# Is Routine Spirometry Justified In Smokers In Primary Care Clinics? A Randomized Clinical Trial

by

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CERTIFICATE OF APPROVAL

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TABLE OF CONTENTS

## FIGURES, TABLES, APPENDICES

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# ABSTRACT

## BACKGROUND

Pulmonary function tests are frequently used in the diagnosis and management of pulmonary diseases. Although spirometry is recommended to screen persons at risk for pulmonary disease such as smokers, benefits of screening have not been studied. Since primary care clinics encounter smokers daily, the role of screening spirometry could be tested in this environment. We implemented a smoking cessation program according to The Agency for Health Care Policy and Research (AHCPR) guidelines in two primary care clinics and tested the hypothesis that adding routine lung function screening and education to AHCPR recommendations would improve motivation to quit, quit attempts, and quit rate when compared to AHCPR recommendations alone.

## STUDY DESIGN

A randomized clinical trial comparing a standardized smoking cessation program with and without an intervention consisting of education with spirometry and carbon monoxide measurements.

## SUBJECTS

Routinely-scheduled smokers in two out-patient primary care clinics at Oregon Health Sciences University.

## METHODS

During the study period, all routinely-scheduled clinic patients were systematically identified as smokers or nonsmokers. Participating smokers were given education, advice and cessation information according to AHCPR guidelines. Half of the participants were then randomized to receive additional education with spirometry and

carbon monoxide measurements ("intervention" group). Motivational stage, quit attempts, and quit rate were compared at 9-months follow-up.

RESULTS

1038 patients were screened during the study period, and 360 (35%) were smokers. 251 smokers (68%) agreed to participate in the study, and 205 were subsequently randomized. The average study subject was 38 years old and smoked 20 cigarettes daily. One-third of the subjects had third-party health insurance, and 51% did not have a high-school diploma. The cross-sectional quit rate was 28% during the study period, and 11% were sustained quitters at study exit. The intervention and control groups did not differ in cross-sectional (30% vs. 26%, p=0.40) or sustained quit rate (9% vs. 14%, p=0.26). However, subjects in the intervention group were significantly more likely to make a quit attempt during the study period than the control group (adjusted odds ratio (OR) 2.7, 95% confidence interval (CI) 1.07 - 7.4). Motivational stage at exit did not differ between the groups. Use of nicotine replacement therapy (NRT) was strongly associated with sustained cessation (OR 6.7, CI 2.3-19.6), whereas insurance status (Medicare, Medicaid, OR 0.15, CI 0.04-0.4) and education (no high-school diploma, OR 0.1, CI 0.09-0.6) were negatively associated with sustained cessation. Only 27% of subjects who made quit attempts or quit used NRT. All subjects received information about community-based cessation programs, and only three out of 205 used this information.

CONCLUSIONS

This randomized clinical trial showed that routine identification of all smokers in a primary care clinic, plus education and intervention according to AHCPR guidelines,

resulted in a 9-month sustained quit rate of 11%. Although subjects in the intervention group were significantly more likely to make a quit attempt, quit rate and motivational stage at study exit were no different between groups. Nicotine replacement therapy was the strongest predictor of cessation, yet was used infrequently. Subgroups of smokers that may benefit from screening spirometry remain to be identified.

# INTRODUCTION

## Tobacco Consumption and Human Health

The health risks associated with tobacco consumption are numerous, and have been well-documented since the mid-1900's. Although physicians began noticing ill effects of cigarettes on health in the late 1800's, the first published reports linking cigarette use to cancer were in the 1920's. Since then, regular cigarette use has been linked with emphysema, lung cancer, coronary heart disease, stomach cancer, bladder cancer, bronchitis, asthma, and several other chronic illnesses. In 1938, Science published data showing reduced life expectancy among smokers; and in 1940 the Mayo Clinic showed a link between cigarette use and coronary heart disease (1). Even people who smoke less than five cigarettes daily have been shown to have a 2.5-fold increased risk of heart attack and death (2). Since 1940, studies have linked cigarette use to other forms of vascular disease, including stroke, sudden cardiac death, peripheral arterial disease, and aortic aneurysm formation (3). In 1950, conclusive epidemiologic studies linked cigarette smoking with lung cancer (4). Lung cancer has since become the leading cause of cancer death in the United States. Over 175,000 new cases occur annually, and cigarette smoking is responsible for over 85% of those cases (3). Smoking has also been associated with at least 10 other cancers, including the mouth, upper airways, gastrointestinal organs, and genitourinary organs (5). Among women, cancer of the breast and cervix are routinely screened for by health care providers, and receive much attention in the lay press. However, in 1993 more women died from lung cancer (56,000) than either breast (46,000) or cervical cancer (13,500) (5).

In 1964, the Surgeon General published the first report "officially" linking tobacco use to lung cancer and heart disease (3). This public statement marked the true beginning of public awareness concerning the adverse health effects of smoking. In addition to causing cancer and heart disease, cigarette use has also been associated with reduced quality of life in patients with asthma (6), peripheral arterial disease, coronary heart disease (7), and in the elderly (8). Similarly, smokers are known to use more health care services than nonsmokers (9, 10). In the United States, more people die each year from tobacco-related illnesses than alcohol, cocaine, heroin, homicide, suicide, accidents, fires, and AIDS combined (11). It is indisputably the leading preventable cause of premature death in the United States (12). In Oregon alone, 5200 deaths per year are attributable to cigarette-related illnesses (13). Likewise, the economic impact is significant: it is estimated that $50 billion is spent annually on health care for cigarette-related illnesses (14).

Trends in Tobacco Consumption

Individual tobacco use increased steadily from 1900 to the 1960's. There was a plateau of stable consumption through about 1970 (when 36% of Americans smoked), which was followed by a 20 year decline (3). Since 1990, cigarette use has again leveled, and it is now estimated that 25% of the adult population smokes regularly. A 1995 Youth Risk Behavior Surveillance (YRBS) survey revealed that 35% of high school students currently use cigarettes (15). The survey's definition of current use was having smoked at least once within the past 30 days. Although this may be a fairly liberal definition, designed to include as many youths as possible, the survey reported that 16% of high school students were frequent cigarette users, defined as smoking on at least 20 of the

previous 30 days. The study included approximately 100,000 students who participated in either local, state, or national surveys. The prevalence of smoking among students in 1995 was greater than in 1993 or 1991, an alarming trend. Among black male students, the smoking rates doubled over the four year period (16). The problem of tobacco use among youths is not unique to the United States: a similar survey conducted in Australia revealed that 16 to 24% of high school seniors were regular smokers (17). In Jerusalem, 29% of underage high school students were current smokers (18). The importance of emphasizing smoking rates among youths is that nationwide, 90% of smokers start smoking regularly by age 18. Oregon lags the national average slightly, but nonetheless an impressive 80% start by age 20 (19).

Smoking Cessation and Primary Care Clinics

Given the significant impact that widespread cigarette consumption has on public health, smoking cessation resources should be readily-available for smokers interested in quitting. Even though 70% of smokers see a physician each year (20), providing effective smoking cessation is a difficult challenge, especially for primary care physicians, who encounter smokers daily. Significant time and energy are frequently spent on cessation efforts, often with disappointingly low participation and success rates (21). For example, about two percent of all smokers will quit following personal advice and encouragement to stop smoking during a single routine consultation (22). Additional encouragement and support, though not standardized between most studies, increases the quit rate to about 5%. More rigorous smoking cessation programs, such as that used by the Lung Health Study, have 12-month success rates in excess of 30% (23). Nonetheless, even smoking cessation efforts with modest success rates can be quite cost-effective: a

minimal intervention approach costs only $1500 per life saved (22). It is therefore important to continue research aimed at defining successful and inexpensive smoking cessation programs for primary care clinics.

Lung Function Testing

Pulmonary function studies are easily-performed tests that provide valuable diagnostic and prognostic information when used in the appropriate clinical setting (24). Although the American Thoracic Society endorses screening spirometry for smokers (25), there is not universal acceptance or application of this recommendation today. Nonetheless, the use of spirometry in The Lung Health Study revealed important information about lung disease in the U.S. smoking population. The study found evidence of obstructive lung disease in 26% of 66,000 volunteer smokers screened with spirometry, over twice as many as expected (26). There was also a higher-than-expected disease prevalence in young smokers screened: one third of their participants were 45 years of age or younger. Advocates of routine lung function testing correctly state that pulmonary function impairment reliably predicts patients at risk for premature death from smoking-related diseases. "Accordingly, it behooves all physicians to measure pulmonary function in all smokers in order to identify individuals who are at increased risk of disease or death" (27). These points argue that routine spirometry should be considered for early diagnosis and management of lung disease in smokers and, more broadly, as a "vital sign" for smokers, since lung function predicts all-cause mortality. However, outpatient studies done to determine if spirometry adds significantly to the clinical examination have been less enthusiastic about its use. Holleman and colleagues reported that peak expiratory flow measurements were equivalent to, but more

cumbersome to perform than, auscultation for wheeze (28). Casanova and colleagues surveyed 148 Internal Medicine and Family Practice physicians for management decisions on two hypothetical outpatients with obstructive pulmonary disease. All physicians were given identical scenarios, and half the physicians were also given lung function tests. There were no significant differences in management plans between the groups (29). Owens and colleagues also questioned the utility of spirometry in outpatients with pulmonary disease: his series of 150 consecutive patients in a chest clinic showed that clinical management plans changed only 5% of the time with the addition of spirometry (30).

Spirometry and Smoking Cessation

The preceding studies challenge the utility of spirometry either as a complement to diagnosis or as an aid for directing immediate therapy in certain populations with lung disease. Relatively few studies have addressed spirometry and its potential for influencing other outcomes pertinent to the primary care setting, for example as an educational or motivational tool to aid smoking cessation. Risser and Belcher used the combination of spirometry and carbon monoxide (CO) measurements to promote smoking cessation. The use of a 10-minute patient briefing consisting of spirometry interpretation, carbon monoxide measurement, and symptoms questionnaire improved 12-month quit rates from 11% to 20% (31). This was a randomized study among Veterans Administration patients attending a health fair, which limits its generalizability to primary care clinics. Jamrozik and colleagues used CO measurements alone for patient education, and when added to counseling, increased cessation rates by 4% (32). To the contrary, Segnan and colleagues reported a study in which one of four randomization

arms included spirometry. They concluded repeated counseling with spirometry was no better than repeated counseling alone (33).

## RESEARCH HYPOTHESIS

It seems, then, that although spirometry and CO measurements have been used with variable success as adjuncts to smoking cessation programs, their precise role in the primary care setting has not been studied. The Agency for Health Care Policy and Research (AHCPR) and the National Cancer Institute (NCI) recommend that primary care clinics have mechanisms in place to systematically identify all smokers and offer every smoker a cessation or motivational intervention (20). We therefore chose to implement the AHCPR recommendations to identify all smokers and provide intervention in two Family Practice clinics at Oregon Health Sciences University (OHSU). We also proposed to test the hypothesis that adding routine lung function screening and education to the AHCPR recommendations would improve motivation to quit, quit attempts, and quit rate when compared to AHCPR recommendations alone. Showing measurable benefits in terms of patient outcomes would have important implications for the routine use of spirometry in smokers.

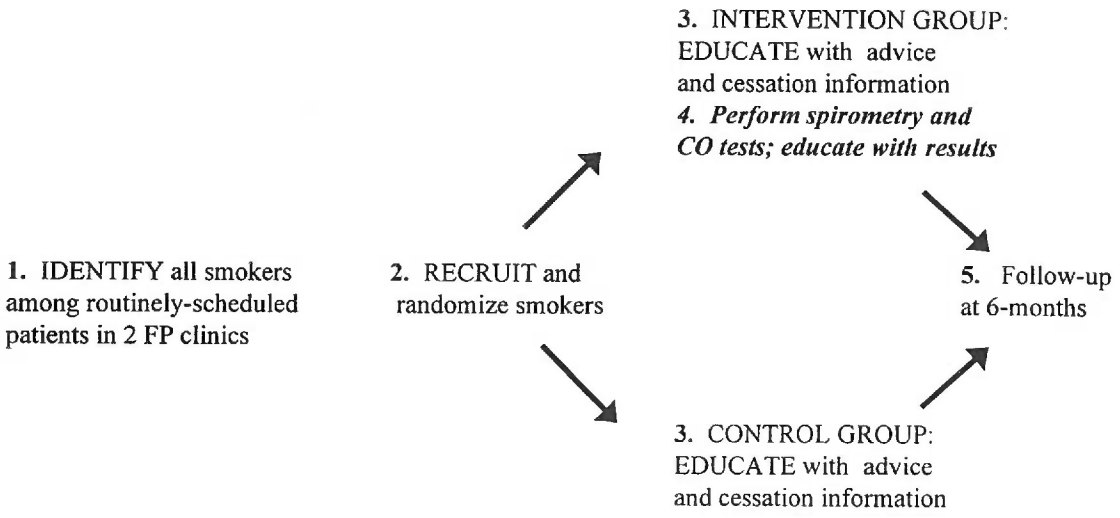
## METHODS

The aims of this study were:

1) Implement a program to identify all smokers among routinely-scheduled outpatients in two community Family Practice clinics;
2) Invite all smokers to participate in the research project, and randomize half of the participants to "control" or "intervention" groups;
3) Provide all smokers with advice and cessation information according to NCI and AHCPR guidelines (20, 34);
4) Provide additional education with spirometry and CO information to the "intervention" group;

5) Compare quit rates, attempt rates, and motivational stages (35, 36) at study exit (6 months) between the "control" and "intervention" groups.

## PROTOCOL




### 1. Identification of Smokers

Two OHSU Family Practice clinics were selected as study sites. Gabriel Park and Richmond Clinics were chosen, which are community-based clinics located in the Portland metropolitan area. At the time of patient registration, a colored card was stamped with each patient's identification and placed on their clinic encounter form. Cards were stamped for all regularly-scheduled adult patients, but were not stamped for non-English speaking patients, children under the age of 18, or walk-in visits considered emergent as determined by the clinic's triage nurse. At patient check-in, the nurse would ask if they smoked cigarettes regularly. If patients responded yes, they were asked if they would volunteer to participate in a research project involving smokers. All responses were circled on the colored card, which were then placed in a collection box, regardless of the patient's responses. With this system, it was possible to track the total number of patients screened and classify them as nonsmokers, smokers willing to participate in the

study, and smokers unwilling to participate in the study. If a patient had more than one clinic visit during the study period, only the results of their first screening were counted.

2A. Subject Recruitment

Patients who identified themselves as regular smokers and stated their willingness to participate in the study were approached by a member of the study staff, who was on-site 30 hours weekly during the enrollment period. The study staff was either the principal investigator or a research assistant, neither of whom were employees of the Family Practice clinics. The patient was informed that their participation was voluntary, not required by the clinic, and would in no way influence their regular care at the clinic; the clinic would provide all patients with information about quit-smoking programs regardless of participation in the study; participation in the study did not constitute automatic enrollment in a quit-smoking program; and half the participants would receive lung function tests. The study protocol was approved by the Oregon Health Sciences University Institutional Review Board, and written informed consent was obtained from all subjects.

2B. Randomization to Intervention vs. Control Groups

Questionnaires were numbered consecutively at each clinic throughout the study period. Subjects receiving odd-numbered questionnaires were selected as the intervention group, and those receiving even-numbered questionnaires were selected as the control group. Subjects were enrolled in chronological order based on time of check-in. The nurses performing patient check-in were blinded to the questionnaire numbers. Since four to six nurses conducted patient check-ins independently and simultaneously at

each clinic, it is unlikely that any given patient would be preferentially enrolled into either study arm.

2C. Questionnaires

All participants completed a standardized questionnaire assessing nicotine dependence (Heaviness of Smoking Index) (37), motivational stage classification (35), and medication use and demographic information (Appendix A). Questionnaires were administered by the study staff.

3. Advice to All Smokers

Smoking cessation programs were established at both clinic sites in accordance with the AHCPR guidelines (20). The programs were administered by the study staff, who completed intensive training in smoking cessation methods at the Lung Health Study clinic in Portland, OR. All smokers received a uniform message encouraging them to quit smoking (Appendix B). The patient's motivational stage was determined by asking three standard questions (Appendix A, questions 4a, 4b, and 4c) (36). The "precontemplative" stage was defined as no intentions to quit within six months, the "contemplative" stage as intentions to quit within six months but not within 30 days, and the "preparation" stage as intentions to quit within 30 days. Patients then received individual cessation plans (34) based on their motivational stage. "Precontemplative" and "contemplative" subjects received a brief counseling(3 minutes) that included a) NIH self-help pamphlet (38); b) a listing with 13 cessation programs and support groups in the community; and c) name and phone number of the staff member to request further information when desired. Patients in the "preparation" stage received all of the above plus additional counseling (10 minutes) that included d) review of NIH self-help pamphlet; e) on-site educational

question/answer session (20, 34, 39); f) solicitation of a quit date; g) clinic or telephone follow-up one week and four weeks after quit date; h) nicotine replacement therapy was encouraged for all patients but not supplied by the study.

4. Additional Education (Intervention Group)

The intervention group performed spirometry and CO measurements, then received a uniform educational interpretation of these results. The intervention took approximately 10 minutes to perform. All tests were performed by the study staff, who completed spirometry training at the Lung Health Study clinic in Portland, OR. Spirometry was performed with equipment that met American Thoracic Society requirements (Nellcor Puritan Bennett Spirometer, Model PB-100, Pleasanton, CA). Standard reference values by Crapo were used to calculate percent predicted values for forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) (40). Each subject performed repeated spirometry maneuvers until three acceptable tracings were obtained. Carbon monoxide level was measured using equipment which met FDA requirements (Discover Carbon Monoxide Monitor, MultiSpiro, Inc., San Clemente, CA, USA). A level over 5 ppm was considered to reflect active smoking. The educational message was given to the subjects by the study staff (Appendix C), and varied depending on spirometry results (normal or obstructed). Subjects were then allowed to ask questions about their test results.

5. Follow-up

Subject contacts made as part of the smoking cessation program were performed by the study staff according to AHCPR guidelines. Based on motivational stage, contacts might have included a) solicitation of a quit date, b) clinic or telephone follow-up one and

four weeks after the quit date, and c) additional contacts if requested by individual subjects. All subjects received six-month telephone follow-up to determine the primary and secondary study outcomes. The six-month follow-up was conducted independently from contacts made for smoking cessation efforts by a research assistant blinded to the subject's randomization arm. The primary outcome variable was smoking cessation rate. Cross-sectional quit rate was defined as a successful quit period of at least 24 hours' duration during the study period. Sustained smoking cessation was defined as a successful quit of at least 7 days' duration that was ongoing at the time of follow-up. Secondary outcome variables were quit attempts and change in motivational stage at follow-up. Follow-up was considered complete after successful telephone contact or after unsuccessful telephone contact and both of the following: a) a working phone number was unavailable from computer records and alternate contact person; b) at least two follow-up questionnaires were sent via mail.

## DATA ANALYSIS

### 1. Power Calculations

Smoking cessation: Based on published data from a study of similar design, we assumed quit rates in the control group would be about 10%, and that the intervention would result in an approximate doubling of the quit rate (31). A sample size of 91 in each group would detect an increase in quit rate from 10% to 25% (alpha = 0.05, power = 0.8, assume control quit rate = 10%).

Motivational change: We expected 15% of smokers to be in "preparation" or "action" stages, 35% to be "contemplative", and 50% to be "precontemplative" at study entry based on published data (35, 36). We also expected 38% of subjects to advance

from "precontemplative" and "contemplative" to "preparation" or "action" over six months (35, 36). A sample size of 73 in each group would detect an increase in the expected motivational change from 38% to 60% (alpha = 0.10, power = 0.8).

Recruitment period: The selected Family Practice clinics have similar patient demographic makeup (15 to 30% Oregon Health Plan patients, 70 to 85% third-party insured patients) and similar daily volumes of adult patients (about 50 per day). We assumed that one in five adult patients smokes (a conservative estimate for a clinic population), and that 50 smokers would be encountered at each clinic weekly. If two in ten chose to participate in the research protocol, then ten smokers would be enrolled weekly. This would allow enrollment of 100 patients from each clinic in 3 months time.

2. Statistical Analysis

Statistical analysis was performed using JMP software (SAS Institute, Cary, NC, USA). Categorical variables were compared using the chi-square statistic, and continuous variables were compared using the Student's t-test (41). Logistic regression analysis adjusted for age and gender was performed to calculate odds ratios for likelihood of quit attempts and sustained smoking cessation at follow-up by subject characteristics. All p-values are two-sided, with "statistically significant" meaning a p-value $< 0.05$. Statistical analysis was performed on an "intention-to-treat" basis, meaning that if follow-up data were not available, subjects were assumed to be currently smoking and in a "precontemplative" stage.

## RESULTS

### 1. Patient Screening

A total of 1038 patients were screened between August 1 and October 15, 1996 (Figure 1). Fifty-two percent (538) were nonsmokers, 35% (360) were regular cigarette smokers, and 13% (140) had unknown smoking status (the screening card was returned incomplete). Of the 360 smokers, 32% (114) declined participation for unspecified reasons, and 68% (251) agreed to participate in the study. Forty-six of the 251 subjects were not randomized because they left the clinic before study enrollment was completed and did not return. Two-hundred and five smokers were therefore entered into the study and randomly assigned to the control or intervention groups.

### 2. Subjects

The study population smoked an average of 20 cigarettes daily, had a 29 pack-year history, and began smoking at a mean age of 16 years. One-hundred and two subjects were randomized to the control group, and 103 to the intervention group. There were no significant differences between the groups in age, gender, race, employment status, level of education, or insurance status (Table 1). Several features known to predict lower rates of smoking cessation, including number of daily cigarettes, prior quit attempts, and motivational stage, were also well-matched between groups. Lung function was normal for the majority of those tested: the mean forced-expiratory volume one-second (FEV1) in the intervention group was 87% predicted, and the mean forced-expiratory volume to vital capacity (FEV1/FVC) ratio was 76%. Abnormal lung function was found in a minority of subjects: 23% had an FEV1/FVC ratio less than 70%, and 36% had an FEV1% predicted less than 80%. Spirometry could not be performed

adequately in 5 subjects. The 114 smokers who declined participation were slightly older than the participants (42.6 ± 1.2 SE vs. 38.6 ± 0.9 SE, p = 0.01), whereas gender (57.5% vs. 62.4% female, p = 0.39) and insurance status (9.7% vs. 13% uninsured, p = 0.10) were no different.

3. Participation Rates for Smoking Cessation Program

Seventy-three of 205 randomized subjects (36%) were in the "preparation" stage at study entry. Sixty of 73 (83%) accepted follow-up planning, which included solicitation of a quit date, clinic or telephone follow-up one and four weeks after the quit date, and additional contacts if requested by individual subjects. All subjects were given information about accessing community-based cessation programs (some free/phone-based, most costing money). Three out of 205 reported using this information. Only 23 of 86 subjects (27%) who made quit attempts or quit during the study period used nicotine replacement therapy. Of those who did not use NRT, 58% stated cost made its use prohibitive.

4. Outcomes: Quit Rates, Quit Attempts, and Motivational Stage

Mean length of follow-up was 9 months (260 days ± 45 SE), and the follow-up rate was 84.4%. Twenty-eight percent of the subjects quit smoking at some time during the study period (cross-sectional quit rate), and 11% were sustained quitters at time of follow-up. The mean duration of abstinence among those who relapsed was 18 days (3.5 SE), and the mean duration of abstinence among sustained quitters was 139 days (18 SE). Cross-sectional quit rates and sustained quit rates were no different between the control and intervention groups (Table 2). Subjects in the intervention group were significantly

more likely to make a quit attempt during the study period than those in the control group (adjusted odds ratio (OR) 2.7, 95% confidence interval (CI) 1.07 - 7.4). Motivational stage at exit did not differ between groups (Table 2). Nicotine replacement therapy was strongly associated with sustained smoking cessation (OR 6.7, CI 2.3 - 19.6). There was no relationship between smoking cessation and age (OR 1.6, CI 0.2 - 13.2), weight (OR 0.8, CI 0.07 - 6.9), or gender (OR 0.6, CI 0.2 - 1.4). Since the study population was 86% Caucasian, we were unable to discern an effect of race on smoking cessation. Number of daily cigarettes, time to first cigarette, education, and insurance status correlated negatively with quitting during the study period (Table 3).

5. Physician Practice Habits and Behaviors

A survey detailing practice habits regarding smokers and pulmonary function tests was distributed to the attending physicians, nurse practitioners, and resident physicians at the Family Practice clinics twice while the study was in progress (to determine reproducibility of the questions), and 6 months after study completion. Both clinics had functioning portable spirometers on-site. Ten of 11 regular staff members and 11 of 15 resident physicians completed all questionnaires. Follow-up survey responses were nearly identical to the entry surveys, so only the entry survey responses are shown (Table 4). The overwhelming majority of responders reported using office spirometry less than one time weekly. Only ten percent reported ordering spirometry or pulmonary function testing solely because of a smoking history, whereas the majority ordered these tests as a diagnostic aid or to direct therapy. Most felt that spirometry was not useful in the management of smokers.

## DISCUSSION

This randomized clinical trial showed that routine identification of all smokers in a primary care clinic, plus education and intervention according to AHCPR guidelines, resulted in an overall sustained quit rate of 11% at 9 months follow-up. Although subjects randomized to receive additional education with lung function and CO measurements were significantly more likely to make at least one quit attempt during the study period than the control group, sustained quit rates and motivational stage at study exit were no different.

About two percent of all smokers will quit following personal advice and encouragement to stop smoking during a single routine consultation (22). Additional encouragement and support, though not standardized between most studies, increases the quit rate to about 5%. Compared to historical controls, it is promising that the implementation of the AHCPR smoking cessation guidelines yielded an overall sustained quit rate of 11% in this study. If nonparticipants were counted as intended-to-treat here, then the overall quit rate would be 7%, which still compares favorably to historical controls.

The goal of the study's recruitment procedure was to evaluate the role of lung function screening tests on all regularly-scheduled smokers seen in the outpatient setting. Our exclusion criteria were few; 68% of the smokers agreed to participate, which is a very high participation rate. Consequently, the study population had many characteristics known to predict low rates of smoking cessation. For example, most subjects smoked 20 cigarettes daily, and three-fourths had their first cigarette within 30 minutes of awakening, suggesting a high level of nicotine addiction among the population (37).

Furthermore, half the subjects had less than a 12th grade education, only one in three had third-party insurance, and nearly two-thirds of the subjects were in a precontemplative or contemplative motivational stage at entry, which also predict low rates of smoking cessation. The high prevalence of these characteristics certainly contributed to relatively low sustained quit rates. However, information gained from this study is more generalizable to the smoking population seen in primary care clinics than if a narrower population were recruited.

Physicians at the two study clinics reported using office spirometry infrequently, and the majority felt that spirometry was not helpful in the management of smokers. We were unable to demonstrate improvements in specific patient-oriented outcomes by the addition of spirometry and CO measurements in our study population. However, one should not interpret this to mean that there is no role for screening spirometry in smokers. In the context of this study, comprised of highly nicotine-addicted and lower socioeconomic status smokers, routine screening was not beneficial. Other studies have shown benefit in more selected populations (31). Furthermore, the results of this study do not negate the important role lung function studies have in the diagnosis of lung disease or their ability to provide assistance with therapy, pre-operative risk assessment, and prognosis for pre-existing lung disease (24).

Less than 2% of smokers in this study used resources outside their clinic when attempting to quit, despite being provided with contact information for 13 community-based smoking cessation programs. This finding strongly supports AHCPR recommendations that all primary care clinics develop on-site smoking cessation resources instead of relying entirely on outside programs. Other community-based

resources may be invaluable for many smokers, but they should not be used as a substitute for clinic-based cessation efforts in primary care clinics with demographic characteristics similar to those studied here.

Although the use of nicotine replacement therapy was encouraged among all participants, it was not provided by the study. Only one in four smokers who made quit attempts used NRT. Most subjects cited cost as the deterrent, and insurance plans did not cover the cost in most cases. Data published elsewhere suggest that as few as 11% of health plans cover nicotine replacement therapy (20). Thirty-six percent of the participants who used NRT in this study quit, and NRT had the highest odds ratio of any characteristic favoring cessation. Other pharmacotherapy such as bupropion was not available when this study was conducted (42). It is likely that quit rates in this study would have been greater had some form of pharmacotherapy been universally available at no cost. Recent estimates suggest that quit rates will double with the use of NRT (43). The quit rate among subjects who used NRT in this study was three-times that of subjects who did not use NRT.

A recent analysis of the AHCPR smoking cessation recommendations demonstrated theoretical program costs ranging from $1500 to $6000 per life saved, varying with the type of intervention and choice of nicotine replacement therapy used (43). Such cost-effectiveness studies rely upon meta-analyses for quit rates. The validity of quit rates derived from meta-analysis may be limited by selection bias, because many studies frequently include only "want-to-quit" subjects and not "all-comers" (43). Since this study was modeled on AHCPR guidelines and recruited a representative cross-section of smokers attending a primary care out-patient clinic (recall that two-thirds were

not motivated to quit at time of enrollment), it would be appropriate to speculate program costs based on quit rates observed here. Using a quit rate of 11% and an estimated "brief counseling" cost of $38 per participant (43), the cost per life saved would be $1036 ($38/.11 x 3 quit to save one life). Had nicotine replacement therapy been available, and the quit rate were 36% (as observed among those who used NRT), the cost per life saved would have been between $2191 (cost $263/.36 x 3). These costs are comparable to estimates published elsewhere (22, 43).

STUDY LIMITATIONS

1. Smoker Identification

The system chosen to identify all clinic patients as smokers or nonsmokers was not without flaws. Even though a colored smoker identification card was stamped for each patient at the time of registration and placed on their clinic encounter form, 13% were returned incomplete. In discussing reasons for incomplete cards with the check-in nurses at both clinic sites, it was revealed that occasionally the nurses inadvertently forgot or were too busy to complete some cards. Rarely, nurses reported that they did not complete the smoker identification cards on patients seen specifically for important psychosocial issues, e.g. the death of a family member. Given the number of nurses involved with check-ins (an average of 5 at each site for any given half-day clinic period), the overall 87% completion rate was considered acceptable.

Two-hundred and fifty-one smokers agreed to participate in the research study, yet only 205 (82%) were enrolled. The primary reason for not capturing all subjects is that there was only one study staff at each clinic site on any given day. Multiple simultaneous enrollments were therefore not possible, and on occasion, potential subjects

left the clinic before registration could be completed. These subjects were contacted and given the opportunity to return for enrollment, but all deferred.

Of the 360 smokers initially screened for this study, 32% refused to participate. Reasons for nonparticipation were not recorded on the smoker identification cards. The nonparticipants were slightly older than the participants, but the other demographic variables recorded, gender and insurance status, were no different. Despite these similarities, it is well-known that smokers not motivated to quit are less likely to participate in research studies than their motivated counterparts. It is therefore possible that if all smokers were screened and included, overall quit rates might have been lower (about 7% sustained quit rate instead of 11%, based on the number of nonparticipants).

2. Randomization

The randomization procedure used in this study was based on order of subject enrollment, which may have been a source of bias. All subjects receiving odd-numbered questionnaires were selected as the intervention group, and those receiving even-numbered questionnaires were selected as the control group. When multiple potential subjects were identified simultaneously, they were enrolled in chronological order based on time of check-in. The nurses performing patient check-in were blinded to the questionnaire numbers. Since four to six nurses conducted patient check-ins independently and simultaneously at each clinic, it is unlikely that any given patient would have been preferentially enrolled into either study arm. However, the study staff were not blinded to the randomization procedure, so it is possible that the numbered questionnaire sequence or enrollment chronology were not strictly followed. Given that the goal of randomization was to evenly distribute demographic variables and patient

characteristics associated with smoking cessation (Table 1), it appears that the procedure was successful.

3. Smoking Intervention (AHCPR Guidelines)

The smoking cessation program used in this study followed guidelines established for primary care settings (20, 34). The program components were to systematically identify all smokers (step 1), provide advice to quit (step 2), and determine the smoker's willingness to make a quit attempt (step 3). For motivated smokers, assistance and planned follow-up were offered (steps 4 and 5). The mechanism of follow-up was primarily telephone-based, which is a fairly minimal intervention compared to interventions published elsewhere (23). Overall quit rates may have been higher had a more intensive smoking cessation program been used. Furthermore, smokers were enrolled in this study regardless of their motivational stage. It is well-known that smoking cessation rates correlate with a smoker's level of motivation to quit (35) and with the intensity of the smoking intervention (22). Enrolling precontemplative and contemplative smokers certainly lowered the overall effectiveness of the smoking intervention. If only prepared smokers were studied, the quit rate would have been 16.4%.

The study staff provided the smoking cessation intervention to all study subjects in accordance with AHCPR guidelines. Since the study staff were not blinded to a given subject's enrollment status, it is possible that the enthusiasm and manner in which the intervention was delivered was biased towards one group. This potential bias could have been minimized if the smoking cessation intervention were conducted by another individual, independently from subject enrollment. Unfortunately, resources were not

available to conduct the study in this fashion. If this bias were present here, it was not reflected in the primary outcome variables.

4. Follow-up

Smoking cessation rates were obtained via self-report from telephone interviews with study subjects. Classification error attributed to self-report has been well-studied in the context of smoking cessation. There is generally a small but significant bias toward over-reporting abstinence, and is about 4% when using biochemical verification of smoking status as the gold standard (44). Biochemical verification is obtained by measuring salivary cotinine or exhaled carbon monoxide levels. This was not done in this study due to logistical limitations. If the bias toward over-reporting were 4% in this study population, the overall sustained quit rate would have been 10.8% instead of 11.2%, which does not affect the overall study results.

5. Outcome Variables

The definitions of smoking cessation used in this study are consistent with those used elsewhere (36), but are admittedly arbitrary. We used cross-sectional quit rate to mean a 24-hour or greater quit period, and sustained quit rate to mean a quit period of at least 7 days' duration that was ongoing at the time of follow-up. Regardless of the definitions used, there was a clear separation within the study population for length of quit: the cross-sectional quit duration averaged only 18 days (range 1 - 60) for those whose quit periods were followed by relapse, whereas the sustained quit duration averaged 139 days (range 27 - 275).

## CONCLUSIONS

In summary, this randomized clinical trial showed that implementation of AHCPR smoking cessation guidelines in two primary care clinics resulted in an overall sustained quit rate of 11% at 9 months follow-up. Although subjects randomized to receive additional education with lung function tests were significantly more likely to make at least one quit attempt during the study period than the control group, sustained quit rates at study exit were no different. The study also revealed that nicotine replacement therapy was the strongest predictor of successful quitting, yet was used infrequently; and that community-based smoking cessation resources were used even less frequently. Although screening lung function tests in this smoking population showed no benefit in terms of quit rate, selected subgroups that may benefit from screening remain to be identified.

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Figure 1. Results of Clinic Screening

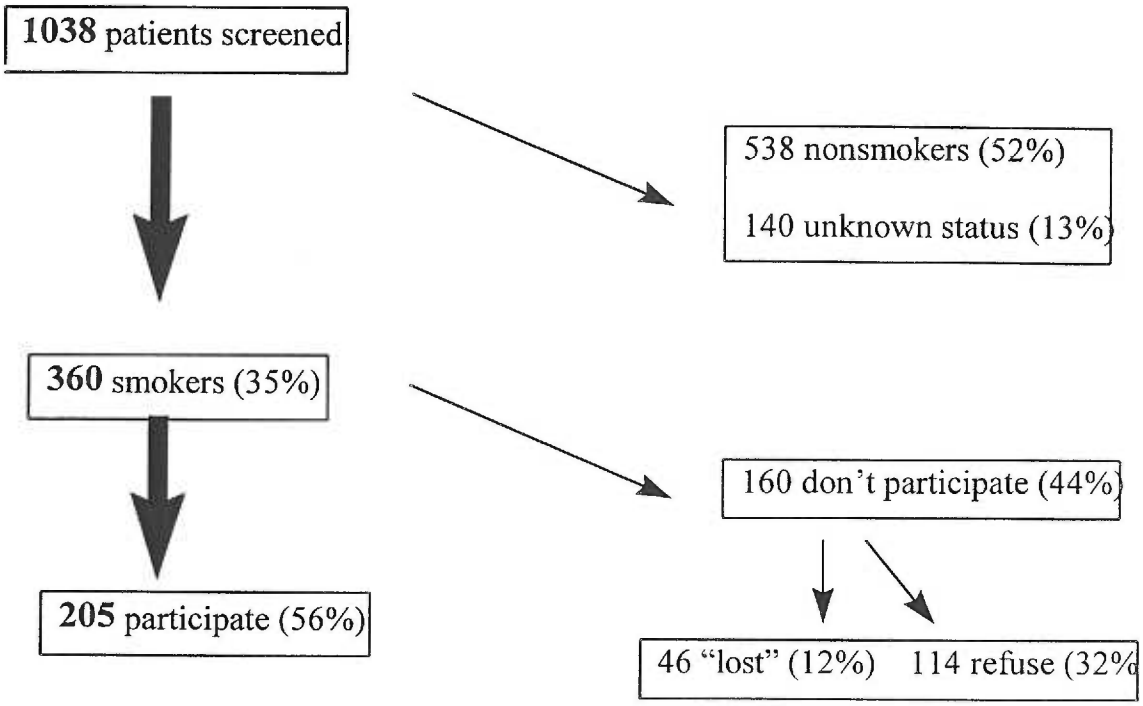

Table 1. Baseline Demographic Characteristics By Study Group

| Characteristic | Control Group (n = 102) | Intervention Group (n = 103) | p-value** |
|---|---|---|---|
| age, years* (range 19 - 75) | 37.7 ± 1.2 | 39.4 ± 1.2 | 0.30 |
| gender: % male | 37% | 38% | 0.93 |
| race: % Caucasian | 89% | 83% | 0.23 |
| **Employment, Education** | | | |
| % working | 50% | 55% | 0.75 |
| % disabled | 18% | 16% | |
| income: <$15K per year | 49% | 45% | 0.70 |
| education: 11th grade or less | 46% | 55% | 0.39 |
| **Insurance** | | | |
| % uninsured | 14% | 13% | 0.79 |
| % with federal insurance† | 55% | 52% | |
| **Smoking History** | | | |
| cigarettes per day* | 20.8 ± 1.0 | 19.2 ± 1.0 | 0.29 |
| pack-years* | 27.9 ± 2.3 | 29.9 ± 2.3 | 0.55 |
| any prior quit attempt, % responding yes | 79% | 85% | 0.27 |
| **Motivational Stage** | | | |
| prepared | 35% | 37% | 0.54 |
| contemplative | 37% | 30% | |
| precontemplative | 28% | 33% | |
| **Lung Function** | | | |
| FEV1 (Liters)* | - | 3.02 ± 0.1 | |
| FEV1% predicted* | - | 87 ± 2.1% (range 31 - 141%) | |
| FEV1% predicted less than 80% | - | 36% | |
| FEV/FVC ratio* | - | 76 ± 0.9% (range 49 - 93%) | |
| FEV/FVC ratio less than 70% | - | 22.5% | |
| CO ppb* | - | 22.4 ± 1.3 | |

* Data expressed as mean ± standard error.

** Two-sided p-values based on analysis of variance for age, cigarettes per day and pack-years, and on Pearson's chi-square analysis for all other comparisons.

† Federal insurance includes Medicare, Medicaid, or Oregon Health Plan.

Table 2. Outcomes by Study Group

| | Control | Intervention | P-value* |
|---|---|---|---|
| **percent quitting:** | n = 102 | n = 103 | |
| cross-sectional quit rate | 26% | 30% | 0.40 † |
| sustained quit rate | 14% | 9% | 0.26 † |
| made at least 1 quit attempt during study | 22% | 39% | 0.04 § |
| no quit attempt made | 64% | 52% | |
| **exit motivational stage:** | | | |
| prepared | 17% | 21% | 0.28 |
| contemplative | 25% | 33% | |
| precontemplative** | 45% | 37% | |
| **lost to follow-up** | 18.6% | 12.6% | 0.24 |

* Two-sided p-value based on Pearson's chi-square test statistic.
** Subjects lost to follow-up were considered to be precontemplative.
† Based on 2 x 2 chi-square table, "control, intervention" x "quit, did not quit."
§ Based on 2 x 3 chi-square table, "control, intervention" x "sustained quit, quit attempt, no quit attempt."

Table 3. Odds Ratios For Sustained Quitting During The Study Period

| Characteristic | Variable for Odds Ratio | Adjusted Odds Ratio** | Confidence Interval** |
|---|---|---|---|
| spirometry | performed | 0.6 | 0.2 - 1.4 |
| abnormal spirometry | yes | 0.6 | 0.1 - 2.7 |
| clinic site | Gabriel Park | 0.7 | 0.3 - 1.7 |
| gender | male | - | 0.2 - 1.4 |
| successful 24-hr quit prior to study period | **yes** | **4.3** | 1.5 - 15.7 |
| NRT used during study period | **yes** | **6.7** | 2.3 - 19.6 |
| insurance | third-party | reference | |
| | **mcaid, mcare, ohp** | **0.15** | 0.04 - 0.4 |
| | none | 1.9 | 0.3 - 9.4 |
| > 10 cigarettes daily | **yes** | **0.17** | 0.06 - 0.5 |
| first daily cigarette within 30 minutes | yes | 0.4 | 0.16 - 1.01 |
| education | beyond high school | reference | |
| | high school diploma | 2.0 | 0.8 - 5.1 |
| | **no diploma** | **0.1** | 0.09 - 0.6 |
| motivational stage | preparation | 1.9 | 0.7 - 5.4 |

* Based on univariate logistic regression analysis.
** Based on logistic regression analysis adjusted for age and gender.

Table 4. Physician Practice Habits and Behaviors

| Question | Staff Response | Resident Response | P-value* |
|---|---|---|---|
| How often do you order office | Never: 48% | 17% | 0.04 |
| spirometry? | <1 weekly: 48% | 83% | |
| Reasons for ordering spirometry or pulmonary function tests: | | | |
| patient request | yes 4% | 4% | 0.95 |
| smoking history | yes 12% | 9% | 0.71 |
| abnormal exam | yes 28% | 35% | 0.61 |
| pre-op evaluation | yes 52% | 26% | 0.07 |
| patient symptoms | yes 56% | 48% | 0.57 |
| to direct therapy | yes 64% | 83% | 0.14 |
| diagnostic aid | yes 88% | 65% | 0.05 |
| Do you find spirometry useful in your management of smokers? | No 68% | 48% | 0.38 |
| In what percentage of your smoking patients have you ordered spirometry? | | | |
| none | 24% | 22% | 0.80 |
| in 1-25% of them | 76% | 74% | |
| To which smokers do you offer vaccines? | | | |
| to all smokers | 32% | 26% | 0.51 |
| to those with additional risks | 64% | 61% | |

* Two-sided p-values based on Pearson's Chi-square test statistic.

Appendix A.

Entry Questionnaire
QUESTIONNAIRE
Is Spirometry Justifiable In Primary Care Clinics?

Consent signed? Yes No

1. Name:_____

   Address:_____

   Home Phone:_____ Work Phone:_____

   Social Security #:_____Medical Record #:_____

   Alternate Contact Name:_____

   Alternate Contact Phone:_____

2. Height:_____ Weight :_____

   Age:_____Date of Birth:_____

   Gender:_____

3. Have you smoked at least one cigarette per day for a year or 20 packs in your lifetime? Yes No

4a. Do you have serious intentions to quit smoking in the next 6 months? Yes No

4b. Do you have serious intentions to quit smoking in the next 30 days? Yes No

4c. Would you be willing to pick a quit date within the next 30 days? Yes No

4d. Have you had a successful 24 hour quit period in the last year? Yes No

## Medical History

5. Have you had any of the following lung problems or illnesses? Yes No

Please circle:

a) Asthma
b) Bronchitis
c) Emphysema
d) Interstitial Lung Disease (fibrosis)
e) Lung Cancer
f) Other

6a. Have you ever taken medicine for high blood pressure? Yes No

6b. Have you had a heart attack, angina, or heart failure? Yes No

6c. Do you have diabetes? Yes No

6d. Do you have high cholesterol? Yes No

6e. Do you have a family history of heart disease? Yes No

## Smoking

8. Do you smoke at least 10 cigarettes daily? Yes No

9. Do you have your first cigarette within 30 minutes of waking? Yes No

10. How old were you when you started smoking regularly? _____

11. How much do you smoke on average (cigarettes per day)?_____

12a. Have you always smoked that amount? Yes No

If no:

12b. When did you change? _____

12c. How much did you used to smoke? (cigarettes per day)?_____

13a. Have you tried to quit before? Yes No

If yes:

13b. How many times have you tried to quit on your own or with self-help programs?_____

13c. How many times have you tried to quit with either a structured program or with prescribed medicines, such as nicotine gum or patches:_____

14a. How many hours per day are you exposed to other people's tobacco smoke?_____

14b. Not counting yourself, how many people in your household smoke regularly?_____

14c. Do people smoke regularly in the room where you work?.....Yes No

## Medications

15a. Do you currently take any inhaled medications to help your breathing? Yes No

If yes:
Which of the following have you used (include over-the-counter)?
(SEE ALPHABETIZED CARD) Please circle:

a) beta-2-agonist inhalers
b) anticholinergic inhalers
c) inhaled steroids
d) cromolyn sodium
e) other

16. Are there any other medicines you use regularly? Include prescription medicines, and any medicines for nasal, sinus, or allergy symptoms. (name of medicine, not dosing)

19. Do you use nicotine gum or patches right now? Yes No

20. Did you receive a seasonal flu vaccine last winter? Yes No

21. Have you ever received a pneumovax (one-time pneumonia vaccine)? Yes No

If yes, when? _____

## Physician

22. What is your primary provider's name?_____

24. Have you ever been seen by a lung specialist (allergist or pulmonologist) for asthma, emphysema or any other lung condition?..... Yes No

## Demographics

25. Which letter describes the highest level of school you have completed?

a) grades 0-8
b) grades 9-11
c) high school
e) some college
f) college graduate
d) post-college work

26. Which letter describes your employment status?

a) employed
b) homemaker
c) retired
d) unemployed
e) student
f) disabled
g) other_____

27. Here is a list of different yearly income groups. Which group comes closest to the total amount that all members of the household combined received last year from all sources before taxes? Please circle:

a) less than $4,999
b) $5,000-$9,999
c) $10,000-$14,999
d) $15,000-$19,999
e) $20,000-$24,999
f) $25,000-$29,999
g) $30,000-$34,999
h) $35,000-$39,999
i) $40,000-$49,999
j) $50,000-$59,999
k) $60,000-$69,999
l) $70,000 and more

28. Which letter describes your race?

a) Caucasian
b) Hispanic
c) American Indian
d) Asian
e) African
f) African-American
g) other:

**Appendix B.**

**Uniform message to all smokers:**

"Smoking causes 7,000 preventable deaths each year in Oregon, and causes heart attacks, strokes, lung cancer, and at least 6 other types of cancer. Quitting smoking is the single most important thing you can do for your health."

**Appendix C.**

**Carbon Monoxide Message:**

Carbon monoxide is a poisonous gas that comes from anything that burns, like cars, factories, heaters, and cigarettes. This gas binds to your blood cells and prevents them from carrying the normal amount of oxygen. Since carbon monoxide lowers the blood oxygen level, it can cause headaches, dizziness, and shortness of breath. We know that smokers have about ten times more carbon monoxide in their blood than nonsmokers. This measurement today shows that your blood has too much carbon monoxide in it, which means it doesn't have as much oxygen in it. The good news is that your body can wash out this extra carbon monoxide, so that if you quit smoking, your oxygen levels will return to normal in about a week.

**Normal Spirometry Message, age less than 60 years old:**

We know that cigarette smoke damages lungs in many ways. The lungs are normally very elastic, and stretch like a balloon every time you breathe. Smoking causes the lungs to lose this elasticity, which is what emphysema or COPD is. The test you just did was normal. There certainly are some smokers who have good genes, and their lungs don't seem to lose as much lung function as others. But we also know that the bad effects of cigarettes accelerate rapidly over time, so that one normal test now doesn't mean you are immune to this effect of cigarettes. This kind of lung damage takes several years to show up on these tests, and once it happens, it doesn't go away - it is permanent. There is no treatment for emphysema, so preventing it is what is most important. If you quit smoking, you are much much less likely to get emphysema or COPD. The important thing is that we did this test today, and caught you before very much damage has occurred. (show graph) In addition, smoking causes hardening of the arteries, heart attacks, strokes, and ulcers. And it causes at least seven kinds of cancer (mouth, larynx, esophagus, pancreas, bladder, uterus, and lung).

**Normal Spirometry Message, 60 and over:**

We know that cigarette smoke damages lungs in many ways. The test you just did measures the elasticity of the lungs, and your results were normal. There certainly are some smokers who have good genes, and their lungs don't seem to lose as much lung function as others. Your lung function is well-preserved, and that's fortunate. But we also know that the bad effects of cigarettes accelerate rapidly over time, so that one normal test now doesn't mean you are completely immune to this effect of cigarettes. Once this kind of lung damage shows up on lung tests, it doesn't go away - it is permanent. But even more importantly for you, cigarettes still are hard at work in your body causing other problems. Smoking causes hardening of the arteries, heart attacks, strokes, and ulcers. And it causes at least seven kinds of cancer (mouth, larynx, esophagus, pancreas, bladder, uterus, and lung). Even if cigarette smoking doesn't cause emphysema in some people, they can still benefit from quitting: we know that if a 60 year old person quits smoking today, they will live 5 years longer.

**Obstructive Spirometry Message:**

We know that cigarette smoke damages lungs in many ways. The lungs are normally very elastic, and stretch like a balloon every time you breathe. The test you just did measures the elasticity of the lungs, and shows that your lungs are being affected by cigarettes. The test shows that your lungs don't blow air out as quickly as normal. This could be an early

sign of damage from cigarettes. We know that the bad effects of cigarettes accelerate rapidly over time, so that one test now showing signs of damage means you are very likely to suffer more lung damage if you continue to smoke. Once this happens, it doesn't go away - it is permanent. There is no treatment for emphysema, so preventing it is what is most important. We know that once smokers quit, this ongoing lung damage slows down to a normal rate. (show graph)

**Obstructive Spirometry Message, in Patients With Asthma:**

We know that cigarette smoke damages lungs in many ways. The lungs are normally very elastic, and stretch like a balloon every time you breathe. Smoking causes the lungs to lose this elasticity, which is emphysema or COPD. The test you just did measures the elasticity of the lungs, but this test can also be affected by asthma. The test shows that your lungs don't blow air out as quickly as normal - and this can be from asthma, but it could also be early signs of damage from cigarettes. This test is not designed to tell the difference, only to screen people and make them aware that some of their lung troubles may be from cigarettes. This kind of lung damage takes several years to show up on these tests, and once it happens, it doesn't go away - it is permanent. Treating asthma successfully is always harder once lung damage from cigarettes occurs. There is no treatment for emphysema, so preventing it is what is most important. If you quit smoking, you are much much less likely to get emphysema or COPD. And, asthma commonly improves when people quit smoking. (show graph)