evaluating the program's impact, both at the organization level and at the patient level.

Telephone Counseling

This will be discussed only briefly because there is a separate paper in this issue discussing telephone counseling for smoking cessation within the VA. Given its many advantages, including effectiveness, low cost, and wide availability, it is likely that telephone counseling for smoking cessation will be a prominent feature of tobacco control within the VA in the future. There are two main ways in which the VA could adopt telephone counseling for smoking cessation. First, it could set up its own national smoking cessation quitline. (This approach was tested in Dr. Anne Joseph's TeleSTOP study, which found a VA-run quitline to be effective both short and long term. More detail is available on this study in Dr. Joseph's article in this volume.) Second, it could contract out the quitline to an existing telephone counseling provider, as has been done by several states. We tested this approach in a recent study at two VA facilities (10 intervention sites) in California.[25] Smoking cessation consults were received by the VA coordinator, who then connected the patient directly to the California Smokers' Helpline and ensured that the patient received smoking cessation medications. Based on previous studies, we were hoping to receive at least ten referrals a week at each of the two facilities, which would have given us approximately 800 referrals. Instead, with minimal marketing, we received over 2,800 referrals in ten months and had a very high rate of use of the California Smokers' Helpline and of long-term abstinence from smoking. We had to omit the

social marketing component of the project, as we were unable to handle additional referrals. As it was, our project accounted for approximately eight percent of all counseling calls that the Helpline provided to the entire state during that time period. This represents the largest source of referrals the quitline has had from a single health care organization. A preliminary cost analysis showed that the cost to produce one quitter (at two months) was highest for treatment within primary care ($606/quitter), in the middle for referral to a smoking cessation program ($350/quitter), and lowest for referral to telephone counseling ($257/quitter).[26] This approach is currently being expanded and tested in all 60 VA sites in California, Nevada, and Hawaii.

Hospital-based Tobacco Use Cessation Programs

While only a minority of VA patients is hospitalized during the course of a year, these admissions remain a window of opportunity to help tobacco users quit. A recent Cochrane review of smoking cessation programs in hospitalized patients found that high-intensity behavioral interventions including at least one month of follow-up contact are effective.[27] Several studies within the VA have demonstrated the effectiveness of this approach to helping smokers quit. Simon et al.[28] randomly assigned 324 patients undergoing noncardiac surgery at the San Francisco VA Medical Center to either an intervention or control group. Intervention patients watched a smoking cessation videotape and received face-to-face in-hospital counseling, self-help literature, nicotine replacement therapy, and three months of telephone follow-up. The control group received self-help materials and ten minutes of counseling. At one-year follow-up, 27 percent of the intervention group were abstinent as compared to 13 percent of the control group (relative risk 2.1, 95 percent confidence interval 1.2-3.5).

In a separate study at the San Francisco VA Medical Center, Simon et al.[29] enrolled 223 smokers in a hospital-based smoking cessation randomized trial comparing intensive counseling and telephone follow-up with minimal counseling. All patients received transdermal nicotine for two months. At one-year follow-up, the self-reported quit rate was 33 percent in the intervention group vs. 20 percent in the control group (relative risk 1.7, 95 percent confidence interval 1.1-2.7).

A third study tested an alternative approach, that of hospitalizing smokers specifically to help them quit. In an uncontrolled study at the Durham VA Medical Center, Green et al.[30] tested the efficacy of a four-day residential program in 23 smokers who had relapsed after attending the outpatient smoking cessation program. At six-month follow-up, 26 percent of smokers were abstinent (by seven-day point prevalence), which the authors point out is comparable to the success rate seen with other smoking cessation programs.

There is no national VA policy at this time on tobacco control interventions for hospitalized patients. Given the evidence of their effectiveness in the VA and elsewhere, it is worth considering a national mandate that inpatient facilities have some program to help tobacco users quit. Even though only a minority of patients is admitted each year, they are generally the sicker ones. They stand to benefit even more than the average patient from smoking cessation treatment. The programs tested thus far have been rather intensive (on the level of outpatient

smoking cessation programs). Future studies should examine the effectiveness of less intensive treatment approaches, as well as ways to integrate inpatient treatment programs with existing resources, such as quitlines.

System-level Interventions

The previous sections discussed interventions or strategies at the level of the patient, the provider, and the clinic. The remainder of our enumeration of best practices will focus on system-level strategies, and indeed this is where the VA has put considerable effort over the last eight years. System-level interventions usually have a lower success rate with individuals than specific treatment interventions, but because they have broad reach their population impact may be much greater.[6, 12]

Smoke-free Environments

After years of lagging behind the tobacco control efforts of other healthcare systems (in part due to a lack of primary care), the VA was one of the first healthcare systems to make all hospitals in the system smoke free.[31] In spite of occasional difficulties,[32] this trend has continued over time, with the elimination of tobacco sales from VA canteen stores and increasing restrictions on where patients and staff can smoke. There is no evidence indicating whether these restrictions on smoking in the VA have had any effect on rates of treatment or of actual cessation. They do, however, have face validity and send a clear message that smoking is discouraged.

One of the leading sites in environmental restrictions on tobacco use is the Minneapolis VA Healthcare System, which is moving towards making the entire campus smoke free. At this time, smoking is allowed in two outdoor smoking areas and in two smoking shelters (one for patients and one for staff). The outdoor areas were due to be closed in the fall of 2004. This will leave the two smoking shelters, which are there by Congressional mandate,[32] as the only places on the campus to smoke. Two areas in which VA facilities can focus their efforts are in ensuring that public bans on smoking are actually enforced and making sure that smoking areas include information on resources available for quitting.

Smoking and Tobacco Use Cessation Technical Advisory Group

Within the VA, the Public Health National Prevention Program is responsible for all smoking and tobacco use cessation programs and policy. Charged with advising the Director of the VA Public Health National Prevention Program on issues related to tobacco control, the Smoking and Tobacco Use Cessation Technical Advisory Group (TAG) is comprised of a diverse group of researchers, clinicians, administrators, and educators.

The TAG has used a data-driven approach to tobacco control, trying to identify strategies that would have a major effect on the population of smokers. The group identified the biggest performance gap as the large group of patients who are interested in quitting smoking and had made a quit attempt, yet did not receive any assistance in that attempt. Previous data showed

that over 60 percent of smokers using the VA had made a quit attempt in the prior year,[9, 33] yet only seven percent received medications to help them quit.[34] Furthermore, of smokers surveyed in 1999, 80 percent of those interested in quitting reported that they did not receive the services they needed to help them quit.[34] Since the VA provides health care for approximately 1.5 million smokers, this would translate into 900,000 veterans who tried to quit each year, of whom most (600,000-750,000) were not assisted in quitting. The TAG decided in 2003 that its top priority was to increase the rate of treatment among patients trying to quit, and it initiated several efforts which are outlined below. While these are in most cases supported by literature in other systems, we do not yet have data on their effectiveness within the VA.

- *Increasing availability of smoking cessation medications*: The first TAG initiative was to remove restrictions on smoking cessation medications. Prior to this time, nearly all VA sites had smoking cessation medications available, but at over 60 percent of sites they were restricted to smoking cessation programs.[7, 8] Since existing data[9, 33] showed that the majority of patients did not attend these programs, this was an attempt to shift the focus of treatment from smoking cessation clinics (a specialty care model) to primary care. After extensive negotiations with VA leadership in pharmacy, medical care, administration, and other areas, the TAG was able to change the national policy. Under the new policy, sites can not place restrictions on prescribing smoking cessation medications within primary care.[35] Current efforts are focusing on developing strategies to increase adherence to the new policy. This is also covered in Dr. Hamlett-Berry's article.

- *Decreasing financial barriers to treatment:* Since studies showed that co-payments act as barriers to use of smoking cessation services,[36] the second initiative, also covered in more detail in Dr. Hamlett-Berry's article, was to decrease patients' out-of-pocket cost for treatment. It was approved in July 2004, with plans to implement it in October 2004 (the beginning of the fiscal year). However, further review suggested that the policy could not change without a revision of federal regulations. The proposed regulatory change is being published in the Federal Register to allow for public comment. It will then undergo review by the Office of Management and Budget.

- *Creating a national database of smokers within the VA:* Nearly all VA sites use electronic clinical reminders for smoking cessation that are embedded within the VA's electronic medical record system. Unfortunately, the data from the clinical reminders (which includes smoking status and counseling provided) are stored locally, and there is no consistent data format from one facility to another. The TAG is leading efforts to standardize the clinical reminders into one national clinical reminder for smoking cessation, which would then allow the creation of a national VA registry of smokers. That in turn would allow for targeted interventions as well as a disease management approach to smoking. This effort, however, is still at least one to two years away from completion.

Smoking Cessation Guidelines and Performance Measurement

Over the last 10 years, the VA has done an outstanding job at improving the rate of *asking* about smoking and *advising* smokers to quit, thanks in large part to performance measurement. In 1997, the VA mandated that the Agency for Health Care Policy and Research smoking cessation guideline be implemented throughout the VA. After adherence to the guideline was mandated, performance began to be measured. The level of adherence became part of the performance package for each facility's director, and was tied directly to salary and job-performance evaluation.

Ward and colleagues[39] reviewed the level of adherence to the smoking cessation guidelines between 1996 and 1998 at every VA facility, using data from both chart review and a national patient survey. They found a huge performance improvement between September 1996 and September 1997. During this interval, the rate of asking about smoking increased from 61 percent to 86 percent and the rate of advising smokers to quit increased from 48 percent to 78 percent. One year later, the rates had increased still further, to 95 percent for screening and 93 percent for advice.

This performance improvement represents a remarkable change in a short period of time. Health care systems are generally very satisfied with a three to five percent improvement in one year. The VA improved screening by 25 percent and advice by 30 percent. Did these represent real process improvement or merely better documentation? Our guess is some of both. In the same article, Ward et al.[37] found that the rate of advice by patient survey was 76 percent in 1996, 79 percent in 1997, and 78 percent in 1998. Clearly, some of the remarkable improvement came from simply documenting what (based on patient survey) was already happening. Nevertheless, the inescapable conclusion to these changes is that performance measurements matter. If you measure performance and hold people accountable, performance improves, often dramatically.

Given this rapid improvement in performance, the TAG made performance measurement a top priority. To push the standard of care further, the two measures that have been proposed for 2005 are:

1. Did a VA doctor or nurse ask you if you were interested in quitting smoking?
2. (If interested,) were you offered treatment to help you quit smoking?

Concurrent with these changes was an effort to revise the VA's own national clinical practice guidelines for smoking cessation. The VA and the DoD had jointly written clinical practice guidelines for smoking cessation in 1999, which outlined the best practices with respect to smoking cessation treatment. The new 2003 VA/DoD guidelines[6] are notable for three changes from the previous version. First, they take a public health approach to tobacco control, looking at the entire population of tobacco users rather than just those willing to attend a treatment program. Second, they unequivocally state that all tobacco users should be offered treatment (counseling and medications) in the *most intensive setting that they are willing to attend*, therefore reinforcing primary care-based treatment if that is what the patient

chooses. The third change is that the guidelines include an entire section and algorithm on prevention of tobacco use. From the short-term perspective this is not an important issue for the VA, since patients who will start smoking have almost all done so by the time they enroll with the VA. However, it is a very important issue for the DoD, which has responsibility for a tremendous number of men and women at exactly the age when tobacco use is often initiated. The VA fully supported the prevention part of the guidelines because it is the right thing for the DoD to do, and also because better prevention means fewer smokers enrolling in the VA in subsequent years.

Public Health Approach

Perhaps the most significant tobacco control intervention within the VA has been one of the least complicated—taking a public health approach. The traditional medical approach has been to focus on *content* rather than *context*, on developing the best possible program with relatively little attention to how to get people to participate. In using a public health approach supported by health services research, the VA is doing the opposite. It is focusing on interventions that are known to be at least moderately effective (the content) and ensuring that it reaches the widest possible audience (the context). This approach underlies many of the interventions outlined in this paper, particularly recruitment strategies; programs to increase use of telephone counseling and improve treatment in primary care and mental health; all of the system-level strategies; and, in fact, this entire conference itself.

Discussion

Let us return one final time to our initial scenario of the play without an audience. After consulting with experts in marketing, you decide to use a multifaceted strategy, targeting theater-goers and critics, in addition to a variety of systematic changes to make your theater more noticeable and desirable (what might be called "publicity"). The combination of these efforts dramatically increases attendance. In addition, that increased attendance itself further increases attendance, as satisfied theater-goers tell their friends and family about your play. We hope to use the same scenario for tobacco control within the VA. We have outlined a wide range of best practices that either currently are in place or will be shortly, examining interventions at the patient level, provider and clinic level, and system level. It is likely that these practices will significantly increase the rate of tobacco use cessation treatment in the near future, as well as the rate of actual cessation.

Our hypothetical director benefited from marketing advice and so can we. In looking over the strategies, we can see many places where there is room for improvement or wonderful opportunities. Table 1 includes our list of strategies for which there is good evidence right now, as well as promising strategies which merit consideration and further study. Let us hope that, just like the director in our scenario, we can continue to improve tobacco control within the VA. Our patients will live longer and healthier lives, and we will be able to feel satisfied that we have made a large impact on the leading preventable cause of death in the United States.[38]

Table 1: Recommended evidence-based strategies to improve tobacco control efforts and promising strategies needing further evaluation

	Evidence-based strategies that should be effective and are ready for implementation	Promising strategies that should be effective but need further study
Patient-level strategies	1. Recruitment by direct mailing	1. Web-assisted tobacco interventions 2. Incentives for patients
Provider- and clinic-level strategies	2. Programs to increase use of telephone counseling 3. Programs to support the primary care or mental health care provider 4. Audit and feedback 5. Smoking cessation program for hospitalized patients	
System-level strategies	6. Newer, more challenging performance measures 7. Remove co-payment from smoking cessation treatment	3. Provide free smoking cessation medications

Figure 1: Card used in Mental Health waiting room at VA Puget Sound Health Care System, Seattle, WA

I WANT TO
STOP SMOKING!

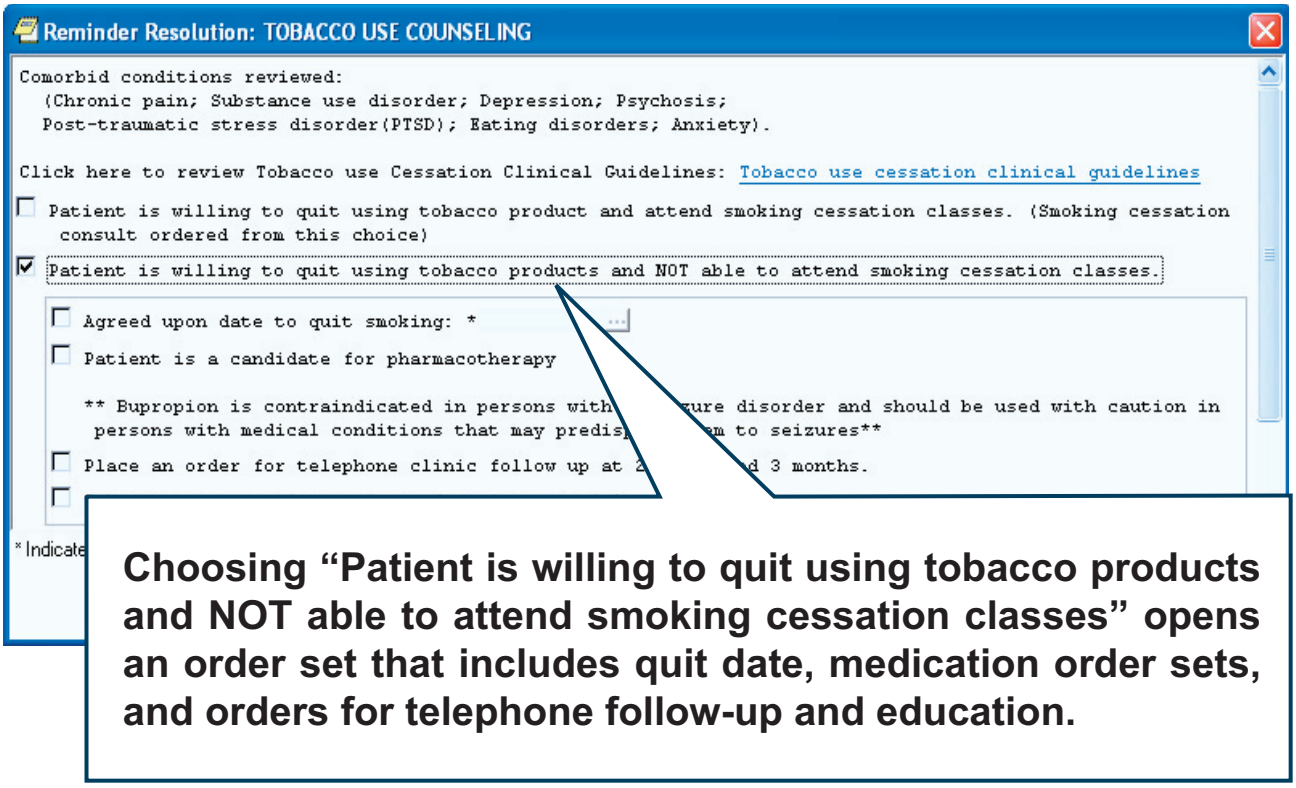
Please enroll me in the
Outpatient Mental Health Service
Smoking Cessation Program

Give this card to your
mental health provider

This card could also be adapted to reflect the range of choices available at a site. For example, there could be a place for the patient to check whether he or she wanted to:

- Attend the smoking cessation program (higher success rate/6 visits to clinic)
- Have a telephone counselor call me (higher success rate/3 telephone calls)
- Be treated by my regular doctor (lower success rate/1 or 2 visits to my doctor)

Figure 2: Screen shot of computer-based program to support smoking cessation treatment by primary care providers – developed by the Erie, PA, VA Medical Center



This approach simultaneously addresses two issues—support and education. It supports providers by automating the tasks that they will likely need, such as ordering medications and arranging follow-up. It also provides ongoing education, as can be seen with the warning above that "bupropion is contraindicated in persons with a seizure disorder."

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are trying to quit each year to use these highly effective strategies? I can't say that we have yet worked this out, but I am certain that a combination of different modalities for accessing treatments, combined with barrier-free access to such treatments, will provide some of the answers. In a large study we recently published in *Preventive Medicine,*[1] in which we provided counseling and medications easily as part of a primary care visit, more than 50 percent of smokers utilized the treatments, often selecting more intensive counseling when it was readily available. We were able to do this in both inner city Milwaukee and more suburban Madison, Wisconsin. The central challenge of increasing patient demand for tobacco dependence treatments, including among VA patients, should take up more of our attention.

I want to end on a positive note: the incredible public health success we have achieved over the last forty years. First, by cutting prevalence in half from about 44 percent in 1964 to about 22 percent today. Second, by citing a statistic that we all can be proud of: we have created a society in which there are now more former smokers than current smokers. We still have a long way to go, but what an incredible public health success. We should celebrate this achievement. This success results from the hard work of an army of clinicians, researchers, and tobacco-control activists who have labored long and hard. Many of them are in this room, but I want to highlight two such champions.

Richard Hurt has been a model to me of the consummate physician researcher, and tobacco-control activist. He has completed some of our best translational science for treating tobacco dependence; he has developed what I believe is the best comprehensive program for treating tobacco dependence in the nation, the Mayo Nicotine Dependence Center; and he led the fight against the tobacco industry as Minnesota completed its successful landmark legal battle against big tobacco in the late 1990s. On a personal note, when I left government in 1988 and attempted to start a program at the University of Wisconsin, I turned to Dr. Hurt who guided me in many ways, including recommending me for participation in my first clinical trial on treating tobacco dependence.

The second person, a giant in our efforts to bring tobacco dependence to the front of our national public health agenda, is former Surgeon General C. Everett Koop. Dr. Koop is a master, far ahead of his time: passionate, effective, and willing to take on foes as large as the tobacco industry and an administration that did not share his recognition of the importance of this issue. I want to set the record straight from my perspective: we would have achieved little of the success we now celebrate today without the tireless leadership of Dr. Koop.

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[1] Fiore MC, McCarthy DE, Jackson TC, Zehner ME, Jorenby DE, Mielke M, Smith SS, Guiliani TA, Baker TB. Integrating Smoking Cessation Treatment into Primary Care: An Effectiveness Study. *Prev Med.* 2004;38:412-420.

COMMENTARY ON BEST PRACTICES

Michael Fiore, M.D., M.P.H.*

I want to start by thanking the organizers of this conference for highlighting the potential of the VA to serve effectively in the role of vanguard. How is it achieving this goal? It is doing so, first, by ensuring universal access to evidence-based treatments and encouraging demand by veterans for these treatments; the VA has gone a long way toward setting the standard. Second, the VA is serving as a model for both the public and private sectors. As initiatives such as Addressing Tobacco in Managed Care (funded by The Robert Wood Johnson Foundation) have shown, successful real world models can be as important as the evidence in stimulating federal and state officials to adopt policy changes that ensure treatment of tobacco dependence.

As I listened to the thoughtful presentations of Drs. Hurt and Sherman and read their papers regarding best practices, I was struck by the potential to intervene at two separate levels: first, at the level of the smoker, and second, at the systems level where policies can be put into place. I want to highlight a couple points regarding each level.

The Patient Level

- The VA population highlights something that our group in Wisconsin has focused on extensively over the last decade: the heterogeneity of smokers. There are differences in level of dependence and in the withdrawal trajectories that smokers experience upon quitting, and these differences have to be particularly important among patients with co-morbid conditions such as post-traumatic stress disorder and alcohol use. These differences argue for a menu of evidence-based strategies—the sorts of counseling and medication approaches identified in the U.S. Public Health Service (USPHS) Guideline, *Treating Tobacco Use and Dependence*—supplemented by approaches that recognize the heterogeneity of smokers. As an example, there is a need to consider extending medication for a prolonged period of time in individuals with withdrawal symptoms that last for months and for those who become depressed upon successful quitting.
- The issue of heterogeneity brings me to my second point: the need to find a balance between the effectiveness of a treatment and the population-wide reach of that treatment. The USPHS Guideline completed a number of meta-analyses that documented the finding that more is better. In particular, a more intensive counseling intervention—one that is thirty or more minutes, over four to seven sessions—yields higher sustained quit rates. At the same time, however, we know that such treatments have limited reach. Most smokers self-select away from intensive interventions. Because of this, and the potential for less

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intensive interventions to have a greater population-wide impact, interventions such as evidence-based quitlines have the capacity to dramatically reduce the rates of smoking across a state or even nationally more than intensive interventions.

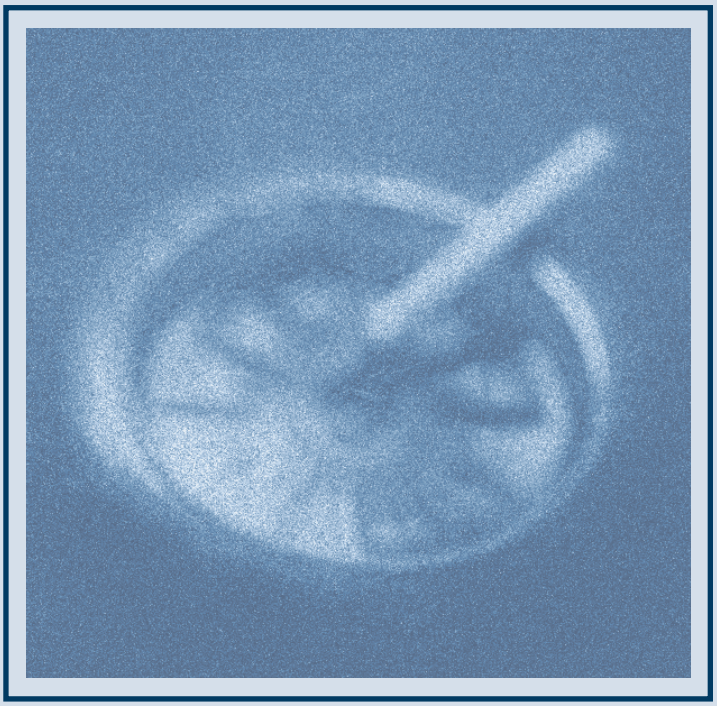
- If I would express my bias, it is toward interventions with greater population-wide reach—brief evidence-based interventions such as quitlines, and brief clinic-based interventions that can be provided to the 30 million smokers each year who visit primary care settings.
- While biased towards brief, greater reach interventions, the success of the really well done *comprehensive* program, such as that designed by Dr. Richard Hurt at Mayo, could be generalized across the VA system if the system intends to implement the most effective program. In the Mayo model, there is the option of intervening at multiple levels of intensity—both in terms of counseling and pharmacotherapy. In an ideal system, such as the proposed VA system, such a comprehensive system providing treatment across a continuum of intensities should be developed.

The Systems Level

In terms of systems level policy interventions, a couple of points are worth emphasizing:

- First, we have heard that the time of hospitalization is a powerful, potential moment of intervention for smokers. I am encouraged by the recent JCAHO policy change that scores health care systems based on whether tobacco dependence treatments are provided to patients admitted with the diagnoses of congestive heart failure, community acquired pneumonia, and acute myocardial infarction. In my view, such scoring should be extended to *all* admissions because when institutional changes are made to ensure that smoking cessation is universally available, I am convinced it will make a difference in terms of system wide quit rates. I was struck by the statement in Dr. Hurt's paper that we need to make it as easy to provide tobacco cessation counseling in hospitals as it is to order a chest X-ray. What a great goal for the VA system!
- Another systems-level policy change that the VA exemplifies is that coverage for evidence-based tobacco dependence treatments is *not* a dichotomous variable; that is, systems don't just have or not have coverage. I am increasingly concerned about coverage systems that, in fact, provide a disincentive to smokers to utilize available tobacco dependence treatments. Health plans can tout their expansion of coverage for a medication such as bupropion or the nicotine lozenge, but if it comes with so many strings attached—attending intensive group or individual counseling sessions over a long period of time—the coverage becomes meaningless.

This highlights what I see as a central challenge in the new century for all of us in tobacco control and one that has particular relevance to the VA system: now that we have an expended armamentarium of evidence-based counseling and medication treatments, we must increase demand for those treatments. How do we convince the millions of smokers nationally who



TOPIC THREE

Racial and Ethnic Minorities

Smoking Cessation in U.S. Ethnic Minority Populations

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The prevalence of smoking has decreased among all ethnic groups in the United States (it now stands at 22.5 percent) but smoking rates for ethnic minorities and those of low socioeconomic status remain higher, particularly among American Indians and Native Alaskans (40.8 percent prevalence rate). A comprehensive review of published studies among ethnic minorities reveals that smoking cessation programs focused on African Americans achieved mixed results; those focused on Hispanics/Latinos were efficacious; those focused on American Indians and Native Alaskans were inconclusive (due to a paucity of data); and those focused on Vietnamese showed mixed results. Since smoking prevalence, age at initiation, patterns of tobacco use, and factors associated with smoking behavior are not consistent across ethnic minorities and sub-groups of ethnic minorities, clinicians and researchers should not presume a given treatment will be effective for all smokers. Only three studies of the effectiveness of pharmacotherapies on ethnic minorities have been conducted; additional research needs to be undertaken.

Tobacco use, especially cigarette smoking, is the leading cause of preventable diseases in the United States.[1] It is responsible for more than 435,000 total deaths and more than 30 percent of all cancer deaths each year.[2] Despite considerable prevention and intervention efforts, approximately 50 million adults in the United States still smoke cigarettes.[3] A recent report by the Centers for Disease Control and Prevention showed that, in 2002, approximately 22.5 percent of adults in the U.S. were current smokers. This prevalence is slightly lower than the 22.8 percent prevalence among U.S. adults in 2001, and substantially lower than the 24.1 percent prevalence in 1998. However, the rate of decline has not been at a sufficient pace to achieve the 2010 national health objective, which is to reduce the prevalence of cigarette smoking among adults to ≤12 percent.[4]

Furthermore, the decline in the smoking rate is not universal across all sub-populations of smokers, and smoking rates for certain segments of the population (e.g., low socioeconomic status and ethnic minorities) remain considerably higher.[5] Although numerous research studies have demonstrated efficacy of behavioral and pharmacological smoking cessation

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interventions, these studies have largely focused on majority populations. Limited information is available about the effectiveness of these interventions in ethnic minority populations.

Because the patterns of cigarette smoking are different between Caucasian and various ethnic populations in the United States, there is a need for readily available, current, and reliable information about smoking cessation among various ethnic minority populations. The purpose of this paper is to provide a comprehensive summary of the state of current knowledge on smoking cessation among ethnic minority populations in the United States. Ethnic minorities discussed include African American, Hispanic/Latino, American Indian/Alaskan Natives, and Asian/Pacific Islander. We have limited our reviews to these minority groups since national-level tobacco use surveillance data are reported for them.[6]

Smoking Prevalence and Trends

African Americans

In 2000, African Americans made up 12.3 percent of the U.S. population.[6] This is projected to increase to 15 percent by the year 2050.[6] Overall, the prevalence of cigarette smoking among African Americans has declined from 37.3 percent to 22.4 percent between 1980 and 2002.[7] Over the same period, prevalence of smoking among African American men declined from 45.0 percent to 27.1 percent, while the prevalence among African American women fell from 31.4 percent to 18.7 percent. The magnitude of decline in smoking prevalence also differed by age, with African Americans aged 18-34 years of age experiencing the largest decline (from 38.7 percent to 21.0 percent), and those aged 55 years and above experienced the smallest decline (from 26.5 percent to 23.5 percent).[8] The pattern of tobacco use varies within and among U.S. racial/ethnic minority groups.[6]

One of the most striking differences in the smoking patterns between African Americans and Whites is the preference for menthol cigarettes by African Americans. Whereas approximately 80 percent of African Americans smokers smoke menthol cigarettes, the proportion among Whites is only about 20 percent.[9] Furthermore, African American smokers reported smoking an average of 15 cigarettes per day (compared to 25 cigarettes per day for Whites).[10] The higher proportion of light smokers in African Americans compared to Whites persists even after adjusting for employment status, blue/white collar status, education and income.[11] While African Americans generally smoke fewer cigarettes, they show a preference for high tar/nicotine (>1.0 mg nicotine/cigarette) and mentholated cigarettes, they inhale more deeply with the capacity to achieve higher net indexes of smoke inhalation, and they have a slower rate of nicotine metabolism.[9, 12, 13] African Americans also begin smoking later in life compared to Whites.[9, 14] In addition, African Americans are more likely to attempt to quit smoking than Whites in any given year.[15, 16] However, the success rate is 34 percent lower for African Americans than it is for Whites.[15, 16] Despite smoking fewer cigarettes per day, African Americans experience disproportionately higher rates of smoking-related health consequences.

[17] African Americans have the highest incidence rates of all cancers combined, and the highest overall cancer mortality rates compared to other racial/ethnic groups.[17]

Hispanic/Latino/Mexican Americans

Hispanic/Latino/Mexican Americans constituted 11.1 percent of the US population in 2000 and are projected to increase to 21.1 percent of the population by the year 2050.[6] Cigarette smoking among Latinos in the United States falls well below the national average, and decreased from 30.1 percent in 1980 to 16.7 percent in 2002. However, during this period of time, the total number of Latinos in the U.S. increased from 14.6 million (6.4 percent of the total population) to almost 38.5 million (13.4 percent of the total population). Therefore, while Latino smoking prevalence has declined, the total number of Latino smokers has increased, and smoking remains the leading preventable cause of morbidity and mortality for the U.S. Hispanic population.[6, 18] Within this population, adult males are approximately twice as likely as females to be current smokers (22.7 percent vs. 10.8 percent, respectively; see Table 1). From 1991 to 2001, cigarette smoking among Hispanic high school students in the U.S. peaked at 32.9 percent in 1995 among females and 35.5 percent in 1997 among males.[19] By 2001, prevalence among this group decreased to 26.0 percent for females and 27.2 percent for males. Hispanic students are similar to white non-Hispanics in trying cigarettes (69.3 percent vs. 64.8 percent respectively), but are less likely to report frequent smoking (7.3 percent vs. 17.2 percent).[19] Compared to non-Hispanic peers, Hispanic youth are more likely to describe smoking as being disrespectful to parents and as resulting in harsher consequences.[20]

Like other minority populations, a host of cultural, ethnic, environmental, and social factors are related to Latino smoking. For example, lower socioeconomic status is associated with higher rates of smoking,[7] and one in five Hispanics live in poverty. Rates of smoking are higher for Latinos who do not complete high school, [6] and for those who are born outside of the United States.[21] Compared to other U.S. minority groups, Hispanics have the highest proportion of individuals who speak a language other than English (77.8 percent).[6] Overall, it is unclear to what extent Latino culture and level of acculturation are smoking risk or protective factors.[22] Value and concern for family within the Latino culture may play a role in promoting abstinence by motivating family members to seek tobacco treatment.[23]

According to the 1998 Report from the Surgeon General, Hispanics are less likely than White non-Hispanics to participate in smoking cessation programs or to receive advice about stopping smoking from their healthcare providers.[6] Potential barriers to interventions include language, literacy, healthcare access, and socioeconomic factors. Interventions targeted at this population must be language appropriate, considerate of cultural values, mindful of barriers to treatment, and must include practical information about health risks, resources, and specific strategies for stopping tobacco use.[6]

Considerations for tailoring interventions may include recognition of the Hispanic population's diversity, variations by country of origin, acculturation, generational status,

stressors related to immigration status, and specific tobacco use patterns within various ethnic communities.[24] Culturally tailored Spanish-language smoking cessation guides have been developed [25] and used within community-wide interventions targeting low acculturated Latino smokers to promote cessation.[21, 26, 27] Recent public health campaigns in California and Massachusetts have attempted to (a) tailor culturally competent and relevant tobacco control messages for Hispanic populations, (b) increase awareness of tobacco-related health risks and treatment resources, and (c) offer telephone counseling to Spanish-speaking smokers. While these public health efforts have had some success, the National Latino Counsel on Alcohol and Tobacco Prevention emphasized the critical need for further advancement of tobacco-control prevention and treatment interventions developed expressly for the special needs of Hispanic Americans.

American Indian/Alaska Natives

American Indian/Alaska Natives constituted 0.8 percent of the U.S. population in 2000 and are expected to increase to 1.1 percent of the population by the year 2050.[6] There are over 500 federally recognized tribes in the United States, with a total of approximately two million people self-reporting American Indian or Alaska Native status. Since July 1, 1990, the U.S. population of American Indians and Alaska Natives has increased by 10.4 percent. The number of American Indians and Alaska Natives is expected to increase steadily to 3.1 million in 2020 and 4.4 million in 2050. Major subgroups in this population are American Indians, Eskimos, and Aleuts. Most American Indians and Alaska Natives have settled across the country; the largest percentage resides in Oklahoma (13 percent).[28] Although many tribes consider tobacco a sacred gift and use it during religious ceremonies and as traditional medicine, the tobacco-related health problems they suffer are caused by chronic cigarette smoking and spit tobacco use. Because of the cultural and geographic diversity of American Indians and Alaska Natives, tobacco use often varies widely by region or subgroup.[29]

A considerable decline in the prevalence of smoking among American adults has been observed from 42 percent in 1965 to 22 percent in 2002.[30] However, the prevalence of current smoking remains highest among American Indians/Alaska Natives, with a smoking prevalence of 40.8 percent.[30] Table 1 shows that the smoking prevalence among all ethnic groups decreased from 1980 to 2002 for both males and females. The only exception is among Native American females, whose smoking prevalence actually increased from 34.1 percent to 40.9 percent. Smoking rates and consumption among American Indian/Alaska Natives vary by region and state. Smoking rates are highest in Alaska (45.1 percent) and the North Plains (44.2 percent), and lowest in the Southwest (17.0 percent).[29] The prevalence of heavy smoking (25 or more cigarettes per day) is also highest in the North Plains (13.5 percent). Compared with Whites, American Indian/Alaska Natives smoke fewer cigarettes each day. The percentage of American Indians and Alaska Natives who reported that they were light smokers (smoking fewer than 15 cigarettes per day) was 49.9 percent, compared with 35.3 percent for Whites.[8]

American Indian/Alaska Native smokers have more difficulty trying to quit smoking than other ethnic groups; their quit ratios are significantly lower than non-Indians.[31] In 2000, 70 percent of smokers said they wanted to quit, and 41 percent made a quit attempt of at least one day, but only 5 percent succeeded in quitting for three months or more.[32] Also, American Indians and Alaska Natives are among the least successful in maintaining long term abstinence. In 2000, 41 percent of all Native Americans who had ever smoked reported that they had successfully quit, compared with 51 percent of Whites.

Asian/Pacific Islanders

The six largest subgroups of Asian Americans are from China, the Philippines, Japan, Asian India, Korea, and Vietnam. Hawaiians, Samoans, and Guamanians are the three largest Pacific Islander subgroups. Although Asian Americans reside across the country, approximately 66 percent live in California, Hawaii, Illinois, New York, and Texas. Approximately 75 percent of the Pacific Islanders' population live in just two states—California and Hawaii. The Asian American population nearly doubled in size from an estimated 3.5 million in 1980 to almost seven million in 1990, while Pacific Islanders population grew by 41 percent between 1980 (259,566) and 1990 (365,024).[33] Currently at 10.6 million people (about 4 percent of the total U.S. population), Asian Americans and Pacific Islanders are projected to reach 41 million U.S. residents (11 percent of the total U.S. population) by the year 2050.

Asian Americans have the lowest smoking prevalence among all ethnic groups. Their smoking prevalence in 2002 was 13.3 percent overall, with men having a higher prevalence rate (19.0 percent) than women (6.5 percent). Research shows an association between cigarette smoking and acculturation among Asian American and Pacific Islander adults from Southeast Asia. Those who had a higher English-language proficiency and those living in the United States longer were less likely to be smokers.[29] However, among Chinese men, the average number of cigarettes smoked per day increased with the percentage of their lifetime spent in the United States. Among Vietnamese, the prevalence of smoking was higher among men who immigrated to the United States in 1981 or later and who were not fluent in English. Among current smokers, Asian Americans and Pacific Islanders were slightly more likely

Table 1. Percentage of persons aged ≥ 18 years who were current smokers by ethnicity/race (National Health Interview Survey, United States, 1978/80, 2002)

	Men		Women		Total	
Race/Ethnicity	1980	2002	1980	2002	1980	2002
White, non-Hispanic	36.8	25.5	30.5	21.8	33.5	23.6
Black, non-Hispanic	45.0	27.1	31.4	18.7	37.3	22.4
Hispanic	37.6	22.7	23.3	10.8	30.1	16.7
American Indian/Alaska Native	63.0	40.5	34.1	40.9	48.2	40.8
Asian	32.5	19.0	14.7	6.5	23.8	13.3

Source: Centers for Disease Control and Prevention

than White smokers to have quit for at least one day during the previous year (32.0 percent, compared with 26.0 percent). Asian Americans and Pacific Islanders (2.5 percent), however, are less likely than Whites (3.4 percent) to remain abstinent for one to 90 days. According to aggregated 1994–1995 National Health Interview Survey data, the prevalence of cessation among Asian Americans and Pacific Islanders aged 55 years and older was higher than among younger Asian Americans and Pacific Islanders.

Clinical Practice Guidelines

Recommendations for the treatment of tobacco dependence are found in the United States Public Health Service (USPHS) Report, *Treating Tobacco Use and Dependence: A Clinical Practice Guideline*.[34] The report was developed by a panel of 30 experts after a review of 6,000 articles from the tobacco research field. This review demonstrated that nicotine dependence treatments have been shown to be effective across different racial and ethic minority groups. Because of these findings, the explicit recommendation was made that members of racial and ethnic minorities should be provided treatments shown to be effective in the guideline.

Specifically, healthcare providers are instructed to assess tobacco use consistently, in order to deliver at least brief interventions to all individuals who currently use tobacco or to those who are in the early period of abstinence. Interventions as brief as three minutes can have a significant effect on smoking abstinence. For individuals who have recently stopped smoking, providers should reinforce the decision to stop and help resolve any residual problems arising from stopping (e.g., depressed mood, weight gain), using prescriptive interventions as needed. For tobacco users who are not ready to make a stop attempt, a brief motivational intervention can help identify the personal relevance of tobacco use, risks of continued use, and rewards of stopping. In addition, tobacco users can be educated that effective treatment options exist and that the provider is available to assist future stop attempts.

Providers can assist individuals interested in making a stop attempt by helping set a stop date, aiding the development of a cessation strategy, encouraging additional support, and recommending pharmacotherapy for those without medical contraindications. Further, the guideline provides specific prescribing instructions for clinical use of pharmacotherapy and brief counseling strategies. First-line pharmacotherapies include nicotine replacement therapy (NRT; gum, patch, nasal spray, inhaler, lozenge) and sustained-release bupropion. The extended use of these medications does not present a known health risk, and may facilitate long-term abstinence. There is also evidence that combined pharmacotherapy (e.g., combination NRTs, combined bupropion and NRT) may increase long-term abstinence rates and may present an appropriate treatment option for some tobacco users.[34-36]

Findings across studies clearly demonstrate a dose-response relationship between nicotine dependence treatment intensity and long-term tobacco abstinence.[34] Intensive interventions produce higher success rates and are more cost effective than less-intensive interventions. Intensive interventions may combine pharmacotherapy with multiple (four or

more) individual or group sessions (≥30 minutes total contact), telephone counseling, adjunct self-help materials, and follow-up assessment. These interventions emphasize practical skills training, problem solving, and social support.

Relatively few studies have examined nicotine dependence treatment interventions designed for specific ethnic or racial groups. However, the guideline recommends interventions be tailored appropriately for ethnic or racial groups when possible. Communicating in a language understood by the individual tobacco user is essential, and incorporating cultural sensitivity and culturally appropriate material into the intervention may increase treatment acceptability.[34]

Methods

We conducted a Medline search of smoking cessation interventions on the ethnic minority populations of interest in the United States published from 1985 through 2003. Additional sources utilized for searches included PsychInfo, Social Science Citation Index, conference abstracts, personal files and contacts, as well as author searches from articles found from earlier searches. Search terms used to identify smoking cessation studies included smoking cessation, tobacco use intervention and treatment, and smoking clinical trials. Population-specific search terms used included African Americans, Blacks, Hispanic Americans, Latino, Mexican Americans, Native Americans, American Indians, Asian Americans, and Pacific Islander. To be selected for inclusion, a study must meet the following criteria: (a) have been conducted in adults 18 years or older, (b) have targeted one or more ethnic minority groups or have at least 10 percent of study participants come from ethnic minority groups, and (c) have reported smoking cessation rate as an outcome. Articles that met these criteria were reviewed by all authors to extract relevant information outlined in Table 2. Categories of information extracted from the articles were developed from similar previous reviews.[37, 38]

Results

African Americans

Table 2 shows a summary of 27 smoking cessation intervention studies with adult African Americans in the United States that met our inclusion criteria. Intervention content and duration, length of follow-up, and abstinence assessment varied across studies. Thirteen of these studies enrolled only African Americans while 14 studies also included Hispanic and/or White participants. Eight of the studies enrolled only women, including six studies that were conducted among pregnant patients. Fourteen studies were clinic-based and 13 were community-based.

Of the community-based studies, two were conducted in churches, and one each at work and school sites. All the community-based studies included interventions that used a combination of self-help materials (print, audio, or video) and counseling. Five community-based studies[39-43] showed that programs were more effective than usual care or no intervention control groups.

Three community-based studies and one clinic-based study compared culturally-tailored materials to standard smoking cessation materials.[42, 44-46] Only one of the studies that used culturally-tailored materials found significantly higher cessation rates among the group that received culturally tailored materials compared to standard non-tailored materials;[42] and this finding is from the authors' opportunistic evaluation of 12-month data on completers only. Further analyses limited to those who received the intervention in another study showed effectiveness of culturally tailored materials compared to standard materials.[45] Neither of the two church-based,[44, 47] one school-based,[48] or one work-site[49] community studies demonstrated effectiveness.[44, 47-49]

Six clinic-based studies demonstrated intervention efficacy. Four of the six studies conducted among pregnant patients demonstrated higher quit rates for intervention compared to usual care controls.[50-53] Of the clinic studies that failed to show program efficacy, one lacked a control group,[54] and the other used physicians in training as the unit of randomization.[55] In the latter study however, only about two-thirds of the physicians received smoking cessation training to be delivered to patients.[55] Pharmacological interventions were included in five clinic studies—one silver acetate,[56] three nicotine replacement therapies,[46, 57, 58] and one bupropion.[59]

Efficacy of pharmacotherapy was only assessed in three of the studies.[56, 57, 59] Non-pharmacological intervention components include videos, print materials, radio or television broadcast, and individual or group sessions. One of the pharmacological studies[58] was a secondary analysis of the Lung Health Study which evaluated whether African Americans (n=200) responded differently than Whites (n=2868) to a smoking cessation intervention program where no adjustments were made in recognition of cultural differences. In that study, although the treatment effect was stronger for Whites than for African Americans, over the five years of the study, there was a significant treatment effect for African Americans. Another pharmacological study[60] assessed the efficacy of silver acetate, which was not an FDA-approved product for smoking cessation, in a sample that included 50 percent African Americans. While the result of the study showed marginal significance for efficacy of silver acetate at three weeks, there was no benefit over the placebo at 12 months. Three of the pharmacological studies (two on the nicotine patch,[46, 57] one on sustained-release bupropion,[59]) were conducted among an exclusively African American sample, with both studies showing significantly higher quit rates compared to a placebo, both at the end of treatment and at six months follow-up. All the pharmacological studies were randomized and placebo-controlled. Efficacy at six months was demonstrated for nicotine replacement[57, 58] and bupropion[59] but not for silver acetate.[60]

All of the pharmacological studies provided self-help material (a printed manual, an audio cassette) or counseling. One of the studies[59] provided motivational interviewing counseling to participants in both intervention and control groups. Biochemical validation of self-reported smoking status was performed in 11 studies, the most common validation method being salivary cotinine (seven studies), followed by urinary cotinine (two studies), and serum

thiocyanate (one study). All but one[53] of the six pregnancy studies and all pharmacological interventions reported biochemically validated quit rates. All but four of the studies reported at least six-month outcomes with two studies reporting more than five-years' of outcomes. The most commonly reported outcomes were self-reported seven-day point prevalence and 30-day continuous abstinence.

Hispanics

Table 2 describes the ten published studies examining smoking cessation interventions with adult Hispanic smokers in the United States. Acknowledging and addressing language differences was common across studies. Nine of the ten studies included a guidebook or self-help manual available in Spanish or English.[25,48,51,61-66] Pérez-Stable and colleagues[25] developed the Spanish-language smoking cessation self-help guidebook, *Guia para Dejar de Fumar,* specifically for use with Hispanic smokers. The *Guia* includes motivational information, pictorial and written information about the health consequences of smoking, quitting techniques, coping and relapse prevention techniques, and testimonials from Latino smokers. In a single group, repeated-measures evaluation, the *Guia* was evaluated as part of a community-wide intervention, and participants demonstrated marked rates of smoking abstinence.[25] This guidebook has been evaluated in experimental studies with multi-component, community-based,[48, 64, 66] and clinical interventions,[63] and it demonstrated efficacy in promoting short-term[63] and long-term[64,66] smoking abstinence. Other English-language smoking cessation self-help materials have been translated into Spanish and used within effective multi-component interventions with Hispanic smokers.[51, 62, 65] In addition, a mood management guidebook for smoking cessation, *Tomando Control de Su Vida*, was evaluated with the *Guia* within a community-based, randomized study, and it produced increased abstinence for smokers with and without a history of major depressive episodes compared to the *Guia* alone.[64]

Three experimental studies[48,64,66] and one quasi-experimental study[61] evaluated community-based interventions using different modes of delivery. Studies evaluating a multi-component community intervention,[61] a self-help, mail-delivered intervention,[64] and an in-home intervention delivered by lay health advisors or "promotores" found significant increases in smoking abstinence among Latino samples. A school-based group counseling with tailored support intervention found no main effect on abstinence, but demonstrated potential utility of schools as a mechanism for reaching underserved communities.[48] An additional 50-minute intervention within a six-week smoking ban during U.S. Air Force basic military training was effective in promoting abstinence in participants from ethnic minorities (African Americans and Hispanics/Latinos), but not in non-Hispanic White participants.[67]

Four experimental, clinic-based studies have evaluated smoking cessation interventions with Hispanic participants.[51, 62, 63, 65] Of the two studies demonstrating short-term efficacy, one study found no long-term effects,[63] and one study found that positive effects of an intervention during pregnancy were not sustained postpartum among Latinas.[51] An additional study evaluating abstinence during pregnancy found no significant difference between the

intervention group (24 percent; received physician advice, self-help materials and peer counseling) and the control group (21 percent; received physician advice and self-help materials without peer counseling).[65] Leischow and colleagues conducted the only published report of pharmacotherapy treatment among Hispanic smokers.[62] Nicotine replacement therapy for ten weeks was effective in increasing abstinence at the end of treatment compared to a placebo (46 percent v. 26 percent, $p = 0.05$); long-term follow-up was not completed.[62]

Studies varied in the duration of intervention and length of follow-up. Length of follow-up ranged from the end of treatment to 12 months. Two studies involving multiple sessions demonstrated a dose-response effect of the intervention whereby participants who stopped smoking completed more sessions than participants who were smoking at follow-up.[63, 67]

Outcome measures varied across studies. While all of the studies in Table 2 included self-reported smoking abstinence, the definition of abstinence varied from unspecified point-prevalence to seven-day point prevalence to continuous abstinence. Studies reported collection of salivary cotinine,[25, 48, 51, 63, 64] breath CO,[61, 62, 65, 66] and urinary cotinine.[65] Biochemical verification was beyond the scope of one study (n=18,010).[25] Many studies were unable to complete biochemical verification for all self-reported abstainers. Protocols varied in cutoffs for abstinence validation. Reported discrepancies between self-report and biochemical measures ranged from 1.5 percent to 31 percent.[51, 63, 66] Three studies included reduction in cigarettes per day as an outcome measure.[27, 65, 68]

Assessment of demographics, smoking history, and social and psychological correlates of smoking behavior varied across studies. Six studies provided some information on the ethnicity or country of origin of participants.[25, 61-64, 66] The make-up of these samples reflects demographic differences across regions of the U.S. Three of five studies conducted in California reported samples with countries of origin from the U.S. (1-16 percent), Mexico (39-78 percent), and Central or South America (7-50 percent).[25, 66, 68] Studies from Arizona[62] and Texas[61] reported predominantly Mexican-American samples. Of two studies conducted in the Northeast, one reported participants originating from the U.S. (7 percent), the Caribbean (25 percent), and Central or South America (66 percent).[63]

Correlates and predictors of smoking abstinence were reported in four studies. Pérez-Stable and colleagues found older smokers (>44 years) were more likely to be abstinent at follow-up than younger smokers ($p = 0.04$).[25] They found no significant association between abstinence and spousal smoking, familial support, cigarettes per day, or acculturation.[25] Nevid and Javier found abstinence at the end of treatment was related to having children in the home ($p = 0.035$), fewer negative partner interactions ($p = 0.001$), and stronger baseline desire to stop smoking ($p = 0.014$).[63] No association was found between abstinence and self-efficacy.[63] Woodruff and colleagues reported baseline cigarettes per day were associated with abstinence ($p = 0.009$) [9]. Klesges and colleagues found that abstainers had lower nicotine dependence ($p < 0.001$) and greater motivation to stop smoking ($p = 0.003$).[67] Motivation to stop smoking moderated the intervention effect ($p = 0.05$), and that effect was stronger for minority participants.[67]

American Indians/Alaska Natives

Table 2 shows the published studies for smoking cessation for American Indians and Alaska Natives. Only a few studies utilized a randomized intervention design, and the others were either observational or single-group intervention with no comparison groups. The GAINS study[69] produced no differences in cessation rates between the intervention group compared to the control group. The median age of participants in this study was 35.6 years, and women accounted for almost two-thirds of the overall sample. Over 35 percent reported less than a high school diploma and fewer than 3 percent had completed college. The abstinence rates at 12 months for the two groups were 7.1 percent in the intervention group and 4.9 percent in the control group. When only the validated cessation was included, these percentages were 6.7 percent and 6.8 percent, respectively. The percentage of current smokers who made a least one quit attempt was higher in the intervention group (82.1 percent) compared to the control group (67.7 percent) (p=0.001).

The study by Hensel and colleagues[70] demonstrated quit rates among a clinic population of Native Americans that are comparable to the rates of other studies which have included both behavioral modification and transdermal nicotine patch. This study did not include a comparison group; however, it showed cessation rates of 30 percent at six months and 21 percent at 12 months. Findings also showed[70] that men had higher cessation rates than women, although not statistically significant, (43 percent and 24 percent, respectively). Finally, patients in the older age group (>45) had better cessation rates (p=0.055).

The study by Henderson[71] is a secondary analysis of baseline smokers from the Strong Heart Study, which is a longitudinal study of cardiovascular disease among American Indians. Predictors of smoking cessation were age, number of cigarettes smoked per day, duration of smoking, age of initiation, and history of diabetes.[71]

Asian/American-Vietnamese

Both studies in table 2 on the Vietnamese population were community-based interventions with a large media component to the intervention. One intervention was conducted in San Francisco,[72] and the other was carried out in Santa Clara, California.[73] The anti-smoking media campaign targeted towards the Vietnamese produced statistically significant differences between the intervention community and the control (Houston, Texas). The post-test current smoking rate was 33.9 percent in the San Francisco sample and 40.9 percent in the Houston or comparison community. The earlier study conducted in Santa Clara, California, did not produce statistically significant differences between the two communities.

Minority group	Author/year	Sample size	Description of intervention	Follow-up time	Biochemical verification	Outcomes	Limitations
African American	Jason et al. (1988)[39]	165 (96 percent African American)	Smokers were randomly assigned either to a comprehensive intervention or to a no-intervention control condition. The intervention consisted of providing the smokers with a self-help manual, the televised broadcast, weekly support meetings, and supportive phone calls.	4 months	None	At a 4-month follow-up, 20 percent of treatment participants were abstinent compared to 9 percent of controls.	High attrition rate. Smokers in the intervention had significantly higher pre-intervention motivation to quit smoking compared to controls. However, motivation was not significantly associated with quitting smoking.
African American	Hymowitz et al. (1991)[40]	7477 (20 communities)	This was a secondary analysis of MRFIT that examined the relationship between baseline variable and smoking cessation and relapse. Intervention group received specialized medical care, including counseling to address risk factors for coronary heart disease, while control received usual medical care.	6 years	SCN	At 6 years, 42.2 percent in the intervention group were abstinent compared with 27.1 percent in the usual care comparison group. In the first 12 months, cessation rates were 20.3 percent and 6.2 percent in intervention and control groups, respectively.	No difference in cessation rates between African Americans and Caucasians in either groups.
African American	Windsor (1993)[50]	814 (52 percent African Americans)	Randomized. Patients were randomly assigned to 2 groups (experimental or control). Patients in experimental group received individual and group counseling, printed materials, and social support in the form of a buddy letter, a buddy contract, and a buddy tip sheet. A sample of 100 smokers from other clinics served as historical controls.	32 weeks	Salivary cotinine	Quit rates were 14.3 percent, 8.5 percent, and 3.0 percent for the experimental, control, and historical control groups, respectively.	African Americans in experimental and control groups. Whites in these groups.
African American	Royce (1995)[54]	153	Cohort, non-randomized. Physicians and nurses previously trained in the NCI smoking cessation program received 3 one-hour booster sessions. Patients received a self-help cessation video ("KICKIT!"), and culturally-tailored manual and	7 months	None	At 7 months, the self-reported quit rate was 21 percent. An additional 27 percent reduced the number of cigarettes smoked per day by 50 percent.	Lack of comparison group. Only 50 percent of health care providers attended training sessions.

			newsletters, and a brief counseling from their personal physician.				
African American/ Hispanic	Lopes (1995)[74]	511 (72 percent African American, 18 percent Hispanic)	Single-group test-retest. Participants watched a 30-minute anti-smoking video, which was followed by a 10-minute group discussion.	6 weeks	None	Quit rate at follow-up was 4.6 percent.	Study included females only. Those lost to follow-up (30 percent) were disproportionately smokers.
African American/ Hispanic	Kendrick (1995)[75]	64 clinics, 5572 participants (16.4 percent African Americans)	Stratified randomized design. Clinics providing prenatal care were randomly assigned to intervention or control groups. Multi-component intervention, varied by state. Intervention generally took place at first prenatal visit and included a printed manual, behavioral exercises and individual counseling.	Varied (4-6 months)	Urine cotinine	Cotinine-verified abstinence rates were not significantly different between the groups (6.1 percent for intervention vs. 5.9 percent for control).	Self-reported abstinence was higher in intervention than control clinics.
African American/ Hispanic[a]	Lillington (1995)[51]	225[a]	Brief 15-minute counseling with a bilingual health educator, guidebook *Time for a Change: A Program for Healthy Moms and Babies*, booster postcard at one month, incentive contest.	9-month gestation 6- week post-partum	Salivary cotinine (completed from 45 percent of reported abstainers; 18 percent misclassifica-tion rate)	Quit rates (intervention vs. control) were 40 percent vs. 30 percent for Latinas, $p<0.01$; and 43 percent vs. 25 percent for total sample, $p<0.01$. 20 percent vs. 17 percent for Latinas, p=ns; 25 percent vs. 17 percent for total sample, $p<0.01$.	Intervention effective for total sample at both time points but significant effect for Latinas only at 9 months.
African American/ Hispanic	Berman (1995)[48]	446	Quasi-experimental design. Students K-12 and their parents were randomly assigned at school level to intervention and control. Intervention included Spanish *Guia para Dejar de Fumar* or English language self-help materials.	12 months	Salivary cotinine	No difference in quit rates between intervention and control groups at 12 months (16.9 percent and 16.3 percent, respectively).	High attrition (40 percent) at follow-up.
African American	Ahijevych (1995)[76]	66	Pilot, low intensity. 3-group design with repeated measures. Participants were randomly assigned to intervention, one-time cessation advice, or control groups. Individual nurse-delivered cessation counseling and 4-weekly mailing of cessation print materials.	3 months	Salivary cotinine	No participant in any of the groups had verified abstinence.	Study included women only.

African American	Hymowitz et al. (1996)[60]	500 (49 percent African American)	2.5 mg silver acetate lozenge and placebo, self-help materials, video. Randomized, double-blind, placebo-controlled.	12 months	Urine cotinine and/or carbon monoxide(co)	Silver acetate lozenge effective for short term (3 weeks—26 percent vs. 16 percent for placebo among those who used product), but not long-term smoking cessation (26 percent vs. 32 percent for placebo among initial quitters). African Americans were more successful in quitting than Whites.	Sample included 49 percent African Americans.
African American	Voorhees et al. (1996)[44]	22 churches	Randomized controlled trial. Churches were randomly assigned to either an intensive culturally-specific intervention or a minimal self-help intervention. Intervention include individual counseling and group sessions; print/video/audio.	12 months	Salivary cotinine and expired CO	Quit rates at follow-up were not significantly different between both groups (19.6 percent vs. 15.1 percent for intensive and minimal groups, respectively).	Participants in the intensive intervention group were nearly twice as likely to make positive progress in stages of change compared to minimal intervention group.
African American	Schorling et al. (1997)[47]	644	Intervention (individual counseling plus self-help materials) was church-based in a rural setting and also included community-wide activities such as gospel anti-smoking nights and a poster contest for children.	18 months	None	No significant difference in the primary outcome (30-day continuous abstinence) between intervention and control groups (9.6 percent vs. 5.4 percent, p=0.18). Intervention group made significantly more progress along stages of change than control group.	Baseline smoking prevalence higher in intervention than control.
African American	Gielen (1997)[77]	391 (85 percent African American)	Randomized. At their first prenatal visit, smokers were randomly assigned to an experimental (E) group to receive usual care plus prenatal and postpartum print materials and individual counseling or to a control (C) group to receive only usual care.	8 months	Salivary cotinine	Quit rates in the third trimester were 6.2 percent and 5.6 percent for the experimental and control groups, respectively.	Follow-up period was variable depending on when first prenatal visit occurred.

African American	Resnicow (1997)[45]	1364	Randomized cluster design. Adult smokers were randomly assigned to receive either a multi-component smoking cessation intervention (printed guide, culturally-specific video, and phone booster call) or health education materials not directly related to smoking.	6 months	None	At 6 months, point prevalence abstinence rates were 11.2 percent and 7.9 percent in intervention and control groups, respectively.	Only 31 percent were contacted for booster calls.
African American	Fisher et al. (1998)[41]	504 (3 intervention communities and 4 control communities), 80 percent African American	Quasi-experimental design. Community organization approach including smoking cessation classes, billboards, door-to-door campaign, "gospelfest."	24 months	None	Prevalence of smoking declined from 34 percent to 27 percent and from 34 percent to 33 percent in intervention and control communities, respectively. Smoking prevalence was reduced from 40 percent to 27 percent among those who were aware of the program.	Reduction in smoking prevalence was consistent across demographically-defined subsamples (e.g., age, gender, ethnicity).
African American	Gebauer (1998)[52]	178 (41 percent African American)	Prospective with control group, non-randomized. Fifteen-minute individualized intervention delivered by an advanced-practice nurse, combined with a telephone contact by an advanced-practice nurse 7-10 days after the clinic visit.	3 months	Salivary cotinine	Intervention group had an abstinence rate of 15.5 percent, compared with 0 percent in the control group.	African Americans were more likely to quit, compared with White participants who received the intervention.
African American	Orleans et al. (1998)[42]	1422	Radio-based media campaign. Participants were randomly assigned to receive standard smoking cessation counseling and a guide or counseling and a guide (*Pathways to Freedom*) tailored to African American smokers.	12 months	None	At 12 months, 7-day quit rates were 25 percent and 15.4 percent in the tailored and standard groups, respectively.	Tailored guide was rated as having more appealing photos and as being more appropriate for family members. Quit attempts and use of pre-quitting strategies were higher in the tailored than the standard groups.
African American	Darity (1998)	8 communities (2544 individual participants)	Quasi-experimental. Two types of interventions were implemented: active and passive. Active consisted of community organizing strategies, direct interpersonal educational activities, and mass media, while passive	18 months	None	At 18-month follow-up, quit rate was significantly higher in active intervention communities (16.7 percent) compared to passive intervention communities (11.8 percent).	

			intervention consisted of mass media only. Four communities received active intervention while the other 4 communities received passive intervention.				
African American	Ahluwalia (1998)[57]	410	Double-blind, placebo-controlled, randomized. Patients were randomized to receive 10 weeks treatment with nicotine transdermal patch (21mg/d for 6 weeks, 14 mg/day for 2 weeks, and 7 mg/day for 2 weeks) or placebo patch. All patients received the *Pathways to Freedom* guide, other print cessation materials, and an audiocassette.	6 months	None	Quit rates at 10 weeks were 21.5 percent and 13.7 percent, and at 6 months were 17.1 percent and 11.7 percent for the nicotine patch and placebo groups, respectively.	High attrition rates.
African American	Allen (1998)[55]	1086 patients; 106 resident physicians	Randomized. Resident physicians received 2-hour smoking cessation training. Patients were randomly assigned to receive brief (3-5 minutes) physician counseling or usual care (control).	12 months	Salivary cotininine/CO	Quit rates were 2 percent and 1.8 percent at 3 months, and 2.2 percent and 2.8 percent at 12 months in intervention and control groups, respectively.	Only two-thirds of the physicians received smoking cessation training.
African American	Ahluwalia (1999)[46]	500	A randomized, investigator-blinded trial, testing a culturally sensitive (CS) videotape and guide (*Pathways to Freedom*) against a commonly available videotape and guide alongside nicotine replacement, brief counseling, and booster phone calls. Results: A total of 500 smokers were enrolled and randomized, with 250 assigned to the CS and standard care (SC) arms. No differences were found in the primary endpoint, 7-day point prevalence at month 6, in the culturally sensitive and usual care groups (18.0 percent vs. 14.4 percent, p=.27). Additionally, no differences were found between	6 months	CO	7-day point prevalence quit rates at 6 months were 18.0 percent and 14.4 percent in the culturally sensitive and usual care groups, respectively.	Significantly more participants in the culturally sensitive group read most or all of the guide compared to those in the standard of care group (68.8 percent vs. 59.6 percent).

			groups for any of the secondary endpoints.				
African American	Lipkus (1999)[78]	160	Randomized. Patients were randomly assigned to one of three study groups: (1), provider prompting only (2), provider prompting with tailored print materials (3), provider prompting with tailored print materials plus tailored telephone counseling.	18 months	None	Quit rates at follow-up were 32.7 percent, 19.2 percent, and 13.2 percent in groups 3, 2, and 1, respectively.	Compliance with provider prompting was low (48 percent).
African American	Manfredi (1999)[53]	1747 (68 percent African American)	Matched-pair random assignment. Multi-component intervention included motivational video, posters, brief provider advice, reminder letter from provider, and chart flagging with "smoker" sticker.	2 months	None	Compared to controls, smokers exposed to the intervention were more likely to have quit (14.5 percent versus 7.7 percent), or take actions toward quitting, and had higher mean action, stage of readiness, and motivation to quit scores.	High attrition.
African American/ Hispanic	Klesges (1999)[67]	2,596	Randomized. All participants were under a 6-week ban from tobacco products. Seventy-five percent were randomized to a brief smoking cessation intervention, with the other 25 percent randomized to a control condition.	12 months	None	At 1-year follow-up, quit rates were 18 percent in intervention, compared to 17 percent in the control group.	Women, ethnic minorities, and those intending to stay quit at baseline were more likely to be abstinent.
African American	Murray (2001)[58]	200	Participants were randomized into one of three groups: smoking intervention (SI) with bronchodilator therapy, SI with placebo inhalers, and usual care. The SI consisted of a 12-week group program using cognitive behavioral approach with NRT.	5 years	Salivary cotinine/CO	At the end of the 5-year study, African Americans in the SI group had quit rate of 30 percent, compared to 15 percent in the usual care group.	This study was a secondary analysis of the Lung Health Study.
African American	Ahluwalia (2002)[59]	600	Randomized, double-blind, placebo-controlled. Participants were randomly assigned to receive 150			At 6 months, the quit rates were 21.0 percent in the treatment and 13.7	Those taking bupropion SR experienced a greater mean reduction in depression

			mg of bupropion SR (n = 300) or placebo (n = 300) twice daily for 7 weeks. Brief motivational counseling was provided in-person at baseline, quit day, weeks 1 and 3, end of treatment (week 6), and by telephone at day 3 and weeks 5 and 7.			percent in the placebo groups.	symptoms at week 6 (2.96 vs. 1.13) than those taking placebo. Those taking bupropion SR also gained less weight than those taking placebo.
African American	Campbell (2002)[49]	9 small to mid-sized workplaces (859 participants; 50 percent African American)	Cluster randomized design. Workplaces were randomly assigned to either intervention consisting of two computer-tailored magazines and a natural helpers program over 18 months or delayed intervention conditions. Delayed worksites received one tailored magazine.	18 months	None	At 18-month follow-up, smoking rates were not significantly different between both groups (27 percent and 19 percent in intervention and control respectively). These rates were 3 percent lower compared to baseline for each group.	Intervention was not specific for smoking but was a general health promotion program.
Hispanic	Pérez-Stable (1991)[25]	431	Guidebook *Guia para Dejar de Fumar* includes multiple topics and culturally tailored messages, as part of a community-wide intervention. No control group.	12 months	Salivary cotinine	Abstinence: 13.7 percent for intervention. No control group.	40 percent of sample lost to follow-up. Part of community effort; did not test impact of guidebook alone (37 of 59 reported abstainers completed salivary cotinine).
Hispanic	McAlister (1992)[61]	295 (>90 percent Mexican/ Mexican-American)	Community-wide campaign, "Programma A Su Salud," included television, radio, and newspaper stories, individual counseling, written materials, neighborhood volunteers.	Approximately 2 years	Breath CO in U.S. samples only	8.1 percent for intervention vs. 1.5 percent for control; p=0.02.	Compared similar communities on U.S./Mexico border.
Hispanic	Leischow (1996)[62]	108 (88 percent Mexican-American)	10-weeks of nicotine transdermal patch + *Committed Quitters* guidebook (English/Spanish); placebo control + guidebook.	10 weeks	CO	Continuous abstinence from week 2 was 46 percent for treatment and 26 percent for placebo, p=0.05.	No post-treatment outcomes reported.
Hispanic	Muñoz (1997)[64]	136 (4 percent U.S. born, 39 percent Mexican, 13 percent El Salvadoran,	Mailed mood management program for smoking cessation + guidebook; self-administered mood management audiotape and written materials, "Tomando control de su Vida" (included relaxation exercises, mood monitoring, increasing pleasant activities) + guidebook	6 months	Salivary cotinine (completed for only half the sample)	7-day point prevalence abstinence was 25.4 percent for intervention vs. 9.2 percent for control, p=0.01.	Intervention had similar efficacy for those with a history of major depressive episodes. Main effect of intervention on reduction in cigarettes per day (cpd).

		13 percent Nicaraguan, 9 percent Guatemalan, 5 percent Peruvian, 16 percent other)	*Guía*; guidebook only control (delayed control: received mood management at 3 months).				
Hispanic	Nevid (1997)[63]	93 (7 percent U.S. born, 66 percent Central/South American, 25 percent Caribbean)	Culturally specific multi-component clinic-based group program of 8 weekly 2-hour sessions, videotape 'cuento'/story therapy, guidebooks (*ALA Lifetime of Freedom from Smoking*, and *Guía*), buddy support system, bi-weekly telephone calls; enhanced self-help control (1 session, guidebooks, telephone calls).	12 months	Salivary cotinine (22-31 percent misclassifica-tion rate)	7-day point prevalence abstinence was 8 percent vs. 7 percent for intervention and control groups respectively, p=ns.	Dose-response between session attendance and abstinence. Abstainers attended average 6 sessions, non-abstainers averaged 4 sessions.
Hispanic/ other[b]	Klesges (1999)[67]	18,010; 29 percent smokers; 29 percent minority[b]	Six-week ban + 50-minute intervention (75 percent randomized to intervention); 6-week ban + control video (25 percent randomized to control); 6-week smoking ban during basic military training + 50-minute group discussion with computer-interactive format, role-playing, commitment cards.	1 year	None	Self-report abstinence rates were 23 percent vs. 19 percent for intervention and control groups, respectively (for minority group, $p < 0.01$).	No main effect of intervention on total group. Ethnic minorities were 40 percent more likely to remain abstinent than Whites (22 percent vs. 17 percent, $p < 0.001$).
Hispanic	Woodruff (2002)[66]	312 (16 percent U.S. born, 78 percent Mexican, 7 percent Central/South American)	"Proyecto Sol": lay health advisors or "promotores" provided 4 home visits and 3 telephone calls + video "Me Muero por Fumar" + guidebook *Rompa con el Vicio*; control referred to state telephone helpline.	3-month intervention	CO	7-day point prevalence abstinence was 20.5 percent vs. 8.7 percent for intervention and control groups, respectively, $p<0.01$.	Dose-response showing that abstainers completed more sessions (4.68) than non-abstainers (3.19), $p = 0.04$.
Hispanic/ other[c]	Malchodi (2003)[65]	142[c]	Physician advice, guidebook *Quitting for You 2* (English or Spanish), median 6 contacts with lay provider; advice + guidebook control.	36 weeks gestation	Urinary cotinine and CO	Abstinence rates were 24 percent vs. 21 percent for intervention and control groups, respectively, p=ns.	Main effect of intervention on reduction in CPD, $p = 0.03$. Note: abstinence for usual care was high.

American Indians	Henderson (2004)[71]	998	Nested cohort study of smokers. Data for the present study were obtained from the Strong Heart Study – a longitudinal, population-based study examining cardiovascular disease among a large and diverse cohort of American Indians (Arizona, Oklahoma, South/North Dakota).	4 years	None	21 percent of smokers quit during the 4-year follow-up period. Factors associated with smoking cessation included older age (65-74 years), non-daily smoking, smoking fewer than 6 cigarettes daily, fewer years of smoking, later age of initiation, and having a history of diabetes.	487 smokers at baseline lost (died, lost to follow-up, missing information). Unknown which smokers participated in smoking cessation programs. Not an intervention, observational cohort study.
Native Americans	Hodge (1999)[79]		Nicotine gum and patch, and clinic physician counseling; also used "It's Your Life" motivational film, self-help guides, and two visits from community health representative.	20 weeks	None	5.7 percent abstinent in the intervention group and 3.1 percent abstinent in the control group.	
Native Americans	Johnson (1997)[69]	601	Clinic-based trial/intervention. Two sites per condition. Intervention was targeted to all adult patients in the clinics who smoke. The GAINS intervention was a modified Doctors Helping Smokers model that incorporated five major principles.	12 months	Salivary cotinine	7-day point prevalence quit rates were 6.7 percent for intervention group and 6.8 percent for control group. Significant differences existed at baseline between the 2 groups.	Problems with early delivery of intervention due to confusion by staff. DHS model was not fully implemented. Many subjects were not exposed to the intervention because they had no clinic visit during the intervention period. High non-response rate of 30 percent in one intervention site; comparison site had the highest response rate.
Alaskan Natives	Hensel (1995)[70]	193	Alaska Native Medical Center tobacco cessation program. Cessation program consisted of both group counseling sessions and nicotine patches. For counseling, patients had choice of American Cancer Society's Fresh Start or American Lung Association's Freedom from Smoking.	12 months	None	Quit rates of 31 percent at 3 months, 30 percent at 6 months, 24 percent at 9 months, and 21 percent at 12 months.	No comparison group. Participants not a random sample but rather a convenience sample. 24 percent of the participants were employees of the medical center. 27 percent attrition at 12 months.
Vietnamese Americans	Jenkins (1997)[72]	5,125	Community-based intervention in San Francisco with pre- and post-test measures.	24 months	None	At post-test, the odds of being a smoker were significantly lower (O.R. 0.82) and the odds of	The results from this study are based on cross-sectional samples rather than a cohort design. The study design

			The intervention was a 2-year media-led campaign targeted to the Vietnamese population. Components included billboards, newspaper ads, television ads, community events, health education materials.			being a quitter were significantly higher (O.R.=1.65) in San Francisco than in the comparison community.	was limited to 2 communities, precluding randomization of communities to experimental or control.
Vietnamese Americans	McPhee (1995)[73]	5,376	Community-based intervention in Santa Clara, CA, with a pre- and post-test surveys. This study used an untreated control group design with separate pre-test and post-test samples. Intervention components consisted of newspaper ads, television ads, billboards, community meetings and events.	24 months	None	Smoking prevalence and quitting remained constant in the intervention community and also the control community between pre-test and post-test time points.	They used cross-sectional samples rather than a cohort design between the two time points. Sampling bias may have occurred due to interviewing only those households with listed telephone numbers.

a Of 225 pregnant baseline smokers: 77 percent African American, 20 percent Hispanic, 3 percent White/Other.

b Of the 29 percent minority: 43 percent African American, 30 percent Hispanic, 12 percent Asian American.

c Of 142 pregnant smokers: 63 percent Hispanic, 12 percent African American, 24 percent White, 1 percent Other.

Discussion

African Americans

Our review of published smoking cessation studies among African Americans over the 18-year period of the review showed mixed findings. Of the 12 community-based behavioral interventions during this period, only four studies[40-43] showed statistically significant long-term (six months or longer) benefit of program intervention compared to minimal or no intervention at all. However, these four trials typically enrolled larger numbers of participants (500 in one study; others, 1,500 to 7,000) and had better designs (all randomized and with long-term follow-up, range 12 to 60 months). This is in contrast to several of the studies showing no effects with smaller sample sizes, shorter follow-up periods, and in some cases, no comparison groups. A meta-analytic review will be necessary to determine the overall effect of these community-based behavioral studies. It is worth noting, however, that the four studies with evidence of long-term efficacy were neither church-based, school-based, or conducted at work sites.

On the other hand, two-thirds (6/9) of the clinic-based behavioral studies demonstrated positive results in favor of intervention. Clinic-based interventions were effective for both pregnant (4/6) and non-pregnant (2/3) patients as evidenced by the number of studies that showed significantly higher quit rates for intervention, compared to usual care groups. This finding of encouraging results among pregnant African American patients is similar to that among the general population.

Our review found that only two studies[57, 59] have assessed the efficacy of any of the FDA-approved pharmacotherapies for smoking cessation among African Americans. This is in contrast to several dozens of similar studies among Whites. Although both studies showed efficacy for these agents among African Americans, there are no published data on the efficacy of other approved phamacotherapies among African Americans. Because of well known differences in the smoking patterns (e.g., number and type of cigarettes smoked) between U.S. racial/ethnic populations, the results of studies among one group do not necessarily generalize to other groups. Differences in nicotine metabolism between racial/ethnic groups have also been reported.[80, 81] Another study also reported reduced efficacy of bupropion for smoking cessation among African American smokers of mentholated cigarettes.[82]

Hispanics/Latinos

The review of published studies evaluating abstinence outcomes in Hispanic adults provides support for the short-term efficacy of smoking cessation interventions. This includes benefits of nicotine patch therapy, counseling, self-help materials, and multi-component community interventions. Six randomized studies found that smoking cessation interventions enhanced short-term smoking abstinence (within the first six months of treatment),[61, 62, 64-67] and three of these studies reported significant long-term effects.[61, 64, 67] Two studies reported the benefit of intervention on promoting short-term abstinence, but did not find long-term benefits of treatment.[51, 63] Another study compared pregnant smokers who received physician advice and

self-help materials with an intervention group that also received repeated counseling from a lay provider and found similar rates of abstinence in both groups.[65] While these findings support at least short-term efficacy of interventions with Latino smokers, questions remain as to what components of an intervention contribute to increased motivation to stop smoking and success with initial quitting, and what components may be needed to sustain motivation and behavior change while preventing subsequent relapse.

Interventions developed to target minority smokers may consider a wide range of factors to be particularly relevant within different racial or ethnic subgroups. In developing and providing smoking cessation interventions to Hispanics in the U.S., one primary consideration is the availability of written materials and counseling in Spanish, in order to provide Spanish-speaking and bilingual smokers with options to meet individual needs. Within the majority of studies, investigators reported specifically addressing language and cultural issues relevant to Hispanics. Most studies included Spanish-language materials and several included bi-lingual interventionists. In addition, several intervention efforts incorporated Latino cultural values such as *familismo, simpatia*, and *respeto*. Baezconde-Garbanati and Garbanati[24] recommend that effective intervention tailoring must recognize the Hispanic population's diversity, variations by country of origin, acculturation, generational status, stressors related to immigration status, and specific tobacco use patterns within various ethnic communities.

Efforts to recruit smokers from the Latino community might include multimedia community-wide messages incorporating television, radio, newspaper, bulletin boards, and face-to-face recruitment at health fairs and community events.[64] Developing partnerships with target groups and community members and using process evaluation techniques may further enhance recruitment of minority participants for smoking intervention studies.[83]

American Indians/Alaska Natives

Our review of published studies evaluating smoking abstinence and quit rates in the American Indian or Alaska Native population provides little information about the effectiveness of current interventions. Very few interventions have been conducted in this population of smokers. The clinic-based intervention trial produced no effect of the intervention. However, there were major problems with the actual delivery of the intervention that may have reduced its effect. In addition, NRT—which has been shown to increase quit rates in other minority groups—was not a component of this intervention. Also, this was not a randomized clinical trial and also did not have a control or comparison group. None of these studies utilized a culturally appropriate approach in their interventions.

The few studies that were carried out had many design and implementation problems that affected their results. In addition, none of these studies utilized a culturally-sensitive counseling supplement to their smoking cessation programs. This is especially important since tobacco is a sacred plant in these cultures and is utilized by many tribes for ceremonial purposes. Therefore, a culturally appropriate approach could be more effective in increasing smoking cessation in this population. The evidence from these studies supports the use of the

NRT for smoking cessation programs for this population. However, studies examining other forms, including sustained release bupropion (e.g., Zyban), should be explored to determine their effectiveness for smoking cessation in this population.

American Indians have the highest smoking rates among all the ethnic groups presented in this review. Furthermore, American Indian women have increased their smoking prevalence, while all other groups have seen a decrease in smoking prevalence. Given the high burden of morbidity and mortality observed in this population, additional smoking cessation interventions for Native Americans are necessary to reduce the future smoking-related illnesses.

Asian Americans/Pacific Islanders

Smoking cessation interventions have focused mainly on the Vietnamese male population. The two studies reported in this review showed that one intervention produced an effect while the other did not. One difference in the interventions was that in the community living in San Francisco, additional components targeting students and their families were included, whereas this was not the case in the communities living in Santa Clara. This suggests that at least among the Vietnamese population, the involvement of the entire family may be more effective than not involving them. More studies with other Asian populations need to be conducted to determine effective methods of smoking cessation.

Recommendations and Future Directions

Variations in outcome assessment, follow-up, and method of analysis restricted comparison of findings across studies. This review found some instances of undefined self-reported abstinence, limited collection of biochemical verification of smoking abstinence, and exclusion of participants lost to follow-up within outcome analyses. The Society for Research on Nicotine and Tobacco (SRNT) subcommittee on abstinence outcome measures recommended that investigators assess and report multiple measures of abstinence within a treatment study.[84] The recommended primary outcome is prolonged abstinence (defined as continuous abstinence following a two-week grace period), using seven- and 30-day point prevalence as a secondary outcome. Six- and/or 12-month follow-ups are recommended to examine long-term treatment effects.[84]

Recommendations for validation of self-reported smoking abstinence were made by the SRNT subcommittee on biochemical verification.[85] Expired breath carbon monoxide (CO) and cotinine in plasma, urine, or saliva provide appropriate data. This group acknowledged that collection of biochemical samples may not always be feasible for some large-population/low-intensity interventions, but recommends reporting both self-report and biochemical data sufficient to allow comparisons of outcomes, especially in smaller population clinical trials.[85] Careful reporting of participants who drop out or are lost to follow-up, combined with intent to treat analysis, would further promote comparisons of findings across studies. Secondary, outcomes to consider include change in smoking behavior (reduction in cigarettes smoked per day)[27, 64] and changes in motivation, or other cognitive processes that may contribute to

behavior change. Increased assessment and reporting of process variables may contribute to further intervention development and enhanced treatment efficacy.

Smoking prevalence, smoking initiation, patterns of tobacco use, and factors associated with smoking behavior and behavior change are not consistent across all segments and subgroups of our population. Therefore, clinicians and investigators should not presume that a given treatment intervention is appropriate and effective for all smokers. Until investigators have the means available to "deconstruct racial and ethnic differences into genetic vs. social vs. pharmacologic differences, and their interactions," empirical evaluation of the efficacy of different smoking cessation interventions across racial and ethnic subgroups is required.[86]

Use of pharmacotherapy to promote cessation is central to the USPHS Clinical Practice Guideline,[34] yet only two studies among African Americans,[57,59] and one study among Latinos,[62] have specifically evaluated pharmacotherapy. Additional research is needed to evaluate treatment using nicotine and non-nicotine medications in minority populations. Such studies should include evaluation of acceptability of pharmacotherapy and treatment adherence. Attention also must be directed beyond identifying effective interventions to increase smoking abstinence. Additional investigation is needed in relapse prevention for former smokers, particularly for recent quitters.[51] Furthermore, because members of minority groups are less likely than Whites to participate in smoking cessation programs, and may have limited access to treatment,[8] efforts are also needed to overcome barriers and further promote knowledge of and access to treatment for all smokers.

Finally, in the effort to reduce tobacco-related morbidity and mortality and to treat nicotine dependence, other forms of tobacco must not be overlooked. Limited data exist on minority populations' use of chewing tobacco, snuff, cigars, and other forms of tobacco. This area deserves further investigation to advance prevention and treatment for all tobacco users.

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COMMENTARY ON SMOKING CESSATION IN ETHNIC MINORITY POPULATIONS

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The American Legacy Foundation has a shared interest and concern for veterans' access to cessation services and health outcomes related to tobacco use.

- Legacy has increased its focus and resources devoted to cessation services, as demonstrated by its new marketing campaigns, D.C.-based Call Center, web-based support for quitting, and North American Quit Line Consortium. Through these efforts, Legacy's message to smokers is, "There is hope and there is help."
- In addition, Legacy has shifted the focus for its Priority Populations' Initiative to include not only racial/ethnic minorities, and gay and low-income populations, but also those with co-morbid conditions. For example, individuals with psychiatric disorders or substance use histories are known to have markedly higher smoking rates. These underserved populations are also of interest to the VA.
- Both the VA and Legacy find that the health care provider's role in promoting cessation is critically important. However, few clinical studies involving sufficient percentages of minorities actually document the valuable role of providers' advice.

Okuyemi, Sanderson Cox, Choi, and Ahluwalia effectively summarized several key points. For example, the trends in smoking prevalence across ethnic minority groups and patterns of tobacco use by these groups illustrate, in the case of African Americans, preference for menthol cigarettes, fewer cigarettes smoked per day, and lower success rates while trying to quit smoking.

Their paper confirms the paucity of research studies that demonstrate the efficacy of behavioral and pharmacological aids among ethnic minorities. In contrast, numerous studies focusing on majority populations have shown the efficacy of these interventions. It also shows that clinical trials and clinical studies have demonstrated greater success than community-based studies, in terms of specific health outcomes.

- The studies based in clinical settings more often show efficacy in cessation treatment outcomes.
- Findings across studies demonstrate a dose-response relationship between nicotine dependence treatment intensity and long-term abstinence. Intensive interventions are more cost-effective and produce higher success rates.

* The American Legacy Foundation

- However, few clinical studies focus exclusively on minority populations' tobacco use; and few enroll sufficient numbers of minority participants to draw definitive conclusions.
- Further, minority populations may lack access to intensive clinic-based interventions or longitudinal studies. For instance, only three large-scale studies since 1997 involved Native Americans.

The paper covers population growth trends and acculturation issues for the six largest subgroups of Asian Americans and several Hispanic sub-populations. While Asian Americans on the whole have the lowest smoking prevalence among ethnic groups, research shows an association between smoking and acculturation, particularly for Southeast Asians, according to this paper. Those with higher English-language proficiency and those living in the U.S. longer were less likely to be smokers.

The paper raises six issues that merit further consideration and discussion:

Acculturation: Are the effects of acculturation, especially for Latino and Asian cultures, a risk factor for smoking or a protective factor? The paper seems to suggest that for some cultural groups, one's generational status (time in the United States) may be a protective factor. This stands in contrast to acculturation's role as a risk factor for obesity. The findings stating that acculturated Asians have lower smoking rates may be confounded by the socio-economic status of those who get to immigrate to the U.S.

Cultural tailoring: Cultural tailoring, according to the review, has not been shown to be of clear benefit for improving health outcomes. There were two exceptions cited, including a study by Tracy Orleans, which showed that African Americans advanced in their stage of readiness as a result of culturally-sensitive materials and had comparable quit rates. However, in most studies cited, the use of quit aids showed similar efficacy in all ethnic groups. Is it worth the extra effort to ensure cultural tailoring of interventions? Do standard materials work as well? What are the pros and cons?

Social Class: Few studies emphasized social class differences within and among ethnic/racial groups, or the essential role that social class plays in determining health outcomes. Isaacs' and Schroeder's article on class as the ignored determinant of health suggests that a shift in focus may generate new insights concerning social- and public-policy level interventions.[1] Should greater focus be placed on class-related risk factors?

Secondary Outcomes: Most research studies focus on abstinence as an outcome. Is it worthwhile to consider secondary health outcomes, such as changes in motivation or smoking behavior?

Health Providers' Role: Use of pharmacotherapy to promote cessation is central to the Clinical Practice Guideline, yet few studies cite the value of advice and counseling on the part of health care providers, particularly regarding their acceptability by minorities. How important is the providers' role for these populations? Have we maximized the health care providers' role?

Multiple Risk Factors: What about the problem of the compound effects of exposure to stressful situations or hazardous working conditions and smoking? Are minority veterans more susceptible to compounded effects or depression due to their concentration in certain military jobs? Are there specific options for multi-level treatments? How might the VA truly be in the vanguard concerning these complex issues?

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[1] Issacs SL, Schroerder SA. Class—the ignored determinant of health. *New England Journal of Medicine*. 2004;351. 1137-1141.

TOPIC FOUR

Mental Health and Post-Traumatic Stress Disorder

Addressing Tobacco Dependence among Veterans with a Psychiatric Disorder: A Neglected Epidemic of Major Clinical and Public Health Concern

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Veterans and non-veterans with a psychiatric disorder are two to three times more likely to be tobacco dependent, and many of these individuals will die of tobacco-caused medical disorders compared to those without a psychiatric disorder. The high rate and severity of tobacco dependence among psychiatric patients is both a silent epidemic and a major health care issue for the VA health care system, since 25 to 40 percent of all veterans receiving treatment within the VA system have a psychiatric disorder. There is a great need to immediately address the issue of tobacco dependence among veterans with psychiatric disorders at the clinical, program, and systems levels, to fund more research to better understand the problem, and to develop and evaluate new interventions. There appear to be several unique biological, psychological, social, and treatment setting factors that account for the increased risk for tobacco dependence in this population, which result in clinical treatment issues. These include when to provide tobacco dependence treatment relative to the acuity of the psychiatric disorder, how best to monitor the effects of quitting smoking on psychiatric medication blood levels and symptoms, and how to enhance quit attempts through more intensive psychosocial and medication treatments. The goals of this paper are to increase VA, national, and international visibility of this neglected clinical and public health concern; to summarize some of the known clinical issues that are unique to this population; and to make specific recommendations for better addressing the problem within the VA health care system. There also appears to be a strong interest in better addressing this issue by national VA leaders, an effort that must be expanded across the 22 relatively autonomous Veterans Integrated Service Networks (VISNs) to address the issue within all VA mental health and addiction treatment settings. The VA is well positioned to develop, test, and promote innovative tobacco dependence treatment approaches to improve the health of veterans, and this work will have a ripple effect in helping behavioral health care practitioners nationally and internationally. The VA must first raise awareness of this issue within the VA; develop a change plan that includes clinical, program, and systems

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level changes; and implement training, services, research, and other initiatives. The largest outpatient and inpatient expenses within the VA are related to treating and managing chronic, tobacco-related or tobacco-caused medical illnesses. Fighting stigma against psychiatric disorders begins with placing equal value on all lives. Addressing tobacco because it increases morbidity and mortality for this population should be enough reason for a call to arms to help veterans with psychiatric disorders get the basic tobacco dependence treatment services that will improve the quality of their lives by reducing the health risks associated with tobacco dependence.

Tobacco dependence among veterans and non-veterans with a psychiatric disorder (either a mental illness and/or a substance use disorder) is two to three times more common than in the general population.[1, 2, 3] In fact, tobacco dependence is the rule in this population rather than the exception. This is an important issue for the VA because the VA is the largest provider of behavioral health care in the nation and about 25 to 40 percent of veterans have a psychiatric disorder. Although public health initiatives and tobacco control strategies for the general population have greatly reduced tobacco use during the past 40 years in the United States, the rate of tobacco dependence among psychiatric patients continues to be extremely high. With the reductions in smoking rates occurring in the general population but not among individuals with psychiatric disorders, the proportion of smokers with psychiatric disorders who smoke has increased, and now nearly half of all the cigarettes consumed in the United States are by individuals with a psychiatric disorder.[4] Tobacco dependence results in increased morbidity and mortality, yet tobacco use and dependence has been largely ignored as a clinical treatment issue in most mental health and addiction treatment settings.[5, 6, 7] The mental health and addiction treatment systems have often not only tolerated smoking, but actually promoted it as a strategy for staff to manage patient behaviors and to structure patients' time.[8] There may be unique biological, psychological, social, and treatment setting factors that account for the increased vulnerability of this population to initiating, maintaining, and failing to abstain from smoking. There is a great need within the VA to initiate treatment services immediately, to invest in research that will help improve our understanding of the problem, and to develop new clinical, program, and system interventions.

The goal of this paper is to increase VA, national, and international visibility of this neglected clinical and public health concern. In addition, the paper summarizes what has been reported about this population of smokers, and makes specific recommendations for better addressing the problem within the VA health care system. The effort to address this issue has begun by national VA leaders and must be expanded across the 22 relatively autonomous Veterans Integrated Service Networks (VISNs). There is a need to make clinical, program, and systems level changes; and to implement training, services, research, and other initiatives. The VA is well positioned to develop, test, and promote innovative tobacco dependence treatment approaches to improve the health of veterans, but this work will have a ripple effect in helping behavioral health care practitioners nationally and internationally. The VA has the opportunity to make changes at all levels due to its being a contained system that has many innovative

clinical structures to facilitate change, including an excellent computerized medical record and an intranet system that links different regions of the country. Based on the literature and expert opinion—including several national meetings on this topic, such as The Robert Wood Johnson Foundation's Addressing Tobacco Dependence in Mental Health and Substance Abuse Treatment Settings national summit meetings—this paper recommends increasing national and international awareness of the issue, enhancing training and clinical services, conducting more research, and involving public health/tobacco control specialists.

The Scope of the Problem in the VA

The VA is the largest provider of behavioral health care in the nation, having treated close to 800,000 veterans in specialized mental health programs in fiscal year 2003, at a total cost of over $2 billion.[9] The extensive use of mental health services among veterans is to be expected considering that 25 to 40 percent of veterans seeking health care at the VA have a psychiatric diagnosis, and more than 80 percent have underlying mental health problems.[10] Severe mental illness, primarily psychoses, is a major problem among veterans. In 1998, about 174,000 veterans were service-connected for psychoses, of which more than 67,700 used VHA services.[11] An estimated 340,000 male veterans had co-occurring serious mental illness (SMI) and a substance use disorder in 2002 and 2003, especially among those individuals aged 18 to 25. Soldiers are returning from combat operations in Iraq and Afghanistan with a wide variety of mental health problems, including post-traumatic stress disorder (PTSD), anxiety, and major depression.

High Rates and Serious Consequences

Individuals seeking treatment at the VA are more likely to be smokers and heavy smokers compared to the general population,[12] including veterans with a psychiatric disorder. Veterans with psychiatric disorders, particularly those with serious mental illness, have high rates of undetected and untreated medical problems and elevated medical mortality rates, many of which are related to tobacco-caused illnesses.[13] The largest outpatient and inpatient expenses within the VA are related to chronic, tobacco-related illnesses. Individuals with psychiatric disorders die disproportionately from cardiovascular and respiratory illnesses that are closely linked to smoking.[14, 15, 16] The life expectancy for patients with schizophrenia is 20 percent shorter than the national average, and the cardiovascular mortality among people with the disorder is twice as high as in the general population.[17] Tragically, many individuals with mental illness or addiction will likely die of medical disorders caused by smoking.[18] Smokers with serious mental illness also appear to have more psychiatric hospitalizations and higher psychotropic medication doses than non-smokers with schizophrenia.[19, 20] Smokers with serious mental illnesses tend to be heavier smokers and to also be effective and efficient smokers with higher levels of tobacco metabolites (cotinine) compared with matched controls, suggesting a deeper inhalation of nicotine.[21] Heavier smoking results in greater exposure to carbon monoxide and tars, in addition to greater vulnerability to nicotine dependence and withdrawal. Of particular

concern for the SMI population is the fact that the tars contained in tobacco smoke induce liver enzymes that hasten the metabolism of many psychiatric medications, resulting in increased dosage requirements, costs, and side effects. Other health consequences are due to the effects of second-hand smoke on family members, friends, and even fetuses. Prenatal smoking is also associated with maternal depression and is strongly linked to conduct problems and later antisocial outcomes in the offspring.[22]

Smokers with psychiatric disorders also suffer financially as a result of smoking. A study by Steinberg et al. revealed that a sample of smokers with schizophrenia spent a median of $142.50 (range $57-319) per month on cigarettes.[23] Given that the median public assistance benefit was $596, this represented an expenditure of at least 27 percent of monthly income on cigarettes. Participants went to great lengths to roll their own cigarettes, purchase generic products, and use tax-free internet sites in order to save money, showing a remarkable level of initiative for this population. In addition, it may cost more to treat tobacco dependence in smokers with psychiatric disorders because they are more likely to be heavier smokers[24, 25] and have an earlier relapse back to smoking after a quit attempt, and need several treatment episodes and more intensive treatment.[26, 27, 28]

The Silent Epidemic

Even with all the growing evidence of the high rates and substantial consequences of smoking in this population, little has been done, and there are many opportunities to address this public health and clinical problem. Why has this silent epidemic occurred? Why has there been little advocacy to help this group of smokers? Many mental health (non-tobacco dependence) experts remain ambivalent about encouraging smokers with mental illness to quit smoking. Neither mental health advocacy groups, nor tobacco advocacy groups are championing the cause, and psychiatrists and other behavioral health staff members are largely uneducated about treating tobacco. Mental health researchers are becoming more aware of the physical health care needs of patients with psychiatric disorders, and yet a recent review of articles on physical health care for this group failed to include smoking as a factor, nor was tobacco dependence treatment specifically recommended.[29] Perhaps stigma is preventing the tobacco control community from increasing efforts to target this substantial group of smokers. Because of the substantial health consequences and the addictive nature of tobacco, this issue has become a major public health issue for the general population. The same standards should apply for individuals with psychiatric disorders. Before an effective tobacco dependence treatment plan can be proposed for the mentally ill, a number of myths must first be dispelled and long-standing questions about the issue answered. Some believe that suffering from a psychiatric illness requires self-administering tobacco to improve psychiatric illness, and that perhaps tobacco is the most cost-effective way to self-medicate daily stresses. Others have suggested that tobacco use is necessary to fill unfulfilled lives. Still others have wondered why, other than increased morbidity and mortality, this issue needs to be addressed. While

these questions and beliefs are unfortunately common with regard to psychiatric populations, they are not raised when considering the general population. Stigma and ignorance maintain the silent epidemic. How have clinicians, family members, and patients who so desperately fight stigma on most other fronts missed the stigma blatantly implied by ignoring tobacco addiction within this population? Many of these issues are due to lack of training and lack of a sense of responsibility for treating tobacco dependence.

Table 1: Recommendations to address smoking among veterans with psychiatric disorders

(1) Raise awareness of the need to address tobacco in this population
* Make a commitment to address the issue and develop a specific change plan * Include clinical, program, and system change * Integrate this into the overall Tobacco Plan
(2) Train staff and promote integrating tobacco treatment into mental health / addiction settings
(3) Increase funding for VA research on the topic
(4) Create and Implement VA policy and other system-level changes

Raising VA Awareness of Tobacco Dependence among Psychiatric Patients

An important first step for the VA health care system will be to recognize the severity of tobacco dependence among the 25 to 40 percent of veterans with a psychiatric disorder. The VA is ideally suited to pursue initiatives in addressing tobacco in mental health and addiction treatment settings. Momentum is slowly building in the private, public, and Veterans Health Administration settings to address this issue. Mental health and addiction treatment programs and clinicians must begin to see addressing tobacco as part of their clinical missions. There is also interest in the academic world in understanding the relationships between nicotine use and psychiatric disorders. Important questions remain unanswered about the onset and progression of both tobacco use and psychiatric disorders and the inter-relationships among these conditions. The VA has developed national programs of excellence in other types of co-occurring mental and substance use disorder sub-types, and there is strong evidence to support the effectiveness of integrated treatment in mental health and addiction treatment settings.[30, 31] Table 2 outlines our key recommendations for raising awareness and creating a VA-wide and VISN-wide plan to address tobacco dependence in this population.

Table 2: Raise Awareness of the Need to Address Tobacco in this Population

- That VA Leadership acknowledges the need to include a focus on addressing tobacco in this population.
- That the topic be included in national VA meetings.
- Create a National Best Practices committee of tobacco treatment experts to develop a plan to target this population's unique needs. Include representatives from:
  - ♦ The Mental Health Strategic Health Care Group (MHSHCG)
  - ♦ The Seriously Mentally Ill (SMI) Committee
  - ♦ The Public Health Strategic Healthcare Group
- Develop a strategic plan and clinical practice guidelines for this population, including a timeline and implementation plan.
- The MHSHCG should designate funding to implement the strategic plan and clinical practice guidelines.
- VA regional service networks should create a workgroup to implement the guidelines developed by the national tobacco committee.
- The Northeast Program Evaluation Committee, or the Serious Mental Illness Treatment Research and Evaluation Center should include the prevalence and treatment of tobacco dependence as part of their national report card.
- Increase information on the link between psychiatric disorders and tobacco using the VA health care system's computerized health care record and require the inclusion of addressing tobacco into computer assessments, treatment plans, and treatment within mental health and addiction treatment settings.
- Addressing tobacco in this population requires:
  - ♦ Including primary care
  - ♦ Including tobacco dependence experts
  - ♦ Including mental health and substance abuse providers

The VA's efforts will support the more global need for increased attention to this public health problem. Examples of other recent national level activities that are making efforts to increase national awareness of the need to integrate tobacco dependence treatment into mental health and substance abuse treatment include:

- The new definition of co-occurring disorders in the Substance Abuse and Mental Health Services Administration (SAMHSA) *Co-occurring Disorders Report* to Congress includes tobacco and recommends the inclusion of tobacco dependence treatment into the National Registry of Effective Programs.

- The Robert Wood Johnson Foundation initiative to Address Tobacco in Mental Health and Addiction has helped create a national strategic plan with the participation of individuals from the National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Mental Health (NIMH), National Cancer Institute (NCI), the VA and numerous other federal and state agencies, universities, and clinical providers.
- Specific NIH grant requests from NCI, NIDA, NIMH, and NIAAA have targeted research efforts to increase the understanding of tobacco dependence with behavioral health co-morbidity and to establish evidence-based clinical treatment interventions for it.
- The Center for Substance Abuse Prevention and other national tobacco control/prevention efforts have targeted prevention programs for adolescents with mental or substance use disorders.
- The American Psychiatric Association has integrated tobacco dependence into its *Substance Use Disorders Treatment* guidelines, instead of conceptualizing it as a separate treatment guideline.
- The National Agency of Drug Abuse Counselors has released a statement that tobacco dependence should be addressed in clinical settings.
- In some states, Medicaid pays for tobacco treatment, including over-the-counter nicotine replacement (NRT) for covered individuals.

Why Do Individuals with Mental Illness and Addictions Smoke So Much?

Research findings suggest that there are unique biological, psychological, social, and environmental factors contributing to the high initiation and continuation rates of tobacco dependence observed in this group. These factors must be considered in developing better ways to address tobacco dependence among individuals with psychiatric disorders on clinical, program, and systems levels. Obviously, this is a very heterogeneous population, even if one just considers the simple categorization according to diagnostic sub-types. The literature that describes the high rates also describes possible explanations for the reasons for association for most psychiatric disorders, including depression,[32, 33] general anxiety disorders,[34, 35, 36] panic disorder,[37] PTSD,[38, 39] schizophrenia,[40, 41] attention deficit hyperactivity disorder (ADHD),[42] alcohol dependence,[43, 44] and drug dependence.[45] A better understanding of the problem may lead to new clinical interventions that consider the heterogeneity of the population. Factors to consider include biological, psychological, and social factors.

Biological factors: Genetics, imaging, and pre-clinical studies emphasize biological factors in creating either a common predisposition to develop both tobacco dependence and another psychiatric disorder, or in contributing to psychological vulnerabilities underlying the "self-medication" hypothesis. The biological perspective has achieved dominance and has been

used to rationalize and excuse ongoing tobacco dependence in this population. There is a need to examine psychosocial factors leading to initiation and continuation, as well as the biological issues of increased morbidity and mortality with ongoing smoking. Appreciating and understanding biological factors may lead to greater knowledge of psychiatric disorders and lead to improvement in the treatment of psychiatric disorders and tobacco dependence.

Data from family, adoption, and twin studies support a substantial genetic influence on the initiation and maintenance of smoking, and several studies suggest a genetic predisposition to both nicotine dependence and depression.[46, 47] Genes that alter dopamine function and transmission may influence the rewarding effects of smoking, as well as tobacco dependence treatment and relapse among these individuals.[48] In adolescents, the likelihood of smoking progression has been strongly associated with the presence of a dopamine D2 receptor allele, and this effect appears most pronounced in those with substantial depressive symptoms.[49] In schizophrenia, genetic studies indicate an autosomal dominant pattern of inheritance linked to chromosome 15q13-14 which is the site of the α-7 nicotinic receptor.[50, 51] There appear to be genetic factors common to all types of substance abuse.

Nicotine exerts its actions by binding to many different types of nicotinic acetylcholine receptors in the brain. Medications targeting the one specific nicotinic receptor, α7, may have potential benefits for the treatment of schizophrenia, ADHD, Alzheimer's disease, and Tourette's syndrome. For example, nicotine's effect on dopamine may account for a reduction in the negative symptoms of schizophrenia,[52] improvement of working memory and selective attention in smokers with schizophrenia, and improvement in the processing of sensory stimulation and abnormal saccadic eye movements.[53] Nicotinic stimulation may improve both cognitive and motor aspects of Parkinson's disease, with a low dose nicotine patch causing improved reaction time, faster central processing speed, reduced tracking errors, and improved motor/extra pyramidal functioning.[54] Another nicotinic receptor, $\alpha 4\beta 2$, is believed to be the key receptor responsible for the development of nicotine addiction and the rewarding aspects of nicotine.[55]

Other non-nicotine chemicals in tobacco may reduce depressive symptoms through their effect on reducing the monoamine oxidase enzyme (MAO B) in a manner similar to MAO inhibitor anti-depressant medications. Reducing MAO B enzyme levels, which is a goal of some antidepressants, slows the breakdown of catecholamines. Studies have shown that the brains of living smokers had 40 percent less MAO B compared with nonsmokers or former smokers.[56] These biological studies reinforce the idea that in spite of any potential benefit from nicotine, the obvious hazards of tobacco smoke point to a need for safer alternatives to tobacco, including increased usage of nicotine replacement and novel drug development for the potential use of nicotinic agonists. The management of smokers with psychiatric disorders may be improved when we better understand how the effects of nicotine are mediated by these receptor sub-types and how these effects influence stress, anxiety, and depression.[57]

Psychological Factors: Smokers with psychiatric disorders report that they, like other smokers, smoke to manage stress and to reduce psychiatric symptoms of depression, anxiety, boredom,

poor concentration, and memory difficulties. Smokers with serious mental illnesses often report that tobacco is considered a "core need," and is purchased in lieu of food.[58] Additionally, a survey of smokers with substance use disorders found that 57 percent felt it would be at least as difficult or more difficult for them to give up their tobacco as it would be to abstain from using the substance for which they primarily sought treatment.[59] The initiation of smoking and the progression from tobacco use to dependence appears to be linked to depressive symptoms and disorders.[60] Psychiatric patients often report that they smoke in an effort to "self-medicate" their symptoms of depression and anxiety.[61] These factors may contribute to lower levels of motivation and self-confidence for quitting and to strong feelings of learned helplessness.[62]

Addressing tobacco use will require clarification of the smoker's perceived reasons for use and for not being able to quit, and providing education about how tobacco withdrawal can mimic psychiatric symptoms. In spite of the low motivation to change, which is characteristic of many psychiatric patients seeking treatment, clinicians know how to enhance motivation and treat the psychiatric disorder. These strategies have been effective in enhancing motivation to stop smoking in patients with schizophrenia, depression, and addiction.[63, 64, 65]

Social Factors: Social factors shown to increase smoking risks among individuals with psychiatric disorders include limited education, poverty, unemployment, and an abundance of smoking peers.[66] Smokers with serious mental illnesses often have a substantial amount of unstructured time and report smoking in response to boredom. Unstructured time is also a risk factor for relapse, with many patients resuming use during unstructured weekends.

Either overtly or covertly, the treatment system and the peer support group culture (e.g., Alcoholics Anonymous) have supported and encouraged smoking. Mental health and addiction treatment programs have a history of reinforcing tobacco usage and using tobacco to modify behavior. These treatment settings have many staff members who smoke and endorse the belief that tobacco helps patients manage their psychiatric disorders. Staff smoking with patients is accepted in many settings, and smoking is also frequently allowed at group homes and shared residences, making it difficult for smokers living in these environments to quit.

Protective Factors: There is a need for more research on non-smokers with psychiatric disorders and disorders with associated low smoking rates, like Parkinson's disease, in order to evaluate the protective factors or interventions that contribute to never smoking, to not progressing from occasional smoking to dependence, and to successful quitting. Although biological and genetic components contribute to tobacco dependence, it is not known if they are more or less robust among smokers with psychiatric disorders. It is possible that the biological factors have been overemphasized and that there are protective aspects of social interventions and policy and treatment system changes.

Tobacco Dependence Screening, Assessment, and Treatment in the VA

The VA has instituted a number of important initiatives in an effort to treat tobacco dependence. The Veterans Health Administration National Smoking and Tobacco Use Cessation Program has adopted a comprehensive, evidence-based tobacco use screening and cessation counseling program, entitled the VA/Department of Defense *Clinical Practice Guideline for Management of Tobacco Use*. It recommends that all veterans seeking care in the VA System be counseled in smoking cessation at least three times a year; however, there is a need to know whether veterans with psychiatric disorders have been effectively targeted by these approaches. The brief counseling sessions recommended by this model involve urging patients to quit, helping them develop a quit plan, providing problem-solving skills training, offering support throughout the quitting process, helping them obtain additional external support, recommending various approved and effective pharmacotherapy interventions, disseminating educational materials, and setting up a follow-up contact to assess progress.[67] Unfortunately, few mental health and addiction treatment staff members have been fully trained to use these approaches and they do not yet consider this to be a responsibility with their patients. There is clearly a need to require all staff, including those in mental health and addictions treatment programs, to be trained in tobacco dependence treatment and to integrate these services at all levels of care. Training could include different approaches such as in-service or computerized training for all psychiatrists and mental health clinicians, and incorporate motivation enhancement techniques in training materials, since many patients may have low motivation to change. Introducing existing tobacco dependence treatments into mental health and addictions treatment settings can be effective in providing treatment to many more smokers.

Another potentially very useful technology to better address tobacco within the VA is the tobacco education clinical reminder system, which appears automatically at fixed intervals in the patient's computerized medical record and reminds the clinician if an intervention is due. The clinician is then required to "clear" the reminder by documenting in the medical record that the appropriate intervention has been implemented. The clinical reminder is linked to a performance or quality improvement measure for smoking cessation counseling, and tracks how often clinicians provide tobacco education and counseling. These types of initiatives—linking clinical practice guideline implementation to report cards and other performance-enhancing measures, and maximizing guideline adherence in this setting—have been successful within the VA.[68] However, it has not been reported whether or not there has been any change in smoking prevalence rates after the introduction of the computerized reminder, or whether there is any difference in cessation rates between smokers whose tobacco use clinical reminders are cleared by the clinician and smokers for whom the reminders remain uncleared. [69]

Assessment Issues

All individuals with psychiatric disorders should have a complete tobacco assessment, including current patterns of tobacco use, motivation to quit, reasons for unsuccessful prior quit attempts, and past experiences with tobacco treatment medications. Although severity

of nicotine dependence is often measured by the six-item Fagerström Test for Nicotine Dependence (FTND), in its current form this measure may not be as appropriate for smokers with schizophrenia—or in others whose smoking is regulated by others—as in the general population due to differences in smoking patterns, living arrangements, and daily routines.[70] These factors may produce an underestimate of nicotine dependence, which may have clinical implications for successful pharmacological treatment if the FTND scores are used to guide the dosage of nicotine replacement medication.

Treatment Issues

Smokers with mental health problems may need more intensive treatments, or treatments modified to address their needs. Treatment planning should focus on the individual needs of the patient and consider the bio-psycho-social risk factors for smoking and mental illness. Requiring that tobacco dependence is on all VA treatment plans for all tobacco users with mental illness and/or addictions is a beginning. All smokers in mental health treatment settings should have a brief tobacco intervention, including a tobacco use assessment, a recommendation to quit, and education about available treatment resources. There is a need to develop patient educational materials on tobacco use in veterans with mental illness and/or addictions for distribution to inpatient units, substance abuse programs, and mental health outpatient clinics.

More intensive interventions include individual and group psychosocial treatments and pharmacotherapy. Intermediate goals for patients not interested in quitting should still be documented in treatment plans. These include forced abstinence in inpatient settings or trying harm reduction approaches. In these cases, as in dealing with any low-motivated client, motivational interventions can be helpful and encourage clients, over time, to adopt more active and abstinence-focused treatment strategies.

In addition to action-oriented treatment interventions, treatment planning for some smokers will include a wider range of options. Assessing motivation to stop smoking is important and helps in determining the appropriate treatment. Treatment plans for low-motivated smokers should focus on education, the desire to quit, and self-efficacy.[71] Smokers in acute psychiatric units often wish to continue smoking after their admission; therefore, inpatient treatment plans should help patients to cope with hospital-imposed abstinence. As with other addictive behaviors, stated motivation to change one's smoking behavior is a strong predictor of initiating and successfully completing a quit attempt. Tailoring interventions to lower levels of motivation can help keep clients in treatment and serve as a legitimate alternative outcome to immediate abstinence. Steinberg and colleagues found that a one-session motivational enhancement therapy session resulted in about one-third of smokers with psychiatric disorders seeking tobacco dependence treatment within one month, compared to none who received only a psycho-educational session or very brief advice.[72] The intervention included personalized feedback of smoking-related information that was presented in both verbal and graphical formats, thus addressing the cognitive limitations of this population. Other creative approaches to help motivate smokers to seek treatment for tobacco dependence are needed.

Table 3: Special Clinical Considerations in Treating Nicotine Dependence in Patients with Psychiatric Disorders

Consideration	Intervention
Complex system with broad range of psychiatric disorders, and varying levels of severity and functional impairment of the disorder	Tailored interventions which address the mental health needs Tobacco treatment provided by mental health professionals Availability of treatment services for all clients Range of services to meet different cognitive and motivational needs
High severity of tobacco dependence Patients tend to smoke more than 25 cigarettes per day (heavy smoking) and have high nicotine withdrawal symptoms	Place extra emphasis on use of NRT or bupropion for treating tobacco dependence Consider use of higher dose or combination medication treatment
Mental health treatment culture tends to support tobacco use as a form of social interaction, and to reward staff and patient with smoking breaks	Eliminate smoking breaks and institute fresh-air breaks Educate health care staff about its role in promoting healthy behaviors Eliminate staff smoking with patients Provide tobacco dependence treatment for mental health treatment providers Provide alternate recreation and other social outlets for patients and providers
Potential for some medication toxicity during early abstinence	Consider adjusting medication dosages during early abstinence Coordinate tobacco dependence treatment with mental health treatment providers
Smoking is prevalent in and around mental health residences, hospitals, and treatment facilities	Eliminate the sale of tobacco in mental health hospitals and treatment facilities Consider tobacco-free grounds policies that restrict smoking in the vicinity of treatment sites Institute tobacco-free housing options for non-smoking and quitting clients

Table 3: *Continued*

Consideration	Intervention
Low and/or fluctuating motivational levels and lack of acknowledgement of tobacco dependence as an acute issue	Consider motivational enhancement strategies for those with low motivation Incorporate long-term treatment planning approaches for addressing tobacco dependence
Cigarettes seen by patients and providers as the only pleasure or comfort	Include in treatment developing alternative sources of pleasure and strategies for mood management Use empowerment strategies to educate clients that they should strive for greater quality of life and tobacco-free lifestyles
Concerns from patients and providers that psychiatric symptoms will worsen and/ or patients will be unable to use tobacco medications safely	Educate patients and other providers Monitor psychiatric symptoms closely, especially mood symptoms Consider concurrent use of appropriate psychotropic medication Educate about safety of tobacco treatment medications, even in the context of some smoking
Patients and providers often believe that tobacco dependence should be treated only after treating other substance abuse and psychiatric disorders have remitted	Delay treatment only during crises or when psychiatric instability interferes with treatment Use long-term chronic disease model to intervene at all opportunities Provide educational and motivational interventions early in treatment
Patients with psychiatric disorders may experience more intense symptoms of craving and withdrawal	Discuss strategies for managing craving and withdrawal symptoms with psychosocial techniques Use medications aggressively to treat craving and withdrawal

Timing of the Intervention

A very important question in treatment planning for this population of veteran smokers is the issue of when to time a quit attempt. Behavioral health clinicians frequently express concern that tobacco abstinence will worsen mental illness or jeopardize recovery from other substances. Although there is no definitive answer to this question, studies suggest that tobacco treatment does not jeopardize recovery from the abuse of other substances, and may even improve the outcomes for other substance use disorders.[73, 74, 75] In fact, there is growing evidence to suggest that many patients receiving drug and alcohol treatment are interested in receiving simultaneous smoking cessation treatment.[76, 77, 78, 79] A recent study by Joseph and colleagues comparing the timing of tobacco dependence treatment in the context of substance abuse treatment, showed little difference between those who received concurrent tobacco treatment and those for whom treatment was delayed for six months after initiating intensive addictions treatment.[80] Both groups had a comparable number of quit attempts, point prevalence smoking abstinence at 12 months, intensity of intervention, and use of NRT. The overall quit rates were also comparable to those of other types of smokers receiving nicotine dependence treatment (about 18 percent achieved abstinence at one year).

It is similarly unclear whether nicotine dependence treatment should be timed to coincide with a specific stage of psychiatric disorder recovery. At present, there is little other than clinical judgment to guide this decision.[81] Smokers with a history of depression who abstain from smoking are at significantly increased risk of developing a new episode of major depression at three and six months after treatment, and many smokers develop symptoms of depression during a quit attempt.[82, 83] Studies have yielded conflicting results about whether depressed smokers experience greater difficulty in quitting during a given quit attempt.[84, 85] A recent meta-analysis, however, showed that lifetime history of major depression does not appear to be a risk factor for failure in smoking cessation treatment.[86]

Pharmacotherapy

Medications for treating nicotine dependence are first-line treatment options for all smokers. Six medications are approved by the Food and Drug Administration (FDA) for nicotine dependence and are considered by all treatment guidelines as first line treatments.[87, 88] These six medications include five nicotine replacement medications (i.e., patch, gum, spray, lozenge, and inhaler) and bupropion SR.

The VA can ensure that all FDA-approved tobacco dependence treatment medications are available on the national formularies and that medications are available without excessive restrictions that create access barriers for patients. Most reports have found the various nicotine replacement therapies used in the general population to be equally effective, although the combination of NRT and bupropion SR, or multiple NRT medications may improve outcomes, especially with heavier smokers.[89, 90] Supplementing the patch with a second nicotine product may be helpful in allowing patients to titrate their nicotine dose based on the presence of

withdrawal symptoms and may be more effective than the patch alone. Although not FDA-approved at present, these combinations are recommended in the Public Health Service (PHS) guidelines.[91] All of the tobacco treatment medications have low abuse liability, and are similar in their effects on nicotine withdrawal, urges to smoke, abstinence rates, and patient satisfaction.[92, 93] Although pharmacotherapy can be effective alone, success rates increase when medications are combined with psychosocial treatment.[94, 95]

While research on using medications in this population is limited, the clinical experience of experts in the field suggests that the use of NRT and bupropion medications in tobacco dependence treatment for this population is very important.[96, 97] Clinical practice should consider the particular issues associated with a specific psychiatric disorder, the current psychiatric medications that are best suited to treat the problem, and the potential for interactions between the medications and tobacco use. Standard treatment regimens should be modified as needed to incorporate necessary adjustments and increases in medications and/or psychosocial treatments to effectively treat both disorders simultaneously. Bupropion is effective for smoking cessation for people with and without a history of depression or alcoholism,[98] and smokers with depression can benefit from receiving monotherapy with bupropion SR, based on its two FDA-approved indications. The nicotine patch is equally effective in smokers with and without a history of alcoholism.[99] Smokers with schizophrenia appear to be able to stop smoking, but overall quit rates are about half those of the general population of smokers.[100, 101] The nicotine nasal spray may be a promising approach for smokers with schizophrenia and schizoaffective disorder and may modestly improve some selected aspects of cognitive functioning in schizophrenia.[102, 103]

When selecting a medication to use in treating tobacco dependence among smokers with psychiatric disorders, one needs to consider factors such as cost, patient preference, and prescription versus over-the-counter status. Compliance appears to be highest with the patch, which is easiest to use and well tolerated. This may make its use preferable in patients with serious mental illnesses. It is less helpful for immediate craving and thus, in clinical practice, it is frequently administered with the nicotine gum, inhaler, or nasal spray. Combinations of bupropion SR and nicotine replacement are being investigated for added efficacy. It is necessary to monitor psychiatric medication side effects during changes in tobacco use, and consideration must be given to the effect of quitting smoking on psychiatric medication blood levels, side effects, and symptoms. When smokers initially abstain from tobacco, rapid shifts in blood levels of medications can occur and there is a risk of increased side effects if the medication dosage is not adjusted.[104] Polycyclic aromatic hydrocarbons (tars) in tobacco smoke induce the hepatic metabolism of medications that are metabolized through the cytochrome P450 enzyme CYP1A2, including many antipsychotics, antidepressants, and anxiolytic medications.[105, 106] Of note, nicotine is not metabolized through the 1A2 isoenzyme like the other components of tobacco smoke, and therefore, it does not have a clinical effect on changing medication blood levels. Nicotine is metabolized by the CYP2D6 isoenzyme. Induction of CYP1A2 results in the increased metabolism of medications and subsequent lowering of blood levels in smokers taking medications such as haldol, prolixin, thorazine, clozapine, and olanzapine.

Psychosocial Treatments

Psychosocial treatments for nicotine dependence are among the first-line treatments in recent practice guidelines.[107, 108] Combining psychosocial and pharmacological therapies increases abstinence rates by 50 percent when compared to either intervention alone; however, most patients' quit attempts have been made without either, and those who get treatment usually only receive medication treatment since psychosocial treatment is far less available.[109] The psychosocial treatments include motivational enhancement and cognitive behavioral therapies, such as social skills training, stimulus control techniques, and relapse prevention. These strategies are designed to increase skills and motivation to quit, and to provide support and education. Psychosocial treatment can range from very brief, single-session interventions to multi-session individual therapy. Though brief interventions can be effective, there is a strong dose-response relationship between the intensity of counseling and its effectiveness. Psychosocial interventions have been successfully adapted for smokers with psychiatric disorders, including schizophrenia,[110, 111, 112] depression,[113, 114, 115, 116, 117] and substance use disorders.[118, 119]

The VA Public Health Strategic Health Care Group, in collaboration with the Northwest Network Mental Illness Research, Education, and Clinical Center and the Center of Excellence in Substance Abuse Treatment and Education in Seattle, Washington, has developed and promoted a targeted brief smoking cessation intervention for use as a standard component of all VA mental health treatment sessions.[120] Recently, 53 VA clinicians from across the nation were trained to use the model in their daily practice with the expectation that they would educate other mental health professionals in their local facilities. This intervention involves educating psychiatric patients about how smoking affects their psychological health, improvements that can be expected following smoking cessation, and healthier strategies than smoking to manage emotional distress. Successful adaptation involves blending traditional mental health interventions with tobacco dependence treatments, while addressing the unique problems associated with specific psychiatric disorders. More VA initiatives are needed for other sub-types of smokers with psychiatric disorders.

Other types of tobacco dependence treatments in the community include telephone-based or internet-based interventions. The VA has an opportunity to develop and test these approaches. Almost nothing is known about the potential role or benefit of internet or telephone-based tobacco dependence treatment for this population. Real-world limitations could include lack of stable telephone service, reduced access to personal computers, and transient homelessness. These techniques may work better for less severe mental illnesses and addictions, although interestingly, we have found that some paranoid clients prefer internet groups over clinic groups. Because these services are often brief or time-limited, and not tailored to mental illness, they will likely never make a significant impact on reducing tobacco use in this group. There is limited information about the extent to which smokers with psychiatric disorders are accessing the internet or phone-line services or whether these interventions are effective for this group. The Quitcenters have found that about 50 percent of their patients have a history

of a psychiatric disorder and about 10 percent have a current psychiatric disorder for which they are receiving psychiatric treatment. These patients are primarily diagnosed with mild to moderate anxiety or depression disorders.[121]

Table 4: Increase Clinical Tobacco Dependence Outreach, Treatment, and Staff Training

- Train mental health and addiction treatment staff on how to screen, assess, and treat tobacco dependence.
- Mandate in-service or computerized training on tobacco dependence assessment and treatment for all psychiatrists and mental health clinicians. Incorporate motivation enhancement techniques in training materials.
- Develop integrated treatment models for mental health and addiction treatment settings
- Require that mental illness and addiction treatment programs have services for tobacco treatment at all levels of care.
- Assess the use and effectiveness of the computer-based smoking education reminder in mental health and addiction treatment settings.
- Require that tobacco dependence be included in treatment plans for all tobacco users with mental illness and/or addictions.
- Ensure that all FDA-approved tobacco dependence treatment medications are available on the national formularies and that medications are available without excessive restrictions.
- Create patient educational materials on tobacco use in veterans with mental illness and/or addictions for distribution on inpatient units, substance abuse programs, and mental health outpatient clinics.
- Initiate a more systematic effort to familiarize staff with existing VA web-based resources:
    - Healthier Feds: www.opm.gov/healthier/feds/smokingcessation.asp
    - Office of Personnel Management: www.opm.gov/ehs/smokgud3.asp

Research Initiatives

The VA system not only provides health care services but also funds research that targets important issues for veterans. There is a need and a great opportunity to include studies that target veterans who smoke and have psychiatric disorders. The above review of clinical issues for this population clearly points out many gaps in the literature for many sub-types of smokers with psychiatric disorders. There is a need to encourage cross-agency initiatives for the target population within and between NIH, SAMHSA and the VA. The NIH roadmap for research was a step in this direction. Two recent requests for proposals (RFPs) from NIDA, NIMH, and NIAAA have focused on the target population. SAMHSA-NIH collaborations could help address the gaps in systems research on the target population by encouraging all NIH and SAMHSA RFPs to include tobacco as it relates to the primary goal of the initiative. For example, NIDA has placed greater emphasis on nicotine in projects addressing other drugs of abuse, thereby increasing the visibility of nicotine in its portfolio. The VA has recently

funded a large treatment study of veteran smokers with PTSD and more research of this nature is needed. With its active program in research, the VA is in an ideal position to begin to increase research funding and activity in this area.

Table 5: Research Recommendations

- Develop a set of guidelines to optimize clinical trials research for this population
- Increase VA research funding for this population
- Include tobacco use measures on all standard reporting and assessment batteries with this population
- Fund secondary data analyses examining the relationship between tobacco dependence and other psychiatric disorders

Program and Systems Change

The VA has an opportunity to do local program interventions, VISN-wide interventions, and VA-wide interventions. Each level of intervention will require different approaches and should be included in an overall comprehensive VA plan.

Program Change: Better addressing tobacco in VA mental health and addiction treatment settings will require program and broader system change, including staff training, new policy implementation, development of harm reduction strategy options, and integration of motivation-based tobacco dependence treatment into existing treatment services. This will require that mental health and addiction treatment programs take ownership of nicotine dependence as a treatable DSM-IV diagnosis and begin to address tobacco in treatment. Program changes must occur at all levels of care and in all VA mental health and addiction treatment programs. The changes may range from minimal (including tobacco in the assessment and treatment plan and providing at least minimal patient educational information) to extensive (placing limits on staff and patient smoking or establishing tobacco-free buildings and grounds).

Effective steps for working with treatment programs and agencies to better address tobacco among smokers with psychiatric disorders have been developed and tested. Through consultations with more than 150 mental health and addiction treatment programs, the New Jersey Tobacco Dependence Program has refined its consultation service to help agencies to address tobacco, including some which have expressed a desire to have tobacco-free grounds.[122, 123] This program's (www.tobaccoprogram.org) consultation service provides staff training activities and provides program consultation to mental health and addiction treatment facilities.[124] There are great opportunities for state and VA partnerships to share developed products.

A program consultation can help the treatment program with developing comprehensive tobacco dependence assessments, providing treatment and continuing care planning, providing patient education, making self-help groups such as Nicotine Anonymous available to patients and their families, providing nicotine dependence treatment, and addressing staff and volunteer use of tobacco. Other program issues include developing policies related to tobacco, changing documentation forms in clinical charts to include more tobacco-related questions, labeling smokers' charts, not referring to breaks as "smoking breaks," forbidding staff and patients to smoke together, providing patient education brochures, and providing NRT for all smokers confined to restricted units.[125] In table 6, we list the steps developed at the UMDNJ Tobacco Dependence Program for effectively addressing tobacco in mental health and addiction treatment settings. Although originally developed for use at the treatment program and agency levels, they are applicable to larger systems and can be adapted to addressing tobacco within the VA.

Table 6: Steps for Addressing Tobacco within Mental Health and Addictions Services

1. Acknowledge the challenge.
2. Establish a leadership group and commitment to change.
3. Create a change plan and implementation timetable.
4. Start with easy systems changes.
5. Assess and document in charts nicotine use, dependence, and prior treatments.
6. Incorporate tobacco issues into patient education curriculum.
7. Provide medications for nicotine dependence treatment and required abstinence.
8. Conduct staff training.
9. Provide treatment and recovery assistance for interested nicotine dependent staff.
10. Integrate motivation-based treatment throughout the system.
11. Develop Addressing Tobacco policies.
12. Establish ongoing communication with 12-step recovery groups, professional colleagues, and referral sources about systems change.

Source: Ziedonis and Williams, note 122.

Tobacco-Free Grounds: In an effort to better address the need for clean air, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) requires that inpatient treatment be smoke-free and that treatment plans for smokers on these units include strategies for coping with the forced abstinence. Studies of the process of treatment units becoming tobacco-free have, in general, not found significant increases in rates of disruptive behaviors, discharges

without medical authorization, or the use of seclusion, restraints, or PRN medications.[126] In these settings, nicotine replacement medications can be very helpful in preventing nicotine withdrawal. A policy issue for the VA and other systems is whether or not to become totally smoke free, which includes addressing staff smoking and numerous other policy changes.[127] New Jersey is one of the few states with a licensure requirement that residential addiction treatment programs treat tobacco and have tobacco-free grounds and buildings. (North Carolina is another state that requires all its inpatient public addiction treatment programs to have smoke-free grounds). The definition of tobacco-free extends beyond requirements for clean indoor air, and refers to environments that are entirely free of tobacco smoke and tobacco use. Tobacco-free programs understand that any use of tobacco products is incongruent with a lifestyle free of addictive drugs and recognize the need to assist patients, employees, and volunteers at the facility to address their own tobacco use.

Tobacco Control

In addition to local program interventions, the VA has the opportunity to do larger system interventions. Another possible area for expanding efforts to help smokers with psychiatric disorders is to include the Tobacco Control perspective. Most clinicians are unaware of the Prevention/Tobacco Control orientation outlined in Table 7.

Table 7: Taxonomy of Tobacco Control Policies

Information and Education	Economic Incentives	Direct Restraints on Tobacco Use
1. Require health warnings on advertisements	1. Increase tobacco taxation (e.g., excise taxes)	1. Restrict smoking in certain places (e.g., public places, workplaces, schools, hospitals)
2. Mandate educational programs --Schools --Mass media (counter-advertising)	2. Mandate insurance incentives --Premium price differentials (smoker-nonsmoker) --Cover smoking cessation treatment costs	2. Restrict distribution or sales --By age (minors) --By certain outlets (e.g., vending machines)
3. Restrict or ban advertising and promotion	3. Change tobacco crop price support system	3. Regulate production composition
4. Issue government reports (e.g., Surgeon Generals' reports)	4. Establish legal liability --Of purveyors/manufacturers --Of employers for environmental tobacco exposure	4. Ban manufacture, sale, or use
5. Require disclosure of constituents of tobacco products or smoke		

Source: Bierer and Rigotti, 1992: Modified from U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control: "Smoking control policies," in *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. DHHS Publication No (CDC) 87-8411, 1989.

As Table 7 indicates, most tobacco control strategies have been broad-based and have targeted the general public. Treatment systems for mental health and addictions disorders have not embraced tobacco dependence, and many of these clients are unable to access traditional tobacco resources that target highly-motivated groups. More focused tobacco control efforts are needed for this population. Targeted interventions can be effective, and have been developed for other sub-groups such as minorities, adolescents, and pregnant women. Common tobacco control strategies include policy formation, taxation, and antismoking media campaigns. Examples might include policies mandating assessment and treatment; requiring managed care to fund tobacco dependence treatment and limiting smoking on treatment facilities and grounds; anti-tobacco messages tailored to these groups; and grass-roots advocacy by consumer and family groups and/or professional organizations. Since little is known about which of these will be most effective with this population, other strategies may be warranted. Smoking prevalence has been reduced in the general population since the 1960s, due in large part to tobacco control interventions; however this has not been the case for smokers with a mental illness or addictive disorders. Smokers with mental illness or addiction have been absent from tobacco control efforts by leading organizations. Similarly, this population of smokers is not included in current definitions of "priority" or "special" populations, but should be, based on a disproportionate consumption of tobacco, the lack of attention to the issue, and not having a natural advocacy base for this topic. Resource allocation and the definition of disparity groups should include target populations with a disproportionate amount of tobacco consumption.

Table 8: Make Broader VA Policy Changes

- Consider the role of tobacco control/public health at the VA for this population.
- Encourage Tobacco Advocacy Organizations to focus on tobacco control efforts in this area.
- Prohibit all staff from smoking with patients.
- Partner with other state and federal agencies.
- Support Clean-Air legislation.
- Consider removing all outdoor smoking kiosks from VA hospital grounds.
- Help provide tobacco dependence treatment for staff who smoke, including on-site employee assistance programs.

Conclusion

The VA health care system has the opportunity to lead the nation in helping both veterans and non-veterans with psychiatric disorders who smoke and are likely to die of tobacco-caused medical disorders. This will require increased awareness throughout the VA about the high rate and severity of tobacco dependence among psychiatric patients. About 25 to 40 percent of all veterans receiving treatment within the VA system have a psychiatric disorder and most of them are tobacco dependent. There is also a great need within the VA to train all mental health and addiction treatment staff on how to treat tobacco dependence. There is a great need to immediately address the issue of tobacco dependence among veterans with psychiatric disorders at the clinical, program, and systems levels, to fund more research to better understand the problem, and to develop and evaluate new interventions. Given the unique biological, psychological, social, and treatment setting factors that account for the increased risk for tobacco dependence in this population, the implications of these factors for clinical treatment must be considered. The VA health care system changes must be expanded across the 22 relatively autonomous VISNs. The VA is well positioned to develop, test, and promote innovative tobacco dependence treatment approaches to improve the health of veterans, but this work will have a ripple effect in helping behavioral health care practitioners nationally and internationally.

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Post-traumatic Stress Disorder and Smoking Cessation in Veteran Smokers

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This paper examines the available information on smoking cessation and post-traumatic stress disorder (PTSD). Unfortunately, there are only two available preliminary smoking cessation intervention studies for smokers with PTSD. The paper first reviews the definitions and epidemiology of PTSD, as well as smoking rates in the VA and veterans with PTSD. Next, it presents preliminary information regarding the relationship between PTSD symptoms and smoking. Finally, it presents various approaches to smoking cessation for PTSD smokers in the VA, and explores potential fruitful avenues for enhancing smoking cessation rates in this population.

Post-Traumatic Stress Disorder

As defined in the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV), PTSD is a set of specific symptoms that an individual develops following exposure to an extreme traumatic stressor (see appendix 1). Individuals with PTSD may be at increased risk for co-morbid anxiety disorders, major depressive disorder, somatization disorder, and substance-related disorders.[1] Furthermore, as part of the diagnostic criteria, individuals with PTSD experience significant distress and debilitating impairment in social and occupational functioning.

Definition

According to the DSM-IV, PTSD is comprised of six different diagnostic criteria.[1] First, the person must be exposed to a traumatic event, defined as an event during which the person experienced, witnessed, or was confronted with actual or threatened death, serious injury, or a threat to the physical integrity of self or others. Moreover, the individual's response must have involved intense fear, helplessness, or horror. The definition of a traumatic event is that the person must experience or witness actual or threatened death or serious injury or a threat of physical integrity to self or others and his or her response must be one of intense fear, helplessness or horror. PTSD symptoms in three clusters must be present, including reexperiencing, avoidance and numbing, and hyperarousal symptoms. The full symptom criteria are presented in Table 1. Symptoms must have been present for at least one month and lead to clinically significant distress or impairment in social, occupational, or other areas of functioning.

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Epidemiology

It is estimated that 60 percent of people in the United States will experience at least one traumatic event in their lifetime, with approximately 8 percent of them developing PTSD. Approximately 30 percent of those affected will develop chronic PTSD.[2] Prevalence rate estimates for PTSD have varied widely as a function of a number of factors including trauma characteristics and study methodology (e.g., sampling and diagnostic methods); however, the overall data suggest that PTSD occurs in a significant proportion of individuals exposed to traumatic events. Davidson and Fairbank reviewed the epidemiological literature on PTSD, grouping studies into those based on community populations and those at high risk based on prior exposure.[3] Community-based samples yielded lifetime prevalence rates ranging from 1 to 19 percent. According to their review, prevalence rates for at-risk populations (e.g., Vietnam veterans, rape victims) ranged from 14 to 75 percent.

Among adults, the rate of lifetime PTSD for victims of sexual assault may be as high as 80 percent [4, 5] and PTSD rates for victims of physical assault have ranged from 23 to 39 percent.[4] Prevalence rates for adults exposed to disasters have ranged from 2 to 80 percent.[6] Epidemiologic data indicate that the lifetime rate for the development of PTSD is higher in women (10 to 12 percent) than in men (5 percent).[2] Saigh and colleagues conducted a review of epidemiological studies involving children exposed to traumas and found that prevalence rates varied widely within and between categories of stressors with exposure to war, crime victimization, and natural disasters or serious accidents being associated with the highest rates of PTSD (up to 75 percent, 71 percent, and 95 percent, respectively).[7] They noted that the high degree of variability in prevalence rates appeared to be a function of the severity of the stressor, time between exposure and assessment of PTSD, and methodological factors (e.g., sampling procedures and diagnostic methods).

In two of the Epidemiological Catchment Area (ECA) sites, several researchers [8, 9] found that 33 to 47 percent of individuals retained the diagnosis of PTSD for more than one year. Therefore, chronicity of PTSD does not appear to be limited to the more severe treatment-seeking samples.[10]

Prevalence of PTSD in Veterans

Rates of PTSD among veterans appear to vary according to combat zone exposure. Veterans from the Vietnam War era were the first population on which systematic and focused studies of PTSD prevalence rates were conducted. The National Vietnam Veterans Readjustment Study (NVVRS) was the most comprehensive of these studies. From this data, [11] as well as data from the National Comorbidity Study, the estimated lifetime prevalence of PTSD among American Vietnam theater veterans is 31 percent for men and 27 percent for women. [2, 11] In addition, another 22 percent of male and 21 percent of female veterans have had partial PTSD at some point in their lives. Thus, more than half of all male Vietnam veterans and almost half of all female veterans (about 1,700,000 Vietnam veterans in all) have experienced PTSD symptoms. Approximately 15 percent of all male Vietnam theater

veterans (479,000 out of 3,140,000) and 8 percent of all female Vietnam theater veterans (610 out of 7,200) are currently diagnosed with PTSD. In contrast, approximately 1 percent of Gulf War veterans from Desert Storm have been diagnosed with PTSD.[12,13] In the only published report to date examining rates of PTSD in veterans from the Afghanistan and Iraq wars, rates of PTSD in these populations was estimated to be 11 percent in Afghanistan era veterans and 15 to 17 percent in Iraqi era veterans.[14]

Etiology and Pathophysiology

PTSD is defined in terms of etiology as much as by phenomenology. The disorder cannot exist unless the individual has been exposed to a traumatic event that elicits a response of helplessness, horror or fear. Trauma exposure is a necessary, but insufficient, requirement for diagnosis. Not all individuals who are exposed to traumatic stressors develop PTSD. Several researchers have suggested that there is a consistent and positive relationship between the magnitude of the traumatic event and the risk of developing PTSD, and this association is applicable to different trauma populations.[15] For example, in the St. Louis ECA study, PTSD rates were three times higher in wounded Vietnam veterans than in non-wounded veterans.[9] In the North Carolina ECA study, PTSD was much more likely to occur in sexual assault victims who were physically injured than in those who were non-injured.[16] Other studies have shown similar results in Vietnam veterans[11] and victims of a volcanic eruption.[17] In addition to the objective event characteristics (actual or threatened death or injury or threat to physical integrity), March concluded that cognitive and affective responses are also important.[18]

Expert Consensus Guideline Series: Treatment of PTSD

The expert consensus guidelines for the treatment of PTSD are based on surveys of experts on psychotherapeutic and medication treatment approaches to PTSD.[19] However, there are few empirical studies that have evaluated combined approaches. The general guidelines for both medication and psychotherapy are as follows:

- With regard to whether to start with psychotherapy, medication, or a combination of both, the PTSD treatment guidelines vary depending on whether the individual is diagnosed with severe vs. mild or acute vs. chronic PTSD.
- In adults with mild acute PTSD, both psychotherapy and medication experts recommend psychotherapy first. In cases of mild chronic PTSD, psychotherapy experts recommend psychotherapy first, while medication experts recommend a combination of both medication and psychotherapy first. In adults with severe PTSD (acute or chronic), psychosocial experts recommend psychotherapy first, whereas the medication experts prefer combination treatment first.
- When a comorbid psychiatric disorder is present, experts recommend treating PTSD with a combination of both psychotherapy and medication from the start. In cases of mild substance abuse or dependence problems, the experts recommend that the treatment for both substance abuse and PTSD be provided simultaneously. In cases with more

severe substance abuse problems, it is recommended that either the substance abuse problems be treated first, or treatment for both substance abuse and PTSD be provided simultaneously.

Guidelines for Psychotherapy

During the initial phase of treatment (first three months or until the patient is stabilized), the experts recommend that psychotherapy be delivered weekly, in 60-minute individual sessions. The most recommended psychotherapeutic techniques include anxiety management (i.e., relaxation training, breathing retraining, positive thinking and self-talk, assertiveness training, thought stopping), cognitive therapy, exposure therapy (*in vivo* and imaginal), play therapy, and psychoeducation. The experts make specific technique recommendations depending on which symptoms are more prominent. Psychoeducation is recommended as a second line option for all types of target symptoms, and is important in the treatment of every patient with PTSD. The type of comorbid disorder affects the choice of specific psychotherapy techniques as well.

For example, cognitive therapy is recommended when there is a comorbid mood or anxiety disorder or a cluster B personality disorder. Anxiety management is especially recommended when a comorbid anxiety disorder is present or there are substance abuse problems. Exposure therapy is also especially recommended when there is a comorbid disorder. The experts believe that techniques effective for PTSD when used alone (anxiety management, cognitive therapy, exposure therapy, and psychoeducation) are also effective when combined. Furthermore, combining techniques may be especially helpful for patients who have a complex presentation or who have had a poor response to treatment. The choice of which and how many of the techniques to combine should be based on clinical judgement and patient preference.

Guidelines for Medication Treatment

Weekly medication visits are recommended for the first month, followed by bi-weekly visits thereafter. The newest antidepressants (selective serotonin reuptake inhibitors, or SSRIs, nefazadone, and venlafaxine), are usually favored regardless of the prominent symptom type. The experts also recommend the newer SSRIs for patients who have a variety of different medical conditions. The second line medication choices vary by type of disorder (see treatment guidelines for details). While benzodiazepines may sometimes be helpful in the short term, they must be used with caution in patients with current or past substance abuse problems. The expert panel recommended similar treatment for acute or chronic PTSD patients who do not respond to the initial treatment (< 25 percent reduction in symptoms). For patients receiving only one type of therapy (i.e., medication or psychotherapy alone), the experts offer two general treatment recommendations which may be helpful either separately or in combination: (1) add the type of treatment the patient has not yet received, and/or (2) switch to a different psychotherapy technique or to a different medication. The PTSD treatment guidelines recommend that clinicians use their clinical judgment in deciding whether to add a new treatment, switch to a different treatment, or do both. For a patient who is not responding to

one of the three preferred psychotherapy techniques (anxiety management, cognitive therapy, or exposure therapy), the experts recommend adding one or both of the other techniques.

When patients have had a partial response to treatment (25 to 75 percent of symptoms remaining), the guidelines recommend continuing the current treatment and adding another medication and/or additional psychotherapy. Similar to when there is no response, if a patient is having a partial response to one of the three preferred psychotherapy techniques, experts recommend adding one or both of the other techniques. Although helpful in guiding clinical decision making, it must be noted that many of the recommendations regarding sequencing and treatment combinations have yet to be empirically investigated.

PTSD and Tobacco Use

Psychiatric Disorders and Cigarette Use

Researchers have demonstrated a clear link between psychiatric disorders and cigarette use, which represents a major health risk for individuals with psychiatric disorders. It is estimated that individuals with psychiatric conditions consume 44 percent of all cigarettes sold in the United States.[20] Between 50 and 80 percent of those suffering from a mental illness smoke, whereas less than 40 percent of those who have never had mental illness smoke.[20] Although many psychiatric patients report repeated attempts to stop smoking, their efforts often result in failure. Smokers diagnosed with schizophrenia and depression, as compared to non-patient smokers who smoked at a comparable level, selected smoking as their preferred activity more often, perceived smoking as having more benefits, and believed they would require greater incentives to quit. This was true despite the fact that the diagnosed smokers recognized the same amount of negative outcomes associated with smoking as the non-patient smokers.[21] A complicating factor is the fact that alcohol and drug use disorders are more prevalent among people with a psychiatric illness,[22] and co-occurring substance abuse is a strong predictor of smoking status among psychiatric patients.[23, 24] Because both substance abuse and psychopathology have been linked to elevated rates of smoking among psychiatric patients, an important unanswered question is whether psychiatric diagnosis and other indices of psychopathology are independently associated with smoking after the effects of substance abuse are controlled. Prior research addressing this question has yielded mixed results; [24-26] however, a more recent study of a large and diverse psychiatric outpatient sample with a wide range of psychiatric conditions suggested that diagnosis and severity of illness contributed to increased smoking rates, even after controlling for the effects of substance abuse.[27]

Trauma, PTSD, and Smoking

Individuals with PTSD are among those most at risk for smoking. Several studies indicate that individuals who have been exposed to a traumatic event are significantly more likely to start smoking[4, 28] and are more likely to be heavy smokers.[20, 29, 30] Thus, the effects of trauma

and associated PTSD symptomatology each appear to be related to both the initiation and maintenance of smoking, with PTSD representing a significantly higher risk factor than trauma exposure alone. A recent study by Breslau and colleagues[28] sheds more light on the nature of the relationship between trauma exposure, PTSD, and nicotine dependence. Both individuals with PTSD and trauma-exposed individuals without PTSD were at higher risk of nicotine dependence than were individuals without trauma exposure. However, the individuals with non-combat related PTSD had an increased odds ratio of 4.03 for smoking, whereas the odds ratio for those with trauma exposure was only 1.0.[28] In a population based prevalence study, Lasser and colleagues reported (based on a sample size of 4,411) that 45 percent of those diagnosed with PTSD were smokers.[20] This smoking rate was significantly different from respondents without mental illness (22 percent). Moreover, of the 14 psychiatric disorders sampled, individuals with PTSD had the fourth highest percentage of smokers, higher than those with social phobia, agoraphobia, panic disorder, major depression, dysthymia, panic attacks, simple phobia, non-affective psychosis, alcohol abuse or dependence, and antisocial personality. The prevalence rate of smoking in individuals with PTSD was only exceeded by generalized anxiety disorder, drug abuse or dependence, and bipolar disorder.

Prevalence rates of smoking among VA enrollees have been estimated at about 30 percent.[31-34] When standardized for sex and age to the 1999 U.S. population, the overall prevalence was 33 percent (37 percent for men and 29 percent for women). This is roughly 10 percent higher than the 1998 Behavioral Risk Factor Surveillance System data from the Centers for Disease Control,[35] which had a U.S. prevalence of 23 percent (25 percent for men and 20 percent for women). In addition, heavy smoking (a minimum of 21 cigarettes per day) was roughly twice as prevalent among VA users (7 percent overall, and 9 percent for men and 6 percent for women), as compared to the United States population prevalence of 4 percent (5 percent men, 2 percent women). As will be discussed in greater detail later, smokers with PTSD are among the least successful psychiatric populations with respect to smoking cessation.

Negative Affect and Cigarette Smoking

Although there is growing evidence regarding factors that influence smoking and nicotine self-administration, there are significant gaps in identifying which subjective and behavioral nicotine effects are particularly reinforcing, and for whom they are reinforcing.[37] In self-medication models of substance abuse, the substance is thought to assist individuals in their efforts to regulate mood.[38] Virtually all smokers, at least in part, attribute their smoking to anxiolytic and sedative properties of smoking.[39, 40] Smokers reliably report that they smoke more when they are anxious, angry, stressed, or sad.[41] They also report the expectation that smoking will alleviate their negative moods and reduce their negative affect.[42] Negative affect may be a particularly salient antecedent for smoking in psychiatric populations.[43]

A review examining smoking, stress, and negative affect carefully presents the current evidence for an association between these variables across three developmental stages of smoking–initiation, maintenance, and relapse.[44] Since negative affect is more common in

psychiatric populations and a predictor of relapse to smoking,[45] the smoking of psychiatric populations may be more likely to be associated with negative mood. In addition, there is evidence that smoking withdrawal symptoms are related to idiosyncratic psychiatric symptomatology; for example, anxious smokers are more likely to have withdrawal symptoms related to anxiety.[46] This raises the possibility that not only are psychiatric symptoms related to craving and increased smoking, but that smoking withdrawal may lead to increased psychiatric symptoms.

Several somewhat discrepant lines of evidence regarding the association between smoking and affect have emerged. One line of evidence suggests that smoking may have an anxiolytic or antidepressant effect,[47-49] and laboratory studies have strengthened the hypothesis that stress and negative affect can lead to increased smoking.[45,50] Conversely, a second line of evidence suggests that smoking may exacerbate negative affect. For example, smoking and nicotine administration have been associated with increased distress[51] and the development of panic attacks.[52,53] In a longitudinal study with adolescents, initiating smoking was associated with increased incidence of psychological problems three years later. Specifically, smoking at age 18 increased the risk of anxiety and depressive disorders.[54] A third line of evidence, consistent with a self-medication model, has hypothesized that smoking allows affect to be actively controlled and managed, and thus possibly lessened.[55] For example, Perkins[56] has suggested that nicotine's subjective effects are related to the person's pre-smoking state and the reinforcing effects of nicotine may come from a normalized mood, rather than from a single mood-altering effect.

Although these studies represent seemingly discrepant findings, Gilbert has asserted that the effect of smoking on mood state is a function of both situational demands and biologically based individual differences in personality, psychopathology, and cognitive ability (i.e., situation X trait adaptive response model – STAR).[57] For example, whereas nicotine may serve to modulate or alleviate negative affect in many instances, in other contexts such as arousal associated with fear or traumatic memory, nicotine may maintain specific symptoms. However, more information is needed to characterize the effect of nicotine on mood states as it relates to the complex interaction between individual and situation, particularly in psychiatric populations.

Assessment of Smoking in PTSD Patients

To date, only a few studies have examined smoking specifically among individuals with PTSD. In a recent study, McFall and colleagues found that the nine-month abstinence rate for smokers who completed smoking cessation with their PTSD provider was 12 percent, while the abstinence rate of smokers completing smoking cessation with standard VA smoking cessation care was 3 percent.[58] These long-term point prevalence rates illustrate the need to identify risk factors and mechanisms that may lead to improved smoking prevention, intervention, and relapse prevention techniques in individuals with PTSD or trauma exposure.

Risk factors for smoking that need to be assessed and which have been documented in the research literature include negative affect, anxiety, PTSD symptomatology, and craving. PTSD is characterized by high levels of anxiety and PTSD patients report that smoking cigarettes reduces their anxiety. Our ambulatory data suggests that compared to non-PTSD smokers, negative affect and PTSD symptoms are significant antecedents to smoking among PTSD smokers.[59] Additionally, our laboratory data suggests that craving and distressing symptoms are decreased in smokers with and without PTSD after smoking a cigarette.[10]

Mechanistic Studies: Ambulatory and Experimental Results

For the past few years, our research group has conducted a number of studies examining the association between PTSD and smoking, as well as smoking cessation efforts with this population. Recently, we began collecting data in carefully controlled experimental sessions to evaluate the effects of nicotine and non-specific behavioral effects of smoking on craving and PTSD symptomatology. We have coupled this work with a small-scale, placebo-controlled trial of bupropion for smoking cessation in PTSD patients,[60] a study of smoking topography by context in smokers with PTSD,[61] and a study examining the effect of smoking and PTSD diagnosis on ambulatory heart rate and blood pressure.[62] At present, we are also investigating the effect and possible mechanisms of smoking on affective modulation of acoustic startle response (ASR) and prepulse inhibition (PPI) in male and female PTSD smokers to provide complementary information regarding maintenance of smoking in this group.

Using ambulatory methods for one day of monitoring, we investigated the association between smoking and situational cues in 63 smokers with PTSD and 32 smokers without PTSD.[59] Generalized estimating equations contrasted 682 smoking and 444 nonsmoking situations by group status. Smoking was strongly related to craving, positive and negative affect, PTSD symptoms, restlessness, and several situational variables among PTSD smokers. For non-PTSD smokers, the only significant antecedent variables for smoking were craving, drinking coffee, being alone, not being with family, not working, and being around others who were smoking. These results are consistent with previous ambulatory findings regarding mood in smokers, but also underscore that in certain populations, mood and symptom variables may be significantly associated with *ad lib* smoking.

In a laboratory setting, the association between recalling neutral, stressful, and traumatic events with craving, affect, and PTSD symptoms in smokers with and without PTSD was evaluated. [10] One hundred thirty-seven smokers (87 PTSD and 50 non-PTSD) completed eight sessions. The first was a diagnostic session and the second was a script procedure to generate personalized trauma, stress, and neutral scripts. In the remainder of the sessions, the effect of script type X nicotine condition (nicotinized or denicotinized cigarette) on craving, affect and PTSD symptoms was evaluated. There was a main effect of script type across both groups for smoking craving, negative affect, and PTSD symptoms, with increased symptoms in trauma and stressful conditions. Responses were significantly higher in PTSD smokers. Smoking either a nicotinized or denicotinized cigarette resulted in decreased craving, negative affect,

and PTSD symptoms in both groups. A second script presentation elicited similar responses, suggesting that the ameliorative effect of having smoked a cigarette was short-lived.

An exaggerated startle response is one of the diagnostic criteria for PTSD and may help explain possible mechanisms related to maintenance of smoking in this group. The acoustic startle response (ASR) represents a reflexive response to a high intensity and abrupt auditory stimulus and is commonly measured as a change in EMG activity resulting from contraction of the orbicularis oculi muscle. The ASR is reduced in amplitude when it is preceded by a lower intensity, non-startling auditory stimulus (the prepulse). A primary advantage of using ASR and prepulse inhibition (PPI) is that the use of a physiological measure allows for data that are more "objective" and more readily quantifiable than self-report data. The exclusive use of self-report in PTSD patients has been a long-standing area of concern among researchers.[63]

PPI and ASR have been studied in individuals (not evaluated for psychiatric condition) pre- and post-smoking cessation and have been shown to predict successful cessation. [64] The effect of smoking and smoking withdrawal on startle and PPI in PTSD patients has not yet been characterized, but may supply potentially predictive information regarding smoking withdrawal in this high-risk population. [65,66] In a recent pilot study, we examined the effects of nicotine on PPI of the startle response in six PTSD and five non-PTSD smokers. Startle and PPI amplitudes were examined separately. Results showed a main effect of cigarette type, reflecting the fact that participants demonstrated less PPI after smoking nicotine cigarettes than de-nicotinized cigarettes. Although statistically non-significant, the group means indicated that amplitudes were higher in both cigarette conditions for PTSD smokers. We are continuing this line of research by evaluating ASR and PPI in smokers with PTSD with an emphasis on investigating possible attentional mechanisms of smoking by administering neurocognitive measures across nicotine conditions. The goal of this line of research is to inform the development of smoking cessation strategies in PTSD smokers by identifying the mechanism of smoking that may be present in smokers with PTSD.

Smoking Cessation

Smoking Cessation Treatment

The relative efficacies of smoking cessation components have been evaluated in meta-analytic studies.[67] Compared to no intervention and self-help, individual or group counseling increases the efficacy of smoking cessation rates twofold (from approximately 8 to 15 percent). Compared to no counseling, minimal counseling (<3 minutes), brief counseling (3 to 10 minutes) or longer counseling interventions (>10 minutes) increase the efficacy of smoking cessation intervention twofold. A longer duration of treatment (>8 weeks) resulted in a two- to threefold increase in efficacy compared to briefer durations. Odds ratios for use of nicotine replacement therapies range from 1.4 to 1.5, compared to control interventions. In general, more intensive interventions result in greater savings in cost per life-year, suggesting that greater spending on interventions yields more net benefit.[68] A combination of intensive

counseling and the nicotine patch was evaluated to be particularly beneficial in increasing cessation rates on a single attempt in general smokers (17 percent).[68] Although the rates of smoking associated with particular treatment components have been evaluated with general smokers, there has been little evaluation of their efficacy with high-risk sub-groups such as PTSD and trauma exposed individuals.[69] In addition, a meta-analytic review of 192 articles indicates that to date, gender and racial/ethnic status have been poorly documented.[70]

Emerging evidence suggests that the majority of individuals attempting to quit smoking will lapse within the first or second week after quitting and will subsequently relapse.[71,72] Brown and colleagues found that even with extensive preparation, 37 percent of participants lapsed on the planned quit date.[73] In our clinic, we have found that help-seeking veterans who currently smoke and are diagnosed with PTSD report a mean number of 22 quit attempts. These findings suggest that increased understanding of smoking relapse is needed. Although nicotine withdrawal might be expected to be the strongest predictor of early lapse and subsequent relapse, studies attempting to relate severity of nicotine-withdrawal symptoms to short-term smoking cessation outcomes have produced mixed results.[74]

Based on the National Comorbidity Study data, PTSD is associated with a lifetime smoking quit rate of 23 percent compared to a 42 percent quit rate in individuals without mental illness.[15] This rate is also third from the bottom in a ranking of quit rates associated with 13 mental disorders,[15] underscoring the importance of developing effective treatments for smoking cessation for patients with PTSD.

Smoking Cessation and Major Depressive Disorder

Although the purpose of this paper is not to review the literature on smoking cessation and major depressive disorder (MDD), since PTSD is highly comorbid with MDD, and there is more research regarding smoking cessation and MDD than PTSD, this research area offers information regarding approaches that may be useful in investigating smoking cessation and PTSD.

In a recent meta-analysis, lifetime history of major depression did not appear to be an independent risk factor for cessation failure in smoking cessation treatment. [75] However, this review did not include sufficient information regarding smoking cessation in smokers with current major depression or recurrent major depression. Glassman [76] found that smokers with recurrent depression were at greater risk for relapse than were those with a single-episode history, and also found that those with lifetime depression and not on antidepressant medications were at significant increased risk of developing a new episode of major depression for at least six months. [77,78] The notion that a recurrent history of depression, compared to a single-episode depression, increased risk for poor outcome was supported in a study by Brown and colleagues.[73] In this study, the efficacy of mood management-smoking cessation treatment was compared to standard treatment in 179 smokers, all of whom had a lifetime history of depression. Among those who received standard treatment, history of recurrent depression (but

not single-episode depression) predicted relapse. Overall, smokers with recurrent depression who received mood management were significantly more likely to be abstinent at one year than were those who received standard treatment. In a study evaluating patterns of change in depressive symptoms during smoking cessation, Burgess and colleagues found that among smokers with an MDD history, there is substantial heterogeneity in patterns of depressive symptoms during quitting, and patterns involving increased symptoms (both rapid and delayed increasers) were associated with especially poor smoking cessation outcomes.[79]

The relevance of these study results in considering smoking cessation treatment in veterans with PTSD is high. First, based on the available evidence, [79] it may be the case that there is also substantial heterogeneity in patterns of psychiatric symptoms (including depressive and PTSD symptoms) during quitting in smokers with PTSD, but this needs to be studied. Second, since the majority of smokers with PTSD also meet criteria for recurrent major depression, training in mood management may be particularly useful in treatment of smokers with PTSD; however, this needs to be evaluated. To date, there have only been two published studies focusing on smoking cessation in smokers with current major depression.[80, 81] Although results of these studies suggest that smokers with current major depression can achieve similar abstinence rates as non-depressed smokers, it may be limited to short term abstinence or less severe depression. Thus, further investigations including smokers with current psychiatric illness need to be conducted.

Smoking Cessation and Psychotic Disorders

There is a relatively extensive literature on smoking and schizophrenia, and aspects of this literature will be presented for considering fruitful areas of research in smoking and PTSD. In schizophrenia, the relationship between symptoms and smoking is complex. Compared to the general population, there are particular sub-types (paranoid, undifferentiated, and residual) that have significantly higher rates of smoking, whereas others (disorganized, catatonic) do not.[82] Frequency of smoking in patients with schizophrenia increases with increasing positive symptoms and decreases with increasing negative symptoms. Contrary to PTSD,[83] smoking initiation occurs in the vast majority of patients prior to, rather than following, disease onset.[82] Results from a recent study suggest that there is an interaction between type of psychiatric medication (e.g., atypical psychotic versus traditional antipsychotic drug treatment) and the efficacy of bupropion as a smoking cessation treatment, such that atypical anti-psychotic drug treatment enhanced smoking cessation response to bupropion. [84] As in the depression literature, these data from the schizophrenia and smoking literature underscore that the heterogeneity represented in the psychiatric population may affect initiation, maintenance, cessation, treatment response, interaction with co-morbid psychiatric disorder, interactions between medications and treatment response, relapse, and chronicity of smoking in other psychiatric populations such as PTSD smokers.

Smoking Cessation and PTSD

As summarized by McFall and colleagues,[58] although pharmacological and behavioral treatments for nicotine dependence have proven efficacious in controlled clinical trials and these may be helpful in the treatment of PTSD smokers, there is general evidence in the VA system that these treatments are not routinely and consistently offered.[85] Only 17 percent of veterans who desire treatment reported having received assistance for their nicotine dependence in the prior year.[86] Research has shown that primary care providers only infrequently apply even brief, cost-effective smoking cessation interventions, even though the majority of smokers report wanting to quit.[36, 86] Evidence suggests that nicotine dependence treatments in patients with mental disorders is particularly neglected, as demonstrated by evidence that psychiatric patients received cessation counseling during only 38 percent of their visits with a primary care physician and 12 percent of their visits with a psychiatrist.[87] Furthermore, a recent study found that psychiatric inpatients ($n = 250$) were not assessed or treated for nicotine dependence during their psychiatric hospital admission.[88] Only 1 percent of smokers were encouraged to quit during their hospital stay, nicotine dependence was unassessed, and smoking status was never included in the treatment plan. Unfortunately, the effectiveness of referring patients to VA smoking cessation clinics is reduced by poor patient compliance, with attendance rates as low as 13 to 14 percent.[33, 89] Moreover, these clinics are limited in their capacity to provide repeated treatment to large numbers of smokers who frequently relapse to smoking.

A recent study by McFall and colleagues evaluated the effect of integrating treatment for nicotine dependence into PTSD smokers' ongoing mental health care.[58] PTSD smokers were randomly assigned to practice guideline-concordant cessation treatment integrated with psychiatric care and delivered by mental health providers [Integrated Care (IC)], versus cessation treatment delivered separately from PTSD care by smoking cessation specialists [Usual Standard of Care (USC)]. IC subjects received smoking cessation intervention modeled after the brief clinical interventions for primary care practitioners published in Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline for Smoking Cessation.[cited in 58] IC subjects received care by their PTSD clinic prescriber and case manager, and clinicians followed a manual that operationalized interventions for each session. Subjects received smoking cessation protocol medications (bupropion, NRT) in both the IC and USC conditions. The IC protocol required case managers to administer five individual behavioral counseling sessions on a once-weekly basis, plus one follow-up contact. After delivering the six core behavioral counseling sessions, the protocol required clinicians to assess smoking status periodically and reinstate cessation treatment for subjects who relapsed. Subjects randomized to USC were referred to the VA Puget Sound Health Care System Specialized Smoking Cessation Clinic.

IC subjects (12.1 percent) were more likely than USC subjects (3.3 percent) to stop smoking as measured by seven-day point prevalence abstinence at four, six, and nine months post-randomization, but the enduring abstinence group difference was nonsignificant. Stopping smoking was not associated with worsening symptoms of PTSD or depression. A

recent VA Cooperative Study (#519) has been funded to examine this issue with sufficient statistical power, and the large-scale study may provide additional opportunities to evaluate treatment components for smoking cessation in veterans with PTSD.

Steinberg and colleagues have carefully outlined psychosocial approaches that may be particularly beneficial in the treatment of psychiatric smokers for smoking cessation.[90] These include relapse prevention and motivational interventions. Steinberg and colleagues found that a 40-minute, one-time psychosocial intervention of motivational interviewing (including personalized feedback by the therapist highlighting the patient's individual issues related to tobacco) increased contact with the tobacco dependence treatment program within one month by 3 percent.[90] Considerations of the patient's psychiatric status are needed and may include difficulty in group administration settings, poor social skills, cognitive limitations, and low motivation.

The only available studies evaluating smoking cessation interventions for PTSD smokers are a small scale placebo controlled trial of bupropion,[60] and a larger scale study evaluating the effect of smoking cessation delivery by mental health providers who were also responsible for smokers' PTSD treatment.[58] In our study of bupropion,[60] 15 veterans with chronic PTSD who desired to stop smoking enrolled in a 12-week double-blind evaluation of bupropion SR or placebo. Ten patients received bupropion SR and five received placebo. Nine of the patients who received bupropion SR were already being treated with at least one other psychotropic medication. Eighty percent of patients receiving bupropion SR successfully stopped smoking by the end of week two, and six (60 percent) of these 10 maintained smoking cessation at the study endpoint (week 12). At the six-month follow-up, 40 percent of the patients (4 of 10) who received bupropion SR maintained smoking cessation. Further investigation of this preliminary data needs to be conducted, including examination of predictors of smoking relapse in this population.

Telephone counseling is an approach that has also not been specifically evaluated for smoking cessation in PTSD smokers. Telephone counseling protocols have substantial support for smoking cessation,[91, 92] and additional investigation of this approach as a treatment intervention component is warranted.

Smokers with trauma exposure or PTSD may potentially benefit from cue reactivity and coping skills training as part of a smoking cessation effort. Social learning and conditioning theories suggest that smokers are likely to have conditioned reactions to stimuli associated with smoking.[50] In heavy drinkers, it has been documented that cue reactivity is predictive of drinking.[93] Also in heavy drinkers, it has been shown that exposure to alcohol stimuli while preventing drinking may extinguish these conditioned reactions.[94] Cue exposure and coping skills training as part of treatment have been shown to result in a higher percentage of abstinent days and consumption of fewer drinks per day.[95] Our preliminary data analyses [10] suggest that cue exposure may be helpful in addressing smoking cessation in smokers with trauma exposure or PTSD. For example, since our preliminary data suggest that both PTSD

and non-PTSD trauma exposed smokers have significant craving increases in response to trauma-related stimuli, inclusion of these cues in cue exposure training could be beneficial in promoting smoking cessation efforts.

Smokers with PTSD or trauma exposure may also benefit from specific relapse prevention skills training. In a study of healthy smokers, individuals with relapse prevention training had superior rates of smoking cessation (41 percent) than individuals in a group discussion (32 percent).[96] Relapse prevention therapy consisted of three weekly group sessions in which participants role-played coping responses likely to be useful in situations they felt would be the most problematic for maintaining abstinence. In smokers, strategies for handling stress and anger and for coping when upset have been associated with level of intention to quit smoking.[97] Supportive counseling and mood management approaches,[98, 99] which have previously been found to increase smoking cessation rates, may also be useful in smokers with PTSD or trauma exposure. Smokers with heightened levels of anxiety sensitivity may smoke more often to manage negative moods and may be less able to tolerate early withdrawal symptoms, specifically during early stages of a quit attempt.[73] So, for example, it may be useful to begin mood management sessions before the quit date and to have additional intervention during the first two weeks of the quit date.

PTSD smokers may also benefit from stages of change feedback.[100] It may be useful to incorporate one-to-one motivational intervention, as this approach has shown modest improvements in smoking cessation rates in at-risk resistant smokers.[101, 102] An expert system intervention for smoking cessation may also be a component that could be useful in this population.[103-105] The expert system intervention for smoking cessation is a computer-based decision-making system designed to utilize smoker information to produce uniquely matched information and intervention. For example, in non-psychiatric smokers, interactive expert-system computer reports plus individualized manuals were the best, or comparable with the best, treatment at all follow-up periods for smokers at all stages of change.[105] However, there is no available data using the expert symptom intervention for smoking cessation in psychiatric populations. Although certain inconsistencies have been noted in the stages of change guided by the transtheoretical model of behavioral change,[106,107] the use of the processes by the general population of smokers has been linked to successful cessation.[108,109]

Length of treatment for psychiatric smokers, including those with PTSD, may need to be longer and more intensive. For example, Bellack and DiClemente[110] have developed a six-month treatment protocol for schizophrenics with comorbid substance abuse. It contains four modules focusing on social skills and problem solving, education about the causes and dangers of substance use, motivational interviewing and goal setting for decreased substance use, and training in behavioral skills for relapse prevention. The program involves 90-minute, twice-weekly sessions, and behavioral rehearsal and complex social repertoires such as refusing substance. Skill behaviors are divided into smaller behavioral elements for practice.

This treatment-adaptation model was developed to minimize the impact of the cognitive and motivational deficits associated with schizophrenia.[110]

Hall and colleagues have recently designed a study to examine a more intensive treatment approach, extended cognitive-behavioral therapy (ECBT) for smoking cessation, in smokers who are alcohol-dependent (T. P. Carmody, personal communication, August 24, 2004). This is a manual-based extended treatment being conducted at the Treatment Research Center at the University of California, San Francisco. It includes five 40-minute individual sessions scheduled at weeks 1-4, focusing on support, preparation for quitting, and issues related to the immediate post-quit period; and eleven 40-minute individual counseling sessions at weeks 6, 7, 8, 10, 12, 13, 16, 18, 20, 23, and 24, focusing on mood management, increased physical activity, motivation for quitting, social support, and management of withdrawal symptoms. The content of the proposed intensive intervention is based on the relapse prevention recommendations of the 2000 *Practice Guidelines.*[67] Although there are no published results to date, this approach will be valuable in evaluating the possible effect of intensive, prolonged treatment for smoking cessation in a psychiatric sample.

Predictor variables of dropout, initial abstinence, relapse, and maintenance are also an important area of study in PTSD smokers. There are a number of variables that could be fruitful to investigate. For example, initial ratings of self-efficacy have been shown to predict dropout, [111] and therapeutic alliance [112-114] has been shown to be a predictor of treatment participation and drinking behavior during treatment and 12-month post-treatment periods.[115,116] Please refer to the companion paper by Douglas Ziedonis for further information regarding smoking cessation and mental health/substance abuse.

As discussed earlier, smoking cessation interventions shown to be helpful in increasing sustained quit rates in other psychiatric populations (e.g., smokers with depression, smokers with schizophrenia) need to be evaluated with PTSD smokers. For example, a program developed by McFall and colleagues suggests that smoking in individuals with PTSD is a chronic condition, and cessation effects require ongoing support.[58] Although not yet evaluated in psychiatric patients, another potentially useful approach for smoking cessation in veterans with psychiatric disorders would be residential treatment. In a small sample of veterans who had failed in outpatient smoking cessation treatment, Green and colleagues evaluated a pilot four-day residential smoking treatment program conducted in a smoke-free environment with NRT and educational sessions. Six month quit rates were comparable to other medical therapies for smoking (26 percent), but were obtained in smokers who had failed the outpatient program.[117] In a large non-veteran sample of 438, residential treatment for tobacco dependence was found to be superior to outpatient treatment in some smokers who were moderately to severely nicotine dependent [at 12 months 45 percent abstinent for residential treatment, versus 23 percent for outpatient treatment, resulting in a significant OR of 3.04 (1.74-5.27, 95 percent confidence interval)].[118] This approach deserves additional empirical attention in psychiatric populations.

Smoking Reduction Approaches

Benefits of Smoking Reduction

The fact that many smokers continue to smoke despite the known health consequences of tobacco use suggests the importance of investigating alternative treatments to aid smokers. Smoking reduction (i.e., reducing the number of cigarettes smoked per day) may be an efficacious alternative strategy. This approach has been shown to be helpful for both smokers who are unable to quit smoking and for those who are unwilling to quit.[119]

Fagerström has suggested several reasons why tobacco smoking may be ideal for this reduction approach.[119,120] First, there is a good dose response relationship between smoking and health outcomes such that the less tobacco smoked, the greater the health benefit. Second, since smokers seek nicotine, providing them with a treatment during which they would have access to nicotine may be particularly appealing. Third, nicotine is comparatively safe.[119, 120]

Although few research studies have examined the health benefits of reduced smoking, the existing data seem to suggest that there are definitive health benefits, particularly when smoking is reduced by at least 50 percent. Rennard and colleagues for example, found that when smokers (with asthma or chronic obstructive pulmonary disease) reduce their cigarette smoking by 50 percent, there is a reduction in neutrophilia in bronchial lavage fluids, and a reduction in total inflammatory cells in distal lavage fluids.[121] Consequently, these smokers were able to reduce their inhaled steroid use by 11 percent. Wennike and colleagues noticed an improvement in both evening peak flow and bronchial reactivity after smoking reduction.[122] Fagerström and Hughes found a significant reduction in carbon monoxide (28 to 31 percent) in smokers who had used nicotine replacement therapy (NRT) to reduce the number of cigarettes consumed daily.[120] Hecht and colleagues found that a moderate reduction in levels of urinary metabolites of a tobacco specific lung carcinogen was achieved by a 75 percent reduction in smoking.[123]

Relationship Between Smoking Reduction and Future Cessation

Several studies comparing smokers in active versus placebo NRT conditions have examined the efficacy of smoking reduction as an aid to smoking cessation. The results of these studies are summarized in Table 2. Another recent study, which improved upon previous studies by including a no treatment condition, found similar results.[124] In this study, Carpenter and colleagues[124] randomized 616 smokers currently uninterested in quitting to receive: (a) telephone-based reduction counseling plus NRT plus brief advice to quit, (b) motivational advice plus brief advice, or (c) no treatment. More smokers in the reduction (43 percent) and motivational (51 percent) conditions made a 24-hour quit attempt over six months than did smokers in the no-treatment condition (16 percent), but the two active conditions did not differ. Similarly, six-month abstinence rates were 18 percent, 23 percent, and 4 percent, respectively for each condition. Results from this study suggest that smoking reduction with NRT does not undermine cessation; rather, it increases the likelihood of quit-

ting to a degree similar to motivational advice and it also increases quit attempts. Conversely, Hughes and colleagues found that in a four-year study using the Community Intervention Trial for smoking cessation (COMMIT) with 1,410 subjects, 40 percent of the smokers had reduced their cigarettes at two-year follow-up, and 52 percent of these reported maintaining that reduction at four-year follow-up.[125] These results suggest that a substantial minority of smokers in the United States are able to reduce their smoking and maintain this reduction for long periods of time, and that the smoking reduction neither promotes nor undermines cessation.[125] Taken together, these studies suggest that smoking reduction may be a useful intervention for smokers who are not interested in quitting. Another important finding from these studies is that NRT and smoking did not result in any significant serious adverse events. Some researchers have suggested that FDA regulations currently prohibiting marketing of NRT for purposes other than quitting should be reconsidered.[126]

How to Implement Smoking Reduction

There are several ways to implement smoking reduction: (a) elimination of cigarettes by increasing the interval between cigarettes;[127-129] (b) rank-ordering cigarettes to delete, beginning with the easiest,[119, 120]; or (c) delaying the first cigarette or moving the last cigarette forward.[120, 121] Fagerström suggests that smokers should take small steps toward achieving their goals.[121, 122] Furthermore, it may be useful to obtain CO levels to provide smokers with a concrete and immediately observable health benefit of reducing cigarettes.[119, 120] These strategies should be aimed toward the ultimate goal of reducing cigarette consumption by at least 50 percent (or <8 cigarettes per day), which, based on previous research studies, appears to be the gold standard. While these strategies may be effective on their own, using NRT and bupropion may also aid smoking reduction in the short-term[130, 121] and over periods of six months or longer.[131-134]

In summary, smoking reduction approaches are worth considering for several reasons. First, smoking reduction may work when other cessation strategies have failed. Second, it may be self-reinforcing in that it produces visible behavioral change. Third, it appears to lead to greater self-efficacy, which could increase subsequent quitting. In a study of gradual reduction as a method of cessation,[135] reduction increased self-efficacy to resist smoking, which was subsequently associated with increased cessation. Fourth, smoking reduction is fairly easy to implement.

Summary and Recommendations for Smoking Cessation Interventions with Individuals with PTSD

PTSD is prevalent, particularly in help-seeking veterans, and it is a risk factor for smoking onset and maintenance. Most help-seeking veterans report not receiving desired assistance with nicotine cessation in the previous year, and psychiatric patients are infrequently treated for nicotine dependence during their routine mental health or primary care visits.

Future basic research regarding smoking behavior and psychiatric symptoms in psychiatric patient groups, including PTSD smokers, is needed. The association between PTSD symptoms and *ad lib* smoking in PTSD smokers [59] is consistent with previous laboratory findings in which exposure to trauma cues increased urges to smoke, [59,136] as well as with a study showing that people suffer from smoking withdrawal symptoms consistent with their psychiatric symptomatology. [46] These findings suggest that at least in some psychiatric populations, smoking may represent a form of self-medication of their psychiatric symptoms. [44] The detection of an association between symptoms and smoking may be more likely in psychiatric smokers because: (a) there may be disorder-specific symptom and smoking associations; (b) certain psychiatric subgroups may use smoking as a coping response; or (c) deliberately increasing the yield of highly symptomatic smokers of any kind may allow a symptom effect to be detected. However, these are simply possibilities; the mechanism of detection of this association in psychiatric populations needs further investigation.

Based on examination of the literature, several recommendations may be important in treating smokers with PTSD, many of which could apply to other psychiatric patients:

- Full access to guideline recommended smoking cessation treatment with ongoing monitoring and reapplication of smoking intervention after relapses.
- Full access to psychiatric treatment for their psychiatric symptoms.
- Access to more intensive treatment, particularly when an adequate trial of smoking cessation guideline recommended treatment has been conducted.
- Repeated application of smoking cessation approaches.

Several promising avenues for additional treatment approaches need investigation. These include intensive psychosocial therapy for tobacco dependence; residential smoking therapy [117] with long-term outpatient follow-up; and smoking reduction [119, 120] and treatment delivery by mental health providers. [58]

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Appendix 1. Diagnostic Criteria for PTSD

A. Exposure to a traumatic event:

The person has experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others. The individual's response consisted of intense fear, helplessness, or horror.

B. Re-experiencing the traumatic event:

The trauma is re-experienced in one or more of the following ways:

(1) Intrusive distressing recollections of the event
(2) Nightmares
(3) Behaving or feeling as if the traumatic event was recurring (e.g., flashbacks)
(4) Exaggerated emotional reactions to triggers that remind the person of the event
(5) Exaggerated physical reactions to reminders of the event

C. Avoidance and emotional numbing:

The person persistently avoids stimuli associated with the trauma as evidenced by at least three of the following:

(1) Avoidance of thoughts, feelings, or conversations related to the trauma
(2) Avoidance of activities, places, or people that arouse recollections of the trauma
(3) Difficulty recalling important aspects of the trauma
(4) Diminished interest or participation in activities
(5) Feeling detached from others
(6) Restricted emotions
(7) Sense of a foreshortened future

D. Increased arousal:

At least two of the following are present:

(1) Sleep disturbance
(2) Irritability or outbursts of anger
(3) Concentration problems
(4) Hyper-vigilance
(5) Exaggerated startle response

E. Symptoms are present for at least one month

F. The symptoms lead to clinically significant distress or impairment in social, occupational, or other important areas of functioning

Appendix 2. Randomized Clinical Intervention Studies for Smoking Reduction that Resulted in Smoking Abstinence [119]

Study	Percent quit				
	NRT	N	Non RT	N	Follow- up in weeks
Bollinger et al., 2000	10	200	8	200	10
Carpenter et al., 2003	13	33	9	34	24
Etter et al., 2002	3	265	1	269	12
Haustein et al., 2002	10	193	8	192	52
Kralikova et al., 2001	19	157	9	157	52
Rennard et al., 2001	9	214	2	215	76
Tonnesen et al., 2001	15	161	5	59	16
Wennike et al., 2001	9	205	3	205	104
Batra et al., 2002	6	180	2	184	17

COMMENTARY ON MENTAL HEALTH AND POST-TRAUMATIC STRESS DISORDER

Sharon Hall, Ph.D.*

From the wealth of information contained in these two presentations, three things are abundantly clear:

First, we need to focus on co-morbid populations and their smoking. Both presenters reviewed the important work of Lasser and others indicating very high tobacco usage rates in individuals with mental disorders.

Second, we have an impressive armamentarium of tools that can be used in mental health settings and whose effectiveness has been demonstrated by numerous studies. The interventions include:

- NRT
- Bupropion
- Second line medications—nortriptyline and clonidine
- Psychological interventions

Third, we have a substantial knowledge base from which to adapt interventions to the special needs of psychiatric patients. As Dr. Ziedonis pointed out from his work with hospitalized patients, inpatient psychiatric hospitalization may be an excellent time to introduce tobacco cessation interventions. And as Dr. Beckham observed, computerized counseling has been shown to be useful in facilitating tobacco cessation and movement towards it in smokers not ready to quit. There are varying reports of readiness to quit among psychiatric patients, as in the general population, and use of such systems may well be successful. Preliminary data from our group at the University of California, San Francisco (UCSF), in an outpatient psychiatric clinic indicates this is the case.

Psychological interventions tested in the general population may be especially useful. For example, our group and others have tested a cognitive behavior therapy (CBT) intervention that is designed to deal with poor mood and which is especially useful for individuals with a history of depression. It seems like a reasonable next step to assume that it would also be useful for individuals who are currently depressed and individuals with post-traumatic stress disorder (PTSD), who are often co-morbid for depression.

In my opinion, psychiatric and mental health practitioners have the skills needed to implement these interventions, or could have them with minimal retraining. They already offer psychological interventions, such as general supportive counseling, CBT, and motivational

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interviewing. Adapting these techniques to nicotine dependence would just be a step away. Additionally, there are not a lot of drugs to treat nicotine dependence, learning about them is fairly straightforward. Five of them—the NRTs—have the same active ingredient, and bupropion (Zyban) is frequently used by mental health practitioners for other reasons.

In 1997, Zarin, Pincus, and Hughes wrote:

> "Those who deliver mental health care often pride themselves on treating the whole patient, on 'seeing the big picture' and on not being bound by financial irrationality or by the biases of their culture; yet many fail to treat nicotine dependence. They forget that when their patient dies of a smoking-related disease, their patient has died of a psychiatric illness they failed to treat."[1]

I like this quotation very much, for it raises important questions. Why is this still the case in most mental health settings? Given the needs and the extent of our knowledge, why has implementation been so slow? What can we do about it?

In addressing the problem, it is first necessary to understand the obstacles. There are many barriers, but among the most important are the following:

Financial Barriers

In private pay systems, mental health practitioners may not be eligible to be reimbursed for smoking treatment (or might not have explored ways that they could be reimbursed). More important, however, is the fact that innovations in the field often come from research that is federally funded, particularly by the National Institutes of Health (NIH). There are other sources of funding, and the VA has its own merit review, Health Services Research and Development Service (HSR&D), and collaborative studies system, but it is the NIH that usually provides scientific leadership and is the major thought leader in this area.

Substance abuse treatment settings are ahead of mental health settings in integrating tobacco dependence treatment into the treatment package. The National Institute on Drug Abuse's (NIDA) nationwide Clinical Trials Network implemented a trial of smoking cessation in substance abuse treatment. One major substance abuse treatment provider, Walden House, publishes a newsletter called the *Tobacco Free Press*. Recently, we held a conference in San Francisco on treating smoking in substance abuse treatment settings, and there will be a follow-up conference this fall. We heard reports from all over the country, but especially from New Jersey, about state and county policy changes that led to the implementation of smoking cessation treatment in substance abuse settings.

Perhaps one of the differences between mental health and substance abuse settings is that the largest funding agency for substance abuse, NIDA, was one of the first to recognize the gravity of the problem—perhaps because it was in the position to recognize an addiction when it saw one. NIDA has been the most likely source of funding on smoking and other co-morbidities. In preparing this talk, I went on the NIH website called CRISP, and searched all

the combinations of nicotine and tobacco and cigarettes and mental health and psychiatric and co-morbidity that I could think of. About 90 percent of the grants were funded by NIDA. This linkage has not yet occurred with the primary funding agency for mental health, the National Institute of Mental Health. I couldn't find a single grant funding tobacco dependence and psychiatric issues by this agency. So, a major thought leader isn't participating.

Through its merit review and HSR&D research funding in treatment of smoking among psychiatric patients, the VA could be a leader in facilitating the shift in thinking that would make smoking cessation a routine part of treatment of veterans in the care of mental health professionals.

Educational Barriers

I did an informal survey of some of my psychiatrist colleagues in clinical leadership positions. The lack of training is evident. Whether in medical school, in residency, or in graduate school, mental health professionals are not taught about nicotine dependence; generally, they are not taught much about addictions at all. Since people tend to conceptualize their discipline by what they learn in graduate school or residencies, and feel most comfortable in using techniques they learned at this time, the VA has the potential again to be a leader.

Many doctoral-level clinical psychologists, especially those coming from academic settings, complete their clinical training in VA medical centers, many of which are sites for psychiatric residency programs. I know that at the UCSF, much of the specialized training that residents receive in substance abuse is through our VA. I am less familiar with the training of nurses and social workers, but if tobacco dependence treatment, and especially its importance in co-morbid populations, was emphasized at their training sites, it would go a long way to changing practice both inside and outside the VA system.

Dr. Ziedonis mentioned the resistance of advocacy groups. In thinking about this, I realized that almost every disorder has an advocacy group these days, except perhaps, people addicted to illicit drugs and cigarette smokers. Certainly, educating advocacy groups is important; for the VA, educating veterans' organizations about the need to address tobacco addiction is especially important.

Stigmatization

Stigmatization of people with mental illness manifests itself in a number of ways, including the three that follow.

The first is an expectation of differences. Those of us who do smoking cessation research have joined with our colleagues in mental health in a subtle sort of stigmatization by emphasizing differences and de-emphasizing similarities. We expect people with mental illness to be different—that is, not like us.

As one example, our group recently completed a study of a smoking cessation intervention in psychiatric patients in outpatient services at UCSF and three Kaiser Permanente sites. The study included any one who smoked at least a cigarette per day—they did not have to want to quit. We were comparing an innovative intervention with a control. The innovation consisted of counseling to increase readiness to quit using an expert system based on DiClemente and Prochaska's stages of change (SOC) model[2]—the idea being to move them along the stages, with the offer of one-to-one counseling and NRT when people reach the contemplation stage.

One of our first analyses was to look at the SOC levels in the clinic. We fully expected that more depressed people would be at earlier stages of change. This was not the case. Depression was uncorrelated with stage, and the sample looked a lot like a general population. My point here is that we went into the study expecting that these individuals would be different than the rest of the population on a crucial variable, and that was not the case. I am not saying that tailoring is not a good idea, nor that we should not address the uniqueness of this population. However, we might have progressed faster had we expected similarities and tested interventions that work in the general population, rather than tailoring them to a population that we expected to be different. In my opinion, we should emphasize what we have in common, and then think about tailoring.

A second, related way that stigmatization is manifested is through what I would call "catastrophizing." Years ago, we feared that if we asked inpatients not to smoke, their symptoms would be exacerbated, or they'd leave, or worse. Many studies, including ones done at UCSF, showed that was not the case. More recently, there has been concern about worsening of depressive symptoms, or relapse to major depressive episodes. The latter is still up for grabs, in my opinion; the existing studies are not entirely controlled or are misinterpreted, or they have such high and differential dropout rates that it is not possible to determine if this is the case.

The third way that stigmatization of mentally ill patients manifests itself is by focusing on the short-term. In dealing with any acute problem, there is always the tendency to ignore prevention. The possibility of suicide, crises in interpersonal relationships, substance abuse—these are survival issues that require immediate attention and tend to relegate treatment of other problems, such as smoking, to the background. On the other hand, the long-term benefits of smoking cessation are very clear. Even though people may sometimes have problems that need immediate attention, they are not always in crisis; they remain in the system, and this is the place where their problems—long term and short term—can and should be treated.

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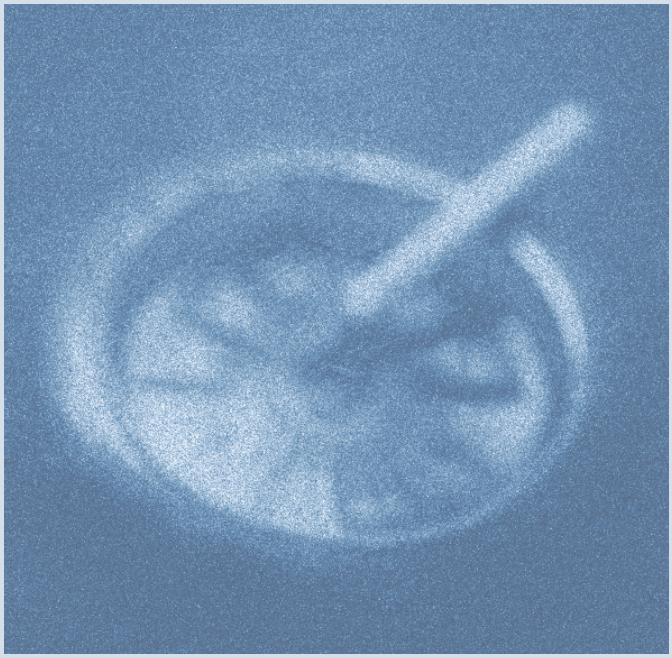
[2] Prochaska, J. O & DiClemente, C. C. (1982) Transtheoretical Therapy: Towards an Integrative Model of Change. *Psychotherapy: Theory, Research and Practice* (19) 3 276-288.



TOPIC FIVE

Quitlines

Telephone Care for Smoking Cessation in the Department of Veterans Affairs

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Telephone quitlines, which have been shown to be effective at increasing long-term smoking cessation in the general population, may be particularly appropriate for veterans. This paper presents the results from a survey of VA lead clinicians and three randomized controlled trials conducted within the VA: a stand-alone quitline; referral to a state quitline; and an intervention to stimulate relapsed smokers to enter treatment. The evidence from these studies suggests that providing telephone care to veterans would increase the rate of treatment and that treatment would be effective.

The Department of Veterans Affairs (DVA) provides comprehensive health care to veterans, including preventive health services such as tobacco cessation treatment. The prevalence of smoking is greater among veterans than the general population,[1,2] and veterans are disproportionately affected by tobacco-related diseases. Current DVA policy stipulates that all veterans receive tobacco use screening, counseling, and other treatment in accordance with the VA/Department of Defense Tobacco Use Cessation Clinical Practice Guidelines.[3,4] This Guideline recommends evidence-based practices including nicotine replacement therapy (NRT).

In spite of the intent to provide comprehensive tobacco treatment services, the 1999 Large Health Survey of VHA Enrollees reported that only 28 percent of smokers with a recent visit said that a provider had referred or treated them for smoking cessation in the previous year.[5] Only 21 percent reported that the VA gave them the services they needed to help quit. Jonk et al. found that the national rate of smoking cessation treatment within VA has remained constant and low, with about 7 percent of VA smokers receiving smoking cessation medications each year from 1999 through 2002.[6]

There are effective behavioral and pharmacological treatments for tobacco use, and the combination of counseling and medications is particularly effective.[7] Comprehensive services can be provided in person, in a group or individual setting, or by telephone. Tobacco treatment services can be integrated with primary care services or stand alone as referral-based services, which predominate in the VA. VA smoking cessation services are commonly provided in a series of group classes scheduled over two to eight weeks. There are some inherent barriers to providing referral based group services, such as delays before scheduling and lack of ability

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to tailor intervention, including content repetition for patients who require additional episodes of treatment. These issues may be compounded by the fact that veterans may live relatively far from their VA source of care and may have disabilities that make attendance more difficult than it would be for the average smoker. These factors contribute to low show rates for clinics: data suggest that less than one-third of patients referred for smoking cessation treatment show up for the initial appointment.[8]

Telephone quitlines have been tested in randomized controlled trials and shown to be effective at increasing long-term smoking cessation rates.[9] Telephone care may be especially appropriate for veterans because of population characteristics such as age and medical co-morbidities that make transportation difficult, psychiatric co-morbidities that may mandate individualized treatment approaches, and markers of a high degree of nicotine dependence, such as heavy smoking and a long duration of smoking.

The purpose of this article is to describe the status of telephone quitlines in the DVA for treatment of tobacco use. Many VAs use telephone care as an adjunct to in-person tobacco cessation services; for example, to provide follow-up care (relapse prevention and maintenance), medication management (e.g. prescription renewals and dose adjustments), or to integrate VA services with state quitline services. For the purposes of this paper, we will only consider comprehensive, stand-alone telephone care for tobacco cessation. We will describe results from an informal survey of VA lead clinicians that provides information about use of VA quitlines and referral to state and national quitlines, and three randomized controlled trials conducted within the VA that have evaluated methods to deliver tobacco cessation services by telephone to veterans (see appendix). They document the effectiveness of: (1) a stand-alone quitline for veterans (TELESTOP Study), (2) referral to the California Helpline, and (3) an intervention to stimulate recycling of relapsed smokers through treatment (RESET Study).

VA Use of Telephone Quitlines

Each VA medical center has a designated lead tobacco clinician, who is the contact for communications from the VA Central Office and others regarding tobacco treatment issues at their facility. A national email survey of lead clinicians conducted in 2004 included a question about use of stand-alone telephone care. Of 137 lead clinicians, 122 responded and 37 sites indicated they used telephone care to provide smoking cessation services to veterans they served. These 37 sites received a more detailed survey about these services. Of these, about two-thirds reported that they referred patients to a state or national quitline. Three sites indicated they used the American Cancer Society line. Five sites reported independent, VA, and stand-alone programs. Counseling for these lines was provided by an individual physician in one case and clinical nurse specialists in the other cases. At two sites, stand-alone telephone care was reserved only for smokers who could not attend standard services and at another site, telephone care was only used for brief intervention. In no instance was the VA telephone service used systematically in a population-based approach.

In addition, a number of sites indicated that they used telephone care to provide follow-up for in-person visits and to arrange medications for patients receiving behavioral counseling from state or national quitlines. Results from these surveys point out that no VAs currently offer intensive behavioral counseling combined with pharmacotherapy in a systematic program to all tobacco users in their system, but some sites refer patients to state and national lines for counseling.

An Experiment: TELESTOP—A VA Quitline

The objective of the TELESTOP Study was to determine if increased access to smoking cessation services (integrated telephone counseling and provision of smoking cessation medications) increased abstinence from cigarette smoking, compared to usual care. It was a randomized, controlled clinical trial funded by VA Health Services Research & Development that was completed in 2004.

This study was conducted among patients at five VA medical centers in Veterans Integrated Service Network 13. Patients who had made a visit to a primary-care clinic in the year prior to the start of the study were eligible to receive an invitation letter to participate. Telephone care included seven calls scheduled over a two-month period in a relapse-sensitive fashion. All subjects were encouraged to use medication aids. Outcomes were ascertained by telephone surveys three and twelve months after enrollment.

Letters were mailed to 68,903 primary-care patients at the participating sites. There were 1,807 callers in response to the mailing; 1,265 were current smokers. Of eligible smokers, 838/988 (84 percent) agreed to participate in this study and were enrolled and randomized.[10] Participants were primarily older males who rated their health as poor. Depression and anxiety were common.

Subjects in the telephone care group reported significantly higher rates of abstinence for both long- and short-term measures of smoking cessation.

Practical Lessons Learned

There were several striking successes in this study. The first one was enthusiastic participation by veterans, evidenced by easy completion of enrollment, ahead of the target date. The 1999 Large Health Survey of VHA Enrollees indicated that 30 percent of veterans in Network 13 are current smokers (or 17,460 of those receiving invitation letters).[5] Recruitment results suggest that close to nine percent of smokers in this population are interested in accessing telephone counseling and pharmacological treatment for tobacco use. This estimate may be conservative, since it is based on interest in participating in a research study; this requires informed consent and agreement to randomization and data collection procedures. These results compare favorably to state quitlines that generally serve one to two percent of smokers and suggest that there is demand for alternative smoking cessation treatment services among veterans.

We also were able to demonstrate that it is possible to deliver intensive behavioral and drug treatment by telephone in the VA system. This experience was enhanced by the computerized medical record system (CPRS) that made communication of decisions between the call center and sites relatively easy. Finally, the smoking cessation outcomes are good for this population, and significantly better than those achieved in the usual care group, which relied on current practices of referral based or primary care based treatment.

There were several barriers noted to smooth operation of the telephone protocol that would require attention if such a system were to be implemented on a larger scale within the VA. Providing bupropion SR, a prescription medication, over the telephone required individual communication with primary care providers using a combination of CPRS notes, telephone, email, and regular mail. This was time consuming, although primary care providers rarely declined to endorse the recommendation to prescribe bupropion SR. Inefficiencies in implementation of medication orders and mailing prescriptions can be particularly important when prescribing smoking cessation medications because gaps in medication coverage may precipitate nicotine withdrawal symptoms, and therefore, relapse. Issues also arose regarding the expense of tobacco treatment medications: some sites did not feel that it was appropriate that the site pharmacy budget should be responsible for these costs. Finally, at one site, the administrative staff was uncomfortable having an "outsider" treat their patients. Although these points are anecdotal, they highlight the need to integrate centralized telephone care with site-based care and to develop acceptable policies and practices to cover pharmacy costs.

An Experiment: Linking Veterans to a State Quitline

A demonstration project funded by the VA Substance Use Disorders Quality Enhancement Research Initiative (QUERI) has been conducted at the VA Center for the Study of Healthcare Provider Behavior at Sepulveda, California, to test a method for increasing referrals to telephone counseling provided by the state of California, and to determine whether intervention increases the overall number of patients treated for smoking cessation. The study is a group randomized trial design, conducted in the VA Greater Los Angeles and Palo Alto Healthcare Systems. Preliminary process data from the intervention sites have been examined.

The intervention comprised a referral from any health care provider to a VA smoking counselor. The counselor made a proactive call to the patient to evaluate interest in referral to the California Smoker's Helpline for services. If the patient was agreeable the counselor made a three-way call to the Helpline. The Helpline attempted to enroll the smoker in its usual counseling protocol. The VA counselor coordinated medication management and dispensing. In addition, the VA counselor followed up with each patient at two, four, six, and eight weeks to provide additional support and medication management.

The main outcomes of the study are the number of patients starting tobacco cessation treatment and the proportion successfully completing the two-month program. Abstinence at six-month follow-up will also be determined. Results to date show that providers rarely, if

ever, referred smokers for telephone counseling at baseline. The intervention was successful at increasing referrals to the Helpline. In the first six months, there were approximately 1,800 patients referred to VA counselors. Of these patients, 37 percent of patients could not be reached and 16 percent were not interested in help. Approximately 40 percent of those starting the two-month program successfully completed it.

Future Directions

Follow-up is only partially complete, but results suggest that the intervention dramatically increased referrals to telephone counseling and that the long-term abstinence rate is comparable to that of a good smoking cessation program. The California Smokers' Helpline indicated that this demonstration project now accounts for approximately eight percent of all counseling calls it receives, the largest source of referrals from any health care organization. On the basis of the experience with this demonstration project the principal investigator, Dr. Scott Sherman, has applied for and received funding from the VA Health Services Research & Development Service to conduct a rigorous study of the effectiveness of translating this treatment model into routine practice. The study will involve all 60 VA sites in California, Hawaii, and Nevada, and randomly assign them in a two-by-two fashion to different levels of counseling (brief primary care-based counseling versus intensive Helpline counseling) and approach to referral (proactive patient contact versus reactive contact).

This project suggests that collaboration between VA healthcare providers and state quitlines is feasible and attractive to both providers and patients. It also suggests that if such a program were to be done in a systematic fashion, it would generate considerable additional workloads for state or national quitlines. If state and national quitlines do not dispense pharmacological assistance for smoking cessation, this model of care would require VA resources to coordinate provision of medications for smoking cessation.

An Experiment: Recycling VA Smokers Through Treatment Using the Telephone (RESET Study)

The RESET study was a multi-center randomized controlled trial testing a health services strategy to stimulate recycling through treatment, funded by VA Health Services Research & Development, and completed in 2004. Participants from five sites were identified from the VA Pharmacy Benefits Management (PBM) database and were eligible if they received a smoking cessation aid in the past year. They were randomized to active treatment (a patient phone call to collect information on smoking status, interest in quitting, and treatment preferences) or usual care. In the active treatment group, information from the phone call was communicated to the patient's health care provider using a CPRS progress note.

There were 951 participants randomized to the active treatment group, and they were called four to nine months after the original prescription fill date. Most relapsed smokers were interested in quitting (about two-thirds within 30 days, more than 90 percent within six

months) and wanted pharmacological treatment (about two-thirds NRT, and half bupropion SR). Slightly less than half were willing to participate in individual behavioral treatment and about 30 percent preferred group counseling.[11]

The intervention significantly increased treatment rates relative to usual care (both pharmacological and behavioral intervention). The intervention had a small positive effect on smoking cessation rates of borderline statistical significance. Intervention subjects were significantly more likely than controls to report being very satisfied with the general smoking cessation help they received and more likely to report satisfaction with the pharmacological help they received.[12]

Lessons Learned

RESET results confirm earlier findings that there is substantial interest in renewed quit attempts among relapsed smokers.[13] The study demonstrates that increased delivery of a recycling intervention can be accomplished using administrative methods, and that this increases treatment rates and satisfaction. This project contributes information about an innovative use of administrative databases (e.g., PBM) to identify smokers likely to be in the action phase of quitting, and an innovative use of the computerized medical record to expedite the recycling process.

Several important implementation issues were identified. These included the complexity of the interaction between a centralized telephone system and local (site-based) clinic models and medication restrictions. Another challenging issue was accurate identification of providers to whom tailored communication should be addressed. This varied considerably by site. It was often difficult to "close the loop" and determine if treatment recommendations had been followed. Finally, an important anecdotal observation was that when relapsed smokers were contacted by telephone, they often expected the person making the inquiry to be able to help them; proposing referral back to another provider was frequently a disappointment. This suggests that a telephone call center that could contact recent relapsers to stimulate recycling *and* provide comprehensive counseling would be efficient.

Needs

Results from these investigations suggest several important VA needs. The TELESTOP Study demonstrated that veterans are extremely likely to access VA telephone care for smoking cessation and that this form of treatment improves quit rates. Linking veterans to a state quitline also improves treatment rates. The RESET Study shows that smokers who try to quit but relapse remain interested in treatment, and that prompting health care providers with reports of patient preferences increases the rate of treatment. In aggregate, the studies suggest that comprehensive telephone care to deliver tobacco treatment for veterans should be made readily accessible. Telephone care should include access to medication treatments, and medication treatment should be fully integrated with behavioral counseling. Telephone care

is particularly suited for individualized treatment, although group telephone care could also be explored.

Looking at the bigger picture, the results suggest that we should explore models to promote delivery of tobacco-dependence treatment that do not depend on health care provider behavior. While providers often do a good job of identifying smoking status and offering advice to quit,[14] delivery of comprehensive treatment is less consistent. It is possible that care could be improved by offering treatment directly to veterans. Ideally, patients would be able indicate their treatment choices from a menu of options, including face-to-face appointments, telephone care, and individual or group formats. There are other examples of successful delivery of preventive care measures independent of primary care providers in the VA, such as influenza vaccinations.[15]

Future Directions

Centralized quitlines can offer state-of-the-art tobacco cessation treatment efficiently. They can offer care from highly trained counselors who are supervised in order to provide quality control of treatment procedures. Individual sites are unlikely to be able to provide this level of service. The evidence from these three studies suggests that providing telephone care to veterans would increase the rate of treatment, and that treatment would be effective. Therefore, it should be implemented.

There are different potential sources of telephone care to deliver smoking cessation services to veterans, each having relative advantages and disadvantages. These include national quitlines such as those provided by the American Cancer Society, the National Cancer Institute, and other models under consideration by the Department of Health and Human Services. About 40 of the 50 states in the U.S. have state quitlines.[16] These are another potential source of care, and are already used by some VAs. Finally, there could be an independent VA quitline organized nationally or regionally to provide service to veterans.

The potential to shift costs from the VA to national and state quitlines makes them an attractive option. Disadvantages would include the lack of integration with VA health care, and uncertainty about how attractive outside services might be to veterans. In addition, most quitlines do not offer pharmacological aid, and integration with the VA system to provide medications may prove complicated and entail additional hidden expenses. This may prove to be a barrier to accessing comprehensive care. Some states (such as Minnesota) do not offer treatment to smokers who have health care coverage from other sources, and this practice may become more common as demands increase, precluding veterans from accessing these services. On the other hand, an independent VA quitline could be operated by the Department of Veterans Affairs, or services could be provided under contract. The VA has successfully implemented remote access to telemedicine services in other areas, such as dermatology and ophthalmology. An independent call center could be specifically tailored to veterans' needs, and might include administration of a limited pharmacy formulary to dispense smoking cessation medications.

Regardless of the source of telephone care, addressing several research questions would help plan for provision of cost-effective telephone care to address tobacco use among veterans. Are non-VA quitlines as effective as a VA quitline for veterans? What intensity of treatment is the most cost-effective for the veteran population? For example, is a four-call protocol as effective as a seven-call protocol? What is the best method to recruit smokers to telephone care? Should they be approached directly from a call center or referred by providers, or both? If they are approached directly, should the recruitment be reactive (passive) or proactive? It is possible that proactive recruitment would succeed at enrolling more tobacco users in treatment, but treatment might be less effective if smokers are less motivated.

Study	Funding Source	Design	Objective	N
VA Use of Telephone Care to Provide Smoking Cessation Services	VA Public Health Strategic Health Care Group	Cross-sectional survey	To describe VA smoking cessation program use of stand-alone quitlines to provide smoking cessation services to veterans	137
TELESTOP: Centralized Telephone Outreach to Assist Smoking Cessation Among Veterans	VA Health Services Research & Development	Randomized controlled trial	To compare the effect of telephone care (counseling + medications) to usual care (either referral or primary care-based)	838
Increasing referrals to telephone counseling for smoking cessation	VA Substance Use Disorders Quality Enhancement Research Initiative (QUERI)	Group randomized controlled trial	To test the effect of an intervention to increase referrals to the California Helpline, to coordinate VA provision of smoking cessation medications with the Helpline, and to increase smoking cessation rates	2800+ (ongoing)
RESET: Facilitating Implementation of the PHS Smoking Cessation Guideline	VA Health Services Research & Development	Randomized controlled trial	To test a health services strategy to stimulate recycling through treatment by calling smokers who recently received smoking-cessation medications from the VA, and communicating future treatment preferences to providers via CPRS	1900

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Tobacco Quitlines: Where They've Been and Where They're Going

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Telephone-based tobacco cessation services, or quitlines, have attracted increasing attention as a central component of comprehensive tobacco control programs. They began with careful research demonstrating efficacy in clinical settings and effectiveness under real-world conditions. With strong backing from public health officials, they spread to more than 40 states and many other countries. In 2002, the Department of Health and Human Services Interagency Committee on Smoking and Health Cessation Subcommittee recommended creation of a national network of quitlines to provide universal access to cessation treatment for all Americans; this has recently been implemented. The main question concerning quitlines now is not whether *they should exist, but on what scale. Important related questions are how much it will cost to achieve a population impact through quitlines, and how to promote them for this purpose. Poised to become a major force to reduce the prevalence of tobacco use, quitlines increasingly are partnering with the health care industry, which every year sees the majority of tobacco users, but does not consistently treat their tobacco use. Health care providers should make the identification of tobacco users, advice to quit, and referral to evidence-based treatments a standard of care; partnering with quitlines will help them do so.*

Even though progress has been made over the last several decades in reducing its prevalence, tobacco use remains the most common preventable cause of death in the United States,[1] as it does in much of the rest of the developed world.[2] Moreover, it is increasingly concentrated in lower socioeconomic populations, contributing to worsening health disparities.[3, 4] Fortunately, tobacco cessation significantly reduces the incidence of premature death in all groups.[5] With appropriate attention to the groups hardest hit by tobacco-related disease, it can also help to reduce health disparities.[6] Behavioral counseling programs conducted over the telephone, commonly called "quitlines," are well suited not only as an aid to tobacco cessation, but as a way of reaching out to underserved populations.[7, 8] In recent years, they have emerged as a key strategy in efforts to promote cessation on the population level,[8] such as those outlined in the U.S. government's National Action Plan for Tobacco Cessation.[9]

Quitlines have many advantages.[8] Their efficacy has been demonstrated both in clinical trials and real-world studies.[10, 11, 12] Because of their centralized nature, they lend themselves to efficient operation and rigorous quality control. They are highly accessible and able to reach diverse and underserved populations.[7] With their single-number point of access, they are easy to promote across an entire state or region, an important consideration in efforts

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to increase cessation on the population level. Furthermore, in the context of an anti-tobacco media campaign which could otherwise be perceived as anti-smoker, the promotion of a free service to help people quit not only makes the campaign's messaging more complete, but also represents good public relations. Also, quitlines make it easier for health care providers to address their patients' tobacco use by providing them with a reliable and effective resource for cessation. These advantages have encouraged the growth of a global quitline movement.

This paper gives an overview of the development of that movement to date, including important milestones and evidence of efficacy. It highlights the contributions of public health officials whose vision of decreased mortality and morbidity led them to embrace quitlines as a central strategy in their tobacco cessation efforts. It offers an analysis of key considerations in the question of how big the movement should become, focusing in particular on the issues of funding and promotion. And it discusses how the medical and behavioral health communities can work together to help patients quit using tobacco.

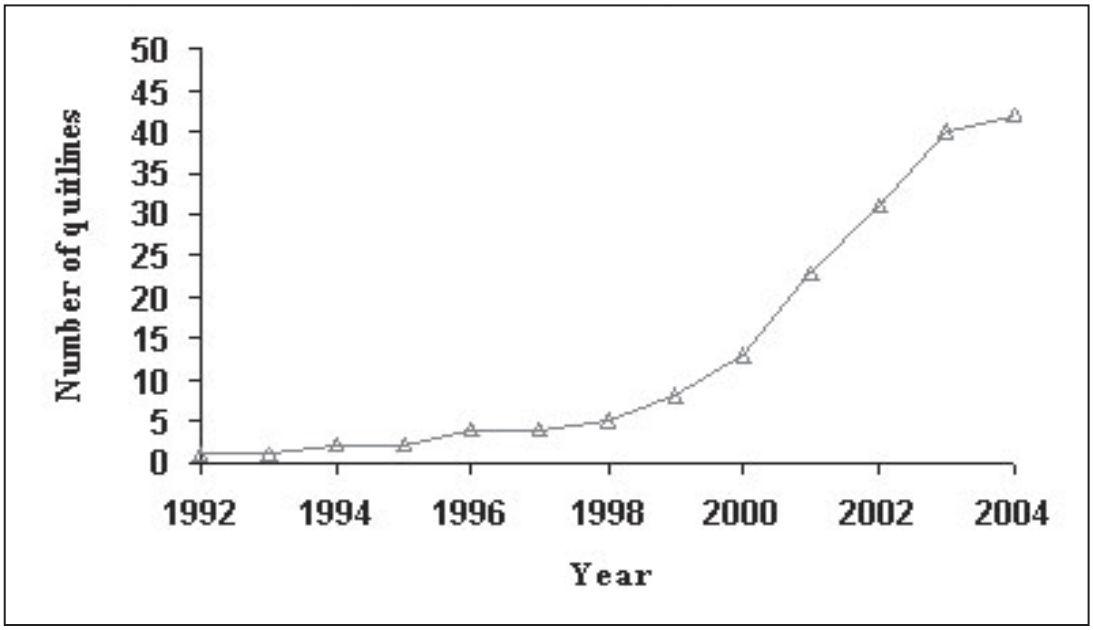
Milestones in the Development of a Quitline Movement

For many years, the telephone has been used as a medium for helping tobacco users quit. In the early1980s, the National Cancer Institute provided the first telephone-based tobacco cessation service as part of its Cancer Information Service (CIS). Limited in the depth and intensity of assistance provided, and not formally tested for efficacy, the cessation service provided by CIS nevertheless demonstrated a demand for telephone counseling for tobacco cessation, arising as it did as a natural response to callers' need for information about how to quit.[13, 14] In 1992, Group Health Cooperative of Puget Sound, a progressive health maintenance organization, made a major commitment to the health of its members by implementing the first large, privately supported quitline, using an experimentally validated counseling protocol.[15] In the same year, the California Department of Health Services established the first publicly funded, statewide quitline, the California Smokers' Helpline, using a protocol validated with a community sample in a large randomized trial funded by the same agency.[16] Massachusetts followed suit in 1994, Arizona in 1996, and Oregon in 1998. In the next several years, quitlines suddenly became quite popular in the United States; today more than 40 states have established some form of quitline, as have many countries around the world.[17, 18]

Few other behavioral interventions have experienced such widespread adoption in such a short time.[19] Figure 1 plots the implementation of quitlines in the United States over the last 12 years. The curve is much like Rogers' standard S-shaped curve for the diffusion of innovations,[20, 21] and shows that following several years of slowly increasing uptake, in the late 1990s and early 2000s quitlines entered a "fast adoption stage." The adoption curve is now decelerating[22]—inevitably, since there are few states left without a quitline. It is true that the period of most rapid proliferation of quitlines in the United States coincided with the Master Settlement Agreement, which for many states provided the means to address tobacco cessation

on a population level for the first time. But a similar diffusion process has also been observed in Canada, Australia, and Europe.[17, 18, 23]

Figure 1. Adoption of State Quitlines in the U.S.



The global rise of quitlines has further been fueled by training conferences and other activities organized by public health officials. In response to frequent inquiries and requests for technical assistance on how to set up a quitline, the California Department of Health Services in 1998 hosted an international quitline training conference in San Diego, with additional financial assistance from the American Cancer Society. The following year, UKQuit hosted a second international training conference in London, in response to a strong corresponding need there for technical assistance. Also in 1999, the European Network of Quitlines (ENQ) was formed to facilitate the exchange of information on quitlines among member nations; the ENQ has convened additional meetings for the same purpose since then. In 2002, North Americans held a large training conference in Phoenix, Arizona, bringing together quitline providers, researchers, and funders from across the United States and Canada, as well as delegates from state health departments that had not yet established quitlines. Arising out of discussions at that conference, a meeting was held in 2003 to launch the North American Quitline Consortium. Public health officials from Asia and Latin America have also attended some of these meetings, and quitlines have begun to spring up in those parts of the world as well.

In 2003, the U.S. government became a major player in the quitline movement when the Department of Health and Human Services (DHHS) Interagency Committee on Smoking and Health Cessation Subcommittee published its National Action Plan for Tobacco Cessation.[9] In the first of ten sweeping recommendations, the Subcommittee urged adoption of a national

network of quitlines to provide universal access to effective tobacco cessation services for all Americans. Another recommendation was a $2 increase in the federal excise tax on packs of cigarettes, a portion of which would support the promotion and operation of quitlines. The tax increase has not been enacted by Congress. However, at the direction of Tommy Thompson, Secretary of Health and Human Services, a modest amount of funding was provided to help support the network of quitlines. Half of this amount was given to the states, either to augment existing quitlines or to help establish new ones. The other half was allocated to the CIS to create a national toll-free "portal" to statewide quitlines, and to provide temporary quitline service for the states that do not yet have one. The new national portal, 1-800-QUIT-NOW, operational as of November 10, 2004, routes calls from English-speaking callers in states with quitlines directly to their statewide quitline. Callers from states without quitlines are served by the CIS. The DHHS and the states are currently engaged in a collaborative effort to ensure that the federal initiative does not lead state legislatures to de-fund their quitlines under the belief that the federal government has taken over this function. If it performs as intended, the federal quitline initiative will protect and enhance state quitlines and will increase the number of Americans receiving effective cessation treatment. Careful attention will need to be paid to the sustainability of the federal funding itself, to avoid a national disruption in service.

Evidence of Effectiveness

Quitlines owe much of their growth in popularity to experimental evidence demonstrating their efficacy. This evidence has been highlighted in several meta-analytic reviews.[10, 24, 25, 26] The most recent Cochrane Review shows a pooled odds ratio of 1.56 for quitline counseling, compared to self-help materials.[10] Moreover, many of the randomized trials showing efficacy had very large and diverse samples of participants, suggesting the broad appeal of quitlines, and creating confidence in the replicability of the study results. Few other behavioral counseling interventions for smoking or for other substance abuse have been tested in such large trials. Large samples are generally more characteristic of high-profile drug trials, such as those for nicotine replacement therapy (NRT). Yet a comparison of the most recent Cochrane Reviews[10,27] shows that the average sample for quitline trials was larger by about 700 than the average sample for NRT trials, one of the most thoroughly studied pharmacotherapies (see table 1). And quitline protocols have been tested and found to be effective across a variety of demographic groups, including those for whom pharmacotherapies have either not been tested or are not approved (e.g., pregnant women).[28] Thus the clinical evidence of the efficacy of telephone counseling for tobacco cessation is strong.

Just as important, the researched effects of quitlines have been successfully translated from clinical settings to the real-world operation of state quitlines. This is an important consideration for behavioral services, whose effectiveness depends in large part on the quality assurance measures that determine how well they are delivered. Some of the more recent quitline studies are directly embedded into the ongoing operations of statewide services.[11, 12, 28, 29, 30] The fact that many of the researchers involved in the clinical trials stayed in the field to help translate the

results into practice has helped to ensure their effectiveness in the real world, and has helped as well with dissemination of evidence-based quitline models.

Table 1—Efficacy and Average Sample Size of Tobacco Cessation Studies Reviewed by the Cochrane Library [10, 27]

Type of Intervention per Trial	Odds Ratio (95STET CI*)	Average Sample Size
Nicotine Replacement Therapy (NRT, n=98*)	1.74 (1.64, 1.86)	385
Telephone Counseling (TC, n=13*)	1.56 (1.38, 1.77)	1100

*n indicates number of studies; CI, confidence interval.

The Credit Goes to Public Health Officials

Notwithstanding the strength of the scientific evidence for quitlines, their acceptance by practitioners was by no means guaranteed. Behavioral research often ends with the publication of findings, rather than in the translation of those findings into practice.[31] In order for any newly proven treatment to be put into practice, the mere publication of findings is usually not sufficient to persuade medical professionals to adopt it. Even new drugs found to be effective in clinical trials generally require intense promotional efforts by drug companies to gain recognition. Mounting such a promotional campaign can be expensive, and often occurs only when there is a significant potential for profit. Perhaps for this reason, awareness within the medical field of effective behavioral treatments tends to be limited. This may explain why quitlines appear to have escaped the notice of the medical establishment until quite recently.

Indeed, despite their great value as an adjunct to clinician advice, quitlines owe their rapid adoption in the United States and elsewhere to key figures in public health, rather than to the medical community. In the early 1990s, the Tobacco Control Section of the California Department of Health Services was quick to appreciate that a quitline not only offered an effective clinical service for those who used it, but that its promotion could help in the broader campaign to change norms around tobacco use. With no examples to follow and unsure how it would fare as a statewide service, the state made a major commitment to fund and promote a comprehensive telephone counseling program that would be available to all California residents, a program which has experienced rapidly increasing demand since then.[8] Likewise, officials in the Massachusetts Tobacco Control Program saw that a quitline could serve as the hub of an integrated network of cessation services, and that it could be used to unite all of the state's health plans and health care systems behind the common goal of addressing

tobacco in health care settings.[32] Even when funding for the state's tobacco control program was severely reduced, these officials managed to preserve the quitline because of its central role in promoting cessation to clinicians. In Arizona, officials in the Tobacco Education and Prevention Program of the Department of Health Services recognized that the expertise that went into the operation of a statewide quitline could also be tapped to train health educators throughout the state on tobacco cessation. Despite deep budget cuts since then, they have always retained the quitline. These early adopters of quitlines had vision and the persistence to pursue a course of action based on new ideas.

How Big a Role Should Quitlines Play?

With quitlines now almost universally accessible in this country (at least to English speakers), the question is how big a role they should play. This question arises because of two key considerations. One is that quitlines will have to reach a large proportion of tobacco users if they are to have a population impact.[33] The other is that, conceivably, there may never be enough resources to allow them to reach all of the tobacco users who could benefit from their services, and of course, there are other effective population-based approaches to cessation besides counseling, each of which also deserves funding.[34] These competing realities will ultimately determine how big a role quitlines will play in the nation's effort to promote cessation.

Current state quitlines, while enrolling far more participants than traditional cessation programs have done, nevertheless reach only one percent to three percent of the tobacco using population per year,[12] not enough to achieve a measurable drop in prevalence through direct service. The primary factor limiting the reach of quitlines today is the level of funding, both for promotion of quitlines and for the service itself.[12] Quitlines' experience with mass media campaigns has made it clear that demand for quitline services is a function primarily of the funding to advertise them, and that increased funding for promotion leads directly to increased demand.[23, 35, 36, 37] Of course, with increased demand, additional funding is needed to build capacity to provide service. The problem of how to build sufficient capacity to meet consistently high demand for cessation services is a new one, having arisen only with the advent of quitlines, and none of the states has yet worked out a long-term solution for it.[17]

The National Action Plan calls on quitlines to play a key role in a grand plan to reduce the prevalence of tobacco use in the United States, and sets a target of 16 percent of the nation's tobacco users receiving quitline services each year, including both counseling and pharmacological quitting aids to be dosed and dispensed by the quitlines. It predicts that a national effort of this magnitude would result in approximately one million tobacco users in the United States quitting each year.[9] Even if only half as many tobacco users were to receive assistance from quitlines—eight percent per year, a level of utilization comparable to that of NRT in states with strong tobacco control programs[38, 39]—the impact would be substantial.

How Much Money Is Needed and Where Will It Come From?

The National Action Plan calls for a $3.2 billion infusion of federal funding for quitline services,[9] an amount that would cover the cost of both counseling and pharmacotherapy for 16 percent of tobacco users per year, as mentioned above. This proposal provides a framework for thinking about the magnitude of the funding issue, even if the political will to fully implement it does not yet exist. It is possible that the political will to implement it will not exist until it is clear that demand is outstripping capacity. This suggests that those who see the potential of quitlines to have a population impact must continue putting into place the systems that increase awareness of and demand for quitlines. In other words, they should not wait for assurances that additional funding from state or federal governments will be made available to meet the ever-increasing demand; they should just push forward.

The public sector has provided and will likely continue to provide the bulk of quitline funding. Most quitlines in the U.S. and around the world are state funded. Few states spend a large percentage of their tobacco taxes or Master Settlement Agreement funds on tobacco control at all, let alone on direct provision of cessation services.[40, 41] Nevertheless, they are increasingly aware of the importance of providing effective treatment for tobacco dependence, as the proliferation of statewide quitlines has shown. Efforts have been made in some states to enact legislation that would identify a reliable funding source specifically for cessation.

The private sector, particularly health plans, can do more to make quitline services available to their members. Preventive health, including tobacco cessation, is a key component of progressive health care and is increasingly viewed as the responsibility of health care providers. The fact that health plans have the resources to cover effective medications suggests that they can also cover evidence-based behavioral treatments, and in fact, some of them already do provide quitline services to their members, either internally or by contracting with an outside vendor. With telephone counseling, as with NRT, a positive return on investment for health plans and their purchasers can be demonstrated.[32, 42] A cost-sharing scheme between the public and private sectors may be a practical and reasonable solution to the question of who pays for service. For example, state health departments may use a portion of their tobacco control monies to seed and promote a statewide quitline; the plans would pay all or part of the cost of their members' participation in quitline services, while the state would cover uninsured users. Some states, such as Minnesota, are already participating in such innovative cost-sharing partnerships with health plans.

The role of for-profit organizations in tobacco cessation should not be overlooked. Managed care organizations that want to realize long-term cost savings, employers who want to increase the productivity of their work forces, and even private quitline operators who would like to earn a profit while helping people quit, can all play important roles in a state's cessation efforts. Just as pharmaceutical companies have found a permanent role in the treatment of tobacco dependence, these other organizations may be able to support cessation in ways that are more insulated from the vagaries of public funding and, therefore, be more sustainable over

the long term. Moreover, for-profit organizations may be more able than government agencies to scale up their operations as demand for service grows. It is likely that competition among for-profit organizations and between for-profit and not-for-profit organizations will increase the overall quality, variety, and availability of services, while helping to control costs.

Until funding levels are adequate to provide comprehensive service to all who need help to quit, choices on some difficult issues must be made. Probably the thorniest of these is how to achieve the greatest possible impact with limited quitline resources. Depending on staffing and call volume, this may mean choosing between providing more intensive, multi-session counseling to a smaller number of people, or less intensive, single-session counseling to a larger number. The resolution of this dilemma may involve some combination of these two extremes, with procedures for matching the intensity of treatment to the needs of each caller.[43] In other words, callers with multiple risk factors would receive comprehensive cessation counseling, while callers with few or no risk factors would receive briefer service. Such an approach would need to be carefully evaluated to ensure that treatment decisions are made appropriately. Another difficulty arises when funding is severely limited. In those circumstances, the question of whether there is a minimally acceptable size for quitlines must be addressed. It is conceivable that a nominal, poorly funded quitline that few people know about or use may hurt the tobacco control program by providing only a "fig leaf" of cessation coverage that gives false comfort to cessation advocates. The Centers for Disease Control and Prevention (CDC) has suggested that states should budget an amount for quitline operations sufficient to reach a minimum of two percent of their tobacco users each year.[8]

Quitline Promotion

Mass media campaigns have been very successful in generating numbers of calls sufficient to keep quitline operators busy. For states with new quitlines, such campaigns are essential to achieve basic public awareness of the service. This is especially true if the quitline aims to reach traditionally underserved populations such as smokers of ethnic minority backgrounds.[7] But even for established quitlines, mass media advertising is important, because most tobacco users remain unaware of their quitlines. For example, a survey in California found that only 4.5 percent of smokers, when asked to name some of the products or services that help people quit smoking, mentioned the state's quitline, whereas 59.5 percent named a form of NRT (see table 2).[38] Even when they were specifically asked whether they had heard of 1-800-NO-BUTTS (the toll-free number for the state's quitline), only 38.7 percent of smokers reported that they had. Given that prompting can result in over-reporting, the percentage of California smokers who really are aware of the quitline may actually be lower. Clearly, much remains to be done to increase awareness of quitline services among those who could benefit from using them, particularly if quitlines are to take on a larger role in reducing the prevalence of tobacco use.

Table 2—Knowledge of Tobacco Cessation Programs Among California Smokers[38]

	Unaided Recall	Aided Recall
	% (± 95 CI*)	% (± 95 CI*)
Telephone Quitline	4.5 (1.1)	38.7 (2.6)
NRT	59.5 (2.5)	--
Hypnosis	9.8 (1.5)	--
SmokEnders	4.5 (1.1)	--
Others	46.3 (2.9)	--

For the unaided recall question, survey respondents were asked, "Can you name up to three programs that are helpful to people who are trying to quit smoking?" The aided recall question was asked only in reference to the quitline: "Have you ever heard of the 1-800-NO-BUTTS (or, in Spanish, 1-800-45-NO-FUME) phone number?"

*CI indicates confidence interval.

An alternative to traditional mass media advertising that has been tried recently is provision of free NRT. Because nicotine replacement products are comparatively well known to tobacco users, and known in particular to have a high retail value, the news that a publicly supported quitline is offering them at no charge spreads quickly, often assisted by earned media coverage due to the apparent newsworthiness of such an exciting "giveaway." Quitlines that have taken this approach have been swamped with calls from people eager to obtain free NRT.[44, 45] The expense of providing NRT may be offset by a reduction in advertising costs, and the overall efficacy of the quitline may improve by including NRT along with its counseling service. On the other hand, it is also possible that by diminishing the role of the media campaign, there may be a corresponding reduction in the number of people who quit on their own as a result of exposure to the campaign. A thorough evaluation of this approach as an alternative to traditional quitline marketing would include careful analysis of the trade-offs in costs and savings, and address the effects it may have on overall cessation activity, both inside and outside of the quitline.

The effect of quitline promotion on tobacco users who do not use quitlines deserves greater attention. Certainly the most obvious goal of quitline promotion is to generate calls from tobacco users who need help to quit. But it should be remembered that it also prompts some tobacco users to try quitting on their own, without actually calling. Many of these extra, unaided quit attempts lead to successful cessation, a highly desirable outcome with respect to cost-efficiency. In an early quitline study in New York State, for example, smokers in counties where a quitline was promoted were much more likely to make a quit attempt than smokers in counties where it was not promoted. This was true despite the fact that only a minority of quitters in the counties with a quitline actually used the service, and the difference in overall outcomes was significant.[46] In other words, quitline promotion can have a beneficial effect apart from that of the service itself.

This notion has important implications for how quitlines are promoted. About 40 percent of tobacco users in the U.S. try to quit each year, and self-quitting accounts for the great majority of those attempts.[3] It is true that quit attempts, on average, are more successful when aided.[9,47] But it does not follow that the sole focus of a tobacco cessation campaign should be to convert unaided quit attempts into aided ones. A better aim would be to provide help to the people who truly need it, while motivating those who can quit on their own to go ahead and try. Since the goal of a cessation campaign is to reduce the prevalence of tobacco use across the whole population, not just among those who receive service, the potential of quitline promotion to increase both aided and unaided quit attempts should be fully exploited.

In addition to tobacco users themselves, other logical targets for quitline promotion are the non-users to whom they have close personal ties. Studies have shown that a large percentage of quitline users report their family and friends as the source of the information that prompted them to call. Moreover, a significant number of non-users call quitlines themselves, seeking information to help their tobacco-using friends and family members quit.[48,49] The convenience of telephones apparently makes it seem natural to non-tobacco users to reach out on others' behalf. Given that social support is an important factor contributing to quitting success, it would make sense for quitline promotion to capitalize on the willingness of non-users to help users quit. Media campaigns have had great success in demoralizing tobacco use in the minds of non-users; for example, revised norms concerning tobacco use have prompted nonsmokers to support limits on smoking.[38] So there is reason to believe that campaigns to *normalize* tobacco cessation may also succeed: revised norms concerning smoking cessation may encourage non-users to take an active role in helping friends and family members quit. They might even be prompted to call the quitline themselves for information on how to help. This strategy may be particularly useful in certain ethnic communities where the bonds of family and friendship are especially strong, and where tobacco users are less likely to seek professional help to quit.[49]

Quitlines and Health Care Providers

Other logical targets for quitline promotion are health care providers. Providers see about 70 percent of tobacco users each year, often in circumstances that create a "teachable moment" concerning the need to quit.[50, 51, 52] To capitalize on this opportunity, clinical guidelines call upon clinicians to follow the "Five A's" with their patients: *ask* whether they use tobacco, *advise* them to quit if they do, *assess* their willingness to make a quit attempt, *assist* them in making that attempt, and *arrange* for follow-up.[25] But compliance with the Five A's is limited. Many clinicians report that they do not know how to help their patients quit, or simply that they do not have enough time.[53,54] This has prompted the Smoking Cessation Leadership Center, a national project funded by The Robert Wood Johnson Foundation, to propose a conceptual model that shifts the heaviest part of the clinician's burden onto quitlines.[54] Under this model, the clinician does the first two A's—asking and advising—and then refers the patient to the quitline. Once the patient calls, the quitline takes care of the last three A's—assessing, assisting, and arranging. Shifting some of the burden in this way may increase the likelihood

that providers will consistently ask all of their patients if they use tobacco, and advise all of those who do use tobacco to quit. This in itself is an effective intervention which, if applied on a population level, would dramatically decrease the prevalence of tobacco use.[25] A significant percentage of quitline callers are already referred by health care providers, especially in states where a quitline has been available for some time, and where special efforts have been made to promote the service among clinicians.[48] This indicates that quitlines address a real need felt by many health care providers.

The need for an effective referral resource for tobacco cessation is one that can be met by establishing evidence-based quitline services, and then actively promoting them to the health care industry.[55] A strategy as simple as asking all callers how they heard about the quitline and, if they report that their provider told them about it, recording the provider's name so that a thank-you letter can be sent out, can help to maintain providers' willingness to refer. Sending them free promotional items such as brochures or cards to hand out can help as well. More sophisticated strategies include partnered mailings to members of professional associations that are co-signed by the health department and the associations' leadership, arranging with health plans to have the quitline mentioned in the materials they send to their members, and persuading clinic systems to urge their providers to identify tobacco users and refer them for treatment. All of these strategies can increase provider awareness of and referral to quitlines.

Health care providers may be even more willing to refer to quitlines under a proactive enrollment model. In this model, patients who tell their provider that they are interested in quitting and are willing to be enrolled in an effective cessation program are signed up right away. Enrollment can be handled in several ways, for example, by having them call the quitline right there in the clinic (perhaps to schedule an appointment for counseling at a later time), or by having them fill out and sign a faxed referral and consent form. This approach helps patients over the threshold of ambivalence about seeking help to quit, and gives clinicians greater confidence that their patients will follow through with the intended treatment. It has been tried in several settings and is clearly feasible.[32, 56, 57] The approach can dramatically increase the use of quitline services among referred patients by a factor of ten or more, relative to simply telling patients to call the quitline on their own.[56,57] However, the question of whether quitline services are as effective for tobacco users enrolled in this manner as for those who call in on their own has not yet been answered, and should be carefully researched. If proven effective and broadly implemented, this approach could potentially have an enormous effect on quitline utilization, exceeding even the ambitious goal of the National Action Plan, and could serve as the linchpin of a nationwide effort to ensure that tobacco use is addressed with all patients in all health care settings.

With 1-800-QUIT-NOW in nationwide operation, all U.S. health care providers can immediately refer patients for tobacco cessation treatment. Not only physicians, but also dentists, pharmacists, nurses, nurse practitioners, physician assistants, dental hygienists, and other health professionals can refer. Tobacco dependence has numerous deleterious effects on human health, and so each provider has a unique perspective on the benefits of cessation.

All of the health care professions are credible sources of information on health and tobacco, and patients may need to hear from more than one of them before deciding to quit. For any given patient, it is difficult to predict which provider will tip the decisional balance in favor of cessation. It may be the family doctor who observes that the patient's chronic colds are worsened by smoking, or the dental hygienist who explains the link between smoking and periodontal disease, or the pharmacist who mentions that smoking reduces the efficacy of a medication being dispensed. All of these providers can play a role in moving patients away from tobacco use and toward improved health.

Conclusion

The rapid adoption of tobacco quitlines in the United States and elsewhere is a result of careful research demonstrating their efficacy and real-world effectiveness, and of public health officials' belief that quitlines are well-suited for a large role in a population-based approach to cessation. The recently formulated National Action Plan has already resulted in the creation of a network of quitlines with nationwide toll-free access. Its goal of increasing quitline utilization to 16 percent of the nation's tobacco users per year will require a major boost in funding for increased capacity and a more ambitious promotional effort. But if this goal is attained, there will be a marked decrease in the prevalence of tobacco use and in associated death and disease. Members of the medical community, who see the majority of tobacco users every year but do not yet consistently address their patients' tobacco use, can seize on the opportunity quitlines represent by asking all of their patients whether they use tobacco, advising the ones who do to quit, and referring them to quitlines for effective treatment.

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COMMENTARY ON QUITLINES

Tim McAfee, M.D., M.P.H*

As with other speakers, the VA helped to launch my career in tobacco control. I was a third-year medical student at the University of California, San Francisco (UCSF), and doing my very first medicine rotation at the VA, where I "met" my first patient, a 53-year-old man who was comatose in the last week of his life as he died from lung cancer. I never was able to have a conversation with him, and the best that 20th-century medicine could provide at this stage was twiddling with his IV fluid rate. On the last night of this two-month rotation, my very last patient was a 52-year-old man who had come in from rural California with a persistent cough. My last lab report was his bronchoscopy results: he had lung cancer. These experiences, and quite a few in between, riveted my attention to the human toll of smoking in America, and our powerlessness to intervene at the later stages.

Creation of a carefully planned and executed infrastructure to provide behavioral support and pharmacotherapy access via the telephone will be a key component of the VA's overall efforts to decrease tobacco use. Drs. Joseph and An and Drs. Zhu and Anderson have carefully laid out the case why this is important and how it can be done, based on their own exemplary work and research, as well as review of experience in the field. I will review a few of their key points, and provide some additional suggestions based on my perspective, including some "Do's and Don'ts."

My perspective comes from working as chief medical officer for Free & Clear, an organization that provides telephone support for tobacco treatment, including support for eight state quitlines and about 50 employers and healthcare systems. Free & Clear grew up in Group Health Cooperative in Washington state and was instrumental in weaving phone treatment for tobacco use into the fabric of health care delivery there. We have been able to achieve eight percent a year utilization rates by smokers for over five years in Group Health.

It is clear from the Joseph and An paper that the VA has an unprecedented infrastructure to support integration of telephone support, including easing access and support for medication fulfillment, and to do this while continuing to study what works best through rapid-cycle evaluations. This will serve the VA well.

- The study of TELESTOP shows that a quitline approach works in the VA specifically, with relatively straightforward and inexpensive promotion having recruited significant numbers of participants and having generated very respectable quit rates compared to controls.

* Free & Clear

- The study by Dr. Scott Sherman provides additional evidence that large numbers of veterans will sign up and use phone counseling, including referral to a state quitline. However, the VA made the recruitment call and four supplemental calls, and did the system support for pharmacotherapy. It is important to think carefully about the appropriate role of state or national quitline support for VA patients.
- The RESET recycling trial emphasized an often-underused potential of telephone support. It is often as expensive to recruit tobacco users as it is to treat them. This recycling trial is an excellent example of using an approach more in the manner of disease management, rather than a single-shot program, taking advantage of ease of access via the phone.

The Zhu and Anderson paper is an outstanding, thorough, and thoughtful review of the status of, and prospects for, quitlines in the U.S. Their key takeaway points include:

- Quitlines can increase reach into the broad population because of easy access, and are accepted and used by lower-income populations (such as many of those in the VA system).
- Quitlines allow for quality control and improvement by centralizing functions.
- The current call rates to quitlines (one to three percent) are a function of the lack of marketing effort, which is tied to budgets. Call rates are below potential by an order of magnitude.
- Most, but not all, states now have quitlines. Zhu and Anderson suggest that we have moved from the adoption to maintenance phase. Glasgow and colleagues developed the RE-AIM model emphasizing that the total population impact of an intervention (reach times effectiveness) is modulated by the rate of adoption, implementation, and maintenance. State-level quitlines have been in large measure adopted by states, but telephone-based support services have not yet been fully implemented. A much larger proportion of the population could and would use these services if they were available and promoted. More aggressive programs with higher utilization rates and more complex services, including pharmacotherapy, are offered by some health plans and employers. These are still in the early adoption phase, and coordination between public and private programs is in its infancy.
- Past experience of Group Health Cooperative, Providence, and other health care systems strongly supports the proposition that phone-based support will increase the enthusiasm of primary care practitioners for the other components of the 5-A model. Moreover, integrating quitlines into the 5-A model is an economical way to recruit smokers to use quitline services.

I would recommend that the VA *not* do the following:

- Do not create an either/or dynamic between phone-based services and in-person services delivered through primary care or tobacco clinics. They can and should synergize with each other.

- Although I oversee eight state quitlines, I don't think that state quitlines are an appropriate long-term stable financial foundation for the VA's phone-based tobacco programs, for the following reasons:
  a. There is too much state-to-state and temporal variability in what services are provided. Many states that have quitlines don't provide proactive calls and most don't provide pharmacotherapy.
  b. States make complex public health triage decisions. Many states see their prime mission as providing a safety net for those with no other options (i.e., the uninsured). Since tobacco treatment (including treatment delivered over the phone) is a form of evidence-based care, states may believe that it should be provided and financed by health care systems. Therefore, some states, based on their triage algorithms, may not provide follow-up proactive calls to VA members, since they are eligible for other cessation treatment.
  c. Many state and national-level quitlines will not have the capacity to provide enough integration with the rest of the VA healthcare system.
- Similar arguments apply to national-level phone services, such as those offered by the National Cancer Institute, the American Cancer Society, the Legacy Foundation, and others, that would be interested in taking VA calls. These organizations are even less likely to provide integration with the VA system.

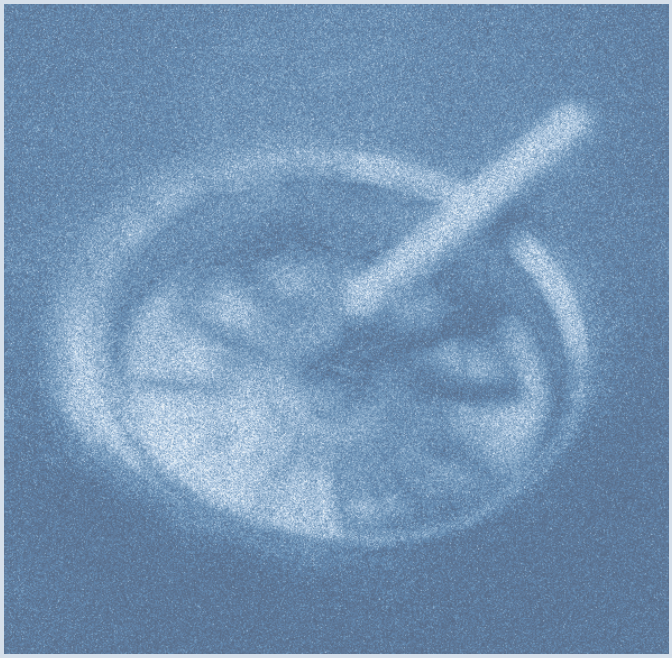
The bottom line: even if the VA succeeds in driving volume to potential (10-20 percent of VA smokers/year), it is likely to overwhelm the funding capacity of any current state or national-level system. This means that the VA will probably have to purchase services at that time or accept lesser levels of service (barring a massive state or federal infusion of long-term guaranteed funding specific to tobacco treatment.)

Here is what I recommend that the VA *do*:

- Offer the best system of telephonic support for tobacco users in the world, deeply integrated into other aspects of tobacco treatment and acute, preventive, and chronic care, with easy access to and decision support for pharmacotherapy.
- Cover counseling and medication as if they were critical services that the VA wants people to use, not ones for which the goal is to limit access, and allow easy access via the telephone to medications without requiring office visits, unless medically indicated.
- Set up the system so that it encourages people who want to use medications to also receive phone counseling, without having the counseling become a barrier to the use of medications.
- Work to demonstrate the return on investment of treating tobacco users by employing VA utilization data, particularly data on chronic conditions. Long-term buy-in for substantive funding of tobacco treatment will probably require further proof.

- Consider the "build versus buy" decision. Start with a "competitive bid" mindset, both internally and externally.
- Create a system that takes advantage of the economies of scale that call centers provide, without inhibiting or undervaluing local resources.
- Collaborate, cooperate, and seek ways to leverage the existence of non-VA-financed telephone support to supplement VA-financed and delivered service, without relying on them as the VA's core service.
- Strive for maximum impact, rather than focusing on either reach or effectiveness to the exclusion of the other. Don't be satisfied with two percent of VA smokers using the service. If it's done right, the VA can reach 10 percent a year, and probably 25 percent with an aggressive effort throughout the system.
- Continue to embed ongoing research and evaluation into the DNA of what the VA is doing, so that the systems can continuously evolve and improve. Continue the commitment of VA funds for this purpose, so that research to answer practical questions rapidly can occur along with NIH-level long-cycle research.
- Take advantage of what we have learned from disease management/chronic care improvement, which relies heavily on telephone service.
    a. For those at high-risk, an opt-out model may create more impact (there may be trade-offs around individual quit rate, but this is likely to be far outweighed by increased reach).
    b. Develop predictive modeling and take advantage of the VA's databases to identify tobacco users at high risk for short-term consequences AND who have a reasonable probability of benefiting from more intense recruitment and interventions
    c. Emphasize both relapse prevention AND recycling—recruitment costs are significant, and quitting is a long-term process, not an isolated acute episode of care.

The VA system is poised to become the case example for the world on how to help a large population with high tobacco prevalence successfully quit smoking. Because the VA holds the financial risk for providing healthcare for its patients for their entire lifetime, the administration will eventually accept that it is in its own self-interest to decrease the prevalence of smoking. The sooner it does, the fewer veterans will die of smoking-related diseases. What better way do we have to honor their service to our country?



TOPIC SIX

Next Steps for the VA

Next Steps for the VA

Stephen L. Isaacs, J.D.,* Steven A. Schroeder, M.D.,†
Joel A. Simon, M.D., M.P.H.,‡ and Elissa Keszler, B.A.§

The presentations and responses stimulated a lively and thoughtful discussion of the issues. The way the meeting was structured—short presentations and a lot of time for comments from the floor—encouraged a thorough airing of ideas. There were no major disagreements expressed among the participants but, rather, an emphasis on learning from the experiences within and outside of the VA, and capitalizing on these experiences to improve the VA's already strong performance. The broad consensus is not surprising given the generally shared set of values with which most participants arrived: smoking is such a serious health concern that it should have the highest priority; best practices, as embodied by the 5 A's, should guide health professionals; counseling and pharmaceutical products are effective and should be used widely; the VA *is* in the vanguard and can play an even more important leadership role; and there is no single approach to strengthening the VA's smoking cessation efforts.

Five main suggestions for the VA emerged from the presentations, the responses, the group discussions, and the written suggestions given to the conference organizers. These are:

- First, make smoking cessation treatment a routine and easily obtainable service offered at VA facilities.
- Second, integrate smoking cessation treatment with other relevant medical services, such as those focused on diabetes or obesity.
- Third, include smoking cessation as a service routinely offered to veterans by mental health professionals.
- Fourth, make greater use of the VA's extraordinary database and research potential, both within the VA and in collaboration with outside researchers.
- Fifth, promote telephone quitlines, which appear to be a particularly effective way of treating addiction to nicotine.

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Implementing the steps, however, will require central, regional, and local levels to take a number of sub-steps and to address challenges both within and outside of the VA. These are discussed below.

Step 1: Make smoking cessation treatment a routine and easily obtainable service offered at VA facilities

The VA has already installed a number of measures to make smoking cessation a routine element of medical care for veterans. For example, it requires primary care physicians to ask patients whether they are smokers and, if they are, to recommend that they quit. It has designated smoke-free areas and has endeavored to make some facilities completely smoke-free, although this has been complicated by Congress, at the behest of some veterans groups, having mandated some smoking areas in VA facilities. This illustrates one of the challenges: although nobody can question the long-term benefits of quitting smoking, some people within the VA question whether smoking cessation should be a priority for veterans with more immediate medical problems. Another challenge has to do with funding. Money for smoking cessation programs will have to come out of existing budgets. With budgets being tight, VISNs and local and regional facilities have been hesitant to reallocate additional funding for smoking cessation. A third challenge is lack of time. Providers are overburdened and have many health issues to cover in brief office visits. Aggressive smoking cessation means finding time for additional work with patients—which is often difficult for busy clinicians. A fourth challenge has to do with pharmacies: the failure to include all effective smoking cessation medications on the formulary and the restrictions on dispensing medications that occur in practice. A fifth challenge is the lack of visibility of smoking cessation programs within the VA.

The participants suggested a number of measures that could make smoking cessation a routine and easy-to-access service within the VA. These are listed below, followed (in parentheses) by the locus of action for implementing them:

- Support those people who are strong advocates for smoking cessation programs. The importance of champions was emphasized as critical to the adoption of policies and programs (central, regional, and local levels).
- Authorize the issuance of standing orders to enable nurses and technicians to prescribe smoking cessation treatment, and involve pharmacists (central office to set policy, to be carried out at regional and local levels).
- Include all NRTs and pharmacotherapies on the VA formulary (central).
- Reduce or eliminate co-payments for smoking cessation therapies (central).
- Revise the performance standards from simply asking about smoking and advising smokers to quit to providing, or referring patients to, treatment (central).
- Develop the capability within VA facilities for smokers to see a counselor quickly—either bringing a counselor to patients or getting patients to counselors quickly (regional and local).

- Rearrange funding priorities so that VISNs making smoking cessation, including counseling, a priority will not lose funding (central).
- Set aside budget funds earmarked for smoking cessation coordinators (responsible for developing comprehensive smoking cessation plans), outreach specialists, and counselors (regional).
- Publicize smoking cessation services more widely—through print publications, the Web, and other vehicles—to patients and staff, including physicians, in order to create more demand for tobacco cessation treatment. This should include information about the availability of counseling and drugs as well as the safety of NRTs and pharmacotherapies (central, regional, and local).

Step 2: Integrate smoking cessation treatment with other related medical services offered by the VA

Smoking cessation is not normally considered as part of the treatment of other medical conditions. Addiction to nicotine should be considered as a chronic condition, one that can be addressed by primary care clinicians as well as specialists. Moreover, there are a number of circumstances where treatment for nicotine addiction ought to be part of a regular plan of treatment. One set of circumstances involves behavior change; for example, obese veterans seeking to lose weight through change in diet and exercise. Since one of the reasons for seeking to change eating and exercise patterns is to protect against cardiovascular disease, it makes sense to address a related behavior that causes cardiovascular disease—smoking. A second set of circumstances involves times of acute illnesses in which veterans' awareness of the need for good health is high; for example, hospitalization for a heart attack. Taking advantage of these "teachable moments" to promote smoking cessation has been shown to increase compliance. A third set of circumstances involves treatment of diseases associated with unhealthy behavior; a good example is diabetes. Among the concrete suggestions for carrying out these steps are the following:

- Encourage smoking cessation treatment to be offered as part of their care plan to all patients hospitalized for tobacco-related illnesses, such as myocardial infarction, stroke, and lung cancer (central).
- Train nurses and technicians, such as respiratory therapists, involved in the care of veterans hospitalized with smoking-related illnesses, to counsel patients and refer them to smoking cessation treatment (regional and local) and provide them with written smoking cessation materials.
- Incorporate smoking cessation into behavioral change programs, such as weight loss programs (regional).

Step 3: Make smoking cessation a routine part of the care of veterans suffering from mental health conditions, including post-traumatic stress disorder (PTSD) and drug and alcohol addictions

Despite the high proportion of veterans with psychological or psychiatric problems who smoke, mental health professionals at the VA do not, as a general rule, offer smoking cessation treatment to their patients. In some cases, mental health professionals view smoking cessation as somebody else's problem; in other cases, they are fully absorbed by the immediate condition; in still other cases, they view smoking as relaxing and therapeutic.

The conference participants agreed that the VA could provide genuine leadership if smoking cessation became a normal part of the job of mental health clinicians. There was a consensus that the death and disability caused by smoking provided medical and ethical grounds for the VA's mental health professionals to expand their scope of practice and to provide or recommend smoking cessation treatment for smokers in their care. As Hall, citing Zarin, Pincus, and Hughes noted in her commentary, "Those who deliver mental health care often pride themselves on treating the whole patient…yet many fail to treat nicotine dependence. They forget that when their patient dies of a smoking-related disease, their patient has died of a psychiatric illness they failed to treat." The following concrete steps were suggested:

- Address the issue that mental health professionals should not treat nicotine addiction because cigarettes help people with mental illness to relax. As one participant noted, "There's got to be a better anti-depressant than cigarettes" (central, regional, local).
- Do more research, both within the VA and in collaboration with outside researchers, on effective smoking cessation treatment for people with mental illnesses. At the moment, mentally ill patients are often excluded from clinical trials of smoking-cessation drugs (central, regional, local).
- Look to complementary medicine, as well as allopathic medicine, to treat nicotine addiction. Hypnotism was mentioned as offering one promising approach (regional, local).
- Utilize carbon monoxide meters during psychiatric consultations. Measuring carbon monoxide has been shown to be effective in raising awareness of the damage of smoking in schizophrenic patients (regional, local).
- Frame the issue to mental health professionals as one whereby failure to address smoking is, in fact, withholding potentially lifesaving treatment from patients (central, regional, local).
- There was also a suggestion that all mental health patients should receive at least a brief smoking cessation intervention. This suggestion was challenged by those who believed that it is not good medical practice to offer only a minimal intervention to those who need more intensive therapy (central, regional, local).

Step 4: Take advantage of the research opportunities afforded by the VA's extensive database and electronic medical records system

The VA's electronic medical recordkeeping system gives it access to a unique and extraordinary database. These data are not, however, always analyzed sufficiently to be helpful to policy makers and practitioners (one participant noted "the wealth of data and the paucity of useful information"). Moreover, the data lack detail on racial, ethnic, and socio-economic status of VA enrollees. The VA could improve its knowledge base by mining its database in a more efficient and timely manner; collecting more data on race, class, and socio-economic status; and inviting outside researchers to share in the data analysis. The concrete steps that emerged from the conference include the following:

- Collect more data on veterans by race, ethnicity, and class (central, regional, local).
- Recognize that ethnic categories such as Latinos or Asians are heterogeneous. As a result, it is advisable to take into account sub-groups within these more global ethnic categories.
- Conduct research studies in a way that is sensitive toward, and understands, the culture of minority, especially ethnic minority, groups. This involves more than translating questionnaires.
- Conduct more research to uncover why certain groups, especially Native Americans, remain heavy smokers and what smoking cessation approaches are most effective with them (central, regional, local).
- Conduct studies specifically designed to find out why certain minority populations such as African Americans have difficulty quitting and what interventions are most effective with them (central, regional, local).
- Standardize the collection of data among the VISNs (central, regional).
- Develop protocols with researchers outside of the VA to analyze data collected within the VA, particularly that collected from electronic medical records (central, regional).
- Use the electronic record system to find out who and where the smokers are (central, regional, local).

Step 5: Promote the use of telephone quitlines

Quitlines have been proven, both within and outside of the VA, as an effective way of providing treatment for nicotine addiction. It should become an important part of the VA's smoking cessation efforts. Quitlines are a particularly appropriate fit for the VA, given the wide use of electronic medical records and performance measures. Emphasizing quitlines and making them easily available to veterans would enable the VA to assert genuine leadership in the tobacco cessation field. (After the conference, Health and Human Services Secretary Thompson announced a new national quitline portal, 1-800-QUITNOW, which should simplify marketing of quitlines to veterans.) The specific suggestions to bring about the greater use of telephone quitlines included:

- Expand significantly and publicize quitlines within the VA, so that they become a central element in the VA's smoking cessation efforts (central, regional).
- Change the perception of quitlines so that they are seen for what they really are: treatment done over the telephone. The name "quitline" is a misnomer and doesn't capture its importance (central, regional).
- Use VA funds to pay for counseling and referrals done by telephone (central, regional).
- Revise performance measures so that credit is given for telephonic smoking cessation counseling and referrals (central).
- Make greater use of available technology, such as cell phones and computers, to increase veterans' awareness of quitlines and to provide therapeutic interventions (central, regional, local).

While there was widespread agreement about the importance of expanding quitlines within the VA, the participants raised a number of questions that still must be addressed, including:

- Should the VA use (and pay for) state and national quitlines or set up its own national quitline?
- How can the high quality of treatment by telephone be assured and monitored?
- What are the best ways to get from a telephone consultation to prescription of medication at a pharmacy and payment for the pharmaceuticals?
- How can the VA best deal with difficult cases, such as veterans with serious mental health problems or those living in rural areas?
- How should recordkeeping be coordinated and records maintained?

As he was saying his good-byes, one of the participants commented, "This has been a terrific meeting—one of the best I've ever attended. But I've been to a lot of good meetings where nothing happened afterward. Let's hope that there is a follow-up to this meeting and that the VA takes advantage of the great expertise that was gathered in the room." The steps proposed by the conference participants offer a map to guide the VA as it builds on its considerable strengths to truly assert its leadership in the field of tobacco cessation.

BIOGRAPHIES OF CONFERENCE ORGANIZERS, PRESENTERS, RESPONDERS, AND RAPPORTEUR

Conference Organizers

Steven A. Schroeder, M.D.

Dr. Schroeder is Distinguished Professor of Health and Health Care, Division of General Internal Medicine, Department of Medicine, University of California, San Francisco (UCSF), where he also heads the Smoking Cessation Leadership Center. The Center, funded by The Robert Wood Johnson Foundation, works with leaders of American health professional organizations and health care institutions to increase the rate at which patients who smoke are offered help to quit.

Between 1990 and 2002, he was President and CEO, The Robert Wood Johnson Foundation. During his term of office the Foundation made grant expenditures of almost $4 billion in pursuit of its mission of improving the health and health care of the American people. During those 12 years, the Foundation developed new programs in substance abuse prevention and treatment, care at the end of life, health insurance expansion for children, and others. In 1999, it reorganized into health and health care groups, reflecting the twin components of its mission.

Dr. Schroeder graduated from Stanford University and Harvard Medical School, and trained in internal medicine at the Harvard Medical Service of Boston City Hospital, and in epidemiology at an Epidemic Intelligence Service (EIS) Office of the Centers for Disease Control (CDC). He held faculty appointments at Harvard University, George Washington University, and UCSF. At both George Washington and UCSF he was founding medical director of a university-sponsored HMO, and at UCSF he founded its division of general internal medicine.

He has published extensively in the fields of clinical medicine, health care financing and organization, prevention, public health, and the work force, with over 250 publications. He currently serves as chairman of the American Legacy Foundation and of the International Review Committee of the Ben Gurion School of Medicine, and he is a member of the editorial board of the New England Journal of Medicine, the Harvard Overseers, the James Irvine Foundation, the Save Ellis Island Foundation, and the Council of the Institute of Medicine, National Academy of Sciences. He has received six honorary doctoral degrees and numerous awards.

Schroeder lives in Tiburon, California, with his wife Sally, a retired schoolteacher. Their two sons are physicians. To date Steve and Sally have one granddaughter and are hoping for more grandchildren.

Joel A. Simon, M.D., M.P.H.

Dr. Joel A. Simon is an Associate Professor of Clinical Medicine, and Epidemiology and Biostatistics at the University of California, San Francisco (UCSF) School of Medicine. He was an intern, resident, and chief resident at Downstate Medical Center in Brooklyn, New York, after which he practiced Internal Medicine for 11 years at Northern California Kaiser. In 1990, he obtained an M.P.H. degree from the University of California, Berkeley, and then went on to do a VA Ambulatory Care Fellowship at the San Francisco VA Medical Center (SFVAMC).

His research interests revolve around cardiovascular risk reduction and specifically include the role of diet and health, and smoking cessation. He has authored or co-authored 41 peer-reviewed papers. For the past 12 years, he and Dr. Timothy Carmody at the SFVAMC have undertaken a series of randomized clinical trials examining innovative approaches to in-patient and out-patient smoking cessation. He has been the principal investigator (PI) on three completed smoking cessation clinical trials and is currently PI on a clinical trial examining the efficacy of bupropion for hospital-based smoking cessation. He is also a co-investigator on two ongoing smoking cessation studies, one examining the effect of self-hypnosis, and another examining the efficacy of pager-cued therapeutic messages.

Dr. Simon sees patients and attends on the medicine wards at the SFVAMC. He also teaches students, residents, fellows, and junior faculty on clinical research methods at UCSF. He is a fellow in the American College of Physicians, the American College of Nutrition, and the American Heart Association Council on Epidemiology.

Presenters

Jasjit S. Ahluwalia, M.D., M.P.H., M.S.

Dr. Ahluwalia is a clinician, educator, researcher, and administrator. He has devoted the past 13 years of his career to improving the health of high-risk populations, such as the under-served and ethnic minorities. His research and clinical interests are in pharmacotherapy and behavior change for chronic diseases, including nicotine addiction, obesity, nutrition and physical activity.

Dr. Ahluwalia received his B.A. degree at New York University, followed by a combined four year M.D./M.P.H. program at the Tulane University Schools of Medicine and Public Health in 1987. At the University of North Carolina at Chapel Hill, he completed a three-year Internal Medicine residency. He then completed the two-year Harvard Medical School General Internal Medicine fellowship in clinical epidemiology, and received a M.S. in Health Policy at the Harvard School of Public Health in 1992. From September 1992 to June 1997, Dr. Ahluwalia was an assistant professor of Medicine at the Emory University School of Medicine, with a joint appointment in the School of Public Health in Health Policy. He served

as the assistant director of the Urgent Care Center and the Director of the Center for Smoking Cessation and Tobacco Control at Grady Memorial Hospital.

In July 1997, he joined the faculty at the University of Kansas School of Medicine as vice-chair, director of research, and associate professor of preventive medicine and associate professor of internal medicine. In July 2001, he was appointed as chair of the department of preventive medicine and in July 2002 became full professor in preventive medicine, internal medicine, pediatrics, and family medicine. Dr. Ahluwalia has received more than $10 million in funding over the past 10 years as a principal investigator (PI) and $9 million as a co-PI and co-investigator. He currently holds a $1.7 million grant for a study titled, "Health Behaviors Among Smokers Living in Low Income Housing," and a $2.7 million award from the National Cancer Institute (NCI) for a study titled "Helping Light African American Smokers Quit." Dr. Ahluwalia is director of the medical center's NIH K-30 Clinical Research Curriculum Award. He has received a number of awards including the University of Kansas Medical Center's Research Investigator of the Year Award in 2000; the inaugural Society of Behavioral Medicine's Mentor of the Year award in Spring 2001; the university-wide Kemper Foundation Teaching award in August 2002; and the F. Marian Bishop Educator of the Year award from the Association of Teachers of Preventive Medicine in March 2003.

Dr. Ahluwalia serves as an associate director of the Kansas Cancer Institute where he directs the Cancer Prevention, Control and Population Sciences program. Dr. Ahluwalia is a fellow of the American College of Physicians, the American College of Preventive Medicine, and the Society of Behavioral Medicine. He speaks extensively on a number of topics to regional and national medical audiences, and has been published in peer-reviewed journals. From 1998 to 2003, Dr. Ahluwalia served on the national advisory committee of The Robert Wood Johnson Foundation's initiative on Addressing Tobacco in Managed Care, and is a current member of the Tobacco Consortium of the American Academy of Pediatrics Center for Child Health Research. Dr. Ahluwalia is on the editorial board of the *American Journal of Preventive Medicine*, and is one of the deputy editors of *the Journal of General Internal Medicine*. In spring 2003, Dr. Ahluwalia was named the Sosland Family Professor of Preventive Medicine and Public Health.

Jean Beckham, Ph.D.

Dr. Beckham is a tenured associate professor in the department of psychiatry and behavioral sciences at Duke University Medical Center, and a staff psychologist in the outpatient Posttraumatic Stress Disorder Clinic at the Durham Veterans Affairs Medical Center. Dr. Beckham completed graduate work at Florida State University and her postdoctoral fellowship at Duke University Medical Center. Dr. Beckham's primary area of interest is the effect of chronic post-traumatic stress disorder (PTSD) on health, with over 75 publications. She serves as principal investigator (PI) on several federally funded projects, including an investigation of optimal smoking cessation treatment strategies for PTSD, and two studies designed to evaluate the relationship between smoking behavior and PTSD symptoms. She currently

serves on the editorial board of the *Journal of Traumatic Stress*, and has served on several NIH review panels.

Kim W. Hamlett-Berry, Ph.D.

Dr. Hamlett-Berry received her doctorate in clinical psychology from the Catholic University of America, her master's degree in general experimental psychology from Wake Forest University, and was an intern and post-doctoral fellow in medical psychology at Duke University Medical Center. As director of the Public Health National Prevention Program in the VA Public Health Strategic Health Care Group, she is responsible for the planning and coordination of national HIV and hepatitis C prevention and tobacco use cessation programs and policy for the Department of Veterans Affairs Health Care System. Prior to joining VA in February 1999, she was on the faculties of the University of Virginia and Case Western University Schools of Medicine. Dr. Hamlett-Berry was chosen as the 1996-1997 William A. Bailey HIV/AIDS Congressional Science Fellow by the American Psychological Association. She served as an American Association for the Advancement of Science Congressional Science Fellow and later served as a professional staff member in the Senate Veterans' Affairs Committee office. Dr. Hamlett-Berry has clinical, research, and public policy experience with chronic illness populations.

Richard D. Hurt, M.D.

A native of Murray, Kentucky, and a graduate of Murray State University (1966), Dr. Hurt received his M.D. from the University of Louisville, interned at Baptist Memorial Hospital in Memphis, Tennessee, and did his internal medicine fellowship at Mayo Clinic. In 1976 he joined the staff of Mayo Clinic in the Division of Community Internal Medicine. He held various leadership positions in the division and served as Division Chair from 1987 to 1997. Through his many academic activities, he rose to achieve the rank of Professor of Medicine at the Mayo Clinic College of Medicine in 1995.

Dr. Hurt's interest in addictive disorders began in the early 70's and since the mid-1980's, has focused on tobacco dependence. He is founder and director of the Mayo Clinic Nicotine Dependence Center. This center embodies the integration of the three parts of the Mayo signature of practice, education, and research and has mature treatment, education, and research programs. Each program is under the direction of an associate director and program coordinator. The goal of the Nicotine Dependence Center is to enhance the quality of life for patients with tobacco dependence by providing the best treatment possible through a program that fully integrates practice, education, and research. Since its inception in April, 1988, the Nicotine Dependence Center Treatment Program staff has treated over 29,000 patients with services including individual counseling, group programs, telephone counseling, and an intensive residential treatment program. Through its Education Program, education services are provided for medical students, residents, trainees, and fellows, in addition to a twice yearly conference for healthcare providers who want to provide treatment services to patients with

nicotine dependence. Most recently we have added a counselor certification course for tobacco treatment specialists. The Research Program staff has conducted scores of randomized clinical trials with pharmacologic agents, in addition to outcomes research, behavioral interventions, epidemiologic studies, and basic science research.

Dr. Hurt is an internationally recognized expert on tobacco, providing perspectives to audiences, ranging from scientific organizations, to Dateline, Good Morning America and the Today Show, to legislative bodies like the United States Senate and the Minnesota Legislature. He has served on numerous study sections and boards and has served as a consultant to the Ministry of Health of Singapore, the Bekterev Psychiatric Institute in St. Petersburg, Russia, and the United States Food and Drug Administration, among many others. Dr. Hurt was the first witness for the State in the historic Minnesota tobacco trial which resulted in a settlement with the cigarette manufacturers, including the release of over 50 million pages of previously secret internal tobacco company documents. From 1998 to 2003, Dr. Hurt served as the Chair of the Board of the Minnesota Partnership for Action Against Tobacco (MPAAT), a new nonprofit organization that was created by the settlement reached in the Minnesota tobacco trial in May, 1998. In 2003 he received a William Cahan Distinguished Professor Award from the Flight Attendant Medical Research Institute and the Research Career Achievement Award from the Mayo Clinic Department of Medicine. Author or coauthor of over 150 scientific publications, Dr. Hurt is a widely sought after speaker.

Anne M. Joseph, M.D., M.P.H.

Dr. Joseph received her doctorate of medicine and bachelor of arts degree from the University of Michigan. She then earned her masters in public health in epidemiology from the University of Minnesota. Dr. Joseph is a general internist at the Minneapolis Veterans Administration Medical Center, and professor of medicine at the University of Minnesota Medical School. Dr. Joseph is the policy research director for the Transdisciplinary Tobacco Use Research Center, as well as one of the Center's principal investigators in conducting research in harm reduction in relation to exposure to tobacco. Throughout her career, Dr. Joseph has published numerous scientific articles and abstracts on the topic of tobacco control. She has conducted clinical trials of treatments for nicotine dependence in patients with heart disease and alcohol dependence, and health services research with the goal of increasing treatment of tobacco use. Dr. Joseph is also a leader in statewide tobacco control efforts, serving on the Board of the Minnesota Smoke-Free Coalition.

Scott E. Sherman, M.D., M.P.H.

Dr. Sherman is a primary care physician at the VA Greater Los Angeles Healthcare System. After receiving his M.D. from New York University School of Medicine, he completed a residency in primary care internal medicine at Bellevue Hospital Center/New York University Medical Center. He then completed a two-year fellowship in general internal medicine at Boston University Medical Center and received his master of public health degree in epidemiology and

biostatistics. His two-year period in Boston also served as a residency in preventive medicine and as fellowship training in geriatrics. Since completing his fellowship in 1991, Dr. Sherman has been at the Sepulveda, California, VA Medical Center, where he has served in a variety of clinical and administrative roles.

Dr. Sherman's research interests have focused on smoking cessation, depression, exercise, and changing provider behavior. He is currently principal investigator on four studies of tobacco control interventions, with funding coming from the VA Health Services Research & Development Service, the California Tobacco-Related Disease Research Program, and the American Legacy Foundation. His recent and current studies have examined using quality improvement to implement smoking cessation guidelines, having an on-call counselor available for smoking cessation, and developing a system to increase referrals to telephone counseling.

At present, he holds a number of national roles in tobacco control within the VA. He is chair of the Smoking and Tobacco Use Cessation Technical Advisory Group, which advises the VA's Public Health National Prevention Program on policy and practice related to tobacco control. He was the co-chair and lead VA author on the recently completed *VA/Department of Defense Clinical Practice Guideline on Management of Tobacco Use*. He is also chair of the group working on creating a national registry or database of smokers within the VA.

Dr. Sherman is an attending physician at the VA Greater Los Angeles Healthcare System and at the Olive View Medical Center county hospital. He has been very active in the Society of General Internal Medicine for over 15 years. He is a fellow of both the American College of Physicians and the American Academy on Physician and Patient.

Shu-Hong Zhu, Ph.D.

Dr. Zhu is an associate professor at the Department of Family and Preventive Medicine, School of Medicine, University of California, San Diego. Dr. Zhu's research focuses mainly on interventions for smoking cessation, with a bent toward population-based studies. He has been the principal investigator for the California Smokers' Helpline since its inception in 1992 and is well-recognized for his work in telephone counseling. Dr. Zhu's research began with general adult populations and has extended to adolescents, pregnant smokers, smokers using pharmacotherapy, smokers of ethnic minority backgrounds, and smokers of low socio-economic status. His work is noted for its quick application of research findings into public health settings. A psychologist with a strong background in methodology, Dr. Zhu has published on clinical intervention as well as on experimental design. He also consults widely with various health and governmental agencies and is a consultant for the World Health Organization and the World Bank on tobacco control initiatives in the Western Pacific Region.

Douglas M. Ziedonis, M.D., M.P.H.

Dr. Ziedonis is a professor of psychiatry and director of addiction psychiatry at the University of Medicine and Dentistry of New Jersey's Robert Wood Johnson Medical School. He is

also a professor in health systems and policy at the UMDNJ School of Public Health and visiting professor at Rutgers University Center for Alcohol Studies and Princeton Seminary. Dr. Ziedonis has dedicated his career to better understanding and treating co-occurring mental illness and addiction, including addressing tobacco dependence in mental health and addiction settings. He is the recipient of numerous awards and grants from the National Institute of Mental Health, National Institute of Drug Abuse (NIDA), Center for Substance Abuse Treatment, Robert Wood Johnson Foundation and other organizations and agencies including a NIDA Career Development Award. He has written over 100 book chapters and peer-reviewed publications and has co-edited three books, including the *Integrated Treatment for Mood and Substance Use Disorders* and the *Handbook on Drug Abuse Prevention: A Comprehensive Strategy to Prevent the Abuse of Alcohol and Other Drugs*. He serves as a co-occurring disorder advisor to many agencies, states, and federal groups including President George W. Bush's New Freedom Commission on Mental Health, NIDA, and the Substance Abuse and Mental Health Services Agency. He also works as a clinician and program director in developing better co-occurring disorder services. Dr. Ziedonis led a national initiative for The Robert Wood Johnson Foundation to develop a national agenda on how to Address Tobacco in Mental Health and Addiction Settings.

Responders

Michael C. Fiore, M.D., M.P.H.

After graduating from Bowdoin College, Dr. Fiore completed medical school at Northwestern University in Chicago and his internal medicine training at Boston City Hospital. His postgraduate education included a Master's of Public Health from Harvard University. Dr. Fiore received additional public health training as an Epidemic Intelligence Service (EIS) Officer for the U.S. Centers for Disease Control where he completed a Preventive Medicine residency.

Dr. Fiore worked as a medical epidemiologist at the U.S. Office on Smoking and Health, where he contributed to a wide range of national research, and educational and policy projects. Since moving to the University of Wisconsin, a chief research and policy focus has been to develop strategies to prompt clinicians and health care systems to intervene with patients who use tobacco. As part of this effort, he developed, studied, and now disseminates an innovative initiative on expanding the vital signs to include tobacco use status. Another major focus of his work has been the development and evaluation of new tobacco cessation treatment.

Dr. Fiore is founder and director of the Center for Tobacco Research and Intervention and a professor of Medicine at the University of Wisconsin Medical School. At the University of Wisconsin, he is clinically active, treating patients both in internal medicine and for tobacco dependence. He is also the principal investigator on a National Institutes of Health-funded Transdisciplinary Tobacco-Use Research Center grant, "Relapse: Linking Science

and Practice." He served as chair of the U.S. Agency for Health Care Policy and Research Panel that produced the Clinical Practice Guideline on Smoking Cessation (No 18), and the U.S. Public Health Service Panel that published an updated guideline, Treating Tobacco Use and Dependence: A Clinical Practice Guideline (2000). Currently, he serves as director of a Robert Wood Johnson Foundation National Program Office, Addressing Tobacco in Managed Care and chairs the Cessation Subcommittee of the United States Interagency Committee on Smoking and Health.

Dr. Fiore is a nationally recognized expert on tobacco, providing perspectives to audiences ranging from "Good Morning America" to the U.S. Senate. He has written numerous articles, chapters, and books on cigarette smoking and was a co-author and consulting editor of *Reducing Tobacco Use—A Report of the Surgeon General* (2000). In 2003, he was one of five national recipients of the Innovators in Combating Substance Abuse Award from The Robert Wood Johnson Foundation.

Sharon M. Hall, Ph.D.

Dr. Hall is a professor of medical psychology for the department of psychiatry at the University of California, San Francisco. Her major areas of research interest are clinical trials for the treatment of substance abuse. Her work has included behavioral and pharmacological trials of therapies to treat nicotine dependence, cocaine dependence, and opioid abuse. She has also produced both theoretical and treatment studies of dually diagnosed patients, most notably the intersection between nicotine dependence and depression. Dr. Hall is an author on approximately 200 scientific articles. She is principal investigator on two National Institutes of Health research project grants, "Maintaining Nonsmoking," now in its 21st year, and "Maintaining Abstinence in Chronic Cigarette Smokers." She is also principal investigator on the National Institute on Drug Abuse-funded P50 Center grant titled, "Treatment of Complex Patients in New Settings," and on a component of that grant, "Treatment of Co-morbid Smokers." She also directs a postdoctoral training program in drug abuse treatment and service research. She has served on advisory and review committees for the NIH, the Institutes of Medicine, the Center for Substance Abuse Treatment, and the American Legacy Foundation.

Helen Lettlow, M.P.H.

Helen Lettlow, recently promoted to assistant vice president, joined the American Legacy Foundation in February, 2000, as director of Program Development for Priority Populations. Currently a doctoral candidate in Public Health, Ms. Lettlow is a health program administrator with more than 18 years of experience working in public health, university, governmental, and community-hospital settings. Primarily her training and experience have focused on women's health, HIV/AIDS prevention, minority health, and cancer prevention.

At Legacy, Ms. Lettlow established and provided oversight to a $21 million grant initiative to address tobacco-related health disparities for vulnerable populations. She now spearheads Legacy's health disparities programming and outreach strategies to identify and address resource

gaps among underserved populations. Central to the foundation's mission, health disparities programming is mainly conducted through Priority Populations, which intersects with Grants, Research and Evaluation, Communications/Marketing, and Strategic Partnerships.

Ms. Lettlow joined Legacy from the University of North Carolina at Chapel Hill, Maternal Child Health, where she developed new funding initiatives. As Director of Women's Health at the American Social Health Association, from 1996 to 1999, she directed a research demonstration project aimed at preventing cervical cancer among African American and Hispanic women in North Carolina. During 1998 to 1999 she chaired the Reproductive Health section, American Public Health Association, focusing on health disparities.

A graduate of Columbia University's School of Public Health, Ms. Lettlow directed the Women's Health Program at the New York State Department of Health, AIDS Institute from 1992 to 1996. Prior to that, she spent four years as Assistant Director of community-based research at the HIV Center for Clinical and Behavioral Research. She also directed the Family Planning Clinic at Harlem Hospital from 1986 to 88. Ms. Lettlow's area of special interest is in health promotion programming for underserved communities.

Tim McAfee, M.D., M.P.H.

Dr. McAfee is the chief medical officer for the Center for Health Promotion (CHP). CHP is a health care company dedicated to supporting health-related behavior change. Its primary services are telephone-based intervention programs for tobacco cessation and weight management. CHP was an operating unit within Group Health Cooperative in Washington State for 15 years. Due to its increasing national business and potential for expansion, it was established as a separate company in 2003.

Dr McAfee has been instrumental in leading efforts over the past decade that catapulted CHP into a national model of multi-system tobacco treatment. He led the expansion of model telephone-based cessation support services to other venues, including eight state tobacco cessation quit-lines, and over 50 other health systems and employers. Dr. McAfee serves as a consultant for numerous national and state-level organizations and committees on tobacco treatment policy and delivery issues. He has been a co-investigator and a site principal investigator on multiple National Cancer Institute-funded research studies focusing on questions relating to effectiveness and dissemination of phone-based tobacco programs in medical systems and through government-sponsored state-level quitlines. He is an affiliate investigator in the Center for Health Studies at Group Health, as well as an affiliate assistant professor in the University of Washington School of Public Health and Community Medicine.

C. Tracy Orleans, Ph.D.

As The Robert Wood Johnson Foundation's senior scientist, Dr. Orleans works in several areas—tobacco, health and behavior, health care quality, childhood obesity, and research and evaluation. Her work has a common theme of promoting the translation of clinical

and behavioral research into practice and policy, and improving health care quality for the prevention and management of chronic disease. She has played a leading role in developing the foundation's grant-making strategy in the areas of tobacco dependence treatment, chronic disease prevention and management, and the adoption of healthy behaviors, including physical activity promotion (active living), and childhood obesity prevention. She has developed and leads or co-leads numerous foundation national programs in these areas, including: Addressing Tobacco in Managed Care, Smoke-Free Families, The National Spit Tobacco Education Program, Improving Chronic Illness Care, The National Partnership to Help Pregnant Smokers Quit, Bridging the Gap and Impact Teen, Helping Young Smokers Quit, Prescription for Health, the Active Living Research Program, Health e-Technologies, and the Substance Abuse Policy Research Program. Dr. Orleans is internationally recognized for her expertise in health behavior change research and translating research findings into practice, and she remains active in behavioral medicine and public health research and publication. She has authored or co-authored over 175 publications, and serves on a number of journal editorial boards, national scientific panels, and advisory groups (e.g., Institute of Medicine, Agency for Healthcare Quality and Research, the Centers for Disease Control and Prevention, National Commission on Prevention Priorities, the Interagency Committee on Smoking and Health Subcommittee on Tobacco Cessation, American Legacy Foundation, Society of Behavioral Medicine). She is a past member of the U.S. Preventive Services Task Force, past president of the Society of Behavior Medicine, and recipient of the Society's Distinguished Service Award. She has also received the Joseph Cullen Tobacco Control Research Award of the American Society of Preventive Oncology.

Rapporteur

Stephen Isaacs, J.D.

An attorney, writer-editor, and former professor of public health at Columbia University, Stephen Isaacs edits *To Improve Health and Health Care: The Robert Wood Johnson Foundation Anthology* series (Jossey-Bass, published annually) and *The Robert Wood Johnson Foundation Health Policy Series* (also published by Jossey-Bass). Mr. Isaacs has written extensively about health, socio-economic development, philanthropy, and human rights for both professional and popular audiences. His book, *The Consumer's Legal Guide to Today's Health Care*, was reviewed as "belonging on the bookshelf right next to Spock, Brazelton, and The Joy of Cooking." Other books edited by Mr. Isaacs include: *Improving Population Health* (Social Policy Press, 2002) and *Salud en América Latina: de la Reforma para Unos a la Reforma para Todos* (Editorial Sudamericana, 2000). A former member of the Advisory Council of the National Institute for Child Health and Human Development, vice-president of the International Planned Parenthood Federation's Western Hemisphere Region, and board member of Human Rights Watch, Mr. Isaacs is a graduate of Brown University and Columbia Law School.

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VA in the Vanguard:
Building on Success in Smoking Cessation

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