

DRAFT of Pap Smear Report

Background on George Papincolaou and the Discovery of the Pap Smear

George Papincolaou was born on the Greek island of Euboea and studied medicine at the University of Athens. In 1910, he married Mache Mavrogenous who became his lifelong research partner. After serving in the Balkan wars, he immigrated to America where he took jobs at New York Hospital and Cornell Medical College.

In _____, Papincolaou discovered a method to determine whether a women is developing or has developed cervical cancer; the method was dubbed the "Pap smear." He recalled the first time he could discern distinctive cells indicating a positive cancer diagnoses as "one of the most thrilling experiences of my scientific career." When he first tried to make his results public in 1928, he was scorned by the scientific community. Eventually, in 1948, he published *The Diagnosis of Uterine Cancer by the Vaginal Smear* which was well-received and highly regarded.

The Impact of the Pap Smear

Today, approximately 14,500 new cases of cervical cancer, and 4,800 deaths from the disease occur each year. Factors which increase a woman's risk of cervical cancer include early age in initiating sexual activity, multiple sexual partners, infection with human papilloma virus 16 and cigarette smoking.

However, since cervical cancer has a lengthy asymptomatic, precancerous phase, the vast majority of deaths from cervical cancer are preventable by regular pap smear testing. A pap smear test can detect precancerous lesions which can be treated to prevent cervical cancer. Authorities recommend screening every 1 to 3 years for women 18 or older and for younger women who are sexually active. The National Cancer Institute has stated that "Evidence strongly suggests a decrease in mortality from regular screening with Pap tests in women who are sexually active or who have reached 18 years of age." Dr. Kenneth Noller of the Umass medical center, a national cervical cancer expert, concurs, noting, "If a woman has a Pap smear every year, the chances of cervical cancer are practically zero."

Studies have confirmed that cervical cancer mortality rates decline greatly in populations of women who obtain regular Pap screening. In the United States, in 1961, 30% of women received pap tests and the cervical cancer rate was 32.6/100,000; in 1987, 87% of women received pap tests and the cervical cancer rate was 8.3/100,000. From 1950 to 1970, incidence and mortality rates of invasive cervical cancer fell by over 70%, and since the early 1970's incidence and mortality rates have declined by about 40%. However, recent evidence indicates that since the early 80's, levels of incidence and mortality are decreasing more slowly. Overall, since the introduction of the Pap smear test in the 1940's, mortality rates from cervical cancer have decreased by 75%.

Further, until the early 70's, around 75% to 80% of cervical cancer in the US was invasive at the time of diagnosis. Today, about 78% of diagnosed cervical cancer cases are found at the in situ (precancerous) stage at which they can best be treated.

Studies of the results of Pap testing in other countries are equally impressive. By implementing well-run Pap testing programs, the country of Iceland cut mortality rates by 80% over 20 years, Finland reduced mortality rates by 50% and Sweden reduced mortality rates by 34%. Reductions in mortality in a country are generally proportional with the intensity of the testing efforts in the country: Scandinavian countries with higher testing rates had greater death reductions, and deaths in Canada decreased most in British Columbia which had 2 to 5 times more testing efforts than other provinces.

The consequences for women who do not have access to Pap testing are severe. The risk of getting cervical cancer is 3 to 10 times greater in untested women, and the risk increases the less frequently women are screened. It is even estimated that if Pap smear screening were abolished in the US, the incidence of invasive cervical cancer would increase by twofold to threefold. 50% of women actually diagnosed with invasive cervical carcinoma have never had a Pap smear, and another 10% haven't had a smear in the past five years. Survival is directly related to the stage of the disease when diagnosed -- the earlier the disease is diagnosed, the more likely a woman is to survive.

Screening and Incidence Rates

Ethnic minorities (especially Hispanics, elderly African Americans and Native Americans), economically disadvantaged women (especially those in rural areas), and elderly women -- groups of women which often have least access to preventive services, are most likely to go untested.

1) The Elderly: The 25% of cases of cervical cancer and the 41% of deaths that happen in women 65 and older correspond closely to data showing that 50% of all women age 60 and older haven't had a Pap smear in the past 3 years. While older women report having the same number of recent physician visits as younger women, older women are screened less often, indicating the need to educate older women and their health care providers about the importance of Pap screening.

2) African-American Women: Among women over the age of 25, the numbers of black women with cancer grows more quickly than the numbers of white women. However, recent evidence shows that the gap in the occurrence of cervical cancer between black and white women under age 50 is disappearing, indicating that more young black women are being screened. However, elderly black women still have very low screening rates: one study indicates that more than 40% of African-American women over 65 have never had a Pap smear. Black women also have the highest age-adjusted cervical cancer mortality rate.

3) Hispanic Women: An analysis of 1987 NHIS data indicates that 20% of Hispanic women

have never even heard of a Pap smear. Another study indicates that only 46% of Mexican-American women have had a Pap test in the last two years. Hispanic women have the second highest rates of invasive cervical cancer among 30 to 54 year old women.

4) Native American Women: In one area of California, only 40% of Native American women had had a Pap test within the last year, and only 22% had had one in the last 3 years.

5) Poor Women: According to a 1985 NHIS study, screening rates for poor women were 10% to 13% lower than those for nonpoor women for all ages and ethnic subgroups. A 1987 analysis of NHIS data indicated that poor women were twice as likely as nonpoor women to never have heard of a Pap smear and to not have had a recent screening. Other studies have found that among women covered by Medicaid, 40% had had no Pap test in the last 3 years, and 90% of women who had not received Pap tests in the last 4 years were covered by Medicaid.

6) Rural Women: Rural women, like black women, poor women and the elderly, also have difficulty obtaining necessary screening. In a recent survey, only 57% of women in rural Texas and 55% in Appalachia had had a Pap smear within 3 years of the survey.

7) Vietnamese Women: Among 30 to 54 year old women, Vietnamese women have the highest cervical cancer rate.

8) Lesbians: Lesbians also have unusually low screening rates. (Finding more information about this)

Reasons Women Are Not Screened

1) Lack of Insurance: Most studies have shown that lack of insurance corresponds to lack of adequate Pap testing. In the United States, 20% of African Americans and 30% of Hispanics are uninsured. In an analysis of 1992 NHIS data, women who took part in HMO's were much more likely to have received appropriate Pap testing than women who were uninsured or in private insurance plans.

2) Language Barriers: One study which used Caribbean-born black people found that 25% of Haitian-born women obtained follow-up smears while 86% of women born in English-speaking Caribbean countries did. Researchers believe the difference was caused by language and socioeconomic barriers. Spanish-speaking women tend to avoid English-only clinics.

3) Lack of knowledge: Lack of knowledge about the importance of the test on the part of both patients and health care providers keeps many women from being screened. Women of all backgrounds reported not obtaining a smear because they did not understand the purpose of the test.

4) Lack of physician reminders: Women often don't obtain Pap smears because their physicians don't recommend it.

5) Poor relationships between patient and provider: Women on public assistance have often complained that health care providers treated them with less respect because they were on welfare. This caused poor communication between patient and provider regarding health care procedures.

6) Fear and misconceptions: Among certain populations of poor women and ethnic minority women, beliefs that cancer is incurable and misconceptions about treatment (including the idea that surgery will make cancer spread by exposing it to air) stop some women from getting tested since they are afraid of discovering that they have cancer.

7) Cultural barriers: Native American and Hispanic women tend to believe that one's health condition is a very private matter. Further, past negative experiences with health care (such as the Tuskegee experiment) may make women uneasy about Pap testing.

8) Logistical barriers: Basic obstacles such as lack of child care, lack of transportation, long work hours, long waiting times and multiple appointments for screening may prevent women from receiving screening.

9) Economic Constraints: The cost of the test may constitute a barrier to economically constrained women. Further, for women in poverty, preventive care is often lower in priority than the daily struggles to make ends meet. Many women are not informed about low-cost programs.

Efforts to Increase Access to Pap Testing

In 1991, the Public Health Service (PHS) established that by the year 2000, 85% of women should receive a Pap smear test within the preceding one to three years.

Ways to expand Pap testing efforts include both "outreach" and "inreach" initiatives.

Outreach initiatives include computerized letters, phone calls and reminders to obtain screening, recruiting community members to become lay health workers to help plan Pap screening education, physician and patient education, and various community partnerships. Other programs focus on targeting cultural or religious centers such as black churches in urban communities in which church leaders are trained to become lay health educators. A program called the Talking Circle Project uses appropriate communication techniques and appropriate stories, myths and legends to encourage Native American women to receive screening. Other programs offer free transportation and childcare services.

Inreach initiatives include offering screening at non-gynecological health visits (e.g. if a patient has an appointment to have a blood pressure test, make it possible for her to receive a Pap test at the same time).

The National Cancer Institute

The National Cancer Institute (NCI) has implemented several outreach programs including:

- * Tracking cancer rates in minority populations: NCI supports the collection, analysis and dissemination of information to prevent, diagnose and treat cancer among minorities.
- * Recruiting minority populations for clinical trials: NCI makes an effort to include minorities in studies by giving research grants to researchers studying minority cancer health.
- * Increasing the participation of members of minority groups in research and medical practice: The NCI conducts programs with the aim of increasing research on cancer among minorities and increasing the pool of minority researchers. One such program, called The Science Enrichment Program, attempts to encourage minority high school students to pursue careers in biomedical studies.
- * Implementing community-based national education and outreach initiatives: NCI supports outreach programs which use both lay and professional coalitions and leaders to decrease risks of cancer among various populations.

CDC's Cervical Cancer Screening Efforts

Passed by Congress in 1990, the Breast and Cervical Cancer Mortality Prevention Act authorized CDC to implement a national program to ensure that women receive appropriate high-quality cervical cancer screening and follow-up. The legislation provides for grants to be allocated to states for activities in six areas:

- 1) Screening medically underserved women for breast and cervical cancer.
- 2) Providing treatment referrals and follow up services for women with abnormal screening results.
- 3) Creating and disseminating public information and education about cervical and breast cancer screening and control.
- 4) Improving health professionals' training.
- 5) Implementing programs to monitor screening and analysis procedures.
- 6) Evaluating program activities through surveillance systems.

The act stipulates that at least 60% of funds given to states must be spent on screening and referral services, and the other 40% may be used for provider and public education, quality monitoring and surveillance activities. Only 10% of state funding may be used for

administrative purposes. States are required to ensure that women with precancerous lesions receive necessary treatment although such services cannot be paid for by money authorized by the Act.

To achieve these goals, CDC developed the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). Through this program, CDC reimburses states for clinical breast exams, screening mammograms, pelvic exams, Pap tests and some diagnostic procedures. State health agencies contract with various provider agencies including the YWCA, family planning organizations, community organizations, county health departments, and private physicians. Fifty states, five territories, the District of Columbia and 13 American Indian/Alaska Native organizations currently participate in the program.

Components of the NBCCEDP

1) Screening and Education/Outreach Programs

CDC works with a number of state, local, national, consumer and voluntary organizations to provide screening services for traditionally underserved populations of women. Examples of such programs include:

- * A program to enable Alaska Natives close to populations of Alaska Native women to create culturally appropriate outreach strategies and education materials.
- * A collaborative program between the Breast and Cervical Cancer Early Detection Program in the California Department of Health, the YWCA of Glendale, the Mission City Clinic, University of California Los Angeles and other community organizations to improve and expand screening services and outreach efforts.
- * The Nebraska Breast and Cervical Cancer Early Detection Program which manages culturally sensitive outreach programs aimed at Vietnamese women (a population with a high rate of cervical cancer). Through this program, letters in Vietnamese are mailed to all women over the age of 18 which invite the women to a local YWCA to learn about screening services.
- * A program run through the Texas Department of Health which uses funds to pay the YWCA to recruit women for screening and treatment services through churches, clinics, senior centers and YWCA programs.
- * A Maryland state health department program which places funded outreach workers at county health departments throughout the state; workers come from the community and are mainly older minority women.
- * An educational program in Massachusetts which provides printed educational materials in languages other than English, including Haitian-Creole, French and Spanish.
- * Collaborative programs with the American Cancer Society, Avon Products Inc., YWCA, National Alliance of Breast Cancer Organizations, National Cancer Institute, National Center for

Farmworker Health Inc., and other organizations to sponsor education and outreach efforts.

Through September 1996, 690,560 Pap tests were provided by NBCCEDP. 21,257 cases of cervical intraepithelial neoplasia (CIN, the precursor to cervical cancer which can be detected by Pap testing) and 258 cases of invasive cervical cancer were discovered. As of January 31, 1995, 48% of Pap tests were provided to minority women.

II) Professional Education Programs:

The CDC established a number of professional education programs for program managers, health care professionals, health educators, administrative staff and outreach workers. The programs have focused on detection and diagnostic procedures, guidelines for screening, communication skills, data collection, reporting requirements and strengthening clinical skills.

III) Quality Assurance:

The CDC has created screening guidelines and helped the FDA to conduct quality assurance training programs. Programs have focused on improving specimen collection by the primary care practitioner and specimen interpretation by the laboratory.

IV) Surveillance Programs:

When the NBCCEDP was created in 1991, the CDC created a program to monitor screening, diagnostic and treatment activities. States collect and report to CDC information on screening location, demographic characteristics of those screened, screening results, diagnostic procedures and outcomes, and initial treatment. Reminder systems have also been implemented to encourage women to return for rescreening.

V) Treatment:

The legislation which authorized CDC to enact NBCCEDP does not allow CDC to use funds for treatment. However, many women manage to obtain treatment through state and local government support, donated medical services and community programs. State-funded cancer clinics and legislative mandates to use cigarette tax revenues for diagnostic or treatment services both help to provide treatment.

Monetary Allocations for NBCCEDP:

In fiscal year 1993, \$72 billion was appropriated for NBCCEDP; in FY 1994, \$78 billion was appropriated; and in 1997, \$140 million was appropriated.

Recent Advances in Pap Testing Technology

There have been several recent advances in Pap testing technology. In March of 1997, a technique for using brushes to take cell samples was developed. This innovation significantly reduced errors in diagnosis that often occurred as a result of smearing the sample on a slide. Another breakthrough was the creation of PAPNET, a program that computerizes examples of positive pap smear patterns, making Pap analysis more efficient and reducing the possibility of

error.

Honors Received by George Papincolaou

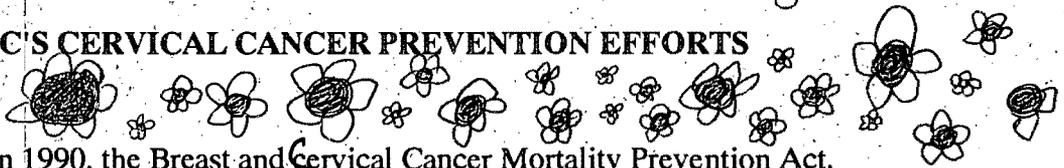
George Papincolaou was elected an Honorary Fellow at the Academy of Athens, an honor that has been bestowed upon only three other individuals (Dwight D. Eisenhower, Conductor D. Metropoulos, and French President Valery Giscard d'Estaing). In 1978, a commemorative 13-cent stamp was issued to honor Papincolaou's achievements. The American Cancer Society has noted, "This man has contributed to progress more than anyone in this century in accelerating cancer research. His name will endure in the same manner as Jenner and Lister, Pasteur and Koch, a one of the immortals in medicine for all times."

Admin. through
Health resources
& services admin
HRSA:

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CDC'S CERVICAL CANCER PREVENTION EFFORTS



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states agree to
treat women - force w/ cancer
partnerships organizations, Assoc. etc.

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How does
this
work?
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do states
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include
in this
how many about
to don't know
cancer
cancer
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also include
how much
are to
more like
full prevent
cancer blown
early treat
etc. if
they
screening

ACF:
Adm. for
children +
family

Medicaid
Medicaid
HCFA

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* A Maryland state health department program which places funded outreach workers at county health departments throughout the state; workers come from the community and are mainly older minority women.

- Is this intentional to reach minority?

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Between 1990 & ?

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- Do they specifically reach minority women? Have special ways to reach over.

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what % of the receive treatment? (these have been some complaints that this helps to identify them)

How do you use treatment? Do you answer? How do you complain? How do you get stuck? How do you get treatment?

Wow! big increase. How have the number of women treated been significantly.

STARTED
HERE

Screening Patterns for Cervical Cancer How Best to Reach the Unscreened Population

Carol L. Brown*

Wife: 66493

Dr. B's wife
Betty Bumpers

(A)
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Dr. Buschig

Although the mortality rate for cervical cancer in the United States has declined steadily since the introduction of the Pap smear for screening in 1945, recent statistics show a rising incidence, with the number of new cases expected in 1996 representing a record high since the mid-1980s. Part of the rising incidence may be because of increasing numbers of women in the United States who did not receive screening or having inadequate screening with the Pap smear. This paper will examine the recent patterns of cervical cancer screening in the United States, with particular attention to defining which populations are not being screened. Barriers to screening in these populations will be defined and grouped into four categories: lack of knowledge, economic, cultural, and belief system; and logistical. Successful approaches that have been used to overcome these barriers in screening programs targeted at the "hard to reach" population will be described. (Monogr Natl Cancer Inst 1996;21:7-11)

Although the mortality rate for cervical cancer in the United States has declined steadily since the introduction of the Pap smear for screening in 1945, recent statistics show a rising incidence. With the 15 700 new cases expected in 1996, increased incidence may be partially accounted for by the human papillomavirus epidemic, part of the increasing incidence may be because of increasing numbers of women who did not receive screening Pap smears. Women from ethnic minorities, Native Americans, African-Americans, and Hispanics have higher rates of cervical cancer than whites, and, along with elderly women, excess mortality (1,5). The percentage of women diagnosed with advanced stage disease is also higher for minorities and the elderly (1,2,4,6), at least suggesting that underutilization of screening Pap smears in these populations may contribute to the observed higher incidence and mortality rates.

Cervical cancer might be described as an ideal disease for which to implement mass population-based screening. A prolonged asymptomatic phase permits early detection of preinvasive disease that is potentially 100% curable, making invasive cervical cancer theoretically a completely preventable disease. The screening test (Pap smear) is simple and risk free and has acceptable levels of sensitivity and specificity. Although the effectiveness of population-based Pap smear screening has never been demonstrated in a randomized, controlled trial, extensive evidence from historical case-control studies and the experience of large screening programs in northern Europe and Canada have shown that Pap smears can decrease the incidence of and

mortality from cervical cancer by as much as 60%-90%. In the United States, it is estimated that abolishing Pap smear screening would increase the incidence of invasive cervical cancer by twofold to threefold (7).

Although it is universally accepted that Pap smear screening is highly effective at decreasing the incidence of invasive cancer in a screened population, no universal consensus has been reached for how frequently and for what age range Pap smear screening should be performed. Current published recommendations from a variety of agencies reflect the debate. The Canadian Task Force and the U.S. Preventive Services Task Force recommend screening every 1-3 years beginning at age 18 years or onset of sexual activity and suspending screening in older women if two consecutive normal Pap smears are seen (8,9). In 1988, the American College of Obstetricians and Gynecologists (ACOG) along with several other professional medical societies issued a consensus recommendation for screening that emphasized annual screening for younger women, leaving any change in frequency up to "the discretion of the physician," and setting no upper age limit (10). Recently, the ACOG issued a technical bulletin reiterating this recommendation and emphasizing the bias of gynecologists to perform annual screening by listing a set of risk factors that should trigger "more frequent," i.e., annual, Pap smears in a woman who has any of

A study (7) advocating a 3-year screening interval for Pap smears is based on data from countries with centralized national cytology laboratories with modern tracking systems and uniform quality control. Concerns about accepting less frequent than annual Pap smear screening in the United States are based on the observed 20% false-negative rate for Pap smears in this country as well as our lack of centralized laboratories and the mobility and poor compliance of women returning for follow-up smears (11,12).

Because of the lack of a nationwide centralized screening program for cervical cancer in the United States, data reflecting the actual rates of screening must be gathered from a variety of sources; no one source accurately reflects all women at risk. Most available data are based on patient self-reporting of Pap smears, which usually overestimates compliance (12). The National Health Interview Survey (NHIS), a large national interview study conducted annually by government agencies, contains data regarding the self-reported use of Pap smears. In Table 1, data compared from the 1987 and 1992 NHIS surveys

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Table 1. Prevalence of Pap smear screening in the United States: National Health Interview Survey, 1987 and 1992 (13-15)

Age, y	% ever having Pap smear		% having Pap smear in last year	
	1987	1992	1987	1992
18-44	90	91	47	50
45-64	92	95	30	41
≥65	79	83	17	22
Total	89	91	38	43

reveal two important trends: the use of Pap smear screening in the United States has increased over time but decreases in direct proportion to increasing age (13-15). The proportion of U.S. women having ever been screened with Pap smears approaches 90%, which is in keeping with the goals set out in the Healthy People 2000 Program (16). However, the proportion having recent screens, and thus the number of women returning for follow-up screens, is much lower, reflecting the problem with compliance.

What summary data from surveys such as the NHIS do not clearly reflect is the identity of the subpopulations of women in the United States who are not receiving any or regular screening Pap smears. These women account for the majority of new cervical cancer cases in this country, with 50% of cancers occurring in women who have never been screened and 60% in women with no smear in the past 5 years (12,17). Women with invasive cervical cancer and no history of a recent Pap smear tend to have more advanced stage disease at time of presentation compared with women who have had recent smears (12,17,18).

Who are the women in the United States who are not receiving any or adequate screening Pap smears? These "unscreened" populations consist of older women, uninsured and impoverished women, members of ethnic minorities, particularly Hispanic and older African-American women, and women residing in rural areas. As shown in Table 2, the percentage of women from all of these groups who have had a recent Pap smear falls far below the Healthy People 2000 goals for Pap smear screening (16,19). Since these NHIS data rely on self-reporting, it is likely that the true impact of age, ethnicity, and socioeconomic status on Pap smear screening is even more substantial.



Table 2. Effect of ethnicity, age, and socioeconomic status on Pap smear screening rates: National Health Interview Survey (16,19)

Group	% having Pap test in last 3 years		
	1987	1992	2000*
White	65	65	85
African-American	57	72	80
Hispanic	57	63	80
Rural	62	60	80
Poor†	64	65	80
Age >70 y	44	46	70

*Goal for year 2000 outlined in Healthy People 2000 Program.

†Household income less than \$10 000 per year.

As reflected in the NHIS data, older women have consistently lower rates of screening with Pap smears. Twenty-five percent of cervical cancer cases and 41% of deaths occur in women older than age 65 years (20). In a study where women older than 65 years were offered Pap screening in a general medical clinic as an outreach intervention, more than 1500 women were screened. Twenty-five percent had never had a Pap smear before, and 75% had had no Pap in the last 5 years (4). In several studies of Pap smear screening patterns in the United States, increasing age is directly correlated with the likelihood of never having had a Pap smear (17,18,21). Although they receive Pap smears less frequently than younger women, older women have the same or a greater number of recent contacts with health care providers (22,23). This suggests that the elderly are not being offered screening at the time of their general medical contact, and for the elderly, most of these contacts are with internists and family physicians, not gynecologists (24-26).

It has been said that socioeconomic status is the most powerful determinant of health status (2), and the effect of this variable on Pap smear screening rates supports this statement. In the 1985 NHIS study, screening rates were 10%-13% lower among poor women than nonpoor women for all ages and ethnic subgroups (27). In an analysis of the 1987 NHIS data, poor women were found to be twice as likely to have never heard of a Pap smear and to not have had recent screening (5). Screening rates among rural women reflect a similar pattern, with only 57% of women in rural Texas and 55% in Appalachia having had a Pap smear within 3 years of the survey (28). In an interesting study, Katz and Hofer (29) compared screening rates in women from Ontario, Canada, with the U.S. NHIS data from 1990 and found that lower socioeconomic status still had a profound negative effect on screening rates, even in Ontario where universal access to care is at least financially available. That the effect of poverty on Pap smear screening is not due solely to the lack of access to care is illustrated by two additional studies in the United States that found that in women covered by Medicaid, 40% had had no Pap test in the last 3 years (28) and 90% of women with no Pap test in the last 4 years were covered by Medicaid (30).

The effect of ethnicity on Pap smear screening rates is complex because ethnicity is often a marker for circumstances that also reflect low socioeconomic status. In the United States, 20% of African-Americans and 30% of Hispanics are uninsured and the lack of insurance has been shown to be a negative predictor for Pap smear screening in most studies (27). In an analysis of Pap smear use among Caribbean-born blacks, 25% of Haitian-born women were compliant with follow-up smears compared with 86% of women born in the English-speaking Caribbean countries, and the authors attributed this discrepancy to differences in socioeconomic status and language barriers rather than "ethnicity" (31). Interestingly, data reveal that young black women have made substantial gains in Pap smear screening rates, and in many studies, their rates of screening approach or exceed those of young white women (5,19,22,27,32,33). However, elderly black women remain much less likely to be screened: in one study (34), more than 40% of African-American women over 65 years of age had never had a Pap smear. Reasons for the disparate rates of Pap smear screening between elderly African-American women and elderly white

Statements supporting the goal of prev. health care health

6

women may relate to differences in knowledge and perceptions about cancer prevention due to cultural attitudes (35);

Members of other ethnic minorities in the United States have excessively high incidence and mortality rates for cervical cancer. Yet data reflect that they have among the lowest use of screening Pap smears. From analysis of the 1987 NHIS, Harlan et al. (5) found that 20% of Hispanic women had never even heard of a Pap smear. In a multivariate analysis of these data that used several contributing factors, having Spanish as the primary language was a negative predictor for compliance with screening. In another study (36), only 46% of the Mexican-American women had had a Pap test in the last 2 years, and the most important predictor of having had a recent Pap test was the number of close friends in the woman's social network. Native American women are also highly "unscreened"; 40% in a defined area of California had had a Pap test within the last year and only 22% in the last 3 years (37).

Data from studies such as those described above allow identification of groups of American women who are not adequately screened with Pap smears. What are some of the barriers to screening encountered by these women? Barriers to Pap smear screening fall into at least four categories: lack of knowledge on the part of the patient or health care provider, economic barriers, barriers inherent in the group's culture or belief system, and logistical barriers.

In the analysis by Harlan et al. (5) of NHIS data from 1987, the most common reason given by women of all ages, ethnicities, and income levels for not utilizing screening was not knowing the purpose of the Pap smear or not understanding it is intended to prevent cervical cancer. Other studies (26,28) reflect the importance of this barrier, particularly among women of low socioeconomic status and women of ethnic minorities. The second most common reason for lack of screening given in this survey of more than 12 000 women was the physician never having told the woman she needed a Pap smear (5). This is particularly important because many of the women who are not being screened are receiving care from internists or family practitioners who may not be aware of the high risk and lack of prior screening among their patients, particularly the elderly and poor women (21,24,25,28,30).

The cost of Pap smear screening is an obvious barrier for the poor and uninsured. Many of these women, particularly those who live in rural areas, may not have access to screening programs (28). For those living in poverty, the trials of day-to-day living, such as securing food and shelter, may make seeking preventive health services such as cancer screening a low priority (2,28,38). Less tangible factors involving the relationship between the patient and her health care provider can also be barriers to screening among poor and uninsured women. In a recent study (39), women were asked what they perceived as barriers to health care. Women receiving public assistance complained that physicians and other health care workers treated them with less respect and caring because they were on welfare.

The attitudes and beliefs of a particular population about cancer are an important barrier to obtaining Pap smears or any type of cancer screening that has been identified in several studies. Fatalistic attitudes about cancer seem to dominate the beliefs of many poor women and women of ethnic minority groups

(5,40,41). Women who believe cancer is not curable avoid screening or any interaction that might result in being told they have cancer. Misconceptions about effects of treatment, such as the belief that surgery will cause cancer to spread by exposing it to air, were also found to be commonly expressed by women in lower socioeconomic groups and ethnic minorities (40,41). Language is another important barrier identified in many studies: Spanish-speaking women avoid contact with the English-only clinics and staff and thus avoid screening (5,42). Specific cultural barriers among Native American and Hispanic women may include a strong sense of the private nature of one's state of health or disease (36,42,43); inherent mistrust of the health care system based on previous negative experiences, such as the Tuskegee experiment, may also prevent women of ethnic minorities from seeking cancer screening services (35,39).

Logistical factors are frequently cited barriers to Pap smear screening. Lack of transportation, lack of child care, and being unable to leave duties of running the household or work are all expressed as reasons for not being screened by the women interviewed in many studies. More subtle are the effects of the difficulty negotiating the complex medical system for the poor and elderly, including long waiting times and multiple appointments, which may also be significant deterrents to screening (30,39-42).

Several published reports describe methods of overcoming the barriers to Pap smear screening in "hard to reach" populations. Successful methods of overcoming the multitude of barriers to Pap smear screening facing elderly women and women of low socioeconomic status have generally followed one of three approaches. One method called "inreach" is based on the principle of offering screening at the time of any health care encounter. Using nurse practitioners who offered same-day education and screening to elderly women attending an inner-city general medicine clinic, one group was able to markedly increase the percentage of women over age 65 years having Pap smears from 18% to 74% (44). In the more traditional "outreach" intervention, computerized letters, phone calls, and other reminders have been successful in increasing the numbers of women obtaining screening Pap smears, in two studies by sevenfold (45,46). Another highly successful approach recruits community members as lay health workers who then help plan and execute Pap smear screening education (33,46-51). Focus groups have been successful tools for determining the needs of a particular population and attitudes toward cancer before planning any intervention strategy (48).

Successful interventions to increase Pap smear screening among the "unscreened" also must be targeted at cultural or ethnic barriers unique to the population at risk. Examples are using the importance of the church in the urban black community to design an outreach program that trains church leaders to become lay health educators (33). The Talking Circle Project uses a culturally acceptable mode of communication and incorporates appropriate stories, myths, and legends to increase screening among Native American women (43). A common feature of most successful interventions is involving community members from the initial phases of the project and empowering women to become more active agents in determining their health status (33,37,39,41,43,46-51).

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To overcome economic barriers to Pap smear screening, many screening programs offer free services, transportation, and babysitting services (44-51). However, the problems of poverty and lack of access to care in the United States require broader, more far-reaching solutions that are beyond the scope of any single targeted screening program. The increasing spread of managed care into our medical care system may have a positive effect on Pap smear screening rates, as two recent studies (52,53) suggest. In an analysis of the 1997 NHIS data, women participating in health maintenance organizations (HMOs) were significantly more likely to have adequate Pap smear screening than those with private insurance or the uninsured (52). A review of more than 10 000 patient records from a single HMO in California found that the number of prepaid patients per primary care physician was the only factor positively correlated with performance of Pap smears. The author concluded that large managed care organizations may have more effective methods to encourage Pap smear screening by primary care providers (53).

Despite the widespread use of Pap smears in the United States, many women remain unscreened or underscreened for cervical cancer: these are the elderly, women of low socioeconomic status, and members of ethnic minorities, particularly older African-American, Hispanic, and Native American women. The barriers to these groups obtaining screening Pap smears include lack of knowledge about screening on the part of the patients and the physicians delivering their general medical care, poverty and lack of access to care, culturally based fatalistic attitudes toward cancer, and language barriers.

What can be done to improve screening rates for cervical cancer in these populations? Organized educational efforts targeted to the health care providers of elderly and poor women to increase awareness of their high risk for cervical cancer and high rate of being unscreened or underscreened should be developed. Community-based screening programs designed to address the specific needs of each underscreened group should be solicited and funded by governmental and private agencies. Programs targeted toward Hispanic women are desperately needed since they represent the fastest growing segment of our population and live among the lowest rates of cervical cancer screening, but the highest incidence rates. Research studies of other potentially underscreened populations, such as southeast Asian-Americans (54), other immigrants, and lesbians (55), who are known to have lower rates of interaction with the health care providers than other women should be performed. By addressing these issues, the low screening rates for cervical cancer in certain subgroups of the U.S. population can be improved, thereby resulting in lowering of incidence of and mortality rates among these women.

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Screening for cervical cancer
 208/04728

** SUMMARY OF EVIDENCE **

Evidence strongly suggests a decrease in mortality from regular screening with Pap tests in women who are sexually active or who have reached 18 years of age. The upper age limit at which such screening ceases to be effective is unknown.

Levels of Evidence: 3,4,5

Evidence obtained from cohort or case-control analytic studies, preferably from more than one center or research group.

Evidence obtained from multiple time series with or without intervention.

Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

** SIGNIFICANCE **

In 1997, an estimated 14,500 cases of invasive cervical cancer are expected to occur, with about 4,800 women dying from this disease. [1] From 1950 to 1970, the incidence and mortality rates of invasive cervical cancer fell impressively by more than 70%. [2] Since the early 1980s, however, the rates of incidence and mortality appear to be decreasing more slowly. According to incidence and mortality rates, screening for cervical cancer should start in the late teens when these rates begin their upward trend. Rates for carcinoma in situ reach a peak for both black and white women between 20 and 30 years of age.

After the age of 25, however, the incidence of invasive cancer in black women increases rapidly with age, while in white women the incidence rises more slowly. Mortality also increases with advancing age, with dramatic differences between black and white women.

Extra effort is warranted to reach older women who have not been screened. Over 25% of the total number of invasive cervical cancers occur in women older than 65, and 40% 50% of all women who die from cervical cancer are over 65 years of age. [3,4] A large proportion of women, particularly elderly black women and middle-aged poor women, have not had regular Pap smears. [5] In some areas, as many as 75% of women over 65 have not had a Pap smear within the previous 5 years. [5] These patterns underscore the importance of special screening efforts targeted to reach women who do not receive regular screening.

Although vaginal smears are often done for follow-up of women who have had a hysterectomy for malignancy, a retrospective study suggests little or no benefit of routine vaginal screening for women who have had a hysterectomy for benign conditions. [7] Investigators found a low prevalence of vaginal

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dysplasia (0.1%) and a high false-positive rate for vaginal smears from women who have had a hysterectomy for benign disease.

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** EVIDENCE OF BENEFIT **

The widespread acceptance of the Pap smear makes the possibility of testing the efficacy of cervical cytology by randomized trials remote. There is, nevertheless, substantial evidence from observational studies that mortality from cervical cancer can be reduced by screening.

Mortality from cervical cancer has decreased in several large populations following the introduction of well-run screening programs. [1-4] Data from several large Scandinavian studies show sharp reductions in incidence and mortality following the initiation of organized screening programs. Iceland reduced mortality rates by 80% over 20 years, and Finland and Sweden reduced their mortality by 50% and 34%, respectively. [1] Similar reductions have been found in large populations in the US and Canada.

Reductions in incidence and mortality seem to be proportional to the intensity of screening efforts. The Scandinavian countries with the highest rates of screening activity reported greater reductions in mortality than those countries with lower rates of screening. [1,5] Mortality in the Canadian provinces was reduced most remarkably in British Columbia, which had screening rates two to five times those of the other provinces. [6]

Case-control studies have found that the risk of developing invasive cervical cancer is 3-10 times greater in women who have not been screened. [7-10] Risk also increases with longer duration following the last normal Pap smear, or

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similarly, with decreasing frequency of screening. [11,12] Screening every 2-3 years, however, has not been found to increase significantly the risk of finding invasive cervical cancer above the risk expected with annual screening. [12,13]

The analysis of survival data shows that survival appears to be directly related to the stage of disease at diagnosis. The 5-year relative survival rate for cervical cancer is 88% for women with an initial diagnosis of localized disease. For those initially diagnosed with distant disease, the survival rate is only 13%. Early detection, using cervical cytology, is currently the only practical means of detecting cervical cancer in localized or premalignant stages.

Targeting high-risk patients:

Progress in mortality reduction will be accelerated most significantly by increasing the percentage of cervical neoplasms discovered in the precancerous or localized stages. This can be accomplished most effectively by screening women at greatest risk for cervical cancer, i.e., those who have not had a Pap test or those who have not had one for several years. Often, these women are older, of lower socioeconomic status, and may be members of minority groups, and are often seen by physicians for a variety of acute and chronic conditions unrelated to preventive medical care. [13-17] Other well-known risk factors, such as early age of first intercourse and multiple sexual partners, have less practical clinical significance due to the difficulty in obtaining adequate histories of these risk factors. Advances in understanding the relationship between specific HPV types and the risk of cervical neoplasia may have future applications in targeting high-risk groups for screening and other preventive interventions. In particular, HPV testing is under investigation as an intermediate test in the evaluation of women with minor cytologic abnormalities. In the majority of such cases, abnormal changes regress spontaneously; however, some women may harbor an occult high grade lesion that should be treated. In one study of women with equivocal Pap smear results, testing for elevated levels of HPV DNA from cancer-associated viral types was found to be more sensitive than repeat cytology alone in identifying women with high-grade lesions who required therapy. [18] In another study, of the 31 women who tested negative for HPV16 by DNA-based methods, 29 (94%) were also negative for systemic IgG antiviral antibodies by an enzyme-linked immunosorbent assay (ELISA). [19,20] However, of the 54 women positive for HPV16 by DNA-based methods, only 32 (59%) were also found positive by the ELISA method.

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SEER MONOGRAPH

**Racial/Ethnic Patterns
of Cancer in the
United States
1988-1992**

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

(15)

This publication was prepared by:

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CERVIX
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Until the early 1970s, approximately 75% to 80% of cervical cancer in the United States was invasive at the time of diagnosis. Today, about 78% of cervical cancer cases are diagnosed at the *in situ* stage. Furthermore, both incidence and mortality for invasive cervical cancer have declined about 40% since the early 1970s. Mortality began declining just before the Papanicolaou screening test

became widely utilized, however, leaving a dilemma as to the relationship between the Pap test and reductions in cervical cancer mortality. Around the world, cervical cancer is often the most common type of cancer among women.

The ethnic patterns of this disease are quite different from those of any of the other female reproductive system cancers. The highest age-adjusted incidence rate in the SEER areas occurs among Vietnamese women (43 per 100,000). Their rate is 7.4 times the lowest incidence rate, 5.8 per 100,000 in Japanese women. Incidence rates of 15 per 100,000 or higher also occur among Alaska Native, Korean, and Hispanic women.

The incidence of invasive cervical cancer exhibits different ethnic patterns by age group. Among women aged 30-54 years, Vietnamese women have the highest rate, followed by Hispanic women, and black women. The rate among Vietnamese women is nearly twice as high as that of Hispanic women, and five times as high as the rate for the group with the lowest rate, Chinese women. Vietnamese women continue to have the highest incidence of invasive cervical cancer in the age group 55-69 years, with a rate that is more than three times higher than the second ranked group, Korean women. Hispanic women have the third highest incidence in this age group, and are followed by black women.

There are too few cases in the 70 and older age group to assess many of the ethnic patterns.

United States mortality rates are about 50% to 80% lower than the incidence rates. The ethnic patterns in mortality differ somewhat from those seen in incidence. Black women have the highest age-adjusted mortality rate from cervical cancer, and are followed by Hispanic women. Mortality rates are not available for comparison, however, for Vietnamese, Korean, Alaska Native or American Indian (New Mexico) women. The lowest mortality from this disease occurs among Japanese women, whose rates are less than one-fourth as high as the rates among black women. Mortality patterns by age are similar, with black women having the highest mortality in each age group. Hispanic women have the second highest mortality in the two youngest age groups, while Chinese women aged 70 years and older rank second.

The major risk factors for cervical cancer include early age at initiation of sexual activity, multiple sexual partners, infection with human papilloma virus 16, and cigarette smoking. Therefore, primary prevention is focused mainly on modification of sexual behavior and eradication of cigarette smoking. Secondary prevention occurs through screening, using the Papanicolaou test.

Stacks Robin
66735
Diabetes + fact sheet
possible event
PE:

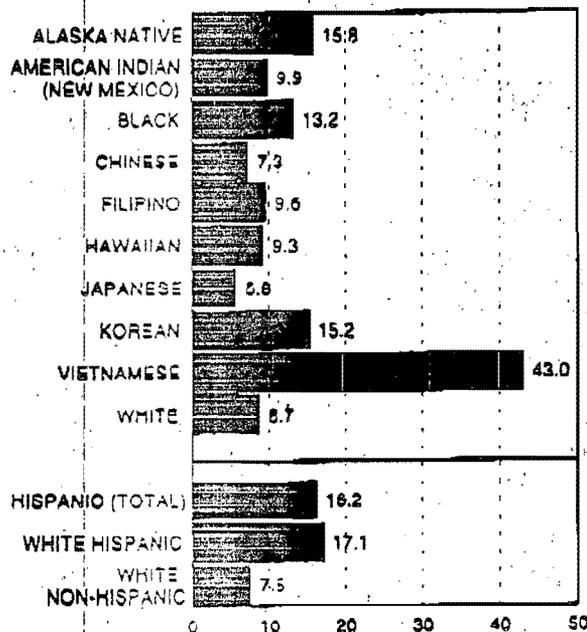
rates of
early Cerv. cancer
at 70 & 80

P6/b(6)
P6/b(6)

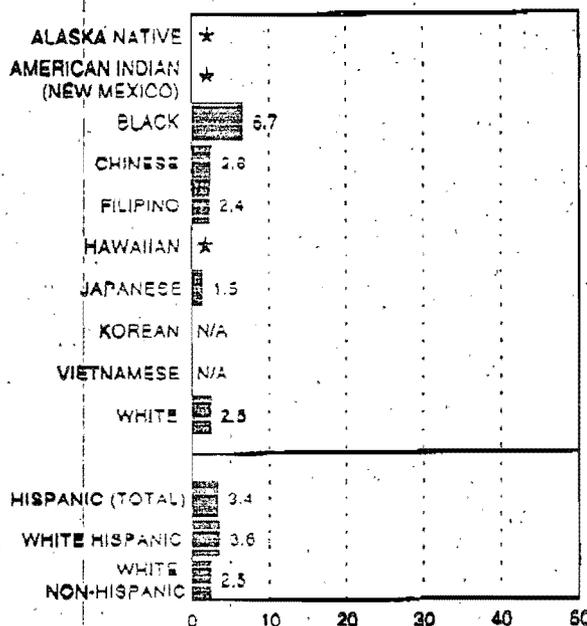
17

CERVIX UTERI

SEER INCIDENCE Rates Among Women, 1988-1992



United States MORTALITY Rates Among Women, 1988-1992



NOTE: Rates are "average annual" per 100,000 population, age-adjusted to 1970 U.S. standard; N/A = information not available; * = rate not calculated when fewer than 25 cases.

18

CANCER CONTROL IN MINORITY AND UNDERSERVED POPULATIONS

Cancer affects various population subgroups in the United States in distinct ways. The statistics in this monograph show that black men have the highest incidence rate of cancer, due to excesses of prostate and lung and bronchus cancers, while American Indian men in New Mexico have the lowest rate. Among women, non-Hispanic white women have the highest incidence rate, due mainly to

their excess of breast cancer, while American Indian women in New Mexico and Korean women have the lowest rates. Interestingly, the five most commonly diagnosed cancers among men in every racial/ethnic group include lung and bronchus, prostate and colorectal cancers. Oral cancers, however, are among the five most frequently diagnosed cancers only in black men and cancers of the kidney and renal pelvis are uniquely among the top five cancers in Alaska Native and American Indian (New Mexico) men. In women, cancer of the breast, lung and bronchus, and colon and rectum are among the top five cancers in every racial/ethnic group except American Indians (New Mexico). The high incidence of cervical cancer in Vietnamese women is a matter for concern and suggests a need to focus prevention and control efforts on this group. Cancers of the kidney and renal pelvis are uniquely high in Alaska Native women, mirroring the high rates seen in Alaska Native men.

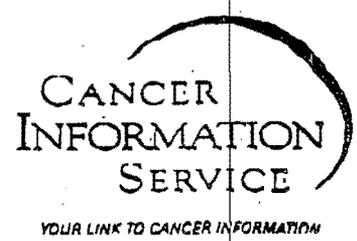
Achieving better cancer control within minority and underserved populations in the United States is an important goal of the National Cancer Institute (NCI). Cancer control has been defined as the reduction of cancer incidence, mortality, and morbidity through an ordered sequence of research and interventions designed to alter cancer rates. Knowledge gained through research on specific interventions to improve cancer rates must be applied toward reducing the

burden of cancer among minority populations. Specific activities supported by the NCI include: 1) cancer surveillance, including special tracking of cancer rates among minority populations; 2) recruiting members of minority populations into clinical trials; 3) increasing and improving research targeting minority populations and increasing the participation of members of minority populations in the fields of biomedical research and medical practice; and 4) instituting community-based, national education and outreach initiatives which target specific minority and underserved populations.

Cancer Surveillance

Cancer surveillance encompasses the collection, analysis and dissemination of data useful in the prevention, diagnosis, and treatment of cancer. As described in the introduction to this monograph, the SEER Program collects and reports statistics on the impact of cancer on major racial/ethnic populations in the United States. Since the composition of the United States population has changed over time, the SEER Program has adjusted its coverage of specific population subgroups to meet new needs. In 1992, to increase its coverage of minority populations, especially Hispanics, the SEER Program expanded to include Los Angeles County and the San Jose/Monterey area in California. The need for increased coverage of Hispanics arose from the tremendous

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Frd Care*



FACE MAIL Region 05

DATE: 7/21/97
TO: Sara Haurwitz
COMPANY: Chris Jennings Office
TELEPHONE#: (202) 456-5594
FAX#: (202) 456-5557
RE: Cervical Screening
FROM: Region 5 CIS, Betty May, Telephone Service Manager
FAX#: (410) 955-3694

Number of pages faxed including cover: 19

Comments

Attached are 3 documents that may be most helpful to your questions relating to cervical cancer and pap smear use.
Document A - pg 2-8 (NCI Monograph Article) answers several of the questions
Document B - pg 9-13 (NCI Cervical Cancer Screening Statement)
Document C - pg 14-19 (NCI Racial/Ethnic Monograph Section on Cervical Cancer)
* I will also put other resources in 1st Class Mail today.

If you have difficulty with transmission or do not receive the number of pages indicated on the cover sheet, please call Dan or Becky at (410) 955-3636.

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A Program of the National Cancer Institute serving Maryland, District of Columbia and N. Virginia in cooperation with the Johns Hopkins Oncology Center

2

MONOGRAPHS

JOURNAL OF THE NATIONAL CANCER INSTITUTE

NATIONAL
CANCER
INSTITUTE

National Institutes of Health Consensus
Conference on Cervical Cancer

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JAN 18 1996
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NIE Publication No. 96-512

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service, National Institutes of Health

reduced errors in diagnosis that often occurred as a result of smearing the sample on a slide. Another breakthrough was the creation of PAPNET, a program that computerizes examples of positive pap smear patterns, making Pap analysis more efficient and reducing the possibility of error.

George Papincaolau was elected an Honorary Fellow at the Academy of Athens, an honor that has been bestowed upon only three other individuals (Dwight D. Eisenhower, Conductor D. Metropoulos, and French President Valery Giscard d'Estaing). In 1978, a commemorative 13-cent stamp was issued to honor Papincolaou's achievements. The American Cancer Society has noted, "This man has contributed to progress more than anyone in this century in accelerating cancer research. His name will endure in the same manner as Jenner and Lister, Pasteur and Koch, as one of the immortals in medicine for all times."

George Papincolaou

W "This man has contributed to progress more than anyone in this century in this century in accelerating cancer research. His name will endure in the same manner as Jenner and Lister, Pasteur and Koch, as one of the immortals in medicine for all times."

-- The American Cancer Society

- born on the Greek island of Euboea, studied medicine at the University of Athens
- Father, also a doctor, made huge financial sacrifices to allow him to study all over the world
- in 1910 married Mache Mavrogenous, who would become his lifelong partner in research
- immigrated to America after serving in the Balkan Wars
- took a job selling carpets and two days later quit (from embarrassment) after he was recognized by a countryman
- "indefatigable" worker...never took a vacation
- took a job at New York Hospital, did life's work there and at Cornell Medical College
- developed "Pap" test after studying guinea pigs
 - The first time he observed the distinctive cells in the vaginal fluid of a woman with cervical cancer was "one of the most thrilling experiences of my scientific career"
 - could never explain how he recognized a positive smear, he just did, and taught it thousands
- laughed off by scientific community when he tried to make results public in 1928
- in 1948 published the famed *Diagnosis of Uterine Cancer by the Vaginal Smear*...had last laugh
- death rate from cervical cancer cut in half from 1951 to 1961, saves countless lives
- "If a woman has a Pap smear every year, the chances of cervical cancer are practically zero."
 - Dr. Kenneth Noller, Umass medical center, national expert on cervical cancer
- regarded as 20th century's most important contribution to war vs. gynecological cancer
- in Icelandic & Nordic countries, cervical cancer fell 15-60% in the 20 years after discovery
- in US...in 1961, 30% of women had pap smears. Cervical cancer rate = 32.6/100,000
- In 1987, 87% had pap smears. Cervical cancer rate = 8.3/100,000
- Thus, widespread use of pap smears cut the cervical cancer rate by 3/4
- work ranks with those of Roentgen and Marie Curie in reducing burden of cancer
- elected an Honorary Fellow at the Academy of Athens...only three others have received this honor: Eisenhower, conductor D. Metropoulos, and French Pres. Valery Giscard d'Estaing
- lesson = nations should concentrate on funding basic medical research, not costly clinical application of imported diagnostic measures and sophisticated instruments. (tie to NIH...maybe even genetic screening as another possible Pap-like opportunity)
- had a commemorative 13-cent stamp in 1978
- Recent advances in Pap technology (possible reason for the posthumous recognition)
 - recently (March 1997, Allentown, PA) a new technique has become available to improve the Pap smear. The major cause of error in diagnosis was from doctors smearing the sample on a slide. Now brushes are being used to significantly reduce the possibility of new diagnosis
 - PAPNET - new tech. that puts positive pap smear patterns on the computer...not in the doctor's mind, making it more efficient and reducing possible error)

Bottom line is that pap smears have saved thousands of women's lives all over the world.

Justification Booklet

✓ CC approx. 14,500 new cases of cervical cancer are diagnosed each year

✓ Pap good almost all deaths from cervical cancer are preventable for women over 50 through pap smear testing

many women who get cervical cancer and are most likely to die from it are minorities and/or economically disadvantaged people -- no access to preventive services

✓ need to be sure low-income women have access to services, physicians educated about screening, pap tests are quality, programs to increase screening are monitored, community partnerships are made to help with detection and follow-up

✓ Pap good Through May 1996, about 612,008 pap tests were given, 24,434 (4%) were found to be abnormal, 19,875 cases of cerv. intraepithelial neoplasia (precursor of cervical cancer that can be treated), and 239 cases of invasive cervical cancer found.

Institute for Cancer faxed info.

1996 info

✓ Cerv cervical cancer is ideal disease to be screened because of long preclinical phase allowing early detection -- using pap test is effective in cutting morbidity and mortality from cervical cancer

✓ Pap good 50% of women diagnosed with invasive cervical carcinoma (I assume this means fully-blown, not just pre-clinical) have never had a Pap smear and another 10% haven't had smear in past five years

✓ Unscreened = often older women, uninsured, ethnic minorities (esp. Hispanics and elderly blacks) and poor women, esp. those in rural areas.

✓ P-9 25% of cases of cervical cancer and 41% of deaths happen in women 65 and older -- data from 1992 National Health Interview Survey indicate that 50% of all women age 60 and older haven't had a Pap smear in the past 3 years

✓ Older women are screened less often, they have the same number of recent physician visits as younger women -- shows that we must educate older women and their health care providers about how important Pap screening is

✓ recent evidence shows that gap in the occurrence of cervical cancer between black and white women under age 50 is disappearing -- shows that more young black women are being screened

✓ need to find out why people aren't screened, should use community-based approaches for

reaching minorities -- need culturally and linguistically appropriate staffing for this maybe

✓ need to address logistical problems too -- transportation, child care, accessible sites, etc.

The Bethesda System (TBS) -- effort to standardize Pap smear terminology -- evaluates system for adequacy, uses diagnostic terminology and makes recommendations regarding the smear when necessary -- need to determine whether specimen is adequate because often they are misread

Screening for cervical cancer -- Nat. Cancer Institute

✓ P3 evidence strongly suggests decrease in mortality from regular pap screening in sexually active women or women who are 18 or older -- upper age limit at which screening is no longer effective is unknown

✓ C 1997 -- around 14,500 case of invasive cerv. cancer are predicted to occur -- about 4800 women dying from the disease,

✓ (P3) from 1950-1970, incidence and mortality rates of invasive cervical cancer fell by over 70%

✓ (P3) Since early 80's, levels of incidence and mortality are decreasing more slowly

screening should start in late teens -- rates for carcinoma in situ reach peak for black and white women between 20 and 30 years old

✓ over age 25, numbers of black women with cancer grows quickly, while number of white grow more slowly

✓ (P3) 25% of cerv. cancer is in women older than 65 and 40-50% of women who die of cerv. cancer are over 65. elderly black women and middle aged poor women often don't have paps enough

in some places, as many as 75% of women over 65 haven't had a Pap within the past 5 years

✓ P3 death from cerv. cancer greatly declined in several large populations like in Scandinavia
Iceland cut death rates by 80% over 20 years

Finland by 50%

Sweden by 34%

similar findings in US and Canada

reductions in mortality = proportional with screening effort intensity

Scand countries with higher screening rate = greater death reductions

✓ P3 deaths in Canada decreased most in British Columbia which had 2 to 5 times more screening than other provinces

R3
risk of getting cerv. cancer is 3 to 10 times greater in unscreened women
risk increases the longer ago you had last Pap smear or the less frequently one is screened
(although screening every 2 to 3 years doesn't significantly increase the risk of finding cancer
more than screening every year)

survival = directly related to stage of disease when diagnosed
5 year survival rate is 88% for women with initial diagnosis of localized disease
those initially diagnosed with distant disease have survival rate of only 13%
early detection is key

target high-risk people -- those who haven't had Paps for several years (often poor, minority
women), had sex at young age, many sex partner

MEMORANDUM

TO: BRUCE REED, ELENA KAGAN

CC: CHRIS JENNINGS, ELIZABETH DRYE, JERRY MANDE, SARAH BIANCHI

FROM: TOM FREEDMAN, MARY L. SMITH

RE: TOBACCO BILLS

DATE: JULY 12, 1997

SUMMARY

This is a follow up to the previous memorandum dated July 9, 1997, that compiled tobacco bills from the 104th Congress and 105th Congress. Below is a more detailed description of various bills.

I. BILLS REGARDING FARMERS

1. **S. 598 by Sen. Bradley (D-NJ) on 3-22-95 (one cosponsor, Sen. Lautenberg (D-NJ)). TOBACCO CONSUMPTION REDUCTION AND HEALTH IMPROVEMENT ACT OF 1995.** This bill amends Section 5701 of the Internal Revenue Code to increase taxes on cigarettes from \$12 per thousand to \$62 per thousand. It also increases taxes on cigars, cigarette papers, smokeless tobacco, and other tobacco products. This act would also impose taxes on tobacco products entering into the United States from a foreign trade zone. This bill also creates a "Tobacco Conversion Trust Fund" by amending Subchapter A of Chapter 98 of the Internal Revenue Code of 1986. The bill would transfer 3 percent of the net increase in revenues received by the increase in tobacco taxes to the trust fund. The funds would then be available to the Secretary of Agriculture for the following purposes:

- (1) providing assistance to farmers in converting from tobacco to other crops and improving the access of such farmers to markets for other crops; and
- (2) providing grants or loans to communities, and persons involved in the production or manufacture of tobacco or tobacco products, to support economic diversification plans that provide economic alternatives to tobacco to such communities and persons.

The bill provides that the "assistance" provided to farmers could include government purchase of tobacco allotments for purposes of retiring such allotments.

2. **S. 804 by Sen. Bradley (D-NJ) on 5-15-95 (no cosponsors). TOBACCO CONSUMPTION REDUCTION AND HEALTH IMPROVEMENT ACT OF 1995.** This bill is virtually identical S. 598 also introduced by Sen. Bradley.

II. BILLS REGARDING THE TAX DEDUCTIBILITY OF ADVERTISING

1. **H.R. 1323 by Rep. McHale (D-PA) on 4-15-97 (34 co-sponsors). TOBACCO ADVERTISING REFORM ACT.** This legislation amends Part IX of subchapter B of Chapter 1 of the Internal Revenue Code of 1986 which adds a section stating: "No deduction shall be allowed under this chapter for expenses for advertising cigars, cigarettes, smokeless tobacco, pipe tobacco, or any similar product."

2. **H.R. 2962 by Rep. McHale (D-PA) on 2-06-96 (22 co-sponsors).** This bill is identical to H.R. 1323 also introduced by Rep. McHale in the 105th Congress.

3. **S. 596 by Sen. Harkin (D-IA) on 3-22-95.** This bill is essentially identical to the two bills listed above.

III. BILL ON ADVERTISING AIMED AT YOUTHS

1. **H.R. 762 by Rep. Hansen (R-UT) on 2-13-97 (5 cosponsors). YOUTH PROTECTION FROM TOBACCO ADDICTION ACT OF 1997.** This legislation bans all advertising of tobacco products. It also prohibits the distribution of any free tobacco product, the sponsorship of any event in a brand name, the marketing of nontobacco products bearing a brand name, and the payment for any tobacco product or brand name to appear in movies, television, and other media or on any toy. This bill prescribes that advertising on tobacco product packages shall be in black and white and shall contain no human figures. Civil actions for injunctions for violations of this Act may be brought in district court.

IV. BILL ON WARNING LABELS

1. **S.527 by Sen. Lautenberg on 4-08-97 (5 cosponsors). TOBACCO DISCLOSURE AND WARNING ACT OF 1997.** This bill makes it unlawful to manufacture for sale any cigarette unless the package contains one of the following warnings:

WARNING: Cigarettes Kill

WARNING: Cigarettes Cause Lung Cancer and Emphysema

WARNING: Cigarettes Cause Infant Death

WARNING: Cigarettes Cause Heart Attacks and Stroke

WARNING: Cigarettes Are Addictive

WARNING: Nicotine Is An Addictive Drug

WARNING: Cigarette Smoking Harms Athletic Performance

WARNING: Smoking During Pregnancy Can Harm Your Baby

WARNING: Cigarette Smoke Is Harmful to Children

WARNING: Smoke from [brand name] Cigarettes Can Cause Cancer in
Nonsmokers

- This legislation also requires labels or other tobacco products which are similar to the labels above. The labels must be placed in the two most prominent sides of the product package and be in a size not less than 33% of the side on which the label is placed. The bill requires the labels to be in black and white.
- This bill also requires a package insert detailing the substances posing a risk to HEALTH contained in the cigarettes.
- Manufacturers also must submit to the Government an annual report listing the nicotine, tar, and carbon monoxide intake for the average consumer.
- The Secretary will also establish a toll-free telephone number and a site on the Internet which shall make available additional information on the ingredients of cigarettes.
- The bill provides that any interested organization may seek to enjoin violations of the act in federal district court.

V. BILL ON PERFORMANCE STANDARDS

1. S. 828 by Senator Durbin (D-IL) on 6-03-97 (2 cosponsors). NO TOBACCO FOR KIDS ACT.

- Within one year after enactment, the Secretary of HHS will conduct a survey to determine the number of children who used each manufacturer's tobacco products within the previous 30 days.
- Manufacturers will face penalties if they do not reduce the number of children who use tobacco products by either a de minimis level (one-half percent of the current number of youth smokers) or by the following percentages:

S.828

Compare to settlement

Year 1: no standard; baseline survey is taken

Year 2: 20% reduction from baseline

Year 3: 40% reduction from baseline

Year 4: 60% reduction from baseline

Year 5: 80% reduction from baseline

Year 6: 90% reduction from baseline

Subsequent years: 90% reduction from baseline

Years 5-6: 30% reduction

Years 7-9: 50% reduction

Year 10 (and after): 60% reduction

- Under the Senate bill, if a manufacturer violates the performance standard, the manufacturer must pay a noncompliance fee of \$1 per pack on all its tobacco sales in the subsequent year (not simply sales to youths). If a manufacturer violates the performance standard for two or more consecutive years, the noncompliance fee is increased by \$1 for each consecutive year of violation. If the manufacturer is within 10% of the required reduction for a particular year, the noncompliance fee will be reduced on a pro rata basis. **Under the settlement:** There is a surcharge of \$80 million for each percentage point

difference between the required percentage reduction applicable to a given year and the percentage by which the incidence of underage use of cigarette products for that year is less than the base incidence percentage. (This amount reflects an approximation of the present value of the profit the cigarette industry would earn over the life of underage smokers in excess of the required reduction). The surcharge may not exceed \$2 billion in any year (as adjusted for inflation).

- Under the Senate bill, the first \$1 billion of noncompliance fees will fund enforcement and public education to discourage children from using tobacco products. Any additional fees will go the Treasury for deficit reduction. **Under the settlement:** 90% of the surcharge goes to state and local government to youth tobacco use.

VI. TOBACCO STATE MEMBER BILLS

1. **S.201 by Senator Ford (D-KY) on 1-23-97 (no cosponsors). TOBACCO PRODUCTS CONTROL ACT OF 1997.** This bill imposes limits on advertisements on billboards within 500 feet of any school; bans advertisements in magazines and newspapers if persons under the age of 18 constitute more than 15% of the total subscribership; prohibits ads in taxis, buses, trains, or in stations unless it is where cigarettes are sold; and bans the use of cigarettes in movies for a fee.

This legislation also amends Section 1926 of the Public HEALTH Service Act (42 U.S.C. sec. 300x-26) to provide that the Secretary may make a grant to a state only if the state makes it unlawful, among other things, (1) to sell tobacco products to anyone under the age of 18 and to sell without verifying the age in face-to-face transactions; and (2) to operate a vending machine unless it is in plain view.

2. **H.R. 516 by Rep. Baesler (D-KY) on 2-04-97 (no cosponsors). YOUTH SMOKING PREVENTION ACT OF 1997.** This bill establishes the federal authority to regulate the sale, distribution, and advertising and promotion of tobacco and other products containing nicotine as a condition to the receipt by states of the Federal Preventive Health and Health Services Block Grant. Under the bill, the Secretary may only make a grant under section 1921 of the Public Health Service Act if the State has a law, that among other things, prohibits the sale of nicotine to minors; prohibits the purchase by minors; requires the posting of signs stating the minimum purchase age; requires retail employers to notify its employees about the laws regarding sales to minors; requires retail employees to sign forms that they have received notice; and requires the licensing of retail sellers of nicotine products .

3. **H.R. 2414 by Rep. Baesler (D-KY) on 9-28-95 (3 cosponsors): YOUTH SMOKING PREVENTION ACT OF 1995.** This bill is identical to H.R. 516 introduced by Rep. Baesler in the 105th Congress.

4. **H.R. 2653 by Rep. Charlie Rose (D-NC) on 2-06-96. TOBACCO AMENDMENTS ACT OF 1995.** The main sections of the Act are the following:

- Sec. 2. Elimination of Federal Budgetary outlays for tobacco programs.
- Sec. 3. Establishment of farm yield for flue-cured tobacco based on individual farm production history.
- Sec. 4. Removal of farm reconstitution exception for burley tobacco.
- Sec. 6. Expansion of types of tobacco subject to no net cost assessment.
- Sec. 7. Repeal of reporting requirements relating to the export of tobacco.
- Sec. 8. Repeal of limitation on reducing national marketing quota for flue-cured and burley tobacco.

5. **S. 1262 by Sen. Ford (D-KY) on 9-20-95. TOBACCO PRODUCT CONTROL ACT OF 1995.** This bill is basically an earlier version of S.201 introduced by Sen. Ford on 1-23-97, which is described above.

VII. BILL REGARDING MEDICAID BY REP. OBERSTAR

1. **H.R. 3779 by Rep. Oberstar (D-MN) on 7-10-96 (16 cosponsors): TOBACCO MEDICAID RECOVERY ACT OF 1996.** The purpose of this bill is to reward states that successfully recover the federal and state health care costs incurred under the Medicaid program for the treatment of individuals with diseases attributable to the use of tobacco products by providing increased funding for their Medicaid programs and to provide increased resources to the National Institute of Health. Section 1903(D) of the Social Security Act is amended to provide that if a state recovers amounts expended as medical assistance for the treatment of diseases attributable to tobacco, the Secretary shall determine the amount of federal expenditures attributable to the amounts recovered, based on the federal medical assistance percentage. The Secretary then will treat this amount as an overpayment and permit the state to retain one-third of such amount for the purpose of using the funds to meet the non-federal share of expenditures under the state plan and pay one-third of such amount to NIH.

VIII. BILL REGARDING NICOTINE ADDICTION BY REP. MEEHAN

1. **H.R. 1853 by Rep. Meehan (D-MA) on 6-15-95 (9 cosponsors): FREEDOM FROM NICOTINE ADDICTION ACT OF 1995.** This bill amends the FDCA to make it illegal to introduce into interstate commerce any tobacco product that contains nicotine in the following amounts per cigarette:

As of January 1, 1997	10.00 MG. Nicotine.
As of January 1, 1998	8.00 MG. Nicotine.
As of January 1, 1999	6.00 MG. Nicotine.
As of January 1, 2000	4.00 MG. Nicotine.
As of January 1, 2001	2.00 MG. Nicotine.
As of January 1, 2002	.05 MG. Nicotine.

July 18, 1997

Medicare Part B premium recapture -- Non-income tax options

This proposal would permit the IRS to collect the Medicare Part B premium recapture -- retaining an effective linkage to participants' income and allowing the enforcement and collection powers of the IRS to be made available -- but would have the IRS do so outside of the Form 1040 and income tax system. *Caveat: If the IRS is to collect the premium recapture, that amount must be treated as a "tax" for purposes of the Internal Revenue Code's enforcement provisions.*

Under this proposal, the IRS would provide taxpayers with a separate "Part B Premium Recapture" form. Taxpayers who participate in Part B would complete the form using data taken from their Form 1040 (adjusted gross income and desired "modifications"). The premium recapture amount would be returned and payable separately from the income tax. It would be assessed and (if underpaid) collected by the IRS like any other tax. Traditional pre- and post-payment remedies for contesting disputed amounts (deficiency proceedings or refund claim proceedings) could be adapted to this tax.

In addition to the tax consequences of collecting the premium recapture amount, an additional sanction could be considered for persons who are liable for the premium but who fail to pay. Such non-payers could ultimately be disenrolled or barred from participation in Medicare Part B.

Variations on this proposal

1. Include the "Part B Premium Recapture" form with the Form 1040 package that the IRS provides to taxpayers in January of each year. Require covered Part B participants to submit the form in the same envelope with their income tax return for the preceding year, *i.e.* by April 15.
2. Provide the "Part B Premium Recapture" form at an entirely different time of year (*e.g.*, July 1) and require the form and payment to be submitted separately (*e.g.*, September 15).

Advantages of this proposal:

- The information on the Part B form, including the adjustments to AGI, can be verified by cross-reference to the taxpayers' income tax form. This will help in achieving a relatively high level of compliance and minimize the discrepancies between the forms. (Higher compliance could probably be obtained under variation 1, because taxpayers will have the information readily available and can obtain assistance completing the forms at the same time they complete their income tax returns. By contrast, under variation 2, more taxpayers will require assistance and more errors or discrepancies will arise.)

- Treating the premium recapture like any other tax will enable the IRS to adapt existing systems (for form processing and data entry, assessment, examination, and collection) easily. (Nonetheless, the cost to the IRS is approximately twice the cost of a Form 1040 system, or



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*** ERROR TX REPORT ***

TX FUNCTION WAS NOT COMPLETED

TX/RX NO. 9440
CONNECTION TEL 92242047
CONNECTION ID
START TIME 07/22 18:35
USAGE TIME 00'00
PAGES 0
RESULT NG 0 #018

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HOW A HIGH-INCOME PREMIUM
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Breast and Cervical Cancer Mortality Prevention Activities

Authorizing Legislation - Section 301 and Title XV of the Public Health Service Act

	<u>1996 Actual</u>	<u>1997 Appropriation</u>	<u>1998 Estimate</u>	<u>Increase or Decrease</u>
BA	\$124,670,000	\$139,659,000	\$141,897,000	\$2,238,000
FTE	66	66	66	-
1998 Authorization	Indefinite			

Purpose and Method of Operation

Breast and cervical cancer will kill more than one-half million women in this decade. Breast cancer accounts for nearly one-third of all cancers in women, and approximately 14,500 new cases of cervical cancer are diagnosed each year. Almost all deaths from cervical cancer and an estimated 30 percent of deaths from breast cancer in women over age 50 are preventable through widespread use of screening mammography and Papanicolaou (Pap) testing. A combination of annual clinical breast examinations and mammography can reduce breast cancer mortality by more than 30 percent for women age 50-74. Early detection, also increases the 5-year survival rate to 91 percent. Early diagnosis of breast and cervical cancer saves money as well as lives. The cost of medical care for a woman whose breast cancer is diagnosed early may be as low as two-thirds of the medical care cost for a woman whose cancer is diagnosed at a later stage.

Many women who develop these cancers and are at highest risk for premature death from cancers of the breast and cervix are minorities and/or the economically disadvantaged. These women often do not have access to preventive services such as screening mammograms and Pap smears. Significant economic, geographic, and knowledge barriers prevent many women, especially women of low-income and minority women, from taking advantage of these life-saving technologies. CDC provides leadership in carrying out critical activities at the national level to remove these barriers.

The CDC Breast and Cervical Cancer Early Detection Program guides public health programs in creating the foundation for an aggressive response to this health problem and will ensure the delivery of successful screening services. CDC supports activities at the State and national level in the areas of screening referral and follow-up services, quality assurance, public and provider education, surveillance, collaboration and partnership development.

The screening program ensures that eligible women have access to these preventive services, and that State programs: inform all women of the value of early detection; educate physicians about recommended screening guidelines; ensure the quality of screening mammography and Pap tests; and monitor program effectiveness through appropriate surveillance and evaluation activities; and build effective community-based partnerships for early detection and follow-up.

The CDC Breast and Cervical Cancer Early Detection Program has developed a broad range of non-traditional partnerships. Two notable examples of partnerships to increase access to breast and cervical cancer screening are with the YWCA of the USA and Avon Products, Inc. The collaborative agreement with the YWCA of the USA broadened the scope of CDC's outreach efforts by providing the YWCA with a key role in bringing both quality screening and enabling services to low income, underserved and minority women in almost all of the CDC-funded States. A formal partnership with Avon Products, Inc. allows CDC and Avon Products, to support national and State-based efforts for the early detection of breast cancer.

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A national early detection program requires a comprehensive approach if cancer mortality prevention programs are to work. CDC will continue to build these elements in collaboration with its governmental, professional, and voluntary partners and will extend and expand support for early detection capability.

This effort will be measured in terms of short and long-term impacts. Short-term impacts can be measured through the comparison of early and late-stage cancers diagnosed during this decade and beyond, consistent with the *Healthy People 2000* objectives for breast and cervical cancer. Expected long-term impacts are reduced mortality from these cancers.

Funding for the Breast and Cervical Cancer program during the last five years:

	<u>Funding</u>	<u>FTE</u>
1993	\$71,303,000	56
1994	\$78,076,000	56
1995	\$100,000,000	51
1996	\$124,670,000	66
1997	\$139,659,000	66

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Rationale for Budget Request

The FY 1998 request of \$141,897,000 represents a net increase of \$2,238,000 over the FY 1997 Appropriation. A minimum of 80% of the total breast and cervical cancer funding is awarded to state programs through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). With the FY 1998 increase of \$2,238,000, CDC will provide additional support to state health agencies. CDC provides leadership in carrying out critical activities at the national level to remove screening barriers and establish early detection programs. A national early detection program requires a comprehensive approach that extends beyond screening subsidies. Public and provider education, quality assurance, surveillance, and evaluation are essential elements if cancer mortality prevention programs are to work. With additional resources, CDC will continue to build these key elements in collaboration with its governmental, professional, and voluntary partners and will extend and expand support for early detection capability.

Breast and Cervical Cancer Screening (+\$2,330,000)

Through May 1996, more than one million screenings were provided by the program. A total of 441,707 mammograms and 612,008 Pap tests were provided. Of the 441,707 mammograms provided to women aged 40 years and older, 28,544 (6.5 percent) were abnormal, and 2,495 breast cancers were diagnosed. Of the 612,008 Pap tests provided, 24,434 (4 percent) were abnormal, and 19,875 cases of cervical intraepithelial neoplasia (a precursor of cervical cancer that can be successfully treated) and 239 cases of invasive cervical cancer were diagnosed.

Office of the Director Savings (-\$92,000)

Programs managed out of the Office of the Director, CDC, give support to and are funded from each of the budget activities of the CDC. These Office of the Director programs will be reduced to realize savings in the operations of the Office of the Director.

Outputs:

	<u>1996 Actual</u>	<u>1997 Appropriation</u>	<u>1998 Estimate</u>	<u>Increase or Decrease</u>
No. of comprehensive breast and cervical cancer programs (all states & District of Columbia & the Virgin Islands & N. Mariana Islands & Palau)	54	54	54	0
No. of state/territorial health agencies receiving support for capacity building (American Samoa and Puerto Rico)	2	2	2	0
No. of States, territories, and American Indian tribal organizations provided consultation and scientific expertise in infrastructure elements necessary for breast and cervical cancer screening programs	63	65	65	0
No. of training centers	1	1	1	0
No. of demonstration projects for women's health	4	3	3	0
No. of Cooperative Agreements awarded to national partners and professional societies to promote the early detection of breast and cervical cancer	12	12	15	3

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Prevention Centers

Authorizing Legislation - Title XVII of the Public Health Service Act

	<u>1996 Actual</u>	<u>1997 Appropriation</u>	<u>1998 Estimate</u>	<u>Increase or Decrease</u>
BA	\$8,099,000	\$8,099,000	\$8,099,000	-
FTE	-	-	-	-
1998 Authorization.....	Indefinite			

Purpose and Method of Operation

CDC's Prevention Centers program provides grants to academic institutions—schools of medicine, public health, or osteopathy—to fund applied research designed to yield tangible results in health promotion and disease prevention. The primary goals of the program are to make communities more accessible and amenable to prevention interventions; increase collaboration among agencies and nontraditional partners; and train public health professionals to seek creative ways to prevent chronic diseases. The network of collaborating academic research centers works to fill the knowledge gaps that block achievement of priority prevention goals. The Prevention Centers work with state and local health departments and other agencies to research findings.

Each Center's theme reflects its area of expertise or the needs of the population served, thereby enabling a range of research and demonstration projects for the development and evaluation of new strategies to improve health. A particular emphasis is to address disparities in access to effective health promotion and disease prevention services. For example, the Columbia University/Harlem Hospital Prevention Center targets the causes, including violence, of excess mortality in Harlem, and the University of Alabama at Birmingham focuses on reducing maternal and child health risks, school-based risk reduction interventions for adolescents, community-based risk reduction for adults and older adults. The University of Washington Prevention Center demonstrated that older adults suffer as much from smoking and benefit as dramatically from quitting as middle-aged men and women.

Many of the research projects are specific areas of importance to meeting the *Healthy People 2000* Objectives. Centers focus on one or more of the following: disease prevention and health promotion among children and youth, older adults and disabled persons; health behaviors among African American, Asian and Hispanic, Native American and rural populations; applied prevention research to serve urban and rural areas that result in improved public health practice at the State, local, and community level; training at the local, state, and regional level to use health data to develop, refine, and implement public health programs.

Through the Prevention Centers program, the expertise of multiple university research centers is made available to federal, state, and local health agencies, community-based organizations, and national nonprofit organizations. This collaboration with various partners has resulted in efficiency and coordination of effort in turning research results into practical, cost-effective, and innovative community programs.

The Centers are also a continuous source of education and training for both current and future disease prevention researchers. By involving academic researchers; federal, state, and local public health workers; personnel from numerous national agencies and community-based organizations; and practitioners from hospitals and managed care environments, the Prevention Centers Program is expanding the capacity of diverse professionals to conduct prevention research and apply the results.

In 1996, 14 centers were supported. Funding for the Prevention Centers program for the last five years:

	<u>Funding</u>	<u>FTE</u>
1993	\$5,456,000	0
1994	\$6,989,000	0
1995	\$7,724,000	0
1996	\$8,099,000	0
1997	\$8,099,000	0

Rationale for Budget Request:

The FY 1998 request of \$8,099,000 represents no change from the FY 1997 Appropriation.

The Prevention Centers Program is due for reauthorization in FY 1998. The FY 1998 request will allow CDC to continue to fund the program at present levels. The 14 Prevention Centers funded in FY 1997 include: University of Alabama at Birmingham; University of California at Berkeley; Columbia University/Harlem Hospital; Johns Hopkins University; University of Illinois; University of North Carolina; University of South Carolina; University of Texas; University of Washington; West Virginia University School of Medicine; St. Louis University; University of Oklahoma; University of New Mexico; and the University of Minnesota.

Outputs:

	<u>1996 Actual</u>	<u>1997 Appropriation</u>	<u>1998 Estimate</u>	<u>Increase or Decrease</u>
Number of grants awarded	14	14	14	0